CMS-1385-P-13730 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Dr. David Hesse** **Date & Time:** **08/31/2007**

Organization : **The Urology Center, P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-13730-Attach-1.DOC

13730

August 30, 2008

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS 1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Comments of CMS 2008 Proposals

Dear Mr. Kuhn:

CMS should work with Congress to fix the Sustainable Growth Rate to prevent the upcoming 10% cut to physicians who provide services to Medicare beneficiaries. Drastic cuts will total 40% over the next 8 years. Over the same period, the Medicare Economic Index (MEI) will increase 20%. How long will physicians be forced to ask for a legislative fix from Congress?

Although no specific proposals exist from CMS, any change to the Stark "in-office" ancillary exception would unduly harm the ability of urologists to provide efficiencies and needed services to patients. Services provided under the exception are important to healthcare delivery. CMS should not further limit this already complex and burdensome regulation.

Under the proposed rule regarding reassignment and diagnostic testing, the only technical or professional services a medical group could mark up would be those by the group's full time employees. This would significantly hurt the ability of group practices with in-office imaging equipment to utilize independent contractors and part-time employees to perform professional services. We understand CMS desire to prevent "mark-ups" and gaming the system but offices with in-office imaging equipment to utilize independent and part-time employees to perform high-quality professional interpretation services.

Prohibition of "under arrangements" rule will prohibit the provision of that are provided to a hospital through a joint venture in which you have an ownership interest, (such as radiation therapy or lasers). This will be detrimental to patient care because of access to these are expensive in our community and across the country. In addition, CMS has taken efforts through a variety of different regulations through the years to eliminate duplication of services. If CMS or Congress were to prevent or further limit the ability to Joint venture with hospitals and other practices it may create an environment that would induce physicians to provide more services in-house under the practice exclusion. Each practice group will buy their own equipment or subject patients to return to the more costly and efficient hospital providers.

We understand the important of striking a balance between fraud and abuse and promoting efficiency and protecting patient access to care. As a urologist, these regulations, if implemented would have a negative effect on innovation, efficiency and patient access to care. Please consider suggested changes and withdraw these proposals.

CMS should not be considering making significant changes to Stark rules on an annual basis or for inclusion in the Physician Fee Schedule. Too many financial and business arrangements, legal contracts and services are involved to be altered on a yearly basis or through a piecemeal approach.

In sum, the proposed rules create two levels of uncertainty: (1) significant lack of clarity within the specific proposals themselves; and (2) general instability due to the prospect of annual changes to Stark.

Thank you for your time and attention to this very important matter.

Sincerely,

Richard Dean, M.D. — Ralph DeVito, M.D.

Richard Dean, M.D. — Ralph DeVito, M.D.

David Hesse, M.D — Stanton Honig, M.D.

David Hesse, M.D. — Stanton Honig, M.D.

Thomas Martin, M.D. — M, Grey Maher, M.D.

Thomas Martin, M.D. — M, Grey Maher, M.D.

CMS-1385-P-13731 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Monica Sachs** **Date & Time:** **08/31/2007**

Organization : **Monica Sachs**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation□a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13732 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Dr. Todd Witzeling** **Date & Time:** **08/31/2007**

Organization : **Dr. Todd Witzeling**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13733 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Mrs. Lisa Yeagley** **Date & Time:** **08/31/2007**

Organization : **Wooster Community Hospital**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Lisa Yeagley. I am a certified athletic trainer who works for Wooster Community Hospital. I work in an outpatient rehabilitation clinic and outreach to a local high school in the area. I have a bachelor's degree in Athletic Training and a master's degree in Exercise Leisure & Sport.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost- effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Lisa Yeagley, MA, ATC

CMS-1385-P-13734 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Mr. Paul Mock** **Date & Time:** **08/31/2007**

Organization : **Mississippi State University**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am the Head Certified Athletic Trainer at Mississippi State University. I have been in this profession working with young athletes for 33 years and at MSU for 27.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Stephen Paul Mock, ATC, LAT

CMS-1385-P-13735 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Dr. Thomas Martin** **Date & Time:** **08/31/2007**

Organization : **The Urology Center, P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-13735-Attach-1.DOC

13735

August 30, 2008

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS 1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Comments of CMS 2008 Proposals

Dear Mr. Kuhn:

CMS should work with Congress to fix the Sustainable Growth Rate to prevent the upcoming 10% cut to physicians who provide services to Medicare beneficiaries. Drastic cuts will total 40% over the next 8 years. Over the same period, the Medicare Economic Index (MEI) will increase 20%. How long will physicians be forced to ask for a legislative fix from Congress?

Although no specific proposals exist from CMS, any change to the Stark "in-office" ancillary exception would unduly harm the ability of urologists to provide efficiencies and needed services to patients. Services provided under the exception are important to healthcare delivery. CMS should not further limit this already complex and burdensome regulation.

Under the proposed rule regarding reassignment and diagnostic testing, the only technical or professional services a medical group could mark up would be those by the group's full time employees. This would significantly hurt the ability of group practices with in-office imaging equipment to utilize independent contractors and part-time employees to perform professional services. We understand CMS desire to prevent "mark-ups" and gaming the system but offices with in-office imaging equipment to utilize independent and part-time employees to perform high-quality professional interpretation services.

Prohibition of "under arrangements" rule will prohibit the provision of that are provided to a hospital through a joint venture in which you have an ownership interest, (such as radiation therapy or lasers). This will be detrimental to patient care because of access to these are expensive in our community and across the country. In addition, CMS has taken efforts through a variety of different regulations through the years to eliminate duplication of services. If CMS or Congress were to prevent or further limit the ability to Joint venture with hospitals and other practices it may create an environment that would induce physicians to provide more services in-house under the practice exclusion. Each practice group will buy their own equipment or subject patients to return to the more costly and efficient hospital providers.

We understand the important of striking a balance between fraud and abuse and promoting efficiency and protecting patient access to care. As a urologist, these regulations, if implemented would have a negative effect on innovation, efficiency and patient access to care. Please consider suggested changes and withdraw these proposals.

CMS should not be considering making significant changes to Stark rules on an annual basis or for inclusion in the Physician Fee Schedule. Too many financial and business arrangements, legal contracts and services are involved to be altered on a yearly basis or through a piecemeal approach.

In sum, the proposed rules create two levels of uncertainty: (1) significant lack of clarity within the specific proposals themselves; and (2) general instability due to the prospect of annual changes to Stark.

Thank you for your time and attention to this very important matter.

Sincerely,

Richard Dean, M.D.	*Ralph DeVito, M.D.*
Richard Dean, M.D.	Ralph DeVito, M.D.
David Hesse, M.D	*Stanton Honig, M.D.*
David Hesse, M.D.	Stanton Honig, M.D.
Thomas Martin, M.D.	*M, Grey Maher, M.D.*
Thomas Martin, M.D.	M, Grey Maher, M.D.

CMS-1385-P-13736 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Jorge Noriega** **Date & Time:** **08/31/2007**

Organization : **Jorge Noriega**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation□s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation□a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC□s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13737 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Mr. John Purdy** **Date & Time:** **08/31/2007**

Organization : **Vanderbilt Sports Medicine and Rehabilitation Serv**

Category : **Other Practitioner**

Issue Areas/Comments

Background

Background

Dear Sir or Madam:

BRIEF INTRO ABOUT SELF ie. Where you work, what you do, education, certification, etc.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost- effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

John D. Purdy, ATC Certified, Certified Personal Trainer, Strength and Conditioning Certified and MsEd
30 years of experience in the field of Sports Medicine and Rehabilitation Services

CMS-1385-P-13738 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Dr. Richard Cross** **Date & Time:** **08/31/2007**

Organization : **UAB Dept. of Anesthesiology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation□a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC□s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13739 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Ree Wilson** **Date & Time:** **08/31/2007**

Organization : **Ree Wilson**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13740 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Mr. Jeffrey Hanson** **Date & Time:** **08/31/2007**

Organization : **Mr. Jeffrey Hanson**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

CMS-1385-P-13741 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Dr. Mary Grey Maher** **Date & Time:** **08/31/2007**

Organization : **The Urology Center, P.C.**

Category : **Physician**

Issue Areas/Comments
GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-13741-Attach-1.DOC

13741

August 30, 2008

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS 1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Comments of CMS 2008 Proposals

Dear Mr. Kuhn:

CMS should work with Congress to fix the Sustainable Growth Rate to prevent the upcoming 10% cut to physicians who provide services to Medicare beneficiaries. Drastic cuts will total 40% over the next 8 years. Over the same period, the Medicare Economic Index (MEI) will increase 20%. How long will physicians be forced to ask for a legislative fix from Congress?

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In sum, the proposed rules create two levels of uncertainty: (1) significant lack of clarity within the specific proposals themselves; and (2) general instability due to the prospect of annual changes to Stark.

Thank you for your time and attention to this very important matter.

Sincerely,

Richard Dean, M.D.

Richard Dean, M.D.

Ralph DeVito, M.D.

Ralph DeVito, M.D.

David Hesse, M.D

David Hesse, M.D.

Stanton Honig, M.D.

Stanton Honig, M.D.

Thomas Martin, M.D.

Thomas Martin, M.D.

M, Grey Maher, M.D.

M, Grey Maher, M.D.

CMS-1385-P-13742 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Mr. Eric Dillow** **Date & Time:** **08/31/2007**

Organization : **Winston-Salem Forsyth County Schools- Glenn H. S.**

Category : **Other Health Care Professional**

Issue Areas/Comments
Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer currently working for the Winston-Salem/Forsyth County School System at Glenn High School. I received my bachelors degree at Greensboro College. I have also worked as a certified athletic trainer for a professional soccer team.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Eric Dillow ATC/LAT

CMS-1385-P-13743 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Mr. David Jacobs** **Date & Time:** **08/31/2007**

Organization : **University of Kentucky Sports Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is David Jacobs. I am a Athletic Trainer, Certified working for the University of Kentucky Orthopeadics and Sports Medicine Center. I have a bachlors degree in sports medicine and secondary education and a masters degree in health education. I have been working as a clinical and secondary school athletic trainer 20 years. I have a certification from the National Athletic Trainers Association and I am also certified as first aid and CPR instructor from the American Heart Association.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost- effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

David Jacobs, MA ATC

CMS-1385-P-13744 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : Logan Morris **Date & Time: 08/31/2007**

Organization : Logan Morris

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation's seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC's recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Logan Morris

CMS-1385-P-13745 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Date & Time: 08/31/2007**

Organization : Weld County School District Re-1

Category : Other Health Care Professional

Issue Areas/Comments
Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Juan J. Garcia Jr. I am a head athletic trainer for a high school in Gilcrest, Colorado. I am in charge of 15 sports and 300+ student- athletes year round. I have worked in clinical and collegiate settings prior to my current position. I have a Masters Degree in Sport Administration and Bachelors in Athletic Training. My certifications include Certified Athletic Trainer, Certified Strength and Conditioning Specialist, CPR Instructor, and EMT-Basic certification.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost- effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Juan J. Garcia Jr.,MS, ATC, CSCS

CMS-1385-P-13746 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Mr. Gordon Gray** **Date & Time:** **08/31/2007**

Organization : **Northside Anesthesia Consultants**

Category : **Other Health Care Professional**

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation□a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC□s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the

Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

CMS-1385-P-13747 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Mrs. Jennifer Hanson** **Date & Time:** **08/31/2007**

Organization : **Mrs. Jennifer Hanson**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

CMS-1385-P-13748 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Paula Walker** **Date & Time:** **08/31/2007**

Organization : **Paula Walker**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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CMS-1385-P-13749 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Mark Vanlandingham** **Date & Time:** **08/31/2007**

Organization : **Mark Vanlandingham**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13750 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Cade Morris** **Date & Time:** **08/31/2007**

Organization : **Cade Morris**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13751 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : Jack Shearer **Date & Time: 08/31/2007**

Organization : Jack Shearer

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13752 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Mr. Christian Hanson** **Date & Time:** **08/31/2007**

Organization : **Mr. Christian Hanson**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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Thank you for your consideration of this serious matter.

CMS-1385-P-13753 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Dr. Anthony DiFilippo** **Date & Time:** **08/31/2007**

Organization : **Dr. Anthony DiFilippo**

Category : **Physical Therapist**

Issue Areas/Comments
Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am a physical therapist and have been practicing for 15 years. I work in the out-patient physical therapy setting. It has become increasingly common for physicians to own and thus profit from sending their patients for rehabilitation in a facility that they own. I am happy that CMS has changed the requirement that physical therapy performed in a physician□s office is to be performed by a physical therapist and not a random worker.

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician-owned physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, overutilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

I have two personal experiences with this type of abuse. For a short period of time, I was employed by a physician to provide physical therapy services. I left after seeing several instances that made me aware that the physician was more concerned about making money from the referral than the treatment of the patient. I overheard the physician tell a patient that he would not give him a referral for physical therapy and that the patient had to come to his office. The patient lived approximately 1 hour away and had several quality physical therapy offices close to where he lived. The physician strong armed the patient into getting a ride, as the patient was unable to drive due to her condition, and receive physical therapy from his office.

Another instance is currently happening at my office. A physician that I have met with multiple times over the past year has referred only a few patients to my office. He is a surgeon and refers most of his patients to the local hospital therapy center. He recently has met with me upon his request and is being told by his billing company that he can make more money for himself if he owns his own therapy and imaging services. He wishes to move his office and have our company provide therapy services for him to enable the physician to bill services rendered to his patients. This brings up the question that if the physician feels that the hospital physical therapy is providing acceptable care for his patients and he typically refers to that physical therapy facility, why then would he refer all of his patients to a facility that has therapists providing care that he does not send to currently. The reason would be because he is going to gain an additional revenue stream.

CMS-1385-P-13754 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Chris Shearer** **Date & Time:** **08/31/2007**

Organization : **Chris Shearer**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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CMS-1385-P-13755 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **W Shearer** **Date & Time:** **08/31/2007**

Organization : **W Shearer**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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CMS-1385-P-13756 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Mr. Michael Widlowski** **Date & Time:** **08/31/2007**

Organization : **Mr. Michael Widlowski**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

CMS-1385-P-13757 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Burt Chappell** **Date & Time:** **08/31/2007**

Organization : **Burt Chappell**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13758 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **S Chaboya** **Date & Time:** **08/31/2007**

Organization : **S Chaboya**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13759 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Dr. Steven licata** **Date & Time:** **08/31/2007**

Organization : **Dr. Steven licata**

Category : **Physician**

Issue Areas/Comments

Background

Background

My primary tool for treating patients is my expertise in Osteopathic Medicine however medicare has been limiting my ability to treat patients my criticizing how many areas I treat and manual therapy is no longer covered except when done by a PT which further takes away from the care given.

CMS-1385-P-13760 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **N Chaboya** **Date & Time:** **08/31/2007**

Organization : **N Chaboya**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation□s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation□a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC□s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13761 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Shirley Douglas** **Date & Time:** **08/31/2007**

Organization : **Shirley Douglas**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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CMS-1385-P-13762 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Sandy Chappell** **Date & Time:** **08/31/2007**

Organization : **Sandy Chappell**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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CMS-1385-P-13763 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **D Chaboya** **Date & Time:** **08/31/2007**

Organization : **D Chaboya**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13764 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Dr. Thomas Martin** **Date & Time:** **08/31/2007**

Organization : **The Urology Center, P.C.**

Category : **Physician**

Issue Areas/Comments
GENERAL

GENERAL

See Attahced Letter (Word Document)

CMS-1385-P-13764-Attach-1.DOC

13764

August 30, 2008

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS 1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Comments of CMS 2008 Proposals

Dear Mr. Kuhn:

CMS should work with Congress to fix the Sustainable Growth Rate to prevent the upcoming 10% cut to physicians who provide services to Medicare beneficiaries. Drastic cuts will total 40% over the next 8 years. Over the same period, the Medicare Economic Index (MEI) will increase 20%. How long will physicians be forced to ask for a legislative fix from Congress?

Although no specific proposals exist from CMS, any change to the Stark "in-office" ancillary exception would unduly harm the ability of urologists to provide efficiencies and needed services to patients. Services provided under the exception are important to healthcare delivery. CMS should not further limit this already complex and burdensome regulation.

Under the proposed rule regarding reassignment and diagnostic testing, the only technical or professional services a medical group could mark up would be those by the group's full time employees. This would significantly hurt the ability of group practices with in-office imaging equipment to utilize independent contractors and part-time employees to perform professional services. We understand CMS desire to prevent "mark-ups" and gaming the system but offices with in-office imaging equipment to utilize independent and part-time employees to perform high-quality professional interpretation services.

Prohibition of "under arrangements" rule will prohibit the provision of that are provided to a hospital through a joint venture in which you have an ownership interest, (such as radiation therapy or lasers). This will be detrimental to patient care because of access to these are expensive in our community and across the country. In addition, CMS has taken efforts through a variety of different regulations through the years to eliminate duplication of services. If CMS or Congress were to prevent or further limit the ability to Joint venture with hospitals and other practices it may create an environment that would induce physicians to provide more services in-house under the practice exclusion. Each practice group will buy their own equipment or subject patients to return to the more costly and efficient hospital providers.

We understand the important of striking a balance between fraud and abuse and promoting efficiency and protecting patient access to care. As a urologist, these regulations, if implemented would have a negative effect on innovation, efficiency and patient access to care. Please consider suggested changes and withdraw these proposals.

CMS should not be considering making significant changes to Stark rules on an annual basis or for inclusion in the Physician Fee Schedule. Too many financial and business arrangements, legal contracts and services are involved to be altered on a yearly basis or through a piecemeal approach.

In sum, the proposed rules create two levels of uncertainty: (1) significant lack of clarity within the specific proposals themselves; and (2) general instability due to the prospect of annual changes to Stark.

Thank you for your time and attention to this very important matter.

Sincerely,

Richard Dean, M.D.

Richard Dean, M.D.

Ralph DeVito, M.D.

Ralph DeVito, M.D.

David Hesse, M.D

David Hesse, M.D.

Stanton Honig, M.D.

Stanton Honig, M.D.

Thomas Martin, M.D.

Thomas Martin, M.D.

M, Grey Maher, M.D.

M, Grey Maher, M.D.

CMS-1385-P-13765 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **H Chaboya** **Date & Time:** **08/31/2007**

Organization : **H Chaboya**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

CMS-1385-P-13766 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **n Chaboya** **Date & Time:** **08/31/2007**

Organization : **n Chaboya**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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CMS-1385-P-13767 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **E Brock** **Date & Time:** **08/31/2007**

Organization : **E Brock**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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CMS-1385-P-13768 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : Dr. shawn schumacher **Date & Time: 08/31/2007**

Organization : St Johns Anesthesia

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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CMS-1385-P-13769 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Neil Douglas** **Date & Time:** **08/31/2007**

Organization : **Neil Douglas**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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CMS-1385-P-13770 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **C Carreno** **Date & Time:** **08/31/2007**

Organization : **C Carreno**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
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P.O. Box 8018
Baltimore, MD 21244-8018

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CMS-1385-P-13771 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **R Henry** **Date & Time:** **08/31/2007**

Organization : **R Henry**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

CMS-1385-P-13772 **Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;**

Submitter : **Eugene Janzen** **Date & Time:** **08/31/2007**

Organization : **Eugene Janzen**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Eugene Janzen

CMS-1385-P-13773 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Mr. Mark Marshall** **Date & Time:** **08/31/2007**

Organization : **Foote Health System**

Category : **Other Health Care Professional**

Issue Areas/Comments
Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
I am employed by Foote Health System in Jackson, MI as a certified athletic trainer. The last four years I worked at a local high school with additional hours at Foote□s Center for Athletic Medicine, providing rehabilitation for a large variety of patients. Recently, because of my experience in the clinic as well as the physician□s preference to have athletic trainers provide rehabilitation versus physical therapists, I will be in the clinic on a full time basis. We have experienced much success in the clinic and many of the area physicians request treatment by an athletic trainer.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost- effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Mark Marshall, ATC, CSCS

CMS-1385-P-13774 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Dr. Frederick Schnell** **Date & Time:** **08/31/2007**

Organization : **The Community Oncology Alliance**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-13774-Attach-1.TXT

Community Oncology Alliance

Dedicated to high quality, affordable, and accessible cancer care

1101 Pennsylvania Ave., NW
Suite 700
Washington, DC 20004
(202) 756-2258
communityoncology.org

President:
Frederick M. Schnell, MD
Georgia
Vice President:
Harry "Mac" Barnes, MD
Alabama
Secretary:
Patrick Cobb, MD
Montana
Treasurer:
Ricky Newton, CPA
Virginia
Officer At-Large (East):
Mark Thompson, MD
Ohio
Officer At-Large (West):
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Leonard Kalman, MD
Florida
Executive Director:
Ted A. Okon
Connecticut
Director of Policy Analysis:
Mary Kruczynski
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Daniel Bradford, MD
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Patrick Cobb, MD
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New York
Steve Coplon, MHA, CMPE
Tennessee & Mississippi
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Oregon
David Decker, MD
Michigan
David Eagle, MD
North Carolina
Gary Gross, MD
Texas
Robert Hermann, MD
Georgia
Dawn Holcombe, MBA
Connecticut
Paul Kaywin, MD
Florida
Grace Kendrick, JD, MHA
Ohio
Donna Krueger, RN, OCN
Illinois
Lynn Kuhn, BBA, CPA
Texas
Steve Leibach, MD
Illinois
Carol Murtaugh, RN, OCN
Iowa & Nebraska
Ricky Newton, CPA
Virginia
William Nibley, MD
Utah
John Ogle, MBA, CPA
Tennessee
Wendy Smith, MSN, ACNP
Mississippi
Virginia Steele
Tennessee
Kurt Tauer, MD
Tennessee
Annette Theis, MHSA
Florida
Tammy Thiel
Alaska
Steve Tucker, MD
California

August 31, 2007
Electronic Submission via http://www.cms.hhs.gov/eRulemaking

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1385-P, Proposed Revisions to Payment Policies under the Physician Fee Schedule and other Part B Payment Policies for CY 2008

Gentlemen:

On behalf of the Community Oncology Alliance (COA) and in accordance with the requested response solicited by the Centers for Medicare & Medicaid Services (CMS) regarding the above captioned proposed rule, we offer the following commentary.

As **Background**, it is noted that CMS did not update the CY 2007 Physician Fee Schedule (PFS) as previously indicated at -5.0 percent. Rather, the conversion factor remained at $37,8975 for CY 2007. Continuing to employ the sustainable growth rate (SGR) as the formula used to calculate updates to Medicare physician reimbursement, CMS is predicting a reduction in the current 2007 conversion factor down to $34.1456; a -9.9 percent reduction to be implemented CY2008, unless Congress legislates against these cuts.

It would seem prudent for CMS, rather than suggesting and then retracting such cuts year after year at the eleventh hour, to make an investment of time and talent, in modifying the currently utilized SGR method in which fee schedule cuts and/or increases are calculated, so as to better represent the costs, and therefore reimbursement, of all goods and services utilized in the delivery of quality medical care. The expenditure of time and money, updating software systems, forms, accounting projections, et cetera, tied directly to these announcements is quite costly. And, to then have to cast aside those efforts, updating once again projections for the new year, places additional financial burdens on the many provider offices already overwhelmed with work.

Resourced Based Practice Expense RVU's, such as rents and wages, now utilize a bottom-up approach to calculate direct costs. Since we are mid-year, it is not yet known what impact such methodology will have long term.

Calculation of the 2008 Practice Expense RVUs for indirect costs will be derived using 2006 procedure-specific utilization data cross walked to 2007 services, thereby utilizing data that is already two years old. Surely, there must be a way to put an assessed value on these costs that is more realistic to that which will be realized in 2008.

In the shadow of the recent five year review and update to work RVUs, CMS is proposing a -11.8 percent budget neutrality factor of 0.8816 to Work RVUs in 2008. The combined impact of the physician fee schedule reductions, if realized, along with the RVU work reductions, translates into an approximate payment reduction of -11% to the specialty of hematology/oncology. We do not think the oncology industry will be able to continue to provide the level of cancer care that our Medicare beneficiaries have become accustomed to in the face of these cuts.

By law, CMS is required to revise the **Geographic Practice Cost Indices (GPCI)** every three years. There are 89 Medicare physician payment localities to which GPCIs are applied and it is noted that those changes must be budget neutral. It is always good to experiment with a small subset before going full scale, which is the intent of CMS in working first with the state of California in making these revisions. The current floor of 1.000, which was set to be removed in 2007, was allowed to remain in order that CMS might have time to consider future revisions. Perhaps CMS should again consider retaining that floor while the agency looks at alternate solutions. COA is uncertain if the suggested modification will achieve the desired result and will therefore yield to those in the area affected for input.

As it relates to the **Coding-Payment for IVIG Add-On Code**, we are most grateful to see that this payment will continue in 2008. Despite numerous attempts by various patient organizations, as well as motions from both House and Senate, there still remains a real crisis insofar as availability and affordability for this blood plasma by-product. COA disagrees that the increased use of off-label uses has caused the current supply and cost problems. A little homework will quickly reveal that most of the IVIG used in the United States is produced abroad with human blood products drawn here in the United States and then shipped over seas for refinement, only to be redistributed world-wide.

Further, it is mentioned in the proposed rule that 59 percent of physicians were able to purchase IVIG at lower than the Medicare payment rate in the third quarter of 2006. This fact truly has no bearing on the reality of today, coupled with the fact that at least 25% of Medicare beneficiaries utilizing this product were unable to afford the twenty percent co-pay, leaving many providers under water. This is one of the reasons why the majority of IVIG infusions now take place in the hospital outpatient department; a true disservice to these immune compromised patients, now exposed to far more infection possibilities than they should be. We are hopeful that CMS will recognize the efforts currently being brought forth by organizations like the Alliance for Plasma Therapies and the personal work of Congressman Steve Israel, to strive for a more equitable reimbursement platform going forward.

There is some discussion once again regarding **ASP Issues**, and while COA is neither a manufacturer nor a distributor, we are deeply concerned about the ability of the community oncologist to buy and administer product currently enveloped in a bundling arrangement and still remain whole. More importantly, we are apprehensive about proposed changes in the ASP methodology, truly concerned that the very patients who require these products, will be unable to receive them.

CMS is already remiss in its calculation of ASP, in that there currently exists a six month payment lag from the time a manufacturer increases its charge for a drug until such time as CMS adjusts its reimbursement in kind. COA is concerned that the two alternative approaches discussed by MedPAC for allocating bundled price concessions may prohibit the use of those products involved in such bundling contracts. Not all providers choose or are able to participate in bundling contracts for multiple drugs, by virtue of the volume of product used. Adopting either of the suggested methods of computation may unfairly penalize this provider subset.

If it is possible to have each and every drug stand alone at its true average selling price, excluding from the calculation any contracting arrangements negotiated between a buyer and manufacturer or distributor, such would be the ideal. For, just as all providers should not be penalized because one or more such providers choose to pay for their drugs either upon delivery or net 10, 20 or 30 days, affording them discounts on their dollars, those very same providers should likewise not be penalized for opting for quantity discounts. Average selling price, by definition, should be reflective of what the average provider pays, exclusive of those sidebar contractual arrangements of a select group. When a manufacturer offers a market share rebate to a provider, the net effect lowers the ASP and thus lowers the cost to the Medicare system. Competition creates competitiveness in the marketplace, thus assuring an overall lower cost. You need not look any further than the Medicare Part D program to see this.

CMS is again looking at a variety of **CAP Issues**, proposing some program revisions. Of particular significance is a clause which will allow participating physicians the ability to exit the program within 30 days of the effective date of their contract if they can substantiate that remaining in such program will negatively impact their business. And, while COA feels this "out clause" is sorely needed, it is suggested that the window of opportunity be extended beyond 30 days to perhaps 90 days, to allow the provider time to truly experience the programs advantages and disadvantages.

Transportation of drugs to more than one practice location is also being considered and election of this option will truly be viewed as a positive by those potentially considering CAP. The inclusion of pre-filled syringes should likewise be considered.

Asking physicians to supply records in a post-payment review as well as suggesting a voluntary agreement wherein the physician notifies the CAP vendor when he or she administers a provided drug, does not come without a price tag. Every single keystroke, every telephone call, every e-mail generated in connection with the CAP program costs the provider unreimbursed money. Placing these burdens upon the back of an already compromised practitioner is simply unfair. If the government wants this program to run optimally, then CMS needs to perfect these operational problems without unfairly taxing a third party; namely, the physician.

Proposed changes to determine the medically acceptable **Drug Compendia** is discussed in light of anticipated changes in the pharmaceutical reference industry. The ability of CMS to determine what points of reference should stand is clouded, as the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) has reported that none of the compendia fully met all of the desired characteristics of acceptable compendia format.

In that CMS is not a clinical organization, the proposition to create a process incorporating public notice and comment to determine medically-accepted indications for drugs and biologicals used in anti-cancer treatment is, in and of itself, a good one. We do urge CMS, however, to not make the process too cumbersome, as many governmental practices are, thereby incorporating time delays that may well mean life and death to a particular patient subset.

It is requested that any drug compendia subsequently approved by CMS, apply universally to all Medicare beneficiary insurance plans, whether they be supplemental or Medigap plans such as AARP, Medicare Advantage Plans, or other stand-alone Part D prescription drug plans. Providers today face a multitude of challenges when prescribing medications for the Medicare beneficiary, as the number of formularies available to our seniors is growing, and with this growth comes a sweeping number of restrictions by payers. If all carriers who supply drugs to Medicare beneficiaries had to adhere to the same clinical compendia, the often times extensive pre-authorization process would be curtailed, thus enabling our seniors to receive their necessary medications in a timely fashion.

It is stated in the proposed rule that CMS may generate a request for a change to the list of compendia at any time. It is therefore suggested that patients successfully being treated based upon then currently acceptable compendia, not be forced to cease such treatment due to a modification of that which was in full force and effect at time treatment was initiated.

The Physician Quality Reporting Initiative **(PQRI)** for 2008 is said to contain all of the quality indicators which went into effect on July 1, 2007. It is premature for COA to comment on the adequacy of the oncology related measures since the program just commenced and results will not be revealed until the second quarter of 2008.

All community oncology clinics strive for excellence in the quality of care afforded their patients every day. The application of a daily formal quality process acts as a reminder of that goal; however, the Medicare quality program that currently exists leaves many questions relating to effectiveness, compliance and return on investment. CMS itself is uncertain as to how the bonus payment may apply, among other things. In light of impending cuts to the PFS in 2008 and a rework of the SGR being considered, perhaps the $1.35 billion in the Physician Assistance and Quality Initiative Fund (PAQI) would be better utilized in buying down the negative update to the physician fee schedule, until such time as CMS can perfect a better system of quality enforcement. CMS should also consider the possible inclusion of electronic health record based reporting in future quality

endeavors, which would go hand in hand with the proposed intention of having all Medicare providers using an electronic medical record in just a few short years. The ease in compliance, utilizing an electronic medical record, will net an accurate assessment of quality for provider, payer and patient alike.

CMS will implement the mandatory **Anemia Quality Indicator** on claims in calendar year 2008. Under consideration, is the use of such quality indicators not only for cancer diagnoses, but rather for all uses of erythropoietin stimulating agents (ESAs). Implementation of this mandate will be burdensome not only for providers, but also for Medicare contractors, as each anti-anemia drug claim will have to be pulled from the general electronic claims transmission and processed individually by a processor for compliance. As has been recently demonstrated by the harsh National Coverage Determination (NCD) issued on July 30, 2007 regarding ESAs, the resolve of CMS to limit the use of ESAs is clear. A directive for providers to list a beneficiary's most recent hemoglobin or hematocrit level on a claim will require yet another level of hands-on compliance at the provider level, straining the already overburdened medical staff. The thought process behind CMS's request for this data was to help determine the prevalence and severity of anemia associated with cancer therapy, as well as the response elicited by treatment with ESAs. Oncologists/Hematologists have been treating patients successfully with ESAs for years. An independent study on the treatment with and resultant outcome of patients treated with these agents would be welcomed by the oncology community at large, assuredly demonstrating the safe and effective use of ESAs in the patient population. Merely recording a hemoglobin or hematocrit on a claim does not tell the entire story behind the appropriate and effective use of ESAs.

In summary, the federal government, through the implementation of rules such as this, has realized a significant savings and improvement to its Medicare program. We hope you will consider utilizing the COA established network of community oncologists, working in unison with CMS, to perfect a truly viable delivery system of quality cancer care, assuring excellent, yet affordable treatment for our Medicare beneficiaries and adequate compensation for the delivery team that cares for them.

Very truly yours,

COMMUNITY ONCOLOGY ALLIANCE

Frederick M. Schnell, MD
President

FMS/mk

CMS-1385-P-13775 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **Dr. Susan Stevens** **Date & Time:** **08/31/2007**

Organization : **University of North Carolina at Greensboro**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:
I am an athletic training educator at University of North Carolina at Greensboro. My job is to ensure that new graduates receive a high quality education and ensure they have the necessary skills to provide quality physical medicine and rehabilitation services.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost- effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Susan W. Stevens, EdD, ATC, LAT

CMS-1385-P-13776 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008;

Submitter : **L Womack** **Date & Time:** **08/31/2007**

Organization : **L Womack**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation□s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation□a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC□s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Anne Friddell** **Date: 08/31/2007**

Organization : **Anne Friddell**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.
Mac Friddell

Submitter : **Dr. Donald Fox** **Date: 08/31/2007**

Organization : **Boise Anesthesia, PA**

Category : **Physician**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Donald Fox, MD
Boise, Idaho

Submitter : **M Elmore** **Date: 08/31/2007**

Organization : **M Elmore**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Mcdicaid Services
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P.O. Box 8018
Baltimore, MD 21244-8018

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Submitter : **K Jopling** **Date: 08/31/2007**

Organization : **K Jopling**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Submitter : **Dr. Mary Grey Maher** **Date: 08/31/2007**

Organization : **The Urology Center, P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-13781-Attach-1.DOC

August 30, 2008

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS 1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Comments of CMS 2008 Proposals

Dear Mr. Kuhn:

CMS should work with Congress to fix the Sustainable Growth Rate to prevent the upcoming 10% cut to physicians who provide services to Medicare beneficiaries. Drastic cuts will total 40% over the next 8 years. Over the same period, the Medicare Economic Index (MEI) will increase 20%. How long will physicians be forced to ask for a legislative fix from Congress?

Although no specific proposals exist from CMS, any change to the Stark "in-office" ancillary exception would unduly harm the ability of urologists to provide efficiencies and needed services to patients. Services provided under the exception are important to healthcare delivery. CMS should not further limit this already complex and burdensome regulation.

Under the proposed rule regarding reassignment and diagnostic testing, the only technical or professional services a medical group could mark up would be those by the group's full time employees. This would significantly hurt the ability of group practices with in-office imaging equipment to utilize independent contractors and part-time employees to perform professional services. We understand CMS desire to prevent "mark-ups" and gaming the system but offices with in-office imaging equipment to utilize independent and part-time employees to perform high-quality professional interpretation services.

Prohibition of "under arrangements" rule will prohibit the provision of that are provided to a hospital through a joint venture in which you have an ownership interest, (such as radiation therapy or lasers). This will be detrimental to patient care because of access to these are expensive in our community and across the country. In addition, CMS has taken efforts through a variety of different regulations through the years to eliminate duplication of services. If CMS or Congress were to prevent or further limit the ability to Joint venture with hospitals and other practices it may create an environment that would induce physicians to provide more services in-house under the practice exclusion. Each practice group will buy their own equipment or subject patients to return to the more costly and efficient hospital providers.

We understand the important of striking a balance between fraud and abuse and promoting efficiency and protecting patient access to care. As a urologist, these regulations, if implemented would have a negative effect on innovation, efficiency and patient access to care. Please consider suggested changes and withdraw these proposals.

CMS should not be considering making significant changes to Stark rules on an annual basis or for inclusion in the Physician Fee Schedule. Too many financial and business arrangements, legal contracts and services are involved to be altered on a yearly basis or through a piecemeal approach.

In sum, the proposed rules create two levels of uncertainty: (1) significant lack of clarity within the specific proposals themselves; and (2) general instability due to the prospect of annual changes to Stark.

Thank you for your time and attention to this very important matter.

Sincerely,

Richard Dean, M.D.

Richard Dean, M.D.

Ralph DeVito, M.D.

Ralph DeVito, M.D.

David Hesse, M.D

David Hesse, M.D.

Stanton Honig, M.D.

Stanton Honig, M.D.

Thomas Martin, M.D.

Thomas Martin, M.D.

M, Grey Maher, M.D.

M, Grey Maher, M.D.

Submitter : **Janet Willis** **Date: 08/31/2007**

Organization : **Janet Willis**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
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Thank you for your consideration of this serious matter.
Janet Willis

Submitter : **Lillian Janzen** **Date: 08/31/2007**

Organization : **Lillian Janzen**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Lillian Janzen

CMS-1385-P-13784

Submitter : J Martin

Date: 08/31/2007

Organization : J Martin

Category : Individual

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Submitter : J Mersch

Organization : J Mersch

Date: 08/31/2007

Category : Individual

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : J Morris **Date:** 08/31/2007

Organization : J Morris

Category : Individual

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Submitter : **Mr. Gordon Gray** **Date: 08/31/2007**

Organization : **Northside Anesthesia Consultants**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

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Gordon Gray

Submitter : **Mary Beagles** **Date: 08/31/2007**

Organization : **Mary Beagles**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Mary Beagles

Submitter : **Loren Lucas** **Date: 08/31/2007**

Organization : **Loren Lucas**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Loren Lucas

Submitter : R Neely **Date:** 08/31/2007

Organization : R Neely

Category : Individual

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

CMS-1385-P-13791

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician-owned physical therapy services.

CMS-1385-P-13791-Attach-1.DOC

Sara Faris, PT MPT
Rehab Professionals of Cleveland, Inc
12221 Madison Avenue
Lakewood, Ohio 44107

Medicare Program: Proposed revisions to payment policies under the physician fee schedule, and other part B payment policies for CY 2008; proposed rule.

Mr. Kerry N. Weems,

I am a physical therapist professional currently employed in Cleveland, Ohio. I have practiced for eight months now, recently graduating with my Master's degree in Physical Therapy from Cleveland State University in December of 2006. As a physical therapist in a private practice setting, it is unsettling to hear news about referral for profit organizations.

The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest, especially in the case of physician-owned physical therapy services. Physicians who own practices that provide physical therapy services have an inherent financial incentive to refer their patients to the practices they have invested in and to over utilize those services for financial reasons. By eliminating physical therapy as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, over utilization of physical therapy services under the Medicare program, and enhance the quality of patient care.

In the past six months or so I have noticed a great deal of patients not educated about their choices in healthcare, specifically physical therapy treatment. For example, a patient had described her surgeon would rather "keep a closer look with her progress" with receiving physical therapy at his office. This was not a convenient location, nor was this patient able to drive a car secondary to her surgical procedure. Based on report, she had spent non-refundable dollars to utilize unnecessary transportation services; and only had appointments to see her physician every six weeks. No more or less contact with her physician. If only she was educated about near-by locations to receive physical therapy treatment, her care may have not been so stressful. Rather, the physician was not "patient first" in understanding her social/economic history; instead concerned with his financial gains.

Other examples of physician abuse include only referring to financial incentive locations, lack of patient education, and providing patient choice in their physical therapy care. Thank you for your consideration in my comments regarding this heated issue. It is important for the patient to utilize choice and receive morally and ethically appropriate physical therapy care.

Sincerely,
Sara Faris, PT, MPT

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-13792-Attach-1.DOC

Mr. Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

October 1, 2007

Re: CMS-1385-P: Physician Self-Referral Issues/In-Office Ancillary Services Exception

Dear Mr. Kuhn:

I'm writing this letter to encourage CMS to consider eliminating physical therapy as a designated health service (DHS) that can be furnished under the in-office ancillary services exceptions. I am a physical therapy administrator of a multi-site rehabilitation company. Over the years I have personally witnessed the abuse of the original intent of the in-office ancillary services exception by physicians who are providing therapy as an "ancillary service" solely to generate the maximum amount of profit. Below are three examples:

1. Our company leased space from a physician practice (orthopedic physicians,) at fair market value, and started a physical therapy clinic. We enjoyed positive patient feedback and had recruited a quality clinical staff. The clinic was in operation for about 2 years.

   A new physiatrist was then added to the group who became aware that they could realize passive income by "owning" their own physical therapy practice. Within a short time, our lease was terminated - and we were out. The physician group with promises of increased compensation and other incentives hired our key clinician. When confronted about this in a meeting, the senior physician said that Medicare had been reducing his income for the last 3 to 4 years, and he had to make up the lost income in order to survive. I couldn't believe it, but he actually said he felt like, "he was in the toilet licking the lid on the way down," meaning that the decrease in Medicare reimbursement was adversely affecting his income.

   Patients did not benefit from the physicians providing PT directly as part of their "practice." The key physical therapy clinician left the physician office soon after due to her perception of excessive referrals and they have had a difficult time recruiting

since (reportedly they were using an athletic trainer or exercise physiologist and continuing to treat patients and billing for physical therapy services).

2. While I was the administrator of a hospital-oriented PT practice, there was a large orthopedic practice that referred many patients to our hospital for surgeries. Historically, they referred to a variety of therapy providers in the community. Their practice administrator attended an orthopedic conference, which included a session on how to make passive income off ancillary services. The presenter argued that physicians who don't have passive income from ancillary services only earn income when they see patients directly. With passive income, they can make money without having to perform the work themselves, but instead indirectly by employing physical therapists, occupational therapist, etc.

   After attending this conference, the surgeons put pressure on the hospital to develop an arrangement where they could realize passive income from physical therapy. Although the surgery group argued that these arrangements were necessary so they would have greater control over therapy services, many of our community board members objected to what they clearly saw as a conflict of interest. One board member described the practice rather like "shooting fish in a barrel". Ultimately, it was determined that the Stark Law's would not allow those efforts to move forward.

   The physicians didn't give up and later opened a satellite office so they can now bill for PT under the in-office ancillary exception. Ironically, they don't directly provide the PT, but outsource under contract with a local therapy provider.

   Historically, this group would refer to many PT practices in town, but now they have implemented <u>active</u> processes to "capture therapy patients" in their office.

3. Our hospital mutually developed a spine program with a physician spine practice (orthopedic and physiatry). Therapy services were independent, but adjacent to the physician clinical practice. For about 10 years, the collaborative physician/therapy services were received and respected in the community. The physicians decided that they wanted to make money on physical therapy services. They relocated, built a physical therapy department in their new offices and recruited our physical therapists. They began billing via the Stark Law's in-office ancillary services exception and referrals to our practice were dramatically reduced. We ultimately closed the clinic.

Many physicians see their peers profiting by providing certain "in-office" ancillary services. Most believe no conflict of interest exists when physicians self-refer to their own physical therapy clinics. Ironically, it's generally accepted that physicians shouldn't profit from selling pharmaceuticals out of their office. How is providing (selling) physical therapy services from their office any different?

Physicians like to argue that they have better control over clinical services they provide through their "office," but that's fiction. First, they frequently contract the services out for

another company to provide. Second, physical therapists shouldn't be controlled (contractually or by a employer-employee relationship) by the physicians. Physical therapists are fully qualified and should be independently determining clinical decisions like which services should be provided and for how long. As a result, when physicians who have direct control get involved, patient care decisions are at times compromised and utilization increased.

From a fiscal perspective I can only anecdotally argue that utilization dramatically increases when physicians are able to refer to themselves. When you research why utilization has risen dramatically for rehabilitation, I suspect you will find that physician self-referral is likely a key component of that equation.

As far as resolution of this problem, I agree with many of the ideas expressed in your proposed regulations.

It's a sad day when physicians make decisions solely for profit, which may compromise the best interests of the patient and unnecessarily reduce scarce resources in our Medicare system.

Thank you for your consideration of my comments.

Submitter : **D Rudd** **Date: 08/31/2007**

Organization : **D Rudd**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter : A Seipp **Date: 08/31/2007**

Organization : A Seipp

Category : Individual

Issue Areas/Comments

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Submitter : **Corey Beagles** **Date: 08/31/2007**

Organization : **Corey Beagles**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Submitter : Lynette Lucas **Date:** 08/31/2007

Organization : Lynette Lucas

Category : Health Care Professional or Association

Issue Areas/Comments

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Lynette Lucas

Submitter : K Smalley

Date: 08/31/2007

Organization : K Smalley

Category : Individual

Issue Areas/Comments

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Submitter : **S Titsworth** **Date: 08/31/2007**

Organization : **S Titsworth**

Category : **Individual**

Issue Areas/Comments

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Submitter : S Webb

Organization : S Webb

Date: 08/31/2007

Category : Individual

Issue Areas/Comments

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CMS-1385-P-13800

Submitter : **Rick Berry**

Date: 08/31/2007

Organization : **Rick Berry**

Category : **Individual**

Issue Areas/Comments

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When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Rick Berry

Submitter : **Charles Morris** **Date: 08/31/2007**

Organization : **Charles Morris**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.
Charles Morris

Submitter : **Dr. Frances Regas** **Date: 08/31/2007**

Organization : **Dr. Frances Regas**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Rc: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter. This is especially important in a state like RI which has such a large Medicare population and this will help insure access for these patients.

Frances Regas, MD

Submitter : V Williams **Date:** 08/31/2007

Organization : V Williams

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Submitter : D Williams **Date: 08/31/2007**

Organization : D Williams

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Submitter : **Sherry Berry** **Date: 08/31/2007**

Organization : **Sherry Berry**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Ancsthcsia Coding (Part of 5-Year Rcview)

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Sherry Berry

Submitter : m Williams **Date:** 08/31/2007

Organization : m Williams

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

CMS-1385-P-13807

Submitter : Carmel Morris **Date:** 08/31/2007

Organization : Carmel Morris

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
Carmel Morris

CMS-1385-P-13808

Submitter : R Williams **Date:** 08/31/2007

Organization : R Williams

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Submitter : **Date: 08/31/2007**

Organization : **Prothrombin-time Self Testing Coalition**

Category : **Device Industry**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

See Attachment

CMS-1385-P-13809-Attach-1.PDF

August 31, 2007

Via Electronic Submission to: http://www.cms.hhs.gov/eRulemaking
Kerry Weems
Administrator, Centers for Medicare and Medicaid Services—Designate
U.S. Department of Health and Human Services
Attn: CMS-1385-P
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008;

CMS-1385-P

Comments on: RESOURCE-BASED PE RVUs

Dear Mr. Weems:

On behalf of the Prothrombin-time Self Testing (PST) Coalition comprising HemoSense, Inc., International Technidyne Corporation and Roche Diagnostics Corporation, we are pleased to submit comments on the above-captioned Proposed Rule[1] regarding Prothrombin Time (PT)/International Normalized Ratio (INR) home monitoring for anticoagulation management. We applaud CMS for recognizing the serious problem with payment for home PT/INR monitoring created with the transition to the new resource-based practice expense (PE) relative value unit (RVU) methodology beginning this year, and we appreciate CMS's attempt to address this in the Proposed Rule. As explained below, we believe an error has been made in the proposed adjustment to the equipment time-in-use input, which would result in a significant underpayment for home PT/INR monitoring. In our comments, we offer several options to correct this error which fit within the framework of the new resource-based PE RVU methodology. We urge the Agency to consider these options carefully and to choose whichever approach CMS believes fits most faithfully within the new PE RVU framework while assuring fair and accurate payment for this service.

As noted in our comments on the 2007 Proposed Rule and as we discussed during a meeting with the Agency earlier this year, between October 2002 and December 2006, Medicare's allowed payments for home PT/INR monitoring under the Physician Fee Schedule appeared to be adequate to cover physician and Independent Diagnostic Testing Facility (IDTF) costs for furnishing home PT/INR monitoring equipment, supplies, and clinical staff support.[2] This was not always the case. When home PT/INR monitoring coverage was first approved in July 2002, the payment was approximately 40-percent lower.[3] The payment increased significantly shortly after coverage was first implemented because CMS recognized—and corrected—a flaw in the application of the standard practice expense methodology to home PT/INR monitoring. A similar flaw was introduced when CMS began the transition to the new resource-based PE RVU methodology this year.

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[1] 72 Fed Reg. 38,122 (Jul. 12, 2007).

[2] The national unadjusted payment rate for code G0249 "Provide test material,equipm" was $119.09 as of October 1, 2002 and was $150.83 during 2006.

[3] The national unadjusted payment rate for code G0249 was $72.40 for July 1 through September 30, 2002.

I. Coding and Practice Expense Inputs for Home PT/INR Monitoring

Home PT/INR monitoring involves the furnishing, by a physician or IDTF, of a PT/INR monitor (a prothrombin time test meter), test strips to run in the monitor, lancets for collecting blood samples, and alcohol swabs for preparing the skin for self-testing of prothrombin time by patients or their caregivers at home (or otherwise outside the physician's office setting) on a weekly basis[4]. Home PT/INR monitoring is reported under the following three HCPCS codes to include the technical component service described above (G0249) as well as an initial training session (G0248) and physician review and interpretation of the test results (G0250):

Code	Descriptor
G0248	Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing
G0249	Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; per 4 tests
G0250	Physician review, interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face service)

II. Concern about the Practice Expense Relative Values in the Proposed Rule

Home PT/INR monitoring is an unusual service under the Physician Fee Schedule because it involves the furnishing of equipment and supplies by physicians or IDTFs for use by patients in their homes. As CMS correctly observed in the Proposed Rule, each PT/INR "monitor is dedicated for use 24 hours a day and unavailable for others receiving this service."[5] Therefore, when applying the PE RVU methodology to home PT/INR monitoring an issue raises as to the appropriate amount of time-in-use to assign to the monitor. If the time-in-use is set to the amount of time the patient actually tests his/her PT/INR value (32 minutes under the 2007 Final Rule practice expense files),[6] then the practice expense input for the

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[4] The coverage policy limits coverage to testing no more than once per-week. The 4-test payment units under code G0249 may reflect weekly testing over a 4 week period or less frequent testing over a longer period. Therefore, the minimum time period under code G0249 is 28 days.

[5] 72 Fed. Reg. 38,122, 38,134 (Jul. 12, 2007).

[6] Equipment input values for code G0249 in: 2007 Final Rule Direct Practice Expense Inputs.for website.xls (Nov. 8, 2006). This file shows an equipment price of $2,000, which is also the price shown in the file supporting the 2008 Proposed Rule (2008 NPRM Direct PE Database 1385-P.xls [Jul. 3, 2007]). Our reference to this price in these comments as well as use of the term "price" and "cost" are not intended to suggest that this is the actual purchase price of any specific product sold or offered for sale by any of the companies comprising the PST Coalition.

monitor is determined to be only $0.3177 per month (4 tests).[7] At this rate, it would take 525 years to recoup the price of the equipment![8]

In 2002, CMS staff recognized the difficulty with applying the standard practice expense methodology to home PT/INR monitoring, which had resulted in the initial inadequate payment rate for code G0249 of $72.40. To accommodate the difference between home PT/INR monitoring and other equipment paid under the Physician Fee Schedule, CMS staff applied a straight line amortization of the equipment price over the useful life of the meter.[9] This resulted in a 64-percent increase in the payment rate for code G0249 to $119.09 per 4 tests.

Unfortunately, despite comments we submitted last year, this "hard coded" fix to the PE RVUs for home PT/INR monitoring was not captured in the new resource-based PE RVU values introduced in 2007. This resulted in a drop in the PE RVUs for home PT/INR monitoring from 3.97 in 2006 to 3.57 in 2007—a reduction of ~10-percent. The 2007 Final Rule also indicated that the PE RVUs for home PT/INR monitoring would drop by a total of ~40-percent with full implementation of the new resource-based PE RVUs by 2010.

We raised our concerns about the PE RVUs for home PT/INR monitoring with CMS staff at a meeting this past March, and we were pleased to see that CMS acknowledged these concerns in the Proposed Rule. However, we are puzzled by the proposed correction to increase the time-in-use of the monitor from 32 minutes to 1,440 minutes. <u>1,440 minutes is only one 24-hour period</u>. In fact, the monitor is in use by patients 24 hours a day for <u>at least 28 days</u> for each unit of service of code G0249 (4 weekly tests). This would translate to 40,320 minutes utilization—not 1,440 minutes.

With 1,440 minutes of time-in-use, one derives an equipment input of $14.30 per 4 tests. This would translate to a period of 11.7 years to recoup the price of the monitor. This is certainly better than 525 years, but is still nearly 3 times the useful life of the equipment. By contrast, with 40,320 minutes-in-use, one derives an equipment input of $400.33, which would recoup the price of the monitor in 5 months. Clearly, neither time-in-use estimate appears appropriate.

If one considers that the equipment time-in-use model comprehends 150,000 minutes per-year at 100-percent utilization (utilization factor 1.0) and the model uses a fixed 50-percent utilization (utilization factor 0.5), then the total time available during a 28 day period would be 11,507 minutes for a 28-day period at 100-percent utilization or 5,753 minutes at 50-percent utilization.[10] If we apply 5,753 minutes as the time-in-use for the monitor, we obtain an equipment input of $57.12 per 4 tests, which would recoup the price of the equipment in approximately 3 years. We believe this is a more appropriate estimate of the time-in-use than the proposed 1,440 minutes.

---

[7] Using the $2,000 equipment price, 4 year useful life, 32 minutes-in-use per-4 tests and the equipment cost per minute formula (1/(minutes per year*usage))*price*((interest rate/(1-(1/((1+interest rate)* life of equipment))))+maintenance).

[8] $2,000 price/$0.3177 per month (4 tests) =6,295 months =525 years.

[9] Through 2004, the equipment was assigned a price of $2,000 and a useful life of 4 years. In the 2005 and 2006 practice expense input databases, the equipment was assigned a price of $2,000 and a useful life of 5 years.

[10] 150,000*(28/365)=11,507 min. 11,507/2=5,753 min.

III. Recommendation

We appreciate CMS's attempt at correcting the problem raised when applying the standard Medicare Physician Fee Schedule PE RVU methodology to home PT/INR monitoring—especially the application of the methodology for equipment time-in-use to the PT/INR monitor. As discussed, however, increasing the minutes-in-use from 32 to 1,440 does not appear to have a rational basis and does not provide for adequate recoupment of the price of the device. We would propose that CMS consider one of the following options to correct this error.

1. **Increase the minutes-in-use to 5,753**. This is consistent with the acknowledgement in the Proposed Rule that home PT/INR monitors are in use 24 hours a day but capping the utilization at the maximum time that a device could be in use under the equipment time-in-use model during the (minimum) 28 day period comprehended by code G0249. This approach is fully consistent with the statement made in the Proposed Rule and would not require any special exception to the application of the standard PE RVU equipment model.

2. **Decrease the utilization factor to 0.0028**. This derives from considering the current 32 minutes-in-use for code G0249 to the total possible minutes-in-use over the 28 day period of 11,507. This would yield an equipment input for code G0249 of $56.74 per 4 tests with recoupment of the equipment price in approximately 3 years. This would maintain use of the equipment time-in-use model, but would involve a special exception to the utilization factor. We understand that CMS believes it does not have adequate data to adjust utilization factors generally, but in the case of home PT/INR monitoring, the utilization is more clearly known than with other technologies given its dedicated use to a single patient and the testing frequency fixed by the national coverage policy.

3. **Amortize the equipment price ($2,000) over the useful life (4 years)**. This derives directly from the PE RVU equipment inputs and does not require any assumption about minutes-in-use or the utilization factor. This would yield an equipment input for code G0249 of $38.46 per 4 weekly tests and provides recoupment in 4 years by definition. Adopting this method would require CMS to go outside the standard equipment use model, but it would maintain the approach adopted by CMS from 2002 through 2006 that resulted in an adequate payment amount for this important service.

We believe option 1 would be the most appropriate alternative for CMS to adopt in the Final Rule as it is rational, consistent with the comments made by CMS in the Proposed Rule and tracks the current equipment time-in-use model without requiring any special exception. At the same time, we would support CMS's adoption of options 2 or 3 as appropriate methods to accommodate home use of PT/INR monitors under the Medicare Physician Fee Schedule, which was not designed to fit dedicated home use devices.

* * * *

Anticoagulation therapy with warfarin sodium can reduce the risk of serious thromboembolic events in patients who are at risk for such events due to mechanical heart valves, atrial fibrillation, deep venous thrombosis or other thrombophilic disorders. At the same time, therapy with warfarin puts patients at-risk for significant bleeding if therapy is excessive or thromboembolism if therapy is insufficient. Studies

have shown that careful monitoring of anticoagulation therapy with home PT/INR can reduce thromboembolic events, hemorrhagic adverse events and deaths.[11]

Despite the benefits, adoption of the home PT/INR monitoring under Medicare has occurred at a very slow pace since coverage was first approved in 2002. Reimbursement has been a key factor inhibiting access to this technology. Until this year, the principal restraint on adoption has been the limited scope of Medicare coverage; coverage is limited to patients with mechanical heart valves, a relatively small subset of the overall population undergoing anticoagulation therapy. We are addressing the coverage issue with the Coverage and Analysis Group through a reconsideration request we submitted in June, and we hope to have a decision about expanded coverage by the end of March 2008.

Appropriate adoption and use will not occur, however, if the payment rate is inadequate to cover the cost of the service. The proposed PE RVUs (3.29 for 2008) represent a 17-percent reduction from 2006. The fully implemented PE RVUs under the Proposed Rule (2.72) represent a 31-percent reduction from 2006. These proposed rates are simply too low for providers to recover their costs to furnish home PT/INR monitoring services to patients who can benefit from home monitoring. We urge CMS to correct the PE RVUs using one of the alternatives recommended above to assure that payment will be adequate to support appropriate use of this technology.

We appreciate the opportunity to comment on this Proposed Rule. Please contact our reimbursement counsel, Paul Radensky, M.D., J.D., at 305.347.6557 or by e-mail at pradensky@mwe.com if you have any questions about our comments or would like to discuss these further. Thank you for your consideration of our comments.

Sincerely,

/s/ Larry Cohen

Larry Cohen
President
International Technidyne Corporation

/s/ David Phillips

David Phillips
Vice President, Marketing
HemoSense, Inc.

/s/ Anthony Callaway

Anthony Callaway
Director Of Health Policy
Roche Diagnostics Corporation

Cc: Denise Garris, American College of Cardiology
Paul Radensky, M.D., J.D., McDermott, Will & Emery LLP

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[11] Heneghan C, Alonso-Coello P, Garcia-Alamino JM, *et al*. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. *Lancet*. 2006; 367: 404–11.

Submitter : **Nathan Biggs** **Date: 08/31/2007**

Organization : **Nathan Biggs**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
Nathan Biggs

Submitter : **A Clark** **Date: 08/31/2007**

Organization : **A Clark**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Submitter : G Arellanes

Date: 08/31/2007

Organization : G Arellanes

Category : Individual

Issue Areas/Comments

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Submitter : **Dr. Michael Repka** **Date: 08/31/2007**

Organization : **American Academy of Ophthalmology**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-P-13813-Attach-1.PDF

Suite 700
1101 Vermont Avenue NW
Washington, DC 20005-3570

Tel. 202.737.6662
Fax 202.737.7061
http://www.aao.org

Federal Affairs Department

August 31, 2007

Via Electronic Mail
Mr. Herb Kuhn, Acting Adminstrator
Center for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS—1385—P Proposed Revisions to Payment Policies Under the Physician Fee Schedule for CY2008
P.O. Box 8018
Baltimore, MD 21244-8018

Dear Mr. Kuhn:

The American Academy of Ophthalmology is writing to share our comments regarding the CY2008 Proposed Medicare Physician Fee Schedule. The Academy is the world's largest association of eye physicians and surgeons—Eye M.D.s—with more than 18,000 members in the U.S. and we appreciate the opportunity to provide our input on this important regulation.

Our comments will focus on the following provisions in CMS—1385—P:

- Resource based Practice Expense Regulations -- Current Methodology
- Specific Coding Issues Related to the PFS --Reductions in the TC for Imaging Services Under the PFS to the Outpatient Department (OPD) Payment Amount
- Specific Coding Issues Related to the PFS --Additional Codes From the 5-Yr. Review of Work
- Development of RVU's --Adjustments to RVU's for Budget Neutrality
- Issues related to PLI Relative Values
- Part B Drug Issues --Average Sales Price (ASP) Issues
- Part B Drug Issues --Competitive Acquisition Program (CAP)
- Percentage Change to the Medicare Economic Index (MEI)
- Division B of the TRHCA 2006 --Section 101(b) PQRI
- Division B of the TRHCA 2006 – Section 101(d) PAQI

Resource based Practice Expense (PE) Regulations -- Current Methodology

The Academy again emphasizes our concerns addressed in both the rules last year that dealt with changes to the practice expense methodology that received *no acknowledgement from CMS* (CMS-1512-PN; Medicare Program; Five Year Review of Work Relative Value Units and Proposed Changes to the Practice Expense

Methodology and CMS-1321 FC and CMS-1317 F: Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology.) Specifically, under the new PE methodology, the approach of basing the specialty adjusted weight on a weighted average of all specialties providing a service is flawed.

Rather, we urged that the weight be based on the weight of the specialty or specialties that represent 95 percent of the total utilization of the appropriate CPT code and modifier. Otherwise, **the practice expense (PE) related payment is impacted by the practice costs of specialties who do not represent the "typical" patient. Even more likely, the weight is impacted by coding errors which is inappropriate and thus unfair to the specialty that provides the service.**

We believe that this adjustment is important for codes that are performed by a wide range of specialties that typically are not performing the entirety of the service. For example, CPT code 66894 which describes cataract surgery is billed by 19 specialties, even though in reality virtually all of the procedures are performed by ophthalmologists.

The specialty-based weights impact the PE RVU calculation because the indirect costs are determined based on the direct cost estimate at the procedure level and the ratio of direct and indirect costs at the practice level. The Academy has analyzed the PE RVUs and determined that the alternative approach described below would correct some of the anomalies that result from the inclusion of specialties that are not typically related to providing a service.

In addition, we believe that the utilization data used in calculating the weighted values for CPT 66984 are incorrect and do not reflect the clinical reality of the non-surgical role of optometrists in the service. The surgical procedure is performed only by ophthalmologists. The utilization data contained on the CMS website indicates that 85.4 percent of the utilization of CPT 66984 is associated with an ophthalmologist while another 14.2 percent is associated with an optometrist and 0.4 percent is associated with some 17 other specialties. The Academy believes that many of these claims must be due to coding error because this belies the clinical reality that the surgery is exclusively provided by ophthalmologists.

Optometrists are involved only during the post-procedure period for a limited number of post-operative visits and not involved in the pre-service, intra-service, and day of service discharge portions of the procedure. CMS limits this co-management fee to 20% of the full procedure payment. This clinical reality could be confirmed if the utilization data at the CPT code level also included modifiers since most optometrists will bill for CPT code 66984 with the "54" modifier to indicate their role during the post-operative period.

With the adjustment in the role for optometry and other specialties listed as providers of 66984, the RVU should be 4.1 percent higher. The proposed RVU deflates the practice costs associated with this procedure by 14 percent because the final value is a blend of the practice costs of both ophthalmology and optometry. The 14 percent utilization estimate is based on inaccurate

data that does not distinguish between the various modifiers used in conjunction with CPT 66984. When billed correctly, optometrists should use a "-54" modifier to indicate the service is for post-operative management only, when one physician performs the post-operative management and another physician performs the surgical procedure.

If CMS were to base the practice expense calculation to reflect the clinical reality where the optometrist role is limited to post-operative care, the PE RVU would be 6.84, or 3.3 percent higher than the current RVU for cataract surgery. The two alternatives that the Academy proposes does not increase the PE RVU by a significant percentage. Nonetheless, the change can have a dramatic impact at the individual practice level and will ensure that the PE RVU reflects the costs that ophthalmologists incur as they provide services related to cataract surgery.

The Academy requests that the PE RVU for CPT 66984 be based solely on ophthalmology utilization, or if a weighting of the optometry practice costs is necessary, then the weight assigned should reflect the clinical reality of the provision of a portion of the postoperative service by optometry. The result will be a PE RVU which better approximates the resources needed to perform this service.

Resource based Practice Expense (PE) Regulations -- Discussion of Equipment Usage Percentage

The Academy agrees both with MedPAC and with the AMA RUC that there are definitely pieces of high cost equipment that are utilized at a much higher rate then the current 50% rate being used by CMS. Conversely, we also agree that there are also machines that are typically used at rates that are less then 50%. The Academy supports the recommendation of the AMA RUC regarding changes to the utilization percentage for high cost equipment. If CMS disagrees or is unable to resolve this issue then we would propose that the Practice Expense Review Committee of the AMA RUC continue to explore alternative options with the cooperation and input of CMS especially in the area of sharing data on utilization.

Specific Coding Issues Related to the PFS-- Reductions in the TC for Imaging Services Under the PFS to the Outpatient Department (OPD) Payment Amount

The Academy disagrees strongly with the proposal in CMS—1385—P that would add six ophthalmology codes to the list of procedures that are subject to the reductions in the Technical Component (TC) for imaging services as required under the 2005 Deficit Reduction Act (section 5102(b)(1). Per the provision in the law, imaging and computer-assisted imaging services includes x-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography

(CT), and fluoroscopy but excluding diagnostic and screening mammography were the technologies targeted for these decreases.

The ophthalmology codes that would now be included absolutely do not fall under the categories of x-ray, ultrasound, MRI, PET, CT or fluoroscopy and CMS was correct in its first delineation of these codes as not being subject to the DRA provisions. CPT Code 92250 is taken via a wide-angle camera and is used primarily for detecting retinopathy in diabetics. Additionally, 92235, 92240, 92285 are also all photos, the first two using injected dyes. For these codes with dye the only difference is that the negatives are viewed instead of the actual photo. Furthermore, as CMS indicates in its proposal, the impact of these changes is negligible. The utilization of these codes is only for eye care services and they have not seen dramatic increases and in fact most of them remain stable or have in fact decreased.

Specific Coding Issues Related to the PFS -- Additional Codes From the 5-Yr. Review of Work

The Academy would like to commend CMS for its decision to accept the vast majority of recommendations from the RUC throughout the 5 Year Review Process. In particular, we are pleased that the results of the review that ophthalmology undertook last winter to demonstrate that indeed, similar to the increased work involved with other evaluation and management office visits, that the physician work of the evaluation and treatments of patients seen by ophthalmologists has also similarly increased.

Development of RVU's –Adjustments to RVU's for Budget Neutrality

The Academy reiterates its concerns expressed last year about the inconsistent method that CMS has used to apply budget neutrality to the work relative value units (RVUs) instead of to the conversion factor as has been done previously. The Omnibus Budget Reconciliation Act of 1989 requires that increases or decreases in relative value units (RVUS) for a year may not cause the amount of expenditures for the year to differ more than $20 million from the expected expenditures without the new RVU changes. For the final codes remaining from the Five Year Review that are being implemented in 2008, CMS is proposing to again effect the statutorily mandated budget neutrality adjustment by developing a new work adjuster. **The Academy strongly objects to this approach and recommends that budget neutrality be applied to the final conversion factor and not solely to work relative value units.**

Issues Related to PLI Relative Values

The Academy strongly supports the recent discussions and recommendations of the AMA RUC PLI Workgroup in regards to the issue that there are inequities that exist between the technical and professional components

regarding PLI RVUs. The work group found that there are no identifiable separate costs for professional liability for technical professionals. **Therefore, the PLI Workgroup recommends that CMS reduce the PLI technical component to zero. The PLI RVUs should then be recalculated to ensure that these PLI RVUs are redistributed across all physician services.**

Part B Drug Issues --Average Sales Price (ASP) Issues

We noted CMS' proposal to address the bundled pricing concessions offered by some drug manufacturers as recommended by the MedPAC in its 2007 Report to Congress. However, in that same report MedPAC also pointed to other problems with the ASP payment program that the Academy requests that CMS also address expeditiously. First, manufacturers may offer prompt-pay discounts to wholesalers who pay for their purchases within a specified time frame. Although these discounts are small in percentage terms, they are an important source of revenue for wholesalers and are unlikely to be passed on to the final purchaser (such as a physician). Prompt-pay discounts lower ASP because they reduce the price manufacturers receive for their products. When these discounts are not passed on to physicians, Medicare's ASP may fall below the average price physicians pay.

Additionally, for those drugs that are only available through wholesalers, it is not uncommon for these sellers to mark up the price they charge to physicians. These fees may include wholesaler profit, handling, and shipping costs. Manufacturers do not receive more for their product and therefore do not include these fees in calculating ASP. Thus, these markups may result in drug prices that are high relative to the ASP manufacturers report.

This is the case for one very common ophthalmology drug that is used in the treatment of age-related macular degeneration, ranibizumab. Currently the July 2007 ASP payment for this drug is $2,031.11 and our members report that there cost is $1950 Such a slim margin does not take into account the storage, handling and other physicians have costs associated with providing this drug to Medicare patients. These distortions on ASP reduced the margin to approximately 4% for ranibizumab and the net affect lowers it even further. We agree strongly with the MedPAC recommendation in their discussion and recommendation on the bundling issue that CMS gather data on the acquisition costs to physicians for commonly bundled drugs that they also gather physician costs on drugs where the payment is reported to be below or less than the allowed six percent. The Academy recommends, **CMS should review the costs associated with administering drugs in the office where the ASP price is less than 6% above the acquisition price or where ASP does not meet the acquisition price.**

We fully understand that there is a lower cost non-FDA approved drug (Avastin) similar to ranibizumab that many ophthalmologists have opted to use, although CMS does not have a national coverage policy on Avastin and

not all carriers allow payment. In states that private practice physicians are referring their AMD patients out for hospital-based treatment because they can not absorb the cost of administering the drug on such a slim ASP margin.

Part B Drug Issues --Competitive Acquisition Program (CAP)

The Academy has been and remains supportive of the CAP for Part B drugs administered in the physician's office. When this program first was initiated in 2006, more then 300 ophthalmologists signed up to participate. However, as the program progressed, several issues that impact on our members ability to provide optimum patient care have caused more then half of those physicians to abandon the program. We continue to see this program an alternative to stabilize drug prices and to remove the physician from the high financial burden of purchasing the drugs. We recommend some modification and therefore asking for some changes.

The primary reason that ophthalmologists provide drugs in the office is for the treatment of age-related macular degeneration (AMD.) Currently AMD is the leading cause of visual impairment in Caucasians over the age of 50 in the United States, affecting more than 1.5 million people. The development of Anti-VEGF drugs that inhibit the development of unwanted blood vessels that cause wet AMD are a major therapeutic advance. This treatment is why ophthalmologists, especially those that treat retinal disease, participate in the CAP program. Two of the biggest problems faced by ophthalmologists in the CAP are discussed in this rule and we would like to provide the following comments.

1. Transporting CAP Drugs: Although ophthalmology is still dominated by solo or small group practices, more and more ophthalmologists are providing care in larger group settings. This means that a practice may have more then one location and some may have several. Under the current statute and rules the CAP vendor may only send the drugs that have been ordered to one main address. The burden of getting the drug to the alternative site where the patient might be seen is on the practice. This has proven to be a deterrent to many of our members who wish to participate in the CAP program and has caused others who initially signed up to stop participating. **The Academy strongly supports any effort that will allow the vendor to ship directly to a satellite office setting where patients would be treated in addition to the main office and we would request that CMS finalize this proposal as soon as possible.**

2. Pre-filled Syringes: **The Academy would also welcome the possibility of rulemaking that was discussed in CMS—1385—P that would allow for the repackaging of drugs in patient specific doses in pre-filled syringes upon request from the participating CAP physician.** Such an option would not only reduce wastage from the usage of 100 mg single use vials for a 1 mg injection as pointed out in the discussion, but it would also ensure more accurate dosing by eliminating the need to overfill a syringe and most

importantly it eliminates the possibility of microbial infections that can occur from reconstituting and repackaging drugs. Currently, ophthalmologists who are participating in the CAP and use bevacizumab must send the drug out to a compounding pharmacy in order to obtain the appropriate dosage for their patients. Moving to pre-filled syringes would provide a convenient and safe alternative for AMD patients. The Academy would not support limiting the use of pre-filled syringes only to CAP participants because the convenience, safety and most importantly savings that it would bring should not be limited. Furthermore, many other drugs are already delivered in such devices so it would not be fair or feasible to suddenly deny access to such a delivery mechanism for Medicare beneficiaries.

Percentage Change to the Medicare Economic Index (MEI)

The Academy strongly supports the comments of the American Medical Association urging CMS to reduce the productivity adjustment to the MEI to 0.65 percentage points, as the Administration has recommended for other Medicare providers.

We also continue to support the issues laid out in the letter sent from the Academy and other medical groups in April urging CMS **to include in the MEI any additional inputs that are needed to ensure that the MEI adequately measures the costs of practicing medicine.** Factors (or inputs) to the MEI are vastly different now then when the MEI was first developed in the early 1970s, and thus additional inputs may be needed to ensure that the current MEI adequately measures the costs of practicing medicine. For example, physicians must comply with an array of government-imposed regulatory requirements that did not exist in 1973, including those relating to: Medicare prescription drug plans and compliance, compliance with rules governing referrals and interactions with other providers; detailed new and modified coverage policies; advanced beneficiary notices; certificates of medical necessity; rules governing Medicare dual eligible patients; limited English proficiency rules; Medicare audits; the Health Insurance Portability and Accountability Act (HIPAA) and Clinical Laboratory Improvement Act (CLIA); billing errors; quality monitoring and improvement; and patient safety. CMS is also promoting the use of electronic medical records and other new health information technology systems that facilitate physician participation in quality improvement initiatives. To ensure compliance with these requirements, physicians often must take actions that increase their practice costs, including such actions as hiring: additional types of office staff; attorneys for legal and regulatory compliance; and accountants and billing companies to ensure proper billing of claims to handle these additional responsibilities. These types of inputs are not currently taken into account for purposes of measuring the MEI, and therefore the MEI undervalues actual medical cost increases.

<u>Division B of the TRHCA 2006 --Section 101(b) PQRI</u>

The Academy appreciates CMS' flexibility and accessibility in the incredibly short timetable for implementation of this program. Working together, in short order, we have been able to get approximately 60 percent of ophthalmologists to participate in the program. This is due in no small part to CMS recognition of physician-developed measures based on the Academy's depth of broadly recognized evidence based guidelines or Preferred Practice Patterns (PPPs). The Tax Relief and Health Care Act of 2007 (TRHCA) calls on CMS to continue implementation of PQRI into 2008 and we appreciate the opportunity to comment on the next phase of this program. The Academy has the following comments concerning the provisions in the proposed rule:

1. Table 16 of the proposed rule lists the quality measures that are included in the 2007 Physician Quality Reporting Initiative (PQRI); however, an eye care measure that was developed by the AMA Physician Consortium for Performance Improvement (PCPI/Consortium), endorsed by the AQA and NQF, and included in the 2007 PQRI program is absent from Table 16. **The Academy urges CMS to correct this error and include to the table the following measure: "dilated macular exam for patients with age-related macular degeneration."** It is an important measure in enhancing quality care for patients with the <u>leading cause of blindness</u> in the Medicare population and for <u>ensuring appropriate use of new treatments</u> that could potentially cost CMS more than $ 1 Billion a year.

2. In Table 17 of the rule, CMS proposes to include measures in the final 2008 PQRI that have been given NQF endorsement and AQA adoption by November 15, 2007. The Academy sees a significant omission on this list in view of newly created eye care measures in the works. The Eye Care Workgroup of the AMA PCPI has been working on additional eye care measures since the beginning of 2007 and is scheduled to vote on them October 5, 2007. The measures were provided to the AQA Alliance in draft form prior to the July 12 proposed rule. The PCPI sent the set of 7 new eye care measures out for public comment on August 21. We expect that several new eye care measures will be ready for the AQA Alliance meeting on October 18. If these measures are approved, they would meet the timetable set forth by CMS in the proposed rule for inclusion in 2008 PQRI. **The Academy believes the following eye are measures should be included in Table 17 for consideration as 2008 PQRI measures:**
   - Measure #1 Primary Open-Angle Glaucoma: Reduction of Intraocular Pressure by 15% or Documentation of a Plan of Care
   - Measure #2 Primary Open-Angle Glaucoma: Counseling on Glaucoma
   - Measure #3 Cataracts: Postoperative Complications within 30 Days Following Cataract Surgery
   - Measure #4 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery
   - Measure #5 Cataracts: Comprehensive Pre-operative Assessment for Cataract Surgery with IOL Placement
   - Measure #6 Cataracts: Counseling on Cataract Prevention

- Measure #7 Revised Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplements

3. **The Academy requests that CMS continue to include 2007 measures in 2008 PQRI that have been endorsed by at least one body, such as AQA, for 2-3 years.** It is extremely costly, time intensive to develop the measures and 2007 is essentially a partial or practice year. By continuing to include measures that have been endorsed by at least the AQA, it will allow the measure developer to identify errors or other problems with the measure(s) before they develop the next generation of measures. Dropping measures that were accepted by AQA, but not endorsed by NQF has led to the deletion of 4 eye care measures after only six months of reporting. Physicians who have arranged their billing systems to report on those 4 measures will have to restructure their practice billing and reporting systems to report on different measures if they want to continue to participate in 2008. Most likely this will deter continued participation by those physicians who have to change their systems and raise concerns among those who do not yet participate.

   To the extent that the new measures supersede the older 2007 measures (in particular the pre-operative cataract surgery testing measures that have been combined into one in the proposed 2008 indicator set) we would endorse sunsetting the older, superseded measures. In such situations, our physician and provider communities have taken the lead in developing better measures.

4. **The proposed rule states that no measure will be used for the 2008 measures set that has not been endorsed by NQF. The Academy urges CMS to exercise caution in weight given to NQF approval over other organizations.** The NQF has limited experience in physician quality measurement approval. Their lack of experience has been evident in their formation of the Technical Advisory Panels (TAPs) and the outcomes. The Eye Care TAP had only four practitioner members on the panel; two ophthalmologists and two optometrists with equal voting power given to the optometrists. Many of the panel members were not individuals with clinical or research experience to appropriately evaluate the use or potential benefits of such measures or the practical problems with other alternatives that might have been considered.

   The NQF TAP panels have had inconsistent structures and processes for evaluating indicators, contrasted to the standardized process used by the AQA. NQF TAP panels have had varying membership criteria, interpretation of approval criteria and as such produced different outcomes. Indeed, the process of the TAP was determined by the chair as opposed to following a structured, standardized set of criteria on how they should operate. Because the NQF is still refining its process and making changes in order to better consider physician-specialty developed quality measures, the Academy joins other organizations in support of retaining AQA-approved 2007 PQRI measures for at least two years.

Division B of the TRHCA 2006 – Section 101(d) PAQI

The TRHCA required the Secretary of the Department of Health and Human Services to establish a Physician Assistance and Quality Initiative Fund (Fund) in the amount of $1.35 billion. TRHCA authorized the Secretary to use these funds for physician payment and quality improvement initiatives, including application of the Fund to adjust the physician conversion factor. Although physicians are facing a 10% payment rate cut on January 1, 2008, CMS has chosen to use the Fund for quality purposes only rather than applying it to the conversion factor. **The Academy strongly believes these funds should be used for the conversion factor. Congress intended that this Fund be established to benefit all physicians. Use of the Fund to establish bonus payments for the voluntary PQRI will allow only a limited number of physicians to be eligible for these funds, while applying the Fund to the conversion factor will allow all physicians to benefit. Furthermore, in addition to statutory authority, MedPAC recommendations specifically indicate that this set aside should be used to reduce the conversion factor reduction in 2008.**

The Academy appreciates the opportunity to comment on the proposed rule. If there are additional questions and/or comments regarding the cost of ophthalmology code inputs we encourage CMS to contact us. Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response to our comments in the final rule.

Sincerely,

Michael X. Repka, M.D.
Secretary of Federal Affairs

Submitter : **Dr. Donald J Fox** **Date: 08/31/2007**

Organization : **Dr. Donald J Fox**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Donald J Fox, MD

Submitter : **Richard Morris** **Date: 08/31/2007**

Organization : **Richard Morris**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Leslie V. Norwalk, Esq.
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Thank you for your consideration of this serious matter.
Richard Morris

CMS-1385-P-13816

Submitter : **M Hankins** **Date: 08/31/2007**

Organization : **M Hankins**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : Danny Hathcock **Date:** 08/31/2007

Organization : Danny Hathcock

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.
Danny Hathcock

Submitter : **K Whipple** **Date: 08/31/2007**

Organization : **K Whipple**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Thank you for your consideration of this serious matter.

Submitter : **Mr. Ray Lane** **Date: 08/31/2007**

Organization : **Mr. Ray Lane**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1385-P-13819-Attach-1.DOC

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05	Interventional Pain Management Physicians

	(Non-Facility)	- 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Ray Lane
81 Lakeview Drive
Paducah, KY 42001

Submitter : **Wick Biggs** **Date: 08/31/2007**

Organization : **Wick Biggs**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Wick Biggs

Submitter : **T Disler** **Date: 08/31/2007**

Organization : **T Disler**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : **Dr. Masha Barenbaum** **Date: 08/31/2007**

Organization : **Children's Hospital of Michigan**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medieare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Rc: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule.
I am a recent graduate from a residency program and I know first hand that this increase in reimbursement will signifieantly improve the quality of training for future trainees.

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Submitter : Mrs. Jaci Widlowski **Date: 08/31/2007**

Organization : Mrs. Jaci Widlowski

Category : Individual

Issue Areas/Comments

GENERAL

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Submitter : **A Johnson** **Date: 08/31/2007**

Organization : **A Johnson**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Submitter : **Dean Morris** **Date: 08/31/2007**

Organization : **Dean Morris**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Dean Morris

Submitter : Mr. Christopher Riedy **Date:** 08/31/2007

Organization : Coordinated Health

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-13826-Attach-1.TXT

1582-6

Dear Sir or Madam:

I am a certified athletic trainer and strength and conditioning specialist. I currently work for Coordinated Health, a large orthopedic practice located in Pennsylvania's Lehigh Valley. As the director of athletic training services for our company, we employ and use athletic trainers in our clinical and outreach programs.

Today, I am writing to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Christopher D. Riedy, ATC, CSCS

Athletic Training Program/PULSE/DME Coordinator

Orthopedic Surgery • Sports Medicine • Employer Healthcare • Chiropractic • Physical Medicine
Pain Management • Podiatry • Physical & Occupational Therapy • Fitness

❑ CH Allentown	1401 N. Cedar Crest Blvd	Allentown, PA 18104	Phone 610-433-8080	Fax 610-433-4376
❑ CH Surgical Specialty Center	2310 Highland Avenue	Bethlehem, PA 18020	Phone 610-691-4300	Fax 610-691-6257
❑ CH Bethlehem / Corporate	2775 Schoenersville Road	Bethlehem, PA 18017	Phone 610-861-8080	Fax 610-861-2989
❑ CH Highland	2300 Highland Avenue	Bethlehem, PA 18020	Phone 610-865-4880	Fax 610-997-7171
❑ CH Easton	400 S. Greenwood Avenue	Easton, PA 18045	Phone 610-515-8080	Fax 610-515-8080
❑ CH East Stroudsburg	505 Independence Road	East Stroudsburg, PA 18301	Phone 570-420-8080	Fax 570-420-1704
❑ CH LVO	1605 N. Cedar Crest Blvd	Allentown, PA 18104	Phone 610-821-4800	Fax 610-289-2089

Toll Free 1-877-247-8080 • www.coordinatedhealth.com

Submitter : Mr. Ben Johnston **Date:** 08/31/2007

Organization : Focus On Therapeutic Outcomes Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

As the leading developer of quality and outcomes measures for outpatient rehabilitation therapy, Focus On Therapeutic Outcomes, Inc., (FOTO) is pleased to provide comments in response to the Notice of Proposed Rulemaking pertaining to the Medicare Physician Fee Schedule (PFS) as published in the Federal Register / Vol. 72, No. 133 / Thursday, July 12, 2007. We comment on several of the above issues in the attached letter. Please contact me if you have questions.

Submitter : L Johnson **Date: 08/31/2007**

Organization : L Johnson

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Submitter : KEN BIGGS **Date:** 08/31/2007

Organization : KEN BIGGS

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Ancsthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.
KEN BIGGS

Submitter : **Denise Boehm** **Date: 08/31/2007**

Organization : **Lotus Heart Holistic Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

RE: Docket #1385-P Therapy Standards and Requirements, Physician Self-Referral Provisions

? My name is Denise Boehm I am a licensed Massage Therapist licensed in Fl #MA49001 and National Certification #521813-06. I have a Masters of Science as well as my LMT.
?I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

?CMS has offered no explanation as to why these significant changes to Hospital Conditions of Participation are necessary. These changes have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

?I am qualified to perform physical medicine and rehabilitation (PMR) services; physical therapy is only a small subset of PMR. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

?The lack of access and current and future workforce shortages to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The current standards of staffing provide hospitals and other rehabilitation facilities the flexibility to ensure patients receive the best, most cost-effective treatment available.

?I strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Denise Boehm, LMT
529 East New Haven Ave., Melbourne, FL

Submitter : **E Johnson** **Date: 08/31/2007**

Organization : **E Johnson**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter : **Cindy Morris** **Date: 08/31/2007**

Organization : **Cindy Morris**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Cindy Morris

Submitter : H Johnson **Date:** 08/31/2007

Organization : H Johnson

Category : Individual

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Submitter : **Greg Bloxom** **Date: 08/31/2007**

Organization : **Greg Bloxom**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Submitter : **T Bruton** **Date: 08/31/2007**

Organization : **T Bruton**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Submitter : Tempus Glass **Date:** 08/31/2007

Organization : Tempus Glass

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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CMS-1385-P-13837

Submitter : **Mr. John Donahue** **Date: 08/31/2007**

Organization : **National Imaging Associates, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-13837-Attach-1.PDF

#13837

August 31, 2007

The Honorable Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1385-P: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Acting Administrator Weems:

As a leader in Radiology Benefits Management, National Imaging Associates, Inc. is pleased to submit the following comments on the Proposed Rule for CY 2008 Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies.[1] Our comments speak to one of the proposed **"Physician Self-Referral Provisions."**

Background on NIA and its Services

National Imaging Associates, Inc., headquartered in Avon, Connecticut, is the largest company in the field of radiology benefits management. A subsidiary of Magellan Health Services, NIA's mission is to promote the clinically appropriate and cost-effective use of advanced imaging procedures.

With operations spanning more than 36 states, NIA touches the work of nearly 185,000 physicians and over 20 million patients nationwide. NIA is fully accredited by URAC, a leading healthcare quality organization. Moreover, NIA was the first radiology benefits management organization to earn a certification from the National Committee for Quality Assurance.

[1] Proposed Rule, "Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and other Part B Policies for Calendar Year 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for Calendar Year 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions," Centers for Medicare and Medicaid Services, 72 Fed. Reg. 38,122 (July 12, 2007).

Overview of Comments

NIA agrees that CMS should act decisively to address the recent significant growth in the cost of imaging benefits to the Medicare program. We urge CMS to ensure that current and future rulemakings address potential abuses of the Physician Self-Referral regulations while continuing to preserve convenient, clinically appropriate access to advanced diagnostic imaging services for all beneficiaries.

We understand that some recent business practices may take advantage of exceptions in the so-called "Stark II Provisions"[2] to create new self-referral patterns that were not contemplated when the regulations were adopted. NIA believes that such practices reflect a growing misalignment of incentives between payers and providers of diagnostic imaging services and may ultimately contribute to escalating utilization that drives excessive growth in the cost of imaging services to the Medicare program[3] without a commensurate improvement in the quality of patient care.

Specifically, NIA supports the CMS proposal to prohibit per click based payments in space and equipment leases to physician owned equipment. We also agree that CMS should develop a prohibition for time or click based payments by physicians as outlined in the comment request.

NIA believes that providing robust decision support to clinicians when they order advanced diagnostic imaging will help better align incentives between payers and providers by ensuring access to advanced imaging, enhancing quality patient care, and compensating providers appropriately for reasonable cost of services.

Specific Comments

Regarding the "per-click" issue, in a recent article in *Health Affairs*, Dr. Jean Mitchell, Ph.D. reported the results of her research into emerging patterns of referrals for imaging services paid by one commercial insurance plan in California.[4] Her analysis highlights two recent business practices apparently intended to take advantage of exceptions in the Stark provisions:

- "Time-sharing" arrangements allow referring physicians to rent an imaging center for a specific period of time each day or week, then send their patients to the facility at that designated time. The referring physician submits a global bill to the insurer for both technical and professional components of the service.

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[2] See 42 US Code, §1320a-7b(b).

[3] "MedPAC Recommendations on Imaging Services," Statement of Mark E. Miller, Ph. D,. Medicare Payment Advisory Committee, before Subcommittee on Health, House Committee on Ways and Means (March 17, 2005).

[4] Mitchell Dr. JM. The prevalence of physician self-referral arrangements after Stark II: Evidence from advanced diagnostic imaging. *Health Affairs* 26(3):w415-w424, 2007.

- "Payment per scan" arrangements allow referring physicians to pay a set fee to an imaging service provider for each scan performed. The referring physician submits a global bill to the insurer, retaining the difference between the amount paid for the scan and the amount reimbursed by the insurer.

Mitchell raises concerns that these practices may exploit loopholes in the law and regulations. Though her data report one payer's experience in one state, she urges decision makers to consider the potential broader policy implications. CMS' notice acknowledges that these and other arrangements may be increasingly common across the country and expresses concern that such practices may represent an abuse of the Stark regulations.

In its Report to Congress in 2005, MedPAC wrote, "Physician ownership of entities that provide services and equipment to imaging centers and other providers creates financial incentives for physicians to refer patients to these providers, which could lead to higher use of services. Prohibiting these arrangements should help ensure that referrals are based on clinical, rather than financial, considerations. It would also help ensure that competition among health care facilities is based on quality and cost, rather than financial arrangements with entities owned by physicians who refer patients to the facility."[5]

We know from our experience reviewing imaging decisions that providers increasingly consider a variety of business models to protect their financial interests in the face of declining payment amounts for advanced diagnostic imaging. We agree that physicians should be paid appropriately for the real practice expenses they carry and for the intensity of professional services rendered. We also agree that appropriate financial arrangements can and must be developed without relying on loopholes in existing regulations. Decision support when diagnostic imaging is ordered offers one solution with demonstrated success.

NIA has found that it can help ensure appropriate access to advanced imaging services and manage the cost for these services through Radiology Benefits Management (RBM). This service, provided by radiology experts at the time of ordering, provides an extra layer of care and enables doctors to receive informed counsel when ordering imaging services.

NIA promotes clinically appropriate, cost-effective imaging through a carefully organized system of radiology benefits management. The system draws on the judgment of clinical experts, applied in individual patient circumstances, as well as on the knowledge derived from the cumulative experience of millions of such patient encounters.

Though NIA's services are often customized to the needs of particular health plans, our process for managing radiology benefits typically involves the following steps:

- The ordering provider contacts NIA for pre-authorization to use imaging services in an individual patient case. The provider makes the contact either by telephone or via "RadMD" – an NIA Web portal that provides near real-time information.

[5] See "Report to the Congress: Medicare Payment Policy," Medicare Payment Advisory Committee (March 2005) at 154-170.

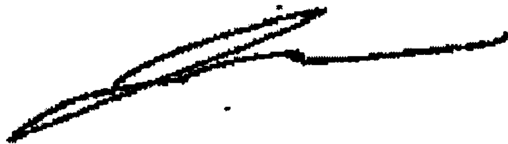
- NIA captures the pertinent clinical information for the case and supplies a consultation to the ordering provider. In carrying out these consultations, NIA relies on over 450 experienced employees, including 30 board-certified physicians with expertise in imaging procedures, as well as specialists in medical science, medical law, information technology, operations management, customer service, accounting, and finance.

- The results of the consultation are transmitted to the appropriate stakeholders, including the ordering provider, the radiologist, and the health plan. The details are also entered into NIA's clinical and financial database – a database that, with 150 million imaging encounters, is the nation's largest. By continually replenishing this database, NIA captures cumulative patient experience, which enables creation of the industry's most advanced algorithms for making decisions on the quality and efficiency of imaging services.

Radiology benefits management is an important way to align payer and provider incentives for advanced diagnostic imaging. It can be effectively implemented without questionable self-referral practices and can form the foundation of a robust system that ensures patient access, addresses program cost concerns, and compensates providers appropriately.

NIA appreciates the opportunity to submit these comments and to provide information on radiology benefits management and its potential for ensuring clinically appropriate, cost-effective imaging services. If it would be helpful to CMS in implementing Medicare's 2008 physician fee schedule, we would be happy to supply additional practice-pattern information from our clinical and financial database. We are also prepared to serve as a technical resource to CMS in connection with any proposals to address Medicare physician-related expenditures for imaging services.

Sincerely,



John J. Donahue
Chairman

Submitter : **C Bruton** **Date: 08/31/2007**

Organization : **C Bruton**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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CMS-1385-P-13839

Submitter : Doug Morris **Date:** 08/31/2007

Organization : Doug Morris

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Doug Morris

Submitter : LAURA BLOXOM **Date:** 08/31/2007

Organization : LAURA BLOXOM

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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LAURA BLOXOM

Submitter : G Bruton **Date: 08/31/2007**

Organization : G Bruton

Category : Individual

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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CMS-1385-P-13842

Submitter : **Mr. Jeffrey Reichman** **Date: 08/31/2007**

Organization : **CardioVision, Inc.**

Category : **Private Industry**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

As such, we specifically ask CMS to provide a continued exemption for cardiac catheterization be it performed in an independent facility, hospital outpatient, or hospital inpatient, in order to best serve the communities, maintain the standard of care in which these facilities operate, reduce cost of care, and in order to meet the intent of Congress and the historical position afforded by CMS s interpretation of an Entity.

In conclusion, while we appreciate the Center s intent of trying to control costs by tightening regulations under which physicians may refer to interests in which they have a economic interest in, we none-the-less feel that the proposed regulations overstep your intent and will specifically result in lower quality and, higher cost cardiac catheterization services. We implore you to reconsider your proposed regulations and offer a continued exemption to those invasive and interventional services that have a long and strong track record for efficiency and effectiveness. I am happy to offer my services to you if you feel that additional information would be helpful as you make your final decisions.

Thank you for your consideration of our response.

Sincerely, Jeffrey A. Reichman, Partner, CardioVision, Inc.

CMS-1385-P-13842-Attach-1.DOC

Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018 **(3 Copies)**

PHYSICIAN SELF REFERRAL PROVISIONS

August 31, 2007

Dear Madame or Sir:

I am writing you in response to CMS's proposed changes to a number of rules governing participation the Medicare program, and the establishment of physician/hospital joint ventures; particularly with regard to the establishment of Cardiac Catheterization programs.

CardioVision is a turn-key, non-equity developer of cardiovascular services. Over the past eighteen years, CardioVision, and the companies that I have developed previously, have established over 60 cooperative physician hospital joint ventures across the United States. While over the years, many of our business structures have changed, the underlying principles relating to alignment of incentives between cardiologists and hospitals has always been of primary consideration. As a result of this alignment, we have seen a higher quality and more cost effective delivery system take hold, ultimately resulting in better patient outcomes and lower cost to consumers and payors including Medicare.

While we appreciate that in many areas physicians continue to over utilize, increasing the cost to Medicare; with specific reference to cardiac catheterization, this has not been the case. In 1998, when the first Stark II regulations were introduced, HCFA specifically excluded invasive and interventional radiology from Stark regulations stating, "It is our view that physicians do not routinely refer patients for [invasive or interventional radiology procedures] in order to profit from unnecessary radiology services."[i] Since this initial publication, CMS has never changed its opinion regarding these invasive and interventional procedures.

With this said, several of the proposed regulations incorporated in the recent July 12, 2007 proposals, significantly and materially impact physicians' ability to enter into cooperative joint ventures with their local hospitals. As such, it is our belief that should these proposed regulations take effect, the result will destabilize the health care delivery system creating patient access issues, costly duplication of capital investment, and expensive dismantling of highly efficient healthcare facilities.

1601 West 5th Avenue, #178, Columbus, Ohio 43212
Tel: (614) 228-8124 Fax: (614) 573-6385

Since Stark II, Part II came out in 2001, most catheterization lab joint ventures have operated through an Under Arrangement relationship between the cath lab company and the hospital. Services provided under arrangement improve access to care and provide high quality, cost effective care under the hospital's professional supervision. Furthermore, because Stark II regulations require fair market value pricing of the services provided by the cath lab to the hospital, physicians are prohibited from making excess profits beyond what independent valuators would reasonability identify as reasonable given the level of risk associated with providing such services. One area in which we would be in favor of strengthening regulations would be to require such valuations be performed by accredited/certified valuators as determined by one of the several national accreditation/certification organizations. This would result in better information being delivered to hospitals and their physician partners while also protecting such parties from potential inadvertent fraud from faulty valuations.

As a recent study by Boston University's School of Public Health concluded, physicians control the majority of hospital costs.[ii] Under arrangement agreements promote greater physician involvement in service delivery efficiency and cost control, focusing on quality, and better alignment of incentives related to the operation of critical hospital service lines.

It is our belief that should the regulations be enacted as promulgated, the loss of Under Arrangement contracting will result in a substantial hardship to hospitals, physicians, and the communities they serve while increasing the cost to provide services to Medicare and other governmental and commercial payors, and to patients themselves. As such, we believe that CMS must address the specific needs of catheterization lab providers, and the providers of like services such as lithotripsy, dialysis, and radiation therapy, by providing an exemption for these high cost, low volume procedures from the proposed regulatory changes.

As it specifically relates to cardiac catheterization, several material facts must be considered:

- Cardiac catheterization services benefit from the clinical oversight of a hospital. Patients benefit from the oversight/services available to them through the hospital relationship including, but not limited to, physician credentialing, quality assurance, and utilization review.
- CMS has taken the position that certain services such as cardiac catheterization that are not a designated health service when directly furnished become DHS hospital services when furnished under arrangements. American Lithotripsy Society et al v. Tommy G. Thompson, No. 01-01812 (D. DC, July 12, 2002), raises the question of whether other services provided "under arrangements" with a hospital are not DHS, and therefore are not subject to the Stark Law's prohibitions. Because CMS proposed that the definition of Entity be changed from the clear bright line test that the entity that bills the Program is the entity

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furnishing the DHS, this clear definition may be replaced with a much less straightforward definition subject to the interpretive whim of CMS, providers, and/or their counsel. As such, we believe that at the very least, CMS needs to clarify specifically its intent and definition of "perform" as it relates to DHS and what constitutes "caused a claim to be presented".

In the Stark II regulations, published in the Federal Register on January 4, 2001[iii], cardiac catheterization was specifically excluded from the list of designated health service:

> We agree with commenters that ''invasive'' radiology includes more than just those procedures used to ''guide a needle, probe or catheter.'' Consequently, we are revising our definition of radiology and certain other imaging services to exclude from the definitional list of codes x-ray, fluoroscopy, and ultrasound services that are themselves invasive procedures that require the insertion of a needle, catheter, tube, or probe. Thus, cardiac catheterizations and endoscopies will not fall within the scope of ''radiology services'' for purposes of section 1877 of the Act.

- Percutaneous coronary interventions are frequently performed immediately following cardiac catheterization rather than scheduling the patient to undergo the second procedure at a later date. An analysis of the 68,528 patients with stable angina entered in American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) from 2001-2003 revealed that 60.6% of these patients underwent ad hoc PCI[iv]. The advantages of such a strategy are quite clear in terms of patient convenience and program savings. These procedures cannot be performed in an independent diagnostic testing facility because the IDTF has no billing mechanism available. They can, however, be performed under arrangements because the Hospital Outpatient Prospective Payment System provides reimbursement methodology.

As such, we specifically ask CMS to provide a continued exemption for cardiac catheterization be it performed in an independent facility, hospital outpatient, or hospital inpatient, in order to best serve the communities, maintain the standard of care in which these facilities operate, reduce cost of care, and in order to meet the intent of Congress and the historical position afforded by CMS's interpretation of an Entity.

In conclusion, while we appreciate the Center's intent of trying to control costs by tightening regulations under which physicians may refer to interests in which they have a economic interest in, we none-the-less feel that the proposed regulations overstep your intent and will specifically result in lower quality and, higher cost cardiac catheterization services. We implore you to reconsider your proposed regulations and offer a continued exemption to those invasive and interventional services that have a long and strong track

record for efficiency and effectiveness. I am happy to offer my services to you if you feel that additional information would be helpful as you make your final decisions.

Thank you for your consideration of our response.

Sincerely:

Jeffrey A. Reichman
Partner

References:

[i] Federal Register, Vol. 63, No. 6, p 1676.
[ii] Health Costs absorb One-Quarter of Economic Growth, 2000-2005. Boston University School of Public Health. February 2005.
[iii] Federal Register, Vol. 66. No. 3, p. 927.
[iv] Krone RJ, Shaw RE, Klein LW, Blankenship JC, Weintraub WS; American College of Cardiology – National Cardiovascular Data Registry. Ad hoc percutaneous coronary interventions in patients with stable coronary artery disease – a study of prevalence, safety, and variation in use from the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR), Catheter Cardiovasc Interv. 2006 Nov;68(5):696-703.

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CMS-1385-P-13843

Submitter : Mr. Jack Cumming

Date: 08/31/2007

Organization : Hologic, Inc.

Category : Device Industry

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

See attached document

CMS-1385-P-13843-Attach-1.DOC

13843

HOLOGIC®

August 31, 2007

Mr. Kerry Weems
Administrator Designate
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1385-P: Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

> Comments on Current Procedural Terminology (CPT) Codes 77080 (Dual energy X-ray Absorptiometry), 77082 (Vertebral Fracture Assessment), 77051 (Computer Aided Detection, Diagnostic), 77052 (Computer Aided Detection, Screening), and 77057 (Mammogram, Screening), and on Healthcare Common Procedure Coding System (HCPCS) Code G0202 (Screening Mammogram, Digital) [RESOURCE-BASED PE RVUs]

Dear Mr. Weems:

Summary

Screening procedures for osteoporosis and breast cancer are critical components of the Centers for Medicare and Medicaid Services' (CMS) preventive medicine campaign. Unfortunately, reimbursement cuts implemented in calendar year (CY) 2007 under the Physician Fee Schedule, which continue to be phased in through CY 2010, will seriously undermine the ability of physicians to provide these services in a timely and effective fashion. Cuts to Dual Energy X-ray Absorptiometry (70%), Vertebral Fracture Assessment (40%), Screening Mammography (4%-6%), and Computer Aided Detection (50%) will result in severely limited access to these life-saving technologies in many areas. At a time when the Department of Health and Human Services is actively encouraging individuals across the country to utilize health care screening and preventive services, it is incumbent upon CMS to act in a manner that is consistent with these efforts and work toward reversing the downward spiral in utilization of these screening technologies. ***Hologic urges CMS to do this by placing a moratorium on these reimbursement cuts until an appropriate mechanism can be developed to ensure that payment rates for these critical services do not impede beneficiary access.*** Such a mechanism must take into account the extra efforts and resources needed to maintain a successful, high-quality screening program with optimal utilization rates, and the overall economic benefits to be gained from such programs.

HOLOGIC, Inc. ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

Introduction

Hologic, Inc. is pleased to submit comments on the Medicare Program Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Payment Under Part B for Calendar Year 2008 issued by CMS. Hologic is a leading women's healthcare company with core business units focused on technologies for the early detection of osteoporosis and breast cancer. Osteoporosis and breast cancer are two diseases that become more prevalent as people age. The effects of both diseases can be minimized with early detection, when treatments are most effective, and least traumatic and costly. Hologic is committed to the development of technologically superior imaging systems to support the early detection of these diseases.

The highly publicized shift of focus by the Department of Health and Human Services (HHS) to preventive medicine and wellness programs is a testimonial to a similar commitment to decreasing morbidity and mortality and providing a better quality of life for Medicare beneficiaries. This goal will be difficult to achieve without broad, convenient access to high quality screening procedures for all eligible Medicare recipients. Hologic believes the significant cuts to the relative value units of the above referenced CPT and HCPCS codes, first implemented in the CY 2007 Physicians Fee Schedule and due to be fully transitioned in by CY 2010, will have the unintended effect of impeding access to key screening and diagnostic services.

Osteoporosis and Breast Cancer Screening

Americans are treated for more than 1.5 million osteoporosis-related fragility fractures annually, at a cost in excess of $18 billion in direct costs alone, while indirect costs, including lost productivity, likely adds billions of dollars to this figure. Women endure 71% of fractures and generate 75% of costs. Most suffer a diminished quality of life and more than 60,000 die within a year following the fracture. However, with appropriate and timely initiation of pharmaceutical intervention, the debilitating effects of osteoporosis can be halted, and, in some cases, reversed.

Dual energy x-ray absorptiometry (DXA) is the gold standard for osteoporosis screening. It is the only technology recognized by specialty societies for diagnosis of the disease, and the only one reimbursed by Medicare for monitoring response to therapy. Vertebral fracture assessment (VFA), combined with DXA, helps identify future fracture risk, thereby permitting more effective and earlier pharmacological intervention. In the 2004 Report of the Surgeon General on Bone Health and Osteoporosis, development of non-invasive tools to measure bone density was hailed by the Surgeon General as "one of the most significant advances in the last quarter century... Thanks to the development of bone mineral density testing, fractures need not be the first sign of poor health. It is now possible to detect osteoporosis early and to intervene before a fracture occurs[1]."

Breast cancer is the most prevalent type of cancer among U.S. women, and is the second leading cause of cancer death in women. According to estimates by the American Cancer

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Society, 240,500 new cases of breast cancer will be diagnosed in 2007 and more than 40,000 women will die of the disease. When detected early, however, the chance for a successful cure is nearly 100%. Death rates from breast cancer have steadily decreased since 1990, with larger decreases in women younger than 50 (3.3% per year) than those 50 years and older (2.0% per year). These decreases are due to a combination of earlier detection and improved treatment[2]. According to the Partnership for Prevention report on Preventive Care, if the percent of eligible patients screened in the last 2 years increased to 90%, an additional 3,700 lives would be saved annually[3].

Screening mammography and computer aided detection (CAD) are the two technologies acknowledged by professional societies to best enable the early detection of breast cancer. On average, mammography will detect about 80%-90% of breast cancers in women without symptoms[2]. The use of CAD as an adjunct to mammography has been shown to detect cancers earlier and at a lower stage, with at least one study showing the mean age at screening detection of cancer with CAD as 5.3 years younger than in those for whom CAD was not used[4]. Breast cancers detected at this early stage can be treated successfully with far less trauma to the patient and at a significantly reduced cost to the healthcare system.

Current Utilization Rates and Issues

The goal of a successful screening program is to have 100% participation of every eligible recipient. In our previous comment letters, we noted that actual utilization rates for Medicare recipients for osteoporosis and breast cancer screening fall far below this goal. Despite the government's vocal desire to increase utilization of screening services, the treatment of some screening services by Medicare will have the opposite effect.

Osteoporosis Screening

The incidence of osteoporosis, already of epidemic proportions, could escalate significantly in coming years. According to the 2004 Report of the Surgeon General on Bone Health and Osteoporosis, "Due primarily to the aging of the population and the previous lack of focus on bone health, the number of hip fractures in the United States could double or even triple by the year 2020[1]."

While there was a significant upswing in utilization for DXA exams for Medicare recipients due in part to the creation of a Medicare osteoporosis screening benefit (an increase of 77,133 in 1994 to 2,555,727 in 2004), DXA screening for osteoporosis has never exceeded 15% of the eligible base in any single year. The noted increase in utilization can be linked to a concentrated effort by professional societies, the Surgeon General's Office, and manufacturers to educate patients and physicians about the value of DXA screening and to make DXA systems more widely available outside of the hospital setting. According to 2004 Medicare claims data, 70% of DXA exams were performed in physicians' offices, and about 60% were done by non-radiologists. In addition to making

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The number of women becoming eligible for screening mammography (i.e., women between the ages of 40 and 85) is also rising. According to the 2000 census, the number of women between the ages of 40 and 85 was 60.9M; 2006 estimates for this same population is 65.9M.

The declining number of facilities and mammography units, combined with the steadily rising number of women becoming eligible for screening mammography will inevitably result in a lack of national capacity to provide accessible, adequate, and timely screening services. Evidence that this phenomenon is already occurring can be seen in the declining utilization rate reported in the NCI study of May 2007, and in reports of lengthy waiting times to schedule a mammogram. For example, some areas in Florida report as much as a 7-month wait to schedule a screening mammogram; the average wait time in the city of New York is 5.4 weeks, with some facilities in the Bronx and Brooklyn having waits in excess of 20 weeks; and, some New Jersey imaging centers are experiencing wait times of 3-4 months. Many areas throughout the country are beginning to experience similar unacceptably long waiting times.

The rising cost of providing mammography services is one of the contributing factors to continuing closures of certified facilities. A report released in July 2007 by the office of Representative Anthony Weiner, 9th Congressional District, New York, cited a nationwide cost increase of 25% between 2002 and 2007 for screening mammography, with the average cost for this service in 2002 of $103 escalating to $125 in 2007. The 2007 Medicare reimbursement rate for this service is $83.69, and will decrease to $80.72 by 2010. Many mammography facilities, already operating as financially marginal ventures, will find it difficult to sustain reimbursement cuts of any magnitude.

This conclusion is supported by the findings of a Government Accountability Office (GAO) report issued in July 2006, which stated that, when asked about the reasons for mammography facility closures, officials most often cited financial considerations. Significantly, the GAO's findings were based on conversations that occurred before the additional reimbursement cuts that began in 2007 and continue until 2010 were announced. The report further stated that "the loss or absence of mammography machines in certain locations may have resulted in access problems, consisting of lengthy travel distances or considerable wait times, including problems for women who are medically underserved[5]." Traditionally, women in rural areas are already less likely to receive screening services than women in, or close to, urban areas; however, recent reports indicate that, in the case of screening mammography, lengthy waiting times are not limited to rural areas.

Computer Aided Detection

CAD is a relatively new technology, first cleared for use in 1999 as an adjunct to screen-film mammography, with subsequent clearance in 2001 for use with digital mammography. Multiple, independent clinical studies have documented the ability of CAD to detect a statistically significant number of cancers at an earlier stage than is

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possible with mammography alone. Currently, less than 50% of all breast imaging practices use CAD. Adoption of this potentially life-saving technology has been slowed by declining reimbursement rates combined with the relatively poor economics of breast imaging.

Impact of Cuts on Access to Screening Technologies

CMS is to be commended for recognizing the value of preventive medicine and beginning the complex task of redefining agency objectives and priorities to drive this focus. An important consideration in this transition should be whether CMS payment policies support or deter the delivery of screening services. In the case of osteoporosis and breast cancer screening, current and projected reimbursement cuts clearly provide a disincentive to facilities providing these services and will in fact act as an impediment to the effective delivery of screening services.

Reimbursement for DXA was cut by 40% in CY 2007 and will be further reduced by a total of 70% by 2010 and reimbursement for VFA will be reduced by nearly 40% by 2010. Reimbursement for screening mammography will be cut by 4.4% (digital screening) to 5.8% (analog screening) by 2010 and CAD reimbursement will be cut by nearly 50%. In addition, scheduled sustainable growth rate (SGR) decreases could result in greater reimbursement cuts for all of these technologies.

In the case of therapeutic services, the CMS mandate is to drive efficiency and keep costs as low as possible in order to make the most effective use of allocated funds. This strategy, as applied to mammography, has clearly been effective; rising costs, inadequate reimbursement, and staffing shortages driven in part by financial constraints forced the closure and consolidation of more than 12% of mammography centers since 1999. Fewer centers with fewer mammography systems are handling an increasing number of procedures each year. However, this drive to increase efficiency may result in dire consequences for this life-saving screening service. Declining utilization rates, lengthy waiting times for appointments, and ongoing shortages of trained personnel are clear signals that hard-won advances made in the early detection of breast cancer are in peril. So too are the active efforts by HHS to increase access to screening mammography, as recipients of these appropriate messages increasingly will find it difficult to find a facility for the service and schedule an appointment.

Osteoporosis assessment, already seriously underutilized, will experience a similar crisis as DXA systems disappear from physician's offices, as will undoubtedly happen as deeper reimbursement cuts are implemented. Anecdotal reports of mobile unit closures, discontinuation of DXA testing, and declining or cancelled system orders indicate that this trend has begun. The draconian cuts scheduled for DXA testing will accelerate this decline and in many areas will result in severely limited access to osteoporosis testing.

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Policy Considerations

It is imperative that the HHS preventive medicine movement be supported without creating unintended consequences for other services. For this to happen, there must a mechanism to develop payment formulas that recognize the special resource requirements necessary to ensure a successful screening program. These factors may include the following:

- Actual equipment utilization rates in an established practice;
- Potential equipment utilization rates in sparsely populated locations;
- Additional staff time required to track compliance and counsel patients;
- Strategies to satisfy special staffing needs;
- Unavoidable inefficiencies associated with delivery of services in a screening environment;
- In mammography facilities, additional resources needed to achieve compliance to MQSA requirements; and
- Additional "value" factor associated with pursuit of preventive medicine initiatives.

Conclusion

We believe that HHS is committed to ensuring and expanding access to screening services for DXA and high quality mammography. Unfortunately, recent Medicare payment policies will act as a deterrent to this goal and instead of encouraging the use of life-saving screening services, will put it out of the reach of many Medicare beneficiaries.

We strongly encourage CMS to take the actions necessary to prevent further erosion of accessibility to these screening services. This can be accomplished by:

- Placing a moratorium on these decreases for CY 2008: and
- Working with the appropriate commission or public advisory agency to develop a mechanism to ensure appropriate and accurate valuation of these critical services.

We trust that these comments will be useful to CMS as it considers revisions to the CY 2008 physician fee schedule. We encourage CMS to contact us promptly with any questions, comments, or requests for additional information. We will be pleased to cooperate with CMS and provide any assistance we can in helping to ensure all Medicare beneficiaries have easy access to these life-saving screening services.

Sincerely,

Jack Cumming
Chairman and CEO

HOLOGIC, Inc. ■ 35 Crosby Drive ■ Bedford, MA 01730 ■ Tel: 781.999.7300 ■ Fax: 781.280.0669 ■ www.hologic.com

References:

1. Bone Health and Osteoporosis; A Report of the Surgeon General; 2004; US Department of Health and Human Services

2. Cancer Facts and Figures; 2007; American Cancer Society.

3. Preventive Care: A National Profile on Use, Disparities, and Health Benefits; Partnership for Prevention; August 2007

4. Impact of CAD in a Regional Screening Mammography Program; Cupples TE, Cunningham JE, Reynolds JC.;AJR 2005; 185:944-950

5. United States Government Accountability Office Report to Congress, "Mammography: Current Nationwide Capacity is Adequate, but Access Problems May Exist in Certain Locations." July 2006. GAO-06-724

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Submitter : **R Woods** **Date: 08/31/2007**

Organization : **R Woods**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to cxpress my strongest support for the proposal to increasc anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Mr. James Thornton** **Date: 08/31/2007**

Organization : **Clarion University of Pennsylvania**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To Whom It May Concern:
My namc is Jamcs L. Thornton, MA, ATC, PES. I am the head athletic trainer and director of athletic training services at Clarion University of Pennsylvania. I am a certificd athletic trainer with a Masters degree in Sports Medicine from the University of the Pacific. I am also a membcr of thc Board of Directors for the National Athletic Trainers Association.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerncd that thesc proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of acccss to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualificd to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposcd changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

James L. Thornton, MA, ATC, PES

Submitter : C Woods **Date: 08/31/2007**

Organization : C Woods

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : WES BOGGS **Date:** 08/31/2007

Organization : WES BOGGS

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Thank you for your consideration of this serious matter.
WES BOGGS

Submitter : **Valerie Morris** **Date: 08/31/2007**

Organization : **Valerie Morris**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Valerie Morris

Submitter : **J Woods** **Date: 08/31/2007**

Organization : **J Woods**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Submitter : Dr. Andrew Triebwasser **Date: 08/31/2007**

Organization : Dr. Andrew Triebwasser

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter. This is vitally important in RI where our ability to serve our large Medicare population is jeopardized by the current low reimbursement for services.

Andrew Triebwasser, MD

Submitter : J Ockershauer **Date:** 08/31/2007

Organization : J Ockershauer

Category : Individual

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.

Submitter : VICKIE BOGGS **Date:** 08/31/2007

Organization : VICKIE BOGGS

Category : Health Care Professional or Association

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
VICKIE BOGGS

Submitter : **Norma Parker** **Date: 08/31/2007**

Organization : **Norma Parker**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Norma Parker

Submitter : **P Ockershauser** **Date: 08/31/2007**

Organization : **P Ockershauser**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Lcslic V. Norwalk, Esq.
Acting Administrator
Centcrs for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : **Mr. Edwin Harris** **Date: 08/31/2007**

Organization : **Champion Sports Medicine**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

My name is Edwin Harris, I am a certified athletic trainer thru the National Athletic Trainers Association (NATA) and began working in this profession in 1985. I am very concerned the changes this bill would make to my profession. I work in Birmingham, Alabama and have a master's degree from the University of Alabama.

I am writing today to voice my opposition to proposal 1385-P. As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as phyiscal therapy. My education, clinical experience, and national cerfification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. Therefore, CMS would further restrict healthcare, especially in rural areas, with these changes. The fexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatmen available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendation of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A & B hospital or rehabilitation facility.

Sincerely,

Edwin E. Harris, B.S., M.S., A.T.,C.
Champion Sports Medicine

Submitter : **Ruth Brush** **Date: 08/31/2007**

Organization : **Ruth Brush**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **ASHLEY BOGGS** **Date: 08/31/2007**

Organization : **ASHLEY BOGGS**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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ASHLEY BOGGS.

Submitter : **B Lewis** **Date: 08/31/2007**

Organization : **B Lewis**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Submitter : S Lewis **Date:** 08/31/2007

Organization : S Lewis

Category : Individual

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

CMS-1385-P-13861

Submitter : Debbie Taylor **Date:** 08/31/2007

Organization : Debbie Taylor

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Debbie Taylor

Submitter : E Lewis **Date:** 08/31/2007

Organization : E Lewis

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Submitter : **ROBERT BOSS** **Date: 08/31/2007**

Organization : **ROBERT BOSS**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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ROBERT BOSS

Submitter : **Dr. Andrea Styron** **Date: 08/31/2007**

Organization : **Duke University Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Submitter : L Dunaway **Date:** 08/31/2007

Organization : L Dunaway

Category : Individual

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Submitter : **Pam Roach** **Date: 08/31/2007**

Organization : **AMAA - MedStar EMS**

Category : **Other Health Care Provider**

Issue Areas/Comments

Ambulance Services

Ambulance Services

This letter serves as our comments on the Geographical Price Cost Indices section of the Proposed Rule (CMS-1385-P). Our organization strongly opposes any reductions in Medicare reimbursement for ambulance service providers which would have an adverse impact on patient access to vital emergency and non-emergency ambulance care. The Proposed Rule would unfortunately cause that exact effect in areas where providers would receive lower reimbursement as a result of the updated Geographical Price Cost Index (GPC) figures.

While we recognize the statutory requirement for CMS to update the GPCI, any reductions in reimbursement would be in direct contradiction to the findings of the May 2007 Government Accountability Office (GAO) report entitled Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly (GAO-07-383) which determined that Medicare reimburses ambulance service providers on average 6% below their costs of providing services and 17% for providers in super rural areas. For those ambulance service providers who would receive lower reimbursement as a result of the changes to the GPCI, the Proposed Rule will further exacerbate the problems already caused by below-cost Medicare reimbursement.

The GAO recommended that CMS monitor the utilization of ambulance transports to ensure that negative Medicare reimbursement does not impact beneficiary access to ambulance services particularly in super rural areas. We believe that the Proposed Rule would have a considerable impact on beneficiary access in all areas adversely affected by the changes in the GPCI. We implore CMS to take this into consideration as it finalizes the Proposed Rule and alleviate any harmful impact these changes in the GPCI will have on providers while ensuring that those providers who would benefit from the changes receive the proposed increases which are desperately needed.

Thank you for your consideration of these comments

Submitter : **Mike Taylor** **Date: 08/31/2007**

Organization : **Mike Taylor**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Mike Taylor

Submitter : RUTH BOSS **Date:** 08/31/2007

Organization : RUTH BOSS

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter
RUTH BOSS.

Submitter : j lane **Date:** 08/31/2007

Organization : j lane

Category : Individual

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : Dr. Theresa Mackey **Date:** 08/31/2007

Organization : Minnesota State University, Mankato

Category : Academic

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Theresa Mackey and I currently serve as the Clinical Coordinator for Athletic Training Education at Minnesota State University, Mankato. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P. While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer and an athletic training educator, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards. In addition, the students that I help to educate to become practicing professionals are impacted by these proposed limitations on their future practice. The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available. By making the proposed change the CMS and the United States government will be eliminating the jobs of many highly qualified and highly educated health care professionals. Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility. Sincerely, Theresa Mackey, EdD, ATC

CMS-1385-P-13873

Submitter : Mrs. Karen Anthony-Little **Date:** 08/31/2007

Organization : Cardiovascular Medical Group

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

As the CEO of a large medical Group, we are desparately trying to contain costs as our revenue has not increased in the past 3 years. We do not want to drop out of the Medicare program, which will switch higher costs to our patients, many of whom are on fixed incomes. If the cuts you propose are inacted it will effect all of our contracts as private insurances base their contracted amounts on Medicare fees. It will be a no win situation for us all around. I have started to educate our patients that we may need to drop out of being contracted with Medicare as well as private insurances and our patients are extremely angry at Congress for allowing this to happen.

Submitter : **W lane** **Date: 08/31/2007**

Organization : **W lane**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Rc: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : L Lane **Date: 08/31/2007**

Organization : L Lane

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Submitter : Mr. Christopher Despins **Date:** 08/31/2007

Organization : St. Johnsbury Academy

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Christopher Despins and I am employed at St. Johnsbury Academy, an independent high school in northern Vermont. I provide full time athletic training services for all of our sports programs at the school with a population of approximately 1000 students. I have a Masters degree in Athletic Training from Indiana State University and have been providing services at the school for 13 years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive
the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Christopher Despins MS,ATC

Submitter : G Lane **Date: 08/31/2007**

Organization : G Lane

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Z Hook** **Date: 08/31/2007**

Organization : **Z Hook**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Submitter : DENNIS BOWMAN **Date: 08/31/2007**

Organization : DENNIS BOWMAN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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DENNIS BOWMAN

Submitter : **R Labutti** **Date: 08/31/2007**

Organization : **R Labutti**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Submitter : R Labutti **Date: 08/31/2007**

Organization : R Labutti

Category : Individual

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

CMS-1385-P-13882

Submitter : Dr. Richard Dean

Date: 08/31/2007

Organization : The Urology Center, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-13882-Attach-1.DOC

13842

TO WHOM IT MAY CONCERN @ CMS:

On July 2, 2007, the Centers for Medicare and Medicaid Services ("**CMS**") issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2008 (the "**2008 PFS**"). The 2008 PFS includes proposed changes to existing reassignment regulations and purchased test anti-markup regulations (collectively the "**Proposed Rules**").

The Proposed Rules are a substantial departure from the rules proposed last year by CMS in its 2007 PFS. Nevertheless, if finalized, the Proposed Rules will impact certain business arrangements utilized by some managed pathology laboratories. The purpose of this letter is to summarize the Proposed Rules as they relate to the provision of in-house pathology services, and to provide you with our perspective on the potential impact of the Proposed Rules on certain business arrangements routinely utilized by managed pathology laboratories.

The Social Security Act generally prohibits Medicare payment to anyone other than the Medicare beneficiary (the patient) or the physician or other person who performed the service for the beneficiary. This prohibition is found at 42 CFR § 424.80. This rule has exceptions known as "reassignment exceptions," which permit Medicare to make payment to an individual or entity other than the performing physician, provided the physician has appropriately "reassigned" his right to payment. One such exception, found at 42 CFR § 424.80(d), permits a physician to contractually reassign to a group practice the right to bill Medicare for services provided by the physician on the group's behalf. The Proposed Rules add certain requirements to this regulation which must be complied with by groups who bill for diagnostic tests pursuant to a contractual reassignment. It is pursuant to such a contractual reassignment that some managed pathology laboratories bill for services provided by their pathologists.

As amended, 42 CFR § 424.80 provides that if either the technical component ("**TC**") or the professional component ("**PC**") of a diagnostic test is billed by a physician or medical group pursuant to a contractual reassignment from a provider who is not a full time employee of the billing group, the following conditions must be met:

(i) the payment to the group, less applicable deductibles and coinsurance, may not exceed the lowest of: (1) the provider's net charge to the group, which must be determined without regard to any charge intended to cover the cost of equipment or space leased to the provider by the billing group payment that is made by the group to the physician; (2) the group's actual charge; or (3) the Medicare fee schedule payment for the service provided;

(ii) the group must identify the provider that performed the PC or the TC and indicate their net charge as a condition of reimbursement; and

(iii) in order to bill for the TC of a service, the group must directly perform the PC of the same service.

A second regulation, 42 CFR § 414.50, provides that if the TC of a diagnostic test was not performed by the billing physician and was not performed or supervised by a physician in the billing physician's group practice, Medicare payment is the lower of (i) the supplier's net charge, (ii) the billing group's actual charge, or (iii) the Medicare fee schedule payment. This is known as the "Anti-Markup Provision." The Anti-Markup Provision is intended to eliminate the opportunity for a group practice to profit by purchasing tests performed by other suppliers at a low price and then billing Medicare at a higher rate. The Proposed Rules amend this regulation by extending it to the PC of a diagnostic test that is either purchased by the billing group or billed by the billing group pursuant to a contractual reassignment. Both of these rules are intended to accomplish the same objectives.

The Proposed Rules are significant in a couple of respects. First, Medicare is limiting its payment to a group for the PC of a diagnostic test provided by an independent contractor physician to the amount of the payment the group makes to the physician. In calculating this payment, Medicare would not consider the cost of space, equipment, or other overhead necessary to permit the physician to provide the PC on the group's premises, despite the fact that the Stark Law requires that the physician perform these services on the group's premises. This does not prohibit a group from charging a physician for this overhead, but any such charge paid by the physician will lower the Medicare reimbursement to the group.

Essentially, this means that a group can no longer make a profit by utilizing a physician on a less than full time basis to provide the PC of Medicare reimbursed diagnostic tests on behalf of the group. It also means that the cost of overhead allocable to these services is now an unreimbursable cost of business to the group. While these limitations also apply to the TC of diagnostic tests, they will not affect the managed pathology laboratories because the TC in the managed laboratories is not performed by personnel who reassign their rights to bill Medicare. In our particular situation, we could not afford to hire a full time uropathologist and we would not have the volume to support such action. This would mean that only the very largest groups that would have the volume or could afford to do this. This also means that only the large groups could afford to render this type of care to their patients.

Second, the Proposed Rules provide that, in order to bill for the TC of a Medicare reimbursed diagnostic test, the group must directly perform the PC of the same service. This change will not affect managed laboratories, because those laboratories all bill for both the TC and PC of all tests, as a condition of Stark compliance. It is likely that this requirement will have a significant effect on other competing pathology delivery systems, particularly those in which a group practice provides its own TC and refers out the PC to independent pathologists who bill for the PC themselves.

Several previously considered rules were not proposed in this rulemaking. For example, there are no proposed rules addressing the size or location of a centralized building used for the provision of diagnostic tests. There is no proposed rule requiring that a centralized building contain on a permanent basis all of the equipment necessary to perform the diagnostic services it performed in that facility. And despite earlier consideration, there is no language in the Proposed Rules limiting their application to either pathology laboratories generally or specifically to pod labs. It appears managed pathology laboratories were successful in their efforts to ensure that the Proposed Rules evenhandedly addressed perceived abuses across the entire spectrum of diagnostic services.

We will also continue to work closely with CMS and Congressional leaders to present our case as to why the use of managed pathology laboratories provides superior urological pathology without any undue risk of program abuse. In our particular situation, we use a managed pathology laboratory model to send our pathology specimens, primarily because by using this particular laboratory model, our pathology specimens are interpreted by only uropathologist. This means that by only having a uropathologist preparing and interpreting our pathology specimens, we can detect possible problems sooner; therefore, we can offer appropriate treatment that much sooner to the patient, instead of having our pathology specimens prepared and interpreted by a general pathologist. In dealing with general pathologist, it may take more than one incident of Prostate biopsy before it is detected by a general pathologist. Possibly months could go by. Months, that when we are dealing with an aggressive Prostate cancer, could mean a life.

We hope this information helps you better understand how this proposal could affect our ability to render good medical care to our patients.

Sincerely,

Richard Dean, M.D. Ralph DeVito, M.D.

Richard Dean, M.D. Ralph DeVito, M.D.

David Hesse, M.D. Stanton Honig, M.D.

David Hesse, M.D. Stanton Honig, M.D.

Thomas Martin, M.D. M. Grey Maher, M.D.

Thomas Martin, M.D. M. Grey Maher, M.D.

Submitter : T Carter **Date: 08/31/2007**

Organization : T Carter

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : TERRI BOWMAN **Date:** 08/31/2007

Organization : TERRI BOWMAN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
TERRI BOWMAN

Submitter : **Dr. James Raker** **Date: 08/31/2007**

Organization : **Ark La Tex Health Center**

Category : **Chiropractor**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: TECHNICAL CORRECTIONS

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

James Raker, DC
1414 Arkansas Blvd
Texarkana, AR 71854

Submitter : **A Carter** **Date: 08/31/2007**

Organization : **A Carter**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter :

Date: 08/31/2007

Organization :

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an Athletic Training student and have personally benifitted from Athletic Trainers in out patient clinics after bilateral shoulder repares and subsiquent rehabilitation.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital
Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I will be qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. Athletic training education, clinical experiences, and national certification exam ensure that my patients will receive quality health care. State law and hospital medical professionals have deemed Athletic Trainers qualified to perform these services and
these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services.

The flexible current standards of staffing in hospitals and other
rehabilitation facilities are pertinent in ensuring patients receive
the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

J A Hill

Submitter : **Ms. Paula Bussard** **Date: 08/31/2007**

Organization : **The Hospital**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

See attached comment letter

CMS-1385-P-13888-Attach-1.DOC

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

August 31, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: (CMS-1385-P) Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule and Other Part B Payment Policies for Calendar Year 2008; Proposed Revisions to the Payment Policies of Ambulance Services under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions (Vol. 72, No. 133) July 12, 2007

Dear Mr. Kuhn:

On behalf of Pennsylvania's 225 hospitals and health care systems, The Hospital & Healthsystem Association of Pennsylvania (HAP) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar year (CY) 2008 physician and ambulance fee schedules. Our comments focus primarily on the proposed changes to regulations related to the prohibition of physician self-referrals under Medicare and Medicaid.

Pennsylvania hospitals and health systems seek to provide coordinated, high-quality, cost-effective and compassionate health care through community-based integrated delivery systems. To that end, HAP believes quality efficient health care is accomplished by teamwork. Hospital care is especially dependent on the ability of hospital leaders and physicians to work together to improve the delivery of health care to provide patients the right care, at the right time, in the right setting. The need for collaboration among health care providers never has been more compelling, as collaboration, quality, and efficiency are inextricably related.

At the heart of the issue surrounding physician self-referral prohibitions is the need to ensure that no patient question whether their physician is acting in the best clinical interest of the patient, or responding to financial investment decisions.

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
www.haponline.org

There is a definite need to establish clear accountability and transparency safeguards regarding financial investment by physicians in facilities that they own in whole or in part. These safeguards should include consideration of limitations on financial investments; clear definition of capabilities needed in such facilities to deal with any complications, or patient safety issues; ownership disclosure to patients; compliance with state and federal laws; adherence to quality standards; commitments to provide access to uninsured, Medicaid, and other publicly supported patients; and fulfillment of an obligation to support the community's emergency service capacity.

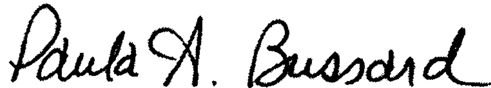
It is important to ensure that there is clarity on the types of self-referral arrangements that clearly need to be prohibited, as well as standards for other types of arrangements that should be permitted to achieve needed improvements in the health care delivery system, sustain access to services, promote integration of clinical care across providers and settings, and enhance institutional or practitioner productivity and efficiencies.

Given the complexity of this issue, HAP encourages CMS to reconsider the proposed changes to ensure that self-referral prohibitions not result in the unintended consequence of nullifying legitimate investment, employment and financial arrangements that are designed to achieve clinical integration and coordination of evidence-based, patient-centered and systems-oriented care delivery.

Attached are detailed concerns for your review and consideration.

If you have any questions regarding our comments, please contact Melissa Speck, HAP's director of policy development at (717) 561-5356, or via email at mspeck@haponline.org

Sincerely,



PAULA A. BUSSARD
Senior Vice President, Policy & Regulatory Services

PAB/dd

Attachment

PHYSICIAN SELF-REFERRAL PROVISIONS

Concerns and comments about this proposed rule follow three overarching themes:

1. The percentage-based compensation proposal would work against achieving clinical integration and coordination.
2. The proposals do not adequately facilitate the coordination and cooperation needed to serve communities, especially in rural areas.
3. The proposed expansion of the exception for subsidizing obstetrical (OB) malpractice insurance is too narrow.

Compensation Proposal:

The percentage-based compensation proposal would work against achieving clinical integration and coordination.

The proposal to limit percentage-based compensation solely to "revenue directly resulting from personally performed physician services" is too limiting and appears to prohibit payment arrangements based on achieving quality measures, patient satisfaction, or efficiencies. It also focuses on an individual physician in a vacuum. Achieving many of the public policy goals for patient care and the delivery system change requires more than what a hospital or a physician can do alone. To be effective, the incentives must drive individuals to work together to achieve the kind of outcomes expected (e.g., achieving immunization goals across a group of children or getting beta blockers within the golden hour to a heart attack victim).

HAP believes percentage-based payments should be permitted for certain types of arrangements when: they are designed to achieve an acceptable purpose; there are mechanisms in place to protect the quality of care provided to beneficiaries and avoid inappropriate influence on physician referrals; and the incentive arrangements are transparent to patients. The types of arrangements that should be permitted include:

- Sharing of cost savings from efficiencies.
- Incentives to meet quality indicators—even when cost savings do not accrue to the hospital.
- Incentives to clinically integrate services and coordinate care across settings.
- Sharing of pay-for-performance bonuses from payers.
- Service contracts to build new service capacities.
- Management contracts.

As proposed, the change in regulation is much too limiting and fails to recognize that the financial model for integrated care delivery has come to rely on sharing revenue in appropriate ways as a mechanism to incentivize appropriate behavior. These efforts will be frustrated if the only factor that may be taken into account is physician-performed services.

Unlike anti-kickback law safe harbors, which do not preclude the evolution of financial relationships, the self-referral law requires strict compliance with exceptions. CMS should be careful it does not limit appropriate innovations. An important consideration in developing the parameters of this exception is to keep in mind the companion anti-kickback law, which can be the ultimate protection against abuse.

HAP urges CMS to take into consideration the larger public policy perspective in which there is a legitimate role for the use of appropriate financial incentives to achieve evidence-based, patient-centered, systems-oriented health care.

Coordination and Cooperation:

The proposals do not adequately facilitate the coordination and cooperation needed to serve communities, especially in rural areas.

HAP supports limiting the in-office ancillary services exception to cover only those services "necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office." The current expansive use of the exception has led to the duplication of services and technology, and as reported by the Medicare Payment Advisory Commission, to over-utilization, higher expenses, and unnecessary procedures for patients. In today's environment, overuse of the in-office ancillary exception is one of the many forces driving hospitals and physicians apart.

While narrowing the in-office exception is a good beginning, it does not adequately address the access issues created for members of rural communities. The rules for the "rural provider" exception also should be revised. As currently applied, it can be used without regard to whether there is unmet need in the community or there will be reduced access for the overall community to needed health care services. Anecdotally, turn-key arrangements between manufacturers and physicians and physician-only owned technology often result in the steerage of more lucrative patients away from the community hospital to physician offices or owned entities. In rural communities where the volume of needed services is not sufficient to support both hospital-based and physician practice-based duplicative services, it is always the hospital-based service that will suffer because physicians control where their patients go. The ultimate effect is to potentially jeopardize the viability of the local hospital and that community's around-the-clock access to vitally needed health care services. It also can jeopardize access to a particular service for less lucrative patients who do not have access to physician practice-based services.

HAP supports CMS' effort to assure that services provided "under arrangements" meet a community need, and that individual patients receive care in the setting most medically appropriate to their medical needs. Only those arrangements that foster needed improvements in the delivery system, sustain community access to essential services, promote clinical integration, or enhance efficiencies should be allowed. However, as proposed, the unintended consequence of the proposal for services furnished "under arrangements" may in fact eliminate hospital-physician joint ventures designed sustain access to essential services in the community.

Subsidizing Obstetrical Services:

The proposed expansion of the exception for subsidizing obstetrical malpractice insurance is too narrow.

As suggested in the rulemaking, maintaining obstetrical services in some communities is an increasingly difficult challenge. In Pennsylvania these challenges demonstrate a growing trend of diminished access to care for pregnant women. In the last decade, Pennsylvania has seen the closure of 33 hospital obstetrical units (13 in the greater Philadelphia area) and loss of neonatal intensive care units.

Multiple factors contribute to the availability of obstetrical services, including lack of timely access for certain populations (prenatal, obstetrics and postpartum), inadequate reimbursement for obstetrical services, inadequate insurance coverage, continuing impact of medical liability coverage crisis, inadequate insurer/managed care provider networks for obstetrical services, growing workforce shortages, aging obstetrical service facilities. Fewer physicians are training for the specialty, and physicians with training and experience have left the field or are considering leaving that area of practice. Permitting malpractice insurance subsidies under a broader range of circumstances may help minimize the loss of obstetrical services in some communities.

The current preconditions for subsidizing coverage—that the physician practice is in a primary care health professional shortage area (HPSA) and that 75 percent of those served live in a primary care HPSA or be medically underserved—are too limiting. It is important to recognize that non-HPSA areas may have a high indigent population, and an increase in primary care physicians may take an area out of the primary care HPSA designation without any increase in physicians providing obstetrical services. The combination of the relatively low payment for obstetrical services and the high cost of insurance premiums works against a physician agreeing to maintain 75 percent of his or her obstetric practice for the underserved.

Another limitation of the current exception is that it only addresses shortages in connection with the medically underserved. In some communities, the shortage is much broader. In relatively affluent areas, a mismatch between increasing insurance premiums and other practice expenses with relatively low payments for obstetric services is leading to obstetric shortages for the general community. The net effect can be "obstetrics-underserved" communities. Permitting subsidies in those communities may similarly help minimize the loss of obstetrical services.

HAP strongly encourages CMS to allow this exception in any area where there is a shortage of physician obstetrical services.

Submitter : Dr. Debashis Bhattacharyia **Date: 08/31/2007**

Organization : Children's Hospital of Michigan

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

Thank you for your consideration of this serious matter.

Submitter : **Gene Guinn** **Date: 08/31/2007**

Organization : **Gene Guinn**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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Gene Guinn

Submitter : A Shaw **Date: 08/31/2007**

Organization : A Shaw

Category : Individual

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Submitter : Mrs. Lisa Miller-Jones **Date: 08/31/2007**

Organization : Heart Rhythm Society

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

The Heart Rhythm Society (HRS) appreciates the opportunity to comment on the proposed rule entitled Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions published in the July 12, 2007 Federal Register.

HRS is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Founded in 1979, HRS is the preeminent professional group representing more than 4,500 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists and their support personnel. HRS members perform electrophysiology studies and curative catheter ablations to diagnose, treat and prevent cardiac arrhythmias. Electrophysiologists also implant pacemakers and cardioverter defibrillators (ICDs) in patients who have indications for these life-saving devices. After device implantation, heart rhythm specialists then monitor these patients and their implanted devices.

MEDICARE PHYSICIAN PAYMENT RATE FOR 2008
The proposed rule confirms that a 9.9% decrease in Medicare payments will occur under the Sustainable Growth Rate (SGR) formula in CY 2008, unless Congress intervenes to avert the cut. The SGR formula clearly is not producing reasonable reimbursement rates. Physician payments are essentially the same as they were six years ago and additional cuts totaling almost 40% are projected over the next eight years. Yet, during this same time period, the Medicare Economic Index (MEI), which measures increases in medical practice costs, is expected to increase approximately 20%. Continued reductions in the physician fee schedule will not be sustainable. Physicians are the foundation of our nation s health care system, and thus a stable payment environment for their services is critical. HRS recommends that CMS work with Congress to remedy this problem and ensure the physician payment update for 2008 and subsequent years accurately reflect increases in medical practice costs.

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

CODING--ADDITIONAL CODES FROM 5-YEAR REVIEW
HRS urges CMS to reconsider its proposal to bundle CPT code 93325 (Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)) into CPT codes 76825, 76826, 76827, 76828, 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317 and 93350 for echocardiography services. The RUC recently discussed the inherent nature of providing the services described in CPT codes 93325, 93320 and 93307 during the same patient encounter and recommended that this issue be referred to the CPT Editorial Panel to determine the appropriateness of creating a single procedure code to reflect these services. The American College of Cardiology and the American Society of Echocardiography will present physician work and practice expense recommendations to support establishment of a new combined echocardiography code during the September 2007 RUC meeting. Once again, we urge CMS to reconsider its proposal to bundle 93325 and allow this issue to be addressed within the CPT and RUC processes to ensure that the practice expense and physician work involved in the performance and interpretation of color flow studies are appropriately allocated.

Recalls and Replacement Devices

Recalls and Replacement Devices

RECALLS AND REPLACEMENT DEVICES
HRS is strongly opposed to the correlation CMS is drawing between hospital-related recall and replacement devices (pacemakers and ICD s), and physician monitoring services provided for patients affected by a recall action. While we understand the rationale for reduced payment when hospitals acquire a device at no cost or with partial credit, there is no compelling reason to reduce payment under the physician fee schedule. The proposed rule purports to seek public input on how best to identify additional Medicare expenditures associated with device recalls and replacements; however, there is major concern that the outcome will result in a payment decrease for physician services, which will threaten continued patient access to care.

HRS is very concerned that CMS effort to mitigate greater costs to the Medicare program will impose a financial penalty on the physician. To penalize the physician who bears no fault for device manufacturer product defects would be unjustified. As such, any solution to offset Medicare expenditures associated with device recalls and replacements should not intrude upon the ability of patients affected by the recall to continue to receive the highest quality care available, nor should the physician be punished when a manufacturer initiates a recall advisory to more closely monitor patients for potential problems.

It is our belief that adoption of a policy that would restrict access to patient care or reduce physician reimbursement would be very disruptive and will not result in significant savings to the Medicare program. In fact, Medicare may wind up paying higher costs for more catastrophic care than what would have been expended to monitor patients.

Due to the significant burden that a policy change would place on access to patient care and physician reimbursement, HRS requests that CMS defer development of any provisions until the potential outcomes have been thoroughly vetted through the appropriate stakeholders with a vested interest in pacemaker and ICD patient care.

The HRS Task Force on Device Performance Policies and Guidelines recently developed comprehensive recommendations for the surveillance, analysis and performance reporting of pacemakers and ICDs. These recommendations have been shared with the FDA s new Risk Communication Advisory Committee to prevent confusion surrounding recalls of implantable devices. The FDA is one of the first Federal agencies to systematically turn to experts to successfully communicate the risks and benefits associated with FDA-regulated products to help consumers and health care professionals make informed decisions.

HRS would welcome the opportunity to work with CMS, in a manner similar to the FDA, to assemble an advisory panel of experts to develop recommendations for appropriate follow-up care that will accurately capture clinically relevant events applicable to certain pacemakers and ICD s. This approach would ensure the objectives of the agency are met and protect the best interest of Medicare beneficiaries, as well as maintain the role of the physician.

Resource-Based PE RVUs

Resource-Based PE RVUs

RESOURCE-BASED PE RVUs
Remote Cardiac Event Monitoring
HRS commends CMS for its willingness to continue working with the Remote Cardiac Services Provider Group to refine the interim direct Practice Expense (PE) inputs adopted for CY 2007 for remote cardiac monitoring services represented by CPT codes 93012, 93225, 93226, 93231, 93232, 93270, 93271, 93733 and 93736. As CMS has acknowledged, remote cardiac event monitoring services have substantial equipment-related costs that remain disproportionately valued as a result of the elimination of the zero physician work pool and use of the new bottom-up approach to calculate direct costs. We are particularly concerned about proposed reimbursement for holter monitoring codes (93232, 93226, 93231 and 93225), which will decrease by 50% once the PE values are fully implemented in 2010. The cardiac event monitoring codes (93271, 93012 and 93270) will also decrease 15% and 30%, respectively. The care rendered for remote cardiac monitoring services is heavily dependent on use of equipment and technology to collect, analyze and transmit vital medical data. Without adequate reimbursement for these services, Medicare beneficiaries will lose access to critical diagnostic services, which will result in undiagnosed life-threatening conditions, increased hospital, emergency room and physician services. HRS encourages CMS to continue working with the provider group to develop direct and indirect inputs that better align with the equipment, technology and operating expenses required to furnish remote cardiac monitoring services.

TRHCS--Section 101(b): PQRI

TRHCS--Section 101(b): PQRI

We urge CMS to actively engage stakeholders in this effort to properly develop measures in a systematic approach that do not disrupt physicians who provide quality care or reduce participation in a voluntary program.

Registry-Based Reporting Of Quality Measures
HRS agrees in principle with the use of registries for PQRI-reporting and encourages the agency to have a face-to-face meeting with interested parties. HRS agrees that the registry-based reporting should be through explicit authorization or permission by the physician to provide such reporting. HRS generally agrees with the American College of Cardiology s comments on data submission of quality measures through a medical registry. Specifically, HRS encourages CMS to consider the following registry requirements in determining eligibility:

" The registry must demonstrate HIPPA and Consolidated Health Informatics Initiative standards (CHI) Compliance.
" The purpose of the registry should be to improve quality of care and patient outcomes.
" The registry must demonstrate a scientifically rigorous and unbiased methodology for developing data elements that is valid for participants and is recognized nationally by appropriately qualified groups.
" The registry must require data submissions be of sufficient size to be statistically and clinically relevant.
" The registry must collect and report data back to the participant to support physician self-assessment and quality improvement initiatives.
" The registry must demonstrate proven systems for data collection, data element structure, on-going personnel training and inter-rater reliability, data storage, monitoring, and review.
" The registry must demonstrate processes and procedures for ensuring data completeness at the individual data element level and the overall data composite level.
" The registry must demonstrate data consistency and validity.

CMS Should Consolidate Quality Programs Within Agency
HRS urges CMS to consolidate quality programs within the agency to support physician s goals to make it easier to provide quality care for patients. CMS needs to make it easier for doctors to care for their patients through reduced documentation requirements and redundant quality programs with incongruent data definitions and participation requirements. We believe that PQRI and Coverage with Evidence Development (CED) programs overlap in intent and requirements that physicians receive incongruent messages from the agency. HRS believes that centralizing quality programs within the agency would be a significant advance in allowing physicians that provide quality care to prove it.
?????????????????
In summary, HRS is grateful for the opportunity to share our views on the proposed rule. Please contact Lisa Miller-Jones, Director of Reimbursement and Regulatory Affairs at lmiller-jones@HRSonline.org or (202) 464-3433 to discuss how HRS and CMS might work together to develop an appropriate solution to address additional Medicare expenditures associated with device recall actions. Please direct any inquiries regarding PQRI to Joel Harder, Director of Quality Improvements and Outcomes at JHarder@HRSonline.org or (202) 464-3489.

CMS-1385-P-13892-Attach-1.DOC

#13892

Department of Health and Human Services
Centers for Medicare & Medicaid Services
Office of Strategic Operations & Regulatory Affairs

The attachment cited in this document is not included because of one of the following:

- The submitter made an error when attaching the document. (We note that the commenter must click the yellow "Attach File" button to forward the attachment.)
- The attachment was received but the document attached was improperly formatted or in provided in a format that we are unable to accept. (We are not are not able to receive attachments that have been prepared in excel or zip files).
- The document provided was a password-protected file and CMS was given read-only access.

Please direct any questions or comments regarding this attachment to (800) 743-3951.

Submitter : **BRIAN BOWMAN** **Date: 08/31/2007**

Organization : **BRIAN BOWMAN**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
BRIAN BOWMAN

Submitter : LS Shaw

Date: 08/31/2007

Organization : LS Shaw

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : **J Creekmore** **Date: 08/31/2007**

Organization : **J Creekmore**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : **P Creekmore** **Date: 08/31/2007**

Organization : **P Creekmore**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Serviccs
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : JUSTIN BOWMAN **Date: 08/31/2007**

Organization : JUSTIN BOWMAN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
JUSTIN BOWMAN

Submitter : **K Creekmore** **Date: 08/31/2007**

Organization : **K Creekmore**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : Mr. Ray Castle **Date:** 08/31/2007

Organization : Louisiana State University (Baton Rouge)

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am Ray Castle PhD, ATC, LAT, and currently serve as Assistant Professor and Director of the degree program in Athletic Training at Louisiana State Universitdy(Baton Rouge, LA). In addition to my academic responsibiltiies, I also provide contracted medical (Certified Athletic Trainer) services to a local high school, in which I perform initial injury/illness evaluations and physical rehabilitation services, as well as on-site event medical coverage. I have been practicing in the profession of Athletic Training since 1991, and hold board credentials to practice as a Certified Athletic Trainer (ATC) through the Board of Certification (BOC) and also the Louisiana State Board of Medical Examiners (LSBME). In my various roles of providing instruction to prepare future credentialed athletic trainers and also providing medical services (injury/illness evaluation; physical rehabilitation; etc.), I have obtained, as well as my peers, an extensive educational background and skill base in the following areas: orthopedic evaluation; internal medicine; physical rehabilitation; neurology; nutrition; psychosocial intervention and referral; medical coding and documentation; and emergency medicine. With my information in mind, I am writing to you to express my concerns regarding the CMS ruling this letter is associated.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Ray Castle, PhD, ATC, LAT
Assistant Professor - Professional Practice
Director - Athletic Training Education Program
Louisiana State University
112 Huey P. Long Fieldhouse
Baton Rouge, LA 70803
#225-578-7175
RCASTL1@LSU.EDU

Submitter : **Vickie Raker** **Date: 08/31/2007**

Organization : **Ark La Tex Health Center**

Category : **Nurse**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: TECHNICAL CORRECTIONS

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Vickie Raker, RN
175 CR 1302
Texarkana, TX 75503

Submitter : **Mark McDaniel** **Date: 08/31/2007**

Organization : **Mark McDaniel**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
Mark McDaniel

Submitter : C Creekmore **Date: 08/31/2007**

Organization : C Creekmore

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : Mr. Rick Zitnik **Date:** 08/31/2007

Organization : Zitnik Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Physical therapy services should not be allowed under the in-office ancillary services exception. I am an outpatient physical therapist that has worked in South Alabama for almost 14 years. In my professional opinion, allowing coverage for physical therapy services provided in physicians office has had a negative impact on the quality of care provided to patients. Individual service and complete freedom of choice in selecting a therapist are critical components in obtaining maximum clinical outcomes and eliminating wasted time and money.

During the course of my career I have worked in physician offices, hospital-based physical therapy departments, therapist-owned clinics, and now my own private practice. It is my opinion that therapy provided in physician offices has the primary purpose of producing revenue; patient best interest has taken a back seat. Most people who receive a physical therapy referral from a doctor who provides therapy "in-house" do not even realize that they have a choice regarding where to go for therapy. We have been raised in our society to trust our medical providers; many individuals will obtain therapy within the physician's office even when they would rather go elsewhere. "The doctor told me to go here" is a common refrain. Previous studies investigating practice patterns are clear: physicians who provide physical therapy service in their own offices (and profit from the endeavor) are far more likely to determine that their patients need a physical therapy referral.

Please take this opportunity to end this abuse of physical therapy services. Allow the general public to experience physical therapy services without the potential abuse of self-referral.

Submitter : Ms. Jim Shlimovitz **Date:** 08/31/2007

Organization : St. Clare Hospital and Health Services

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

As an atheltic trainer, I am trouble by the language and restricting trade and practice of athletic tic training in a hospital setting. We have been seeeing pt. in the hospital for 7 years with no complaints. To limit our practice is a big injustice and will cost many jobs and employement opportunities to athletic trainers in the U.S.. Having equal access and letting the patient and medical professionals make a decision on who to see to get them better the best that they can be in the ulitmate goals and this should not rely on the federal agency to amke these rules. Athletic trainers can see the physical active population. These people can range from 5 to 85 years of age. Do not limit access to other professionals that can assist these people in their rehab.

Submitter : **RUSSELL BOYD** **Date: 08/31/2007**

Organization : **RUSSELL BOYD**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
RUSSELL BOYD

CMS-1385-P-13906

Submitter : A Vetter **Date:** 08/31/2007

Organization : A Vetter

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : **Ms. Susan Breister** **Date: 08/31/2007**

Organization : **EMPI**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:
My name is Susan Breister. I work for EMPI, an electrotherapy manufacturer. I also work as a Certified Athletic Trainer for the Institute for Athletic Medicine in Minneapolis, Minnesota. I have been certified by the National Athletic Trainers Association for over 25 years. I hold a BS and an MA degree. In addition, I am Registered by the State of Minnesota Board of Medical Practice.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
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Sincerely,
Susan Breister, ATC/R

Submitter : **Mr. Eric Odegard** **Date: 08/31/2007**

Organization : **The PT Clinics**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Former CMS studies have shown that physician owned physical therapy practices have an inherent financial incentive that can lead to overutilization. Closing the current "in office ancillary services exception" is needed to prevent the proliferation of such practices. This will not only protect the consumer/patient, but it will also protect the private practice physical therapy practices that deliver efficacious and cost-effective care.

CMS-1385-P-13908-Attach-1.DOC

13908

8/20/07

Mr. Kerry Weems
Administrator Designate
Centers for Medicare and Medicaid Services
US Dept. of Health and Human Services
Attn: CMS-1385-P
PO Box 8018
Baltimore, MD 21244-8018

RE: Medicare program: Proposed revisions to payment policies under the physician fee schedule and other Part B payment policies for CY 2008

Mr. Weems:

I wanted to write and express my support for revising current Medicare regulations that allow physicians to have "in house" out patient physical therapy practices. As you know, former studies done by CMS have proven that such arrangements lead to over utilization of therapy services due to the inherent financial incentives that these arrangements provide.

The current "ancillary services exception" has created a loophole that has allowed the proliferation of these physician owned physical therapy practices. In the Sacramento, California area where I practice, one such physician owned practice adversely affected mine within a very short time after opening.

I sincerely hope that CMS will abolish this practice.

Thank you for your consideration.

Eric Odegard, PT
Owner, The Physical Therapy Clinics, Inc.

Submitter : S Perkins **Date: 08/31/2007**

Organization : S Perkins

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **James Lightbody** **Date: 08/31/2007**

Organization : **James Lightbody**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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James Lightbody

Submitter : **B Perkins** **Date: 08/31/2007**

Organization : **B Perkins**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Submitter : CINDY BOYD

Date: 08/31/2007

Organization : CINDY BOYD

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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CINDY BOYD

13913

CMS-1385-P-13913

Submitter : **Dr. Ralph DeVito** **Date: 08/31/2007**

Organization : **The Urology Center, P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-13913-Attach-1.DOC

TO WHOM IT MAY CONCERN @ CMS:

On July 2, 2007, the Centers for Medicare and Medicaid Services ("**CMS**") issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2008 (the "**2008 PFS**"). The 2008 PFS includes proposed changes to existing reassignment regulations and purchased test anti-markup regulations (collectively the "**Proposed Rules**").

The Proposed Rules are a substantial departure from the rules proposed last year by CMS in its 2007 PFS. Nevertheless, if finalized, the Proposed Rules will impact certain business arrangements utilized by some managed pathology laboratories. The purpose of this letter is to summarize the Proposed Rules as they relate to the provision of in-house pathology services, and to provide you with our perspective on the potential impact of the Proposed Rules on certain business arrangements routinely utilized by managed pathology laboratories.

The Social Security Act generally prohibits Medicare payment to anyone other than the Medicare beneficiary (the patient) or the physician or other person who performed the service for the beneficiary. This prohibition is found at 42 CFR § 424.80. This rule has exceptions known as "reassignment exceptions," which permit Medicare to make payment to an individual or entity other than the performing physician, provided the physician has appropriately "reassigned" his right to payment. One such exception, found at 42 CFR § 424.80(d), permits a physician to contractually reassign to a group practice the right to bill Medicare for services provided by the physician on the group's behalf. The Proposed Rules add certain requirements to this regulation which must be complied with by groups who bill for diagnostic tests pursuant to a contractual reassignment. It is pursuant to such a contractual reassignment that some managed pathology laboratories bill for services provided by their pathologists.

As amended, 42 CFR § 424.80 provides that if either the technical component ("**TC**") or the professional component ("**PC**") of a diagnostic test is billed by a physician or medical group pursuant to a contractual reassignment from a provider who is not a full time employee of the billing group, the following conditions must be met:

(i) the payment to the group, less applicable deductibles and coinsurance, may not exceed the lowest of: (1) the provider's net charge to the group, which must be determined without regard to any charge intended to cover the cost of equipment or space leased to the provider by the billing group payment that is made by the group to the physician; (2) the group's actual charge; or (3) the Medicare fee schedule payment for the service provided;

(ii) the group must identify the provider that performed the PC or the TC and indicate their net charge as a condition of reimbursement; and

(iii) in order to bill for the TC of a service, the group must directly perform the PC of the same service.

A second regulation, 42 CFR § 414.50, provides that if the TC of a diagnostic test was not performed by the billing physician and was not performed or supervised by a physician in the billing physician's group practice, Medicare payment is the lower of (i) the supplier's net charge, (ii) the billing group's actual charge, or (iii) the Medicare fee schedule payment. This is known as the "Anti-Markup Provision." The Anti-Markup Provision is intended to eliminate the opportunity for a group practice to profit by purchasing tests performed by other suppliers at a low price and then billing Medicare at a higher rate. The Proposed Rules amend this regulation by extending it to the PC of a diagnostic test that is either purchased by the billing group or billed by the billing group pursuant to a contractual reassignment. Both of these rules are intended to accomplish the same objectives.

The Proposed Rules are significant in a couple of respects. First, Medicare is limiting its payment to a group for the PC of a diagnostic test provided by an independent contractor physician to the amount of the payment the group makes to the physician. In calculating this payment, Medicare would not consider the cost of space, equipment, or other overhead necessary to permit the physician to provide the PC on the group's premises, despite the fact that the Stark Law requires that the physician perform these services on the group's premises. This does not prohibit a group from charging a physician for this overhead, but any such charge paid by the physician will lower the Medicare reimbursement to the group.

Essentially, this means that a group can no longer make a profit by utilizing a physician on a less than full time basis to provide the PC of Medicare reimbursed diagnostic tests on behalf of the group. It also means that the cost of overhead allocable to these services is now an unreimbursable cost of business to the group. While these limitations also apply to the TC of diagnostic tests, they will not affect the managed pathology laboratories because the TC in the managed laboratories is not performed by personnel who reassign their rights to bill Medicare. In our particular situation, we could not afford to hire a full time uropathologist and we would not have the volume to support such action. This would mean that only the very largest groups that would have the volume or could afford to do this. This also means that only the large groups could afford to render this type of care to their patients.

Second, the Proposed Rules provide that, in order to bill for the TC of a Medicare reimbursed diagnostic test, the group must directly perform the PC of the same service. This change will not affect managed laboratories, because those laboratories all bill for both the TC and PC of all tests, as a condition of Stark compliance. It is likely that this requirement will have a significant effect on other competing pathology delivery systems, particularly those in which a group practice provides its own TC and refers out the PC to independent pathologists who bill for the PC themselves.

Several previously considered rules were not proposed in this rulemaking. For example, there are no proposed rules addressing the size or location of a centralized building used for the provision of diagnostic tests. There is no proposed rule requiring that a centralized building contain on a permanent basis all of the equipment necessary to perform the diagnostic services it performed in that facility. And despite earlier consideration, there is no language in the Proposed Rules limiting their application to either pathology laboratories generally or specifically to pod labs. It appears managed pathology laboratories were successful in their efforts to ensure that the Proposed Rules evenhandedly addressed perceived abuses across the entire spectrum of diagnostic services.

We will also continue to work closely with CMS and Congressional leaders to present our case as to why the use of managed pathology laboratories provides superior urological pathology without any undue risk of program abuse. In our particular situation, we use a managed pathology laboratory model to send our pathology specimens, primarily because by using this particular laboratory model, our pathology specimens are interpreted by only uropathologist. This means that by only having a uropathologist preparing and interpreting our pathology specimens, we can detect possible problems sooner; therefore, we can offer appropriate treatment that much sooner to the patient, instead of having our pathology specimens prepared and interpreted by a general pathologist. In dealing with general pathologist, it may take more than one incident of Prostate biopsy before it is detected by a general pathologist. Possibly months could go by. Months, that when we are dealing with an aggressive Prostate cancer, could mean a life.

We hope this information helps you better understand how this proposal could affect our ability to render good medical care to our patients.

Sincerely,

Richard Dean, M.D.   Ralph DeVito, M.D.

Richard Dean, M.D.   Ralph DeVito, M.D.

David Hesse, M.D.   Stanton Honig, M.D.

David Hesse, M.D.   Stanton Honig, M.D.

Thomas Martin, M.D.   M. Grey Maher, M.D.

Thomas Martin, M.D.   M. Grey Maher, M.D.

Submitter : **T Davis** **Date: 08/31/2007**

Organization : **T Davis**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Amy Mitchell** **Date: 08/31/2007**

Organization : **Ark La Tex Health Center**

Category : **Individual**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: TECHNICAL CORRECTIONS

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Amy Mitchell
504 S Merrill
New Boston, TX 75570

Submitter : A Davis **Date: 08/31/2007**

Organization : A Davis

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

CMS-1385-P-13917

Submitter : **Craig Hill** **Date: 08/31/2007**

Organization : **Craig Hill**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Submitter : K Davis **Date: 08/31/2007**

Organization : K Davis

Category : Individual

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Submitter : **Jim Greenawalt** **Date: 08/31/2007**

Organization : **Jim Greenawalt**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Jim Greenawalt

Submitter : TONY GUINN **Date:** 08/31/2007

Organization : TONY GUINN

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Tony Guinn

Submitter : Dr. David Hesse **Date:** 08/31/2007

Organization : The Urology Center, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter(Word Document)

CMS-1385-P-13922-Attach-1.DOC

13922

TO WHOM IT MAY CONCERN @ CMS:

On July 2, 2007, the Centers for Medicare and Medicaid Services ("**CMS**") issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2008 (the "**2008 PFS**"). The 2008 PFS includes proposed changes to existing reassignment regulations and purchased test anti-markup regulations (collectively the "**Proposed Rules**").

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A second regulation, 42 CFR § 414.50, provides that if the TC of a diagnostic test was not performed by the billing physician and was not performed or supervised by a physician in the billing physician's group practice, Medicare payment is the lower of (i) the supplier's net charge, (ii) the billing group's actual charge, or (iii) the Medicare fee schedule payment. This is known as the "Anti-Markup Provision." The Anti-Markup Provision is intended to eliminate the opportunity for a group practice to profit by purchasing tests performed by other suppliers at a low price and then billing Medicare at a higher rate. The Proposed Rules amend this regulation by extending it to the PC of a diagnostic test that is either purchased by the billing group or billed by the billing group pursuant to a contractual reassignment. Both of these rules are intended to accomplish the same objectives.

The Proposed Rules are significant in a couple of respects. First, Medicare is limiting its payment to a group for the PC of a diagnostic test provided by an independent contractor physician to the amount of the payment the group makes to the physician. In calculating this payment, Medicare would not consider the cost of space, equipment, or other overhead necessary to permit the physician to provide the PC on the group's premises, despite the fact that the Stark Law requires that the physician perform these services on the group's premises. This does not prohibit a group from charging a physician for this overhead, but any such charge paid by the physician will lower the Medicare reimbursement to the group.

Essentially, this means that a group can no longer make a profit by utilizing a physician on a less than full time basis to provide the PC of Medicare reimbursed diagnostic tests on behalf of the group. It also means that the cost of overhead allocable to these services is now an unreimbursable cost of business to the group. While these limitations also apply to the TC of diagnostic tests, they will not affect the managed pathology laboratories because the TC in the managed laboratories is not performed by personnel who reassign their rights to bill Medicare. In our particular situation, we could not afford to hire a full time uropathologist and we would not have the volume to support such action. This would mean that only the very largest groups that would have the volume or could afford to do this. This also means that only the large groups could afford to render this type of care to their patients.

Second, the Proposed Rules provide that, in order to bill for the TC of a Medicare reimbursed diagnostic test, the group must directly perform the PC of the same service. This change will not affect managed laboratories, because those laboratories all bill for both the TC and PC of all tests, as a condition of Stark compliance. It is likely that this requirement will have a significant effect on other competing pathology delivery systems, particularly those in which a group practice provides its own TC and refers out the PC to independent pathologists who bill for the PC themselves.

Several previously considered rules were not proposed in this rulemaking. For example, there are no proposed rules addressing the size or location of a centralized building used for the provision of diagnostic tests. There is no proposed rule requiring that a centralized building contain on a permanent basis all of the equipment necessary to perform the diagnostic services it performed in that facility. And despite earlier consideration, there is no language in the Proposed Rules limiting their application to either pathology laboratories generally or specifically to pod labs. It appears managed pathology laboratories were successful in their efforts to ensure that the Proposed Rules evenhandedly addressed perceived abuses across the entire spectrum of diagnostic services.

We will also continue to work closely with CMS and Congressional leaders to present our case as to why the use of managed pathology laboratories provides superior urological pathology without any undue risk of program abuse. In our particular situation, we use a managed pathology laboratory model to send our pathology specimens, primarily because by using this particular laboratory model, our pathology specimens are interpreted by only uropathologist. This means that by only having a uropathologist preparing and interpreting our pathology specimens, we can detect possible problems sooner; therefore, we can offer appropriate treatment that much sooner to the patient, instead of having our pathology specimens prepared and interpreted by a general pathologist. In dealing with general pathologist, it may take more than one incident of Prostate biopsy before it is detected by a general pathologist. Possibly months could go by. Months, that when we are dealing with an aggressive Prostate cancer, could mean a life.

We hope this information helps you better understand how this proposal could affect our ability to render good medical care to our patients.

Sincerely,

Richard Dean, M.D. *Ralph DeVito, M.D.*

Richard Dean, M.D. Ralph DeVito, M.D.

David Hesse, M.D. *Stanton Honig, M.D.*

David Hesse, M.D. Stanton Honig, M.D.

Thomas Martin, M.D. *M. Grey Maher, M.D.*

Thomas Martin, M.D. M. Grey Maher, M.D.

Submitter : K Doughty **Date: 08/31/2007**

Organization : K Doughty

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Jeanetta Chatman** **Date: 08/31/2007**

Organization : **Ark La Tex Health Center**

Category : **Individual**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: TECHNICAL CORRECTIONS

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

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I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Jeanetta Chatman
PO Box 5554
Texarkana, TX 75505-5554

Submitter : Mr. Cort Widlowski **Date: 08/31/2007**

Organization : Mr. Cort Widlowski

Category : Individual

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Submitter : **Dr. Russell Levin** **Date: 08/31/2007**

Organization : **West Chester Anesthesia Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P

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Thank you for your consideration of this serious matter.

Russell Levin, MD

Submitter : S Doughty **Date: 08/31/2007**

Organization : S Doughty

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : ZACH BOYD **Date:** 08/31/2007

Organization : ZACH BOYD

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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ZACH BOYD

Submitter : **M Galles** **Date: 08/31/2007**

Organization : **M Galles**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter : **Paul Willis** **Date: 08/31/2007**

Organization : **Paul Willis**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Paul Willis

Submitter : **Mr. Kurt Jacobson** **Date: 08/31/2007**

Organization : **Mr. Kurt Jacobson**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dr. Sir or Madam:

My name is Kurt Jacobson. Work at Luther Midelfort in Eau Claire, Wisconsin. Work in a multi-practice hospital and clinic setting. Also, I work with 4 area high schools, various local touraments and a semi-professional football team. I graduated from St. Olaf College in 1992 and received my master's degree from Indiana University in 1993.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Kurt Jacobson, MS, ATC

Submitter : **Naudine Greenawalt** **Date: 08/31/2007**

Organization : **Naudine Greenawalt**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Naudine Greenawalt

Submitter : **Greg Banks CRT** **Date: 08/31/2007**

Organization : **Greg Banks CRT**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Greg Banks CRT

Submitter : S Galles **Date: 08/31/2007**

Organization : S Galles

Category : Individual

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Submitter : **BLAKE BOYD** **Date: 08/31/2007**

Organization : **BLAKE BOYD**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
BLAKE BOYD

Submitter : **Jessica Maynard** **Date: 08/31/2007**

Organization : **Ark La Tex Health Center**

Category : **Individual**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

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I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Jessica Maynard
145 Arizona Ave
Wake Village, TX 75501

Submitter : Dr. Stanton Honig

Date: 08/31/2007

Organization : The Urology Center, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-13937-Attach-1.DOC

13937

TO WHOM IT MAY CONCERN @ CMS:

On July 2, 2007, the Centers for Medicare and Medicaid Services ("**CMS**") issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2008 (the "**2008 PFS**"). The 2008 PFS includes proposed changes to existing reassignment regulations and purchased test anti-markup regulations (collectively the "**Proposed Rules**").

The Proposed Rules are a substantial departure from the rules proposed last year by CMS in its 2007 PFS. Nevertheless, if finalized, the Proposed Rules will impact certain business arrangements utilized by some managed pathology laboratories. The purpose of this letter is to summarize the Proposed Rules as they relate to the provision of in-house pathology services, and to provide you with our perspective on the potential impact of the Proposed Rules on certain business arrangements routinely utilized by managed pathology laboratories.

The Social Security Act generally prohibits Medicare payment to anyone other than the Medicare beneficiary (the patient) or the physician or other person who performed the service for the beneficiary. This prohibition is found at 42 CFR § 424.80. This rule has exceptions known as "reassignment exceptions," which permit Medicare to make payment to an individual or entity other than the performing physician, provided the physician has appropriately "reassigned" his right to payment. One such exception, found at 42 CFR § 424.80(d), permits a physician to contractually reassign to a group practice the right to bill Medicare for services provided by the physician on the group's behalf. The Proposed Rules add certain requirements to this regulation which must be complied with by groups who bill for diagnostic tests pursuant to a contractual reassignment. It is pursuant to such a contractual reassignment that some managed pathology laboratories bill for services provided by their pathologists.

As amended, 42 CFR § 424.80 provides that if either the technical component ("**TC**") or the professional component ("**PC**") of a diagnostic test is billed by a physician or medical group pursuant to a contractual reassignment from a provider who is not a full time employee of the billing group, the following conditions must be met:

(i) the payment to the group, less applicable deductibles and coinsurance, may not exceed the lowest of: (1) the provider's net charge to the group, which must be determined without regard to any charge intended to cover the cost of equipment or space leased to the provider by the billing group payment that is made by the group to the physician; (2) the group's actual charge; or (3) the Medicare fee schedule payment for the service provided;

(ii) the group must identify the provider that performed the PC or the TC and indicate their net charge as a condition of reimbursement; and

(iii) in order to bill for the TC of a service, the group must directly perform the PC of the same service.

A second regulation, 42 CFR § 414.50, provides that if the TC of a diagnostic test was not performed by the billing physician and was not performed or supervised by a physician in the billing physician's group practice, Medicare payment is the lower of (i) the supplier's net charge, (ii) the billing group's actual charge, or (iii) the Medicare fee schedule payment. This is known as the "Anti-Markup Provision." The Anti-Markup Provision is intended to eliminate the opportunity for a group practice to profit by purchasing tests performed by other suppliers at a low price and then billing Medicare at a higher rate. The Proposed Rules amend this regulation by extending it to the PC of a diagnostic test that is either purchased by the billing group or billed by the billing group pursuant to a contractual reassignment. Both of these rules are intended to accomplish the same objectives.

The Proposed Rules are significant in a couple of respects. First, Medicare is limiting its payment to a group for the PC of a diagnostic test provided by an independent contractor physician to the amount of the payment the group makes to the physician. In calculating this payment, Medicare would not consider the cost of space, equipment, or other overhead necessary to permit the physician to provide the PC on the group's premises, despite the fact that the Stark Law requires that the physician perform these services on the group's premises. This does not prohibit a group from charging a physician for this overhead, but any such charge paid by the physician will lower the Medicare reimbursement to the group.

Essentially, this means that a group can no longer make a profit by utilizing a physician on a less than full time basis to provide the PC of Medicare reimbursed diagnostic tests on behalf of the group. It also means that the cost of overhead allocable to these services is now an unreimbursable cost of business to the group. While these limitations also apply to the TC of diagnostic tests, they will not affect the managed pathology laboratories because the TC in the managed laboratories is not performed by personnel who reassign their rights to bill Medicare. In our particular situation, we could not afford to hire a full time uropathologist and we would not have the volume to support such action. This would mean that only the very largest groups that would have the volume or could afford to do this. This also means that only the large groups could afford to render this type of care to their patients.

Second, the Proposed Rules provide that, in order to bill for the TC of a Medicare reimbursed diagnostic test, the group must directly perform the PC of the same service. This change will not affect managed laboratories, because those laboratories all bill for both the TC and PC of all tests, as a condition of Stark compliance. It is likely that this requirement will have a significant effect on other competing pathology delivery systems, particularly those in which a group practice provides its own TC and refers out the PC to independent pathologists who bill for the PC themselves.

Several previously considered rules were not proposed in this rulemaking. For example, there are no proposed rules addressing the size or location of a centralized building used for the provision of diagnostic tests. There is no proposed rule requiring that a centralized building contain on a permanent basis all of the equipment necessary to perform the diagnostic services it performed in that facility. And despite earlier consideration, there is no language in the Proposed Rules limiting their application to either pathology laboratories generally or specifically to pod labs. It appears managed pathology laboratories were successful in their efforts to ensure that the Proposed Rules evenhandedly addressed perceived abuses across the entire spectrum of diagnostic services.

We will also continue to work closely with CMS and Congressional leaders to present our case as to why the use of managed pathology laboratories provides superior urological pathology without any undue risk of program abuse. In our particular situation, we use a managed pathology laboratory model to send our pathology specimens, primarily because by using this particular laboratory model, our pathology specimens are interpreted by only uropathologist. This means that by only having a uropathologist preparing and interpreting our pathology specimens, we can detect possible problems sooner; therefore, we can offer appropriate treatment that much sooner to the patient, instead of having our pathology specimens prepared and interpreted by a general pathologist. In dealing with general pathologist, it may take more than one incident of Prostate biopsy before it is detected by a general pathologist. Possibly months could go by. Months, that when we are dealing with an aggressive Prostate cancer, could mean a life.

We hope this information helps you better understand how this proposal could affect our ability to render good medical care to our patients.

Sincerely,

Richard Dean, M.D.	*Ralph DeVito, M.D.*
Richard Dean, M.D.	Ralph DeVito, M.D.
David Hesse, M.D.	*Stanton Honig, M.D.*
David Hesse, M.D.	Stanton Honig, M.D.
Thomas Martin, M.D.	*M. Grey Maher, M.D.*
Thomas Martin, M.D.	M. Grey Maher, M.D.

Submitter : **A Mullen** **Date: 08/31/2007**

Organization : **A Mullen**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

A Mullen

Submitter : **Mr. Michael Ruggiero** **Date: 08/31/2007**

Organization : **Astellas Pharma US**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1385-P-13939-Attach-1.PDF

#13939

August 31, 2007

BY HAND DELIVERY AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

Mr. Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS 1385-P; Comments Regarding the Proposed Physician Fee Schedule Rule for Calendar Year 2008

Dear Mr. Kuhn:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to comment on the Medicare Physician Fee Schedule Proposed Rule for 2008 published by the Centers for Medicare and Medicaid Services (CMS).[1] Astellas is among the top 20 global research-based pharmaceutical companies, with global sales of approximately $8 billion, and the number two Japan-based pharmaceutical company. Our fundamental goal is to use our expertise in key therapeutic areas to improve the health of Americans by developing and marketing cures for unmet medical needs. Our North American product lines, which focus on the therapeutic areas of infectious disease, immunology, cardiology, dermatology, and urology, are used by Medicare beneficiaries in a variety of settings, including physician offices and other outpatient settings.

Our detailed comments are set forth below, and focus on two important goals: developing clear ground rules that produce consistency and accuracy in manufacturers' Average Sales Price (ASP) calculations; and refining the Part B Competitive Acquisition (CAP) so that it can better serve the needs of physicians and patients.

* * *

[1] Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B Payment Policies for CY 2008; Proposed rule, 72 Fed. Reg. 38122 (July 12, 2007).

Astellas Pharma US, Inc.
Three Parkway North, Deerfield, IL 60015-2537
Tel: 847-405-1640 www.us.astellas.com

I. ASP Calculations and Bundling

Because of its importance in setting providers' payment rates for Medicare Part B drugs, Average Sales Price (ASP) should be calculated by rules that are clear, free of unnecessary complexity, and designed to produce accurate figures. Clear ground rules are essential for allowing manufacturers to calculate ASPs in a consistent manner that accords with CMS' expectations.

Given these principles, we have concerns about CMS' proposal to extend to ASP calculations the new bundling provisions in the Medicaid prescription drug rule.[2] These provisions define a "bundled" sale and require that manufacturers proportionately allocate discounts on bundled sales across the drugs in the bundle. The definition of a "bundled sale" in the Medicaid rule (which is substantially similar to the "bundled arrangement" definition CMS proposes to adopt in the ASP context) is confusing and potentially overbroad.[3] Both definitions define bundling to include arrangements that involve unspecified "performance requirements," even if such requirements relate to the "same drug." We are concerned that without additional clarifying guidance from CMS, this language will apply too broadly. Specifically, CMS should avoid a construction of "bundled sale" that sweeps in arrangements that do not involve attempts to use the discount on one drug to reduce the effective price of another. For example, CMS

[2] 72 Fed. Reg. 39142 (July 17, 2007). More specifically, CMS proposed to extend to ASP the approach to bundling that it had adopted in the proposed Medicaid rule (which is substantially identical to the language adopted in the final Medicaid rule), and stated that it intended to "remain consistent with the final policy in the Medicaid final rule on this issue, as appropriate." 72 Fed. Reg. 38122 at 38151.

[3] The Medicaid rule defines a "bundled sale" as "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle." 42 C.F.R. § 447.502. In the ASP context, CMS proposes to define a "bundled arrangement" as "an arrangement, regardless of physical packaging under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those that would have been available had the drugs or biologicals sold under the bundled arrangement been purchased separately or outside of the bundled arrangement." 72 Fed. Reg. at 38151. CMS also proposes to require that "all price concessions on drugs sold under a bundled arrangement must be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement." Id.

should clarify that a "bundled sale" only occurs where there is a purchase or market share requirement in exchange for the discount, and not in an arrangement that merely conditions the discount for one drug on the formulary inclusion or placement of another drug. Avoiding such an overbroad construction of "bundled sale" is appropriate both to reduce the confusion faced by manufacturers, and because such a definition would require the reallocation of discounts on a larger set of sales that would tend to undermine, rather than improve, the accuracy of ASP calculations.

We agree with CMS that, other things being equal, adopting consistent rules for ASP calculations and Medicaid rebate calculations is a desirable step that should increase the efficiency of manufacturers' pricing calculations. As noted above, however, extending the Medicaid rule's bundling provisions to ASP calculations could potentially produce greater confusion and complexity, more errors, and reduced consistency between manufacturers. If CMS wishes to adopt this approach in the ASP context, the Agency should provide manufacturers with clear guidance on the many questions that remain unanswered regarding how to apply the Medicaid bundling definition and the related allocation procedures. Among other things, CMS should explain how the bundled discount allocation procedure intersects with the 12-month rolling average methodology for estimating lagged price concessions, and how manufacturers should handle any cases where the information needed to reallocate discounts was unavailable before the deadline for ASP submissions. CMS also should specify how manufacturers should allocate discounts for bundled sales involving a combination of drugs that are ASP-eligible and drugs that are not.

We strongly encourage CMS to study these kinds of issues carefully and, if CMS ultimately decides to require allocation of bundled discounts, to commit itself to giving manufacturers the clear guidance that they would need to understand and implement these requirements.

II. Competitive Acquisition Program Issues

CAP has significant potential to improve Medicare beneficiaries' access to Part B drugs as the program attains higher levels of physician participation. Consequently, Astellas encourages CMS to adopt refinements to CAP that will help make the program more "user friendly" for physicians and increase their CAP participation rate.

Along these lines, Astellas supports the effort by CMS to explore "narrowing the restriction on [the physician] transporting CAP drugs where this is permitted by State law and other applicable laws and regulations."[4] Allowing physicians to transport CAP drugs to a

[4] 72 Fed. Reg. 38122 at 38158.

satellite office or to the patient's home, when this can be done safely and in accordance with other applicable laws and regulations, could give physicians participating in CAP a degree of increased flexibility that would make CAP participation more attractive, and increase patients' access to needed medicines.

Astellas also supports the proposal by CMS to define additional exigent circumstances in which physicians could withdraw from CAP,[5] since we believe that this could ease physician concerns about enrolling in CAP in the first instance and thus ultimately boost participation in CAP. To that end, CMS may wish to consider liberalizing the proposed procedures for physicians to withdraw from CAP due to "significant burden," by giving physicians a period longer than 30 days in which to submit a written request to withdraw from the program.

Finally, CMS should also consider encouraging physicians to participate in CAP by eliminating the current requirement that CAP-participating physicians submit claims for drug administration services for CAP drugs within 14 days of administering the drug. There may be many physician practices that do not customarily submit claims within this window, and eliminating the 14-day claims submission requirement could therefore make CAP participation a more attractive prospect for those practices. CMS initially adopted the 14-day claims submission requirement because, at that time, it was necessary to match the physician's drug administration claim with the CAP vendor's drug claim before the CAP vendor could be paid; imposing the 14-day claims submission requirement on CAP-participating physicians was therefore the only mechanism to enable the CAP vendor to be paid relatively promptly. However, due to recent statutory changes the claims matching requirement (and the related 14-day physician billing requirement) are no longer necessary for this purpose; under Section 108 of the Medicare Improvements and Extension Act (Division B of the Tax Relief and Health Care Act of 2006) payment for drugs and biologicals supplied by the CAP vendor must be made upon receipt of the vendor's claim, and a separate post-payment review process confirms that the drugs have in fact been administered to beneficiaries. CMS therefore has the opportunity to remove an administrative requirement now imposed on CAP-participating physicians that likely has been an impediment to CAP participation for some physician practices. We encourage CMS to take this step, and any other steps it identifies that can make it simpler and more convenient for physicians to participate in CAP.

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[5] Currently physicians can withdraw from CAP early (before their one-year commitment expires) in certain "exigent circumstances," i.e.: (1) if the physician's CAP vendor ceases to participate in CAP; (2) if the physician leaves the group practice that selected the CAP vendor; (3) if the physician moves to another competitive acquisition area (if multiple CAP areas are created); or (4) for other exigent circumstances defined by CMS. CMS now proposes to define an additional exigent circumstance in which a physician could opt out of CAP if he or she submitted a written request to do so within 30 days of entering the CAP physician election agreement and if CMS granted the request due to remaining in CAP being a "significant burden" on the physician.

* * *

Astellas appreciates the opportunity to provide these comments. If you have any questions or would like additional information, please contact me at 202-812-6162 or via e-mail (michael.ruggiero@us.astellas.com).

Sincerely,

Michael J. Ruggiero
Senior Director, Government Policy and External Affairs

Submitter : **Dr. Blake Mitchell** **Date: 08/31/2007**

Organization : **American Society of Anesthesiologists**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Blake Mitchell, MD
President, Anesthesia Partners of Montana
Billings, MT 59102

Submitter : **Therasa Williams** **Date: 08/31/2007**

Organization : **Ark La Tex Health Center**

Category : **Individual**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: TECHNICAL CORRECTIONS

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Therasa Williams
PO Box 518
Fouke, AR 71837

CMS-1385-P-13942

Submitter : **Ms. Tamara Beeler** **Date: 08/31/2007**

Organization : **Dallas Veterans Affairs Medical Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

RE: Docket #1385-P Therapy Standards and Requirements, Physician Self-Referral Provisions

My name is Tamara Beeler, BS, Registered Kinesiotherapist (RKT) and I live in Lake Dallas, TX. I received my Certificate of Registry in July 2003 after satisfying all the requirements set forth by the Council on Professional Standards for Kinesiotherapy. I currently work as an RKT in the Spinal Cord Injury and Disease Center of the Dallas Veterans' Affairs Medical Center in Dallas, TX.

I am writing today to voice my opposition to the proposed therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and other facilities proposed in Federal Register issue #1385-P. As a Kinesiotherapist, I would be excluded from providing physical medicine and rehabilitation services under these rules.

I am concerned that these proposed rules will create additional lack of access to quality health care for my patients. This is particularly important because my colleagues and I work with many wounded Veterans, an increasing number of whom are expected to receive services in the private market. These Medicare rules will have a detrimental effect on all commercial-pay patients because Medicare dictates much of health care business practices.

I believe these proposed changes to the Hospital Conditions of Participation have not received the proper and usual vetting. CMS has offered no reports as to why these changes are necessary. There have not been any reports that address the serious economic impact on Kinesiotherapists, projeeted increases in Medicare costs or patient quality, safety or access. What is driving these significant changes? Who is demanding these?

As a Kinesiotherapist, I am qualified to perform physical medicine and rehabilitation services. My education, clinical experience, and Registered status insure that my patients receive quality health care. Hospital and other facility medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards and accepted practices.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the health care industry. It is irresponsible for CMS to further restrict PMR services and specialized professionals.

It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to reconsider these proposed rules. Leave medical judgments and staffing decisions to the professionals. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Tamara Beeler, RKT

Therapy Standards and Requirements

Therapy Standards and Requirements

RE: Docket #1385-P Therapy Standards and Requirements, Physician Self-Referral Provisions

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Sincerely,
Tamara Beeler, RKT

Submitter : Mr. Jim Raynor **Date:** 08/31/2007

Organization : St. John's Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

My name is Jim Raynor and I am the Administrative Director of Sports Medicine for St. John's Hospital in Springfield, MO. I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

I am concerned regarding the exclusion of certified athletic trainers from the proposed therapy standards. I have been associated and/or employed with St. John's Hospital since 1991 and have had the opportunity to be a part of an organization that has provided medical care to a diverse population in conjunction with other members of the medical team. Throughout the years we have seen change for the benefit of the patients with increased collaborative approaches to care for our patient population.

The inclusion of athletic trainers to perform physical medicine and rehabilitation services can only bring a diverse and comprehensive approach to patient care. The education, clinical experience, and national certification exam ensure that our patients receive quality health care. Our care team that includes certified athletic trainers has recieved appropriate support from state law and hospital medical professionals that deem athletic trainers qualified to perform these services. The proposed regulations in 1385-P attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available. The inclusion and not the ommitance of qualified professionals will only improve the ability to provide quality cost effective care. In doing so, it will allow a comprehensive approach to care enabling better access with decreased delays therfore resulting in decreased complications resulting from injury.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. Our physicians and hospital administration strongly support and utilize the services of athletic trainers and it is of our opinion that the decision making responsibility should remain with them. They have the best interest in mind for their patients and organizaiton. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jim Raynor, MSATC
Administrative Director
St. John's Sports Medicine Service Line

Submitter : **Ms. Emory Widlowski** **Date: 08/31/2007**

Organization : **Ms. Emory Widlowski**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **WAYNE BRISTOW** **Date: 08/31/2007**

Organization : **WAYNE BRISTOW**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
WAYNE BRISTOW

Submitter : **Deanna Welch** **Date: 08/31/2007**

Organization : **Deanna Welch**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.
Deanna Welch

Submitter : **Foster Mullen** **Date: 08/31/2007**

Organization : **Foster Mullen**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Foster Mullen

13948

Submitter : **Dr. Thomas V. Martin** **Date: 08/31/2007**

Organization : **The Urology Center, P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-13948-Attach-1.DOC

TO WHOM IT MAY CONCERN @ CMS:

On July 2, 2007, the Centers for Medicare and Medicaid Services ("**CMS**") issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2008 (the "**2008 PFS**"). The 2008 PFS includes proposed changes to existing reassignment regulations and purchased test anti-markup regulations (collectively the "**Proposed Rules**").

The Proposed Rules are a substantial departure from the rules proposed last year by CMS in its 2007 PFS. Nevertheless, if finalized, the Proposed Rules will impact certain business arrangements utilized by some managed pathology laboratories. The purpose of this letter is to summarize the Proposed Rules as they relate to the provision of in-house pathology services, and to provide you with our perspective on the potential impact of the Proposed Rules on certain business arrangements routinely utilized by managed pathology laboratories.

The Social Security Act generally prohibits Medicare payment to anyone other than the Medicare beneficiary (the patient) or the physician or other person who performed the service for the beneficiary. This prohibition is found at 42 CFR § 424.80. This rule has exceptions known as "reassignment exceptions," which permit Medicare to make payment to an individual or entity other than the performing physician, provided the physician has appropriately "reassigned" his right to payment. One such exception, found at 42 CFR § 424.80(d), permits a physician to contractually reassign to a group practice the right to bill Medicare for services provided by the physician on the group's behalf. The Proposed Rules add certain requirements to this regulation which must be complied with by groups who bill for diagnostic tests pursuant to a contractual reassignment. It is pursuant to such a contractual reassignment that some managed pathology laboratories bill for services provided by their pathologists.

As amended, 42 CFR § 424.80 provides that if either the technical component ("**TC**") or the professional component ("**PC**") of a diagnostic test is billed by a physician or medical group pursuant to a contractual reassignment from a provider who is not a full time employee of the billing group, the following conditions must be met:

(i) the payment to the group, less applicable deductibles and coinsurance, may not exceed the lowest of: (1) the provider's net charge to the group, which must be determined without regard to any charge intended to cover the cost of equipment or space leased to the provider by the billing group payment that is made by the group to the physician; (2) the group's actual charge; or (3) the Medicare fee schedule payment for the service provided;

(ii) the group must identify the provider that performed the PC or the TC and indicate their net charge as a condition of reimbursement; and

(iii) in order to bill for the TC of a service, the group must directly perform the PC of the same service.

A second regulation, 42 CFR § 414.50, provides that if the TC of a diagnostic test was not performed by the billing physician and was not performed or supervised by a physician in the billing physician's group practice, Medicare payment is the lower of (i) the supplier's net charge, (ii) the billing group's actual charge, or (iii) the Medicare fee schedule payment. This is known as the "Anti-Markup Provision." The Anti-Markup Provision is intended to eliminate the opportunity for a group practice to profit by purchasing tests performed by other suppliers at a low price and then billing Medicare at a higher rate. The Proposed Rules amend this regulation by extending it to the PC of a diagnostic test that is either purchased by the billing group or billed by the billing group pursuant to a contractual reassignment. Both of these rules are intended to accomplish the same objectives.

The Proposed Rules are significant in a couple of respects. First, Medicare is limiting its payment to a group for the PC of a diagnostic test provided by an independent contractor physician to the amount of the payment the group makes to the physician. In calculating this payment, Medicare would not consider the cost of space, equipment, or other overhead necessary to permit the physician to provide the PC on the group's premises, despite the fact that the Stark Law requires that the physician perform these services on the group's premises. This does not prohibit a group from charging a physician for this overhead, but any such charge paid by the physician will lower the Medicare reimbursement to the group.

Essentially, this means that a group can no longer make a profit by utilizing a physician on a less than full time basis to provide the PC of Medicare reimbursed diagnostic tests on behalf of the group. It also means that the cost of overhead allocable to these services is now an unreimbursable cost of business to the group. While these limitations also apply to the TC of diagnostic tests, they will not affect the managed pathology laboratories because the TC in the managed laboratories is not performed by personnel who reassign their rights to bill Medicare. In our particular situation, we could not afford to hire a full time uropathologist and we would not have the volume to support such action. This would mean that only the very largest groups that would have the volume or could afford to do this. This also means that only the large groups could afford to render this type of care to their patients.

Second, the Proposed Rules provide that, in order to bill for the TC of a Medicare reimbursed diagnostic test, the group must directly perform the PC of the same service. This change will not affect managed laboratories, because those laboratories all bill for both the TC and PC of all tests, as a condition of Stark compliance. It is likely that this requirement will have a significant effect on other competing pathology delivery systems, particularly those in which a group practice provides its own TC and refers out the PC to independent pathologists who bill for the PC themselves.

Several previously considered rules were not proposed in this rulemaking. For example, there are no proposed rules addressing the size or location of a centralized building used for the provision of diagnostic tests. There is no proposed rule requiring that a centralized building contain on a permanent basis all of the equipment necessary to perform the diagnostic services it performed in that facility. And despite earlier consideration, there is no language in the Proposed Rules limiting their application to either pathology laboratories generally or specifically to pod labs. It appears managed pathology laboratories were successful in their efforts to ensure that the Proposed Rules evenhandedly addressed perceived abuses across the entire spectrum of diagnostic services.

We will also continue to work closely with CMS and Congressional leaders to present our case as to why the use of managed pathology laboratories provides superior urological pathology without any undue risk of program abuse. In our particular situation, we use a managed pathology laboratory model to send our pathology specimens, primarily because by using this particular laboratory model, our pathology specimens are interpreted by only uropathologist. This means that by only having a uropathologist preparing and interpreting our pathology specimens, we can detect possible problems sooner; therefore, we can offer appropriate treatment that much sooner to the patient, instead of having our pathology specimens prepared and interpreted by a general pathologist. In dealing with general pathologist, it may take more than one incident of Prostate biopsy before it is detected by a general pathologist. Possibly months could go by. Months, that when we are dealing with an aggressive Prostate cancer, could mean a life.

We hope this information helps you better understand how this proposal could affect our ability to render good medical care to our patients.

Sincerely,

Richard Dean, M.D. | Ralph DeVito, M.D.

Richard Dean, M.D. | Ralph DeVito, M.D.

David Hesse, M.D. | Stanton Honig, M.D.

David Hesse, M.D. | Stanton Honig, M.D.

Thomas Martin, M.D. | M. Grey Maher, M.D.

Thomas Martin, M.D. | M. Grey Maher, M.D.

Submitter : **Paula Wade** **Date: 08/31/2007**

Organization : **Paula Wade**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Paula Wade

Submitter : Dr. Christopher Frandrup **Date:** 08/31/2007

Organization : Dr. Christopher Frandrup

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018<p>

Re: CMS-1385-P <p>

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Thank you for your consideration of this serious matter. <p>

Christopher Frandrup, M.D.
5500 Rocky Point
Gillette, WY 82718

Submitter : **ROBBIE BRISTOW** **Date: 08/31/2007**

Organization : **ROBBIE BRISTOW**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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ROBBIE BRISTOW

Submitter : **Date: 08/31/2007**

Organization : **Athletico**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a graduate of the University of Wisconsin-Madison where I received a BS in Movement Science and a certificate in Athletic Training. As a part of the Athletic Training Education Program, I worked with a local high school and with our university s Division 1 football, men s and women s basketball, men s hockey, women s volleyball and men s and women s crew. Over the summers in college I would work to provide AT coverage to the kids aged 8-18 participating in summer sports camps hosted by UW-Madison. Since graduating college I have been working as an Athletic Trainer for Athletico. Currently, I work as a fulltime Athletic Trainer for a high school in Chicago, while last year I divided my time between working at an Athletico clinic and covering events for an intramural sports league.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Sarah Felt, ATC

Submitter : C Hook **Date: 08/31/2007**

Organization : C Hook

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter : **Shannan Nealy** **Date: 08/31/2007**

Organization : **Ark La Tex Health Center**

Category : **Individual**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: TECHNICAL CORRECTIONS

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Shannan Nealy
142 Westline Rd
Wake Village, TX 75501

Submitter : **S Hook** **Date: 08/31/2007**

Organization : **S Hook**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter : **Terry Welch** **Date: 08/31/2007**

Organization : **Terry Welch**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Terry Welch

CMS-1385-P-13957

Submitter : Dr. Mary Grey Maher

Date: 08/31/2007

Organization : The Urology Center, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-13957-Attach-1.DOC

13957

TO WHOM IT MAY CONCERN @ CMS:

On July 2, 2007, the Centers for Medicare and Medicaid Services ("**CMS**") issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2008 (the "**2008 PFS**"). The 2008 PFS includes proposed changes to existing reassignment regulations and purchased test anti-markup regulations (collectively the "**Proposed Rules**").

The Proposed Rules are a substantial departure from the rules proposed last year by CMS in its 2007 PFS. Nevertheless, if finalized, the Proposed Rules will impact certain business arrangements utilized by some managed pathology laboratories. The purpose of this letter is to summarize the Proposed Rules as they relate to the provision of in-house pathology services, and to provide you with our perspective on the potential impact of the Proposed Rules on certain business arrangements routinely utilized by managed pathology laboratories.

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A second regulation, 42 CFR § 414.50, provides that if the TC of a diagnostic test was not performed by the billing physician and was not performed or supervised by a physician in the billing physician's group practice, Medicare payment is the lower of (i) the supplier's net charge, (ii) the billing group's actual charge, or (iii) the Medicare fee schedule payment. This is known as the "Anti-Markup Provision." The Anti-Markup Provision is intended to eliminate the opportunity for a group practice to profit by purchasing tests performed by other suppliers at a low price and then billing Medicare at a higher rate. The Proposed Rules amend this regulation by extending it to the PC of a diagnostic test that is either purchased by the billing group or billed by the billing group pursuant to a contractual reassignment. Both of these rules are intended to accomplish the same objectives.

The Proposed Rules are significant in a couple of respects. First, Medicare is limiting its payment to a group for the PC of a diagnostic test provided by an independent contractor physician to the amount of the payment the group makes to the physician. In calculating this payment, Medicare would not consider the cost of space, equipment, or other overhead necessary to permit the physician to provide the PC on the group's premises, despite the fact that the Stark Law requires that the physician perform these services on the group's premises. This does not prohibit a group from charging a physician for this overhead, but any such charge paid by the physician will lower the Medicare reimbursement to the group.

Essentially, this means that a group can no longer make a profit by utilizing a physician on a less than full time basis to provide the PC of Medicare reimbursed diagnostic tests on behalf of the group. It also means that the cost of overhead allocable to these services is now an unreimbursable cost of business to the group. While these limitations also apply to the TC of diagnostic tests, they will not affect the managed pathology laboratories because the TC in the managed laboratories is not performed by personnel who reassign their rights to bill Medicare. In our particular situation, we could not afford to hire a full time uropathologist and we would not have the volume to support such action. This would mean that only the very largest groups that would have the volume or could afford to do this. This also means that only the large groups could afford to render this type of care to their patients.

Second, the Proposed Rules provide that, in order to bill for the TC of a Medicare reimbursed diagnostic test, the group must directly perform the PC of the same service. This change will not affect managed laboratories, because those laboratories all bill for both the TC and PC of all tests, as a condition of Stark compliance. It is likely that this requirement will have a significant effect on other competing pathology delivery systems, particularly those in which a group practice provides its own TC and refers out the PC to independent pathologists who bill for the PC themselves.

Several previously considered rules were not proposed in this rulemaking. For example, there are no proposed rules addressing the size or location of a centralized building used for the provision of diagnostic tests. There is no proposed rule requiring that a centralized building contain on a permanent basis all of the equipment necessary to perform the diagnostic services it performed in that facility. And despite earlier consideration, there is no language in the Proposed Rules limiting their application to either pathology laboratories generally or specifically to pod labs. It appears managed pathology laboratories were successful in their efforts to ensure that the Proposed Rules evenhandedly addressed perceived abuses across the entire spectrum of diagnostic services.

We will also continue to work closely with CMS and Congressional leaders to present our case as to why the use of managed pathology laboratories provides superior urological pathology without any undue risk of program abuse. In our particular situation, we use a managed pathology laboratory model to send our pathology specimens, primarily because by using this particular laboratory model, our pathology specimens are interpreted by only uropathologist. This means that by only having a uropathologist preparing and interpreting our pathology specimens, we can detect possible problems sooner; therefore, we can offer appropriate treatment that much sooner to the patient, instead of having our pathology specimens prepared and interpreted by a general pathologist. In dealing with general pathologist, it may take more than one incident of Prostate biopsy before it is detected by a general pathologist. Possibly months could go by. Months, that when we are dealing with an aggressive Prostate cancer, could mean a life.

We hope this information helps you better understand how this proposal could affect our ability to render good medical care to our patients.

Sincerely,

Richard Dean, M.D. | Ralph DeVito, M.D.

Richard Dean, M.D. | Ralph DeVito, M.D.

David Hesse, M.D. | Stanton Honig, M.D.

David Hesse, M.D. | Stanton Honig, M.D.

Thomas Martin, M.D. | M. Grey Maher, M.D.

Thomas Martin, M.D. | M. Grey Maher, M.D.

Submitter : **C Loomis** **Date: 08/31/2007**

Organization : **C Loomis**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Maybelle Mullen** **Date: 08/31/2007**

Organization : **Maybelle Mullen**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Maybelle Mullen

Submitter : M Loomis **Date:** 08/31/2007

Organization : M Loomis

Category : Individual

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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Submitter : **Mr. Rod Morrison** **Date: 08/31/2007**

Organization : **Mr. Rod Morrison**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Submitter : **Elaine Banks RN** **Date: 08/31/2007**

Organization : **Elaine Banks RN**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Elaine Banks RN

Submitter : **Ms. Annette Cooper** **Date: 08/31/2007**

Organization : **Trident Anesthesia Group**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

August 20, 2007
Ms. Leslie Norwalk, JD
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES

Dear Ms. Norwalk:

As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

This increase in Medicare payment is important for several reasons.

? First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
? Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
? Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.

Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).

America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.

Sincerely,

Annette Cooper, CRNA
2758 Stamby Place
Mt. Pleasant, SC 29466

Submitter : **Garnett Wade** **Date: 08/31/2007**

Organization : **Garnett Wade**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Garnett Wade

Submitter : L Gawey **Date: 08/31/2007**

Organization : L Gawey

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : **Wendi Humes** **Date: 08/31/2007**

Organization : **Wendi Humes**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Wendi Humes

Submitter : **Ms. Katherine Brown** **Date: 08/31/2007**

Organization : **Resurgens Orthopaedics**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Consideration of patient care and the benefits patient's receive from imaging and rehabilitation services based in physicians offices is the prime concern of my practice. Having immediate access to physicians while you have a patient in therapy or in a scanner saves not only needless additional visits and care but stress and possible adverse outcomes to the patient.

Submitter : l Gawey **Date: 08/31/2007**

Organization : l Gawey

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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Submitter : **Tim Paslay** **Date: 08/31/2007**

Organization : **Ark La Tex Health Center**

Category : **Individual**

Issue Areas/Comments

Chiropractic Services Demonstration

Chiropractic Services Demonstration

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: TECHNICAL CORRECTIONS

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Tim Paslay
Texarkana, TX

Submitter : **Lisa Guild** **Date: 08/31/2007**

Organization : **Lisa Guild**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Lisa Guild

Submitter : A Gawey **Date:** 08/31/2007

Organization : A Gawey

Category : Individual

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Submitter : **BOB BROWN** **Date: 08/31/2007**

Organization : **BOB BROWN**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.
BOB BROWN

Submitter : **Elizabeth Peterson** **Date: 08/31/2007**

Organization : **Elizabeth Peterson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Elizabeth Peterson

Submitter : **Dr. Christos Vasakiris** **Date: 08/31/2007**

Organization : **Dr. Christos Vasakiris**

Category : **Chiropractor**

Issue Areas/Comments

Technical Corrections

Technical Corrections

The Proposed rule dated July 12th, contained an item under the technical corrections section to essentially eliminate a chiropractors' ability to order plain film x-rays, even if referred to a non-treating provider to take the x-rays is disturbing. I am very opposed to such discriminatory legislation/rules against my ability to practice good clinical chiropractic. In many cases I utilize X-Rays to aid in ruling out serious pathology or to evaluate whether specific spinal conditions are present which may eontra-indicate or alter certain treatment approaches which I may typically utilize.This techical correction essentially eliminates a chiropractor from referring a patient for x-ray evaluation. Forces other health care practitioners services to be utilized/incorporated in a consultory fashion which in many cases may not have been necessary, thus driving overall case costs up.

I am strongly urging you to table this proposal. These plain Film X-Rays when needed are an essential piece of the clinical evaluation and treatment of our senior population.Unfortunately it is the patients who will ultimately be bearing the brunt of possible injury or delay in seeking treatment for undiagnosed serious pathology should X-Rays be denied by the "consulting" practitioner.

Thank you for you attention to this very important matter.

Sincerely,
Christos Vasakiris, D.C., D.A.C.A.N.

Submitter : JERRY BROWN **Date: 08/31/2007**

Organization : JERRY BROWN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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JERRY bROWN

Submitter : **Stephanie Sanders** **Date: 08/31/2007**

Organization : **Stephanie Sanders**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Stephanie Sanders

Submitter : **Shawn Humes** **Date: 08/31/2007**

Organization : **Shawn Humes**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Shawn Humes

CMS-1385-P-13981

Submitter : **Amy Emerson** **Date: 08/31/2007**

Organization : **Amy Emerson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Amy Emerson

Submitter : VANCE BROWN **Date:** 08/31/2007

Organization : VANCE BROWN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
VANCE BROWN

Submitter : **Robert Peterson** **Date: 08/31/2007**

Organization : **Robert Peterson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Robert Peterson

CMS-1385-P-13984

Submitter : Ms. Patty Collins **Date:** 08/31/2007

Organization : Ms. Patty Collins

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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Submitter : JANET BROWN **Date: 08/31/2007**

Organization : JANET BROWN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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JANET BROWN

Submitter : **Dr. Thomas Ryan** **Date: 08/31/2007**

Organization : **American Society of Echocardiography**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

Coding-- Additional Codes From 5-Year Review

See attached letter.

CMS-1385-P-13986-Attach-1.DOC

#13986

American Society of Echocardiography

#13986

August 31, 2007

Herbert B. Kuhn, Acting Administrator
Centers for Medicare and Medicaid Administration
Department of Health and Human Services
CMS 1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Mr. Kuhn:

The American Society of Echocardiography (ASE) very much appreciates your involvement in the meeting of August 28. Because your schedule prevented you from attending the entire meeting, I wanted to provide you with a summary of our points relative to the proposed bundling of color Doppler (93325).

- **ASE strongly believes in the RUC approach to valuation of services.** At the urging of the RUC, the ACC/ASE submitted a new code request that bundles not only color Doppler but also spectral Doppler into the principal echo base code (93307).

- **CMS's proposal to bundle color Doppler into all of the base echo codes undermines the RUC process.** RUC staff has confirmed in writing that the ACC/ASE new code proposal is responsive to the RUC's request that color Doppler be bundled. This approach, which is inconsistent with CMS's proposal, will result in a valuation for the bundled code that has been vetted through the RUC process. We strongly urge CMS **not** to eliminate Medicare payment for a RUC-valued service while continuing to rely on the RUC (and the physician community's confidence in the RUC process) to establish RVUs.

- **CMS's rationale for eliminating payment for color Doppler is unsupportable**. CMS claims that color Doppler payment should be eliminated because color Doppler is integral to the performance of all echo services and does not require any special equipment. However, Medicare data demonstrates that color Doppler is not integral to the performance of all echo services, but is

performed relatively infrequently with some echo services, such as stress echo. And, although it is true that today's echo equipment generally includes color Doppler capability, color Doppler requires additional equipment time and cardiac sonographer time, which are the resources used to determine practice expense payment under CMS's methodology.

- **Under CMS's resource-based methodology, there is no duplication of payment for color Doppler and other echo services.** Under this methodology, PE-RVUs for color Doppler are based on 11 minutes of cardiac sonographer and equipment time that is not included in any other echo code.

- **It should be noted that, even in the absence of bundling, Medicare payment for color Doppler will be reduced by over 60%, to about 1.0 RVU, as the result of the ongoing transition to resource-based methodology.**

We understand that CMS is focusing on bundling as a policy matter beyond echo, and we would be delighted to work with CMS on formulating an appropriate process. However, we strongly oppose any proposal that eliminates Medicare payment for a RUC-valued service whose payment is already scheduled to be reduced substantially and whose valuation is not duplicative of any other service.

Sincerely yours,

/s/ Thomas Ryan, MD/by DSM

Thomas Ryan, MD
President
ASE

Submitter : **Fran Derrick** **Date: 08/31/2007**

Organization : **Fran Derrick**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Fran Derrick

Submitter : **Dr. dana Dol** **Date: 08/31/2007**

Organization : **Dr. dana Dol**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
Baltimore, MD 21244-8018

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Submitter : **Justin Hall** **Date: 08/31/2007**

Organization : **Justin Hall**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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Justin Hall

Submitter : **LIBBY BROWN** **Date: 08/31/2007**

Organization : **LIBBY BROWN**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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LIBBY BROWN

Submitter : **Rainer Kohrs** **Date: 08/31/2007**

Organization : **Rainer Kohrs**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.

Rainer Kohrs

Submitter : **Dr. Chris Centeno** **Date: 08/31/2007**

Organization : **Dr. Chris Centeno**

Category : **Physician**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

Physician Self-Referral Provisions

Physician Self-Referral Provisions

The ability to treat physical therapy patients under close supervision in the physician office improves care for Medicare patients. Without this provision, many of my Medicare patients would not be able to easily access PT services.

Submitter : **Steven B Cobb** **Date: 08/31/2007**

Organization : **Steven B Cobb**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Steven B Cobb

Submitter : **Mr. Richard King** **Date: 08/31/2007**

Organization : **Mr. Richard King**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Submitter : **Phil Jones**

Organization : **Phil Jones**

Category : **Individual**

Date: 08/31/2007

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Phil Jones

Submitter : **Stacy Kohrs** **Date: 08/31/2007**

Organization : **Stacy Kohrs**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Stacy Kohrs

Submitter : **JANET BROYLES** **Date: 08/31/2007**

Organization : **JANET BROYLES**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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JANET BROYLES

Submitter : **Mr. Dana Doll** **Date: 08/31/2007**

Organization : **Mr. Dana Doll**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : **Gebhard Blum** **Date: 08/31/2007**

Organization : **Gebhard Blum**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Gebhard Blum

CMS-1385-P-14000

Submitter : **Ms. Justine Coffey** **Date: 08/31/2007**

Organization : **American Society of Health-System Pharmacists**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14000-Attach-1.DOC

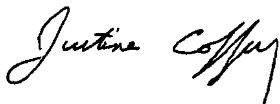
While ASHP does support the elimination of the exemption, the Society has some concerns about the effective date of the change, and recommends that CMS determine, prior to eliminating the exemption, that pharmacies and physician offices are able to comply with the requirement, and would not revert to paper prescribing rather than update current software.

Currently, e-prescribing standards and their implementation into pharmacy systems provide no advantage over faxes. Most pharmacy computer systems that receive an e-prescription require the pharmacist to print the e-prescription to paper and transcribe the information into the computer. Additionally, the situation needs to be avoided where a physician practice prints their e-prescriptions to paper and then faxes the printed copy to the pharmacy. The legibility of electronic prescriptions faxed directly from e-prescribing systems is better than the legibility of prescriptions scanned and transmitted by a fax machine. Fax machine scanning and transmission in combination with the use of tamper-resistant prescription forms could create faxed paper prescriptions whose readability is significantly compromised.

ASHP recommends that CMS continue the exemption for computer-generated faxes until pharmacies and physician offices are able to comply with the requirement, and not revert to paper prescribing rather than update current software. CMS should address this issue again in its Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2009.

ASHP appreciates this opportunity to present its written comments on the proposed elimination of the exemption for computer-generated facsimiles. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,



Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs

CMS-1385-P-14001

Submitter : DON BURMAN **Date:** 08/31/2007

Organization : DON BURMAN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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DON BURMAN

Submitter : **Joanie Blum** **Date: 08/31/2007**

Organization : **Joanie Blum**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Joanie Blum

Submitter : **Marlene Jones** **Date: 08/31/2007**

Organization : **Marlene Jones**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Marlene Jones

Submitter : **Dr. Dana Doll** **Date: 08/31/2007**

Organization : **Dr. Dana Doll**

Category : **Physician**

Issue Areas/Comments

GENERAL

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CMS-1385-P-14005

Submitter : **Jon W. Horton** **Date: 08/31/2007**

Organization : **Jon W. Horton**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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CMS-1385-P-14005

Jon W. Horton

Submitter : **Renner Barnes** **Date: 08/31/2007**

Organization : **Renner Barnes**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Mcdicare and Mcdicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimorc, MD 21244-8018

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Renner Barnes

Submitter : **Dr. Jack Nolle** **Date: 08/31/2007**

Organization : **Dr. Jack Nolle**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

See Attached letter

CMS-1385-P-14007-Attach-1.DOC

14007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: "TECHNICAL CORRECTIONS"

Dear Dept of HHS,

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Jack J. Nolle, DC
6631 Breckenridge Ct
Reno, NV 89523

Submitter : **Sandy Gross** **Date: 08/31/2007**

Organization : **Sandy Gross**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Jennifer Gross

Submitter : DEBOROAH BURMAN **Date:** 08/31/2007

Organization : DEBORAH BURMAN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
DEBORAH BURMAN

Submitter : **Kelly Barnes** **Date: 08/31/2007**

Organization : **Kelly Barnes**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Kelly Barnes

CMS-1385-P-14011

Submitter : Mrs. Erika Doll **Date:** 08/31/2007

Organization : Mrs. Erika Doll

Category : Individual

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : **Jonathan Chancellor** **Date: 08/31/2007**

Organization : **Jonathan Chancellor**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Jonathan Chancellor

Submitter : **Robert Jones** **Date: 08/31/2007**

Organization : **Robert Jones**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Robert Jones

Submitter : **Dranna Ball** **Date: 08/31/2007**

Organization : **Dranna Ball**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
Dranna Ball

Submitter : **Dana Chancellor** **Date: 08/31/2007**

Organization : **Dana Chancellor**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Dana Chancellor

Submitter : **James Connors** **Date: 08/31/2007**

Organization : **James Connors**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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James Connors

Submitter : **CLYDE CAIN** **Date: 08/31/2007**

Organization : **CLYDE CAIN**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
CLYDE CAIN

Submitter : **Phil Jones, SR** **Date: 08/31/2007**

Organization : **Phil Jones, SR**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Phil Jones, Sr

Submitter : Mr. James Cuddeford **Date:** 08/31/2007

Organization : AANA

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
__James Cuddeford CRNA, MA______________________________
Name & Credential
__6424 Westminster Ct______________________________
Address
_Lincoln, NE 68510______________________________
City, State ZIP

Submitter : **Joel Dyer** **Date: 08/31/2007**

Organization : **Joel Dyer**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Thank you for your consideration of this serious matter.

Joel Dyer

CMS-1385-P-14023

Submitter : **Larry Dennis** **Date: 08/31/2007**

Organization : **Larry Dennis**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Larry Dennis

CMS-1385-P-14024

Submitter : **Thomas Gillock** **Date: 08/31/2007**

Organization : **Thomas Gillock**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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Thomas Gillock

Submitter : **Date: 08/31/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I have been a certifed athletic trainer for several years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Thank you for your time!

CMS-1385-P-14026

Submitter : **Dr. David Maine** **Date: 08/31/2007**

Organization : **Mercy Medical - Center for interventional Pain Med**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14026-Attach-1.DOC

14026

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05	Interventional Pain Management Physicians

	(Non-Facility)	- 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

David N. Maine

Director, Center for Interventional Pain Medicine
Mercy Medical Center
301 St. Paul Place
Burk Building Suite 321
Baltimore, MD 21202
Direct: 410-332-9036
Fax: 410-332-9030

Submitter : c McKeown **Date: 08/31/2007**

Organization : c McKeown

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **Dustin Schramm** **Date: 08/31/2007**

Organization : **Sanford Health**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Dustin Schramm. My credentials include ATC since 1999 and CSCS since 2001. I am employed through Sanford Health in Sioux Falls, SD. My time at work is split throughout the year between our professional minor league basketball team, high school athletic training coverage for 5 schools, and speed/agility training.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Dustin Schramm, ATC, CSCS

CMS-1385-P-14029

Submitter : **Gail Gillock** **Date: 08/31/2007**

Organization : **Gail Gillock**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Gail Gillock

Submitter : **D McKeown** **Date: 08/31/2007**

Organization : **D McKeown**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : KAY CAIN **Date: 08/31/2007**

Organization : KAY CAIN

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
KAY CAIN

CMS-1385-P-14032

Submitter : **Kevin Shannon** **Date: 08/31/2007**

Organization : **Kevin Shannon**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : **James Greenawalt** **Date: 08/31/2007**

Organization : **James Greenawalt**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

James Greenawalt

Submitter : **Mr. Asbel Montes** **Date: 08/31/2007**

Organization : **Med Express Ambulance Service Inc**

Category : **Other Health Care Provider**

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

Dear Mr. Kuhn:

This letter serves as our comments on the Geographical Price Cost Indices section of the Proposed Rule (CMS-1385-P). Our organization strongly opposes any reductions in Medicare reimbursement for ambulance service providers which would have an adverse impact on patient access to vital emergency and non-emergency ambulance care. The Proposed Rule would unfortunately cause that exact effect in areas where providers would receive lower reimbursement as a result of the updated Geographical Price Cost Index (GPC) figures.

While we recognize the statutory requirement for CMS to update the GPCI, any reductions in reimbursement would be in direct contradiction to the findings of the May 2007 Government Accountability Office (GAO) report entitled Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly (GAO-07-383) which determined that Medicare reimburses ambulance service providers on average 6% below their costs of providing services and 17% for providers in super rural areas. For those ambulance service providers who would receive lower reimbursement as a result of the changes to the GPCI, the Proposed Rule will further exacerbate the problems already caused by below-cost Medicare reimbursement.

The GAO recommended that CMS monitor the utilization of ambulance transports to ensure that negative Medicare reimbursement does not impact beneficiary access to ambulance services particularly in super rural areas. We believe that the Proposed Rule would have a considerable impact on beneficiary access in all areas adversely affected by the changes in the GPCI. We implore CMS to take this into consideration as it finalizes the Proposed Rule and alleviate any harmful impact these changes in the GPCI will have on providers while ensuring that those providers who would benefit from the changes receive the proposed increases which are desperately needed.

Thank you for your consideration of these comments

Sincerely,

Asbel Montes, Corporate Administrator

CMS-1385-P-14034-Attach-1.PDF

14034

"COMMITTED TO EXCELLENCE"

MEDEXPRESS

AMBULANCE SERVICE, INC.

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, Maryland 21244-8018

Re: CMS-1385-P: "Geographical Price Cost Indices"

Dear Mr. Kuhn:

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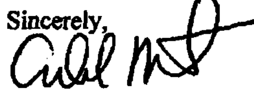
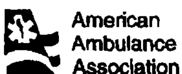
Thank you for your consideration of these comments

Sincerely,



Asbel Montes, Corporate Administrator



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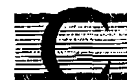

Submitter : **Kathy Greenawalt** **Date: 08/31/2007**

Organization : **Kathy Greenawalt**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Kathy Greenawalt

CMS-1385-P-14036

Submitter : Sandy Simpson **Date:** 08/31/2007

Organization : Sandy Simpson

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Sandy Simpson

Submitter : **James Hansard** **Date: 08/31/2007**

Organization : **James Hansard**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Centers for Medicare and Medicaid Services
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James Hansard

Submitter : JERRY CAMPBELL **Date:** 08/31/2007

Organization : JERRY CAMPBELL

Category : Health Care Professional or Association

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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JERRY CAMPBELL

Submitter : **Jill Hansard** **Date: 08/31/2007**

Organization : **Jill Hansard**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Jill Hansard

CMS-1385-P-14040

Submitter : **Mr. Michael Mitchell** **Date: 08/31/2007**

Organization : **Practice Management Group LLC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-1385-P-14040-Attach-1.DOC

14040

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	**Anesthesiologists - 05**	**Interventional Pain Management Physicians**

	(Non-Facility)	- 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

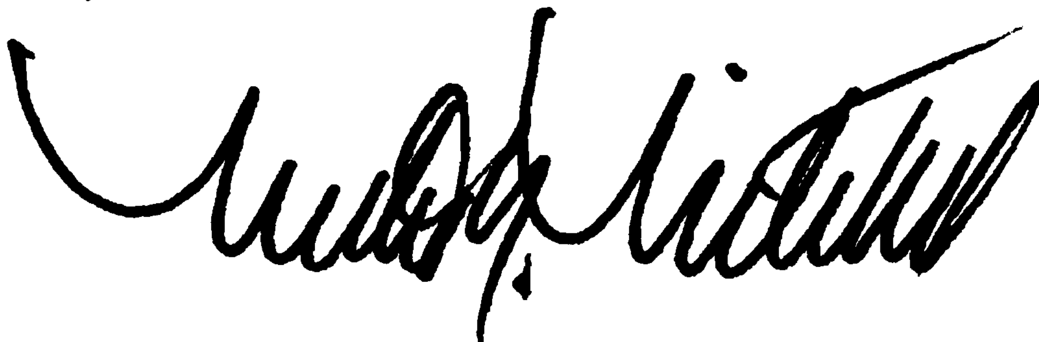
Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,



Michael T. Mitchell
Practice Management Group LLC
5127 Ocean Highway
Murrells Inlet, SC 29576

Submitter : **Bri Campbell** **Date: 08/31/2007**

Organization : **Bri Campbell**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Bri Campbell

Submitter : **Cathleen Jones** **Date: 08/31/2007**

Organization : **Cathleen Jones**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Cathleen Jones

Submitter : Mr. Philip Pieplow **Date:** 08/31/2007

Organization : Lowndes High School

Category : Other Health Care Professional

Issue Areas/Comments

Therapy Standards and Requirements

Therapy Standards and Requirements

Dear Sir or Madam:
My name is Philip Pieplow. I am a teacher and the Head Athletic Trainer at Lowndes High School in Valdosta, Georgia. I have a B.S. degree in Athletic Training and a Master s degree in Health and Physical Education. I have started my twelfth year at Lowndes High School, teaching and overseeing the health care of all our student-athletes in all sports.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Philip K Pieplow, M.Ed., ATC, LAT
Head Athletic Trainer
Lowndes High School
1112 N. St. Augustine Road
Valdosta, GA 31602

Submitter : Janell Crowl **Date:** 08/31/2007

Organization : Janell Crowl

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Janell Crowl

CMS-1385-P-14045

Submitter : Ken Mason **Date:** 08/31/2007

Organization : Ken Mason

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Ken Mason

Submitter : LOUISE CAMPBELL **Date: 08/31/2007**

Organization : LOUISE CAMPBELL

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
LOUISE CAMPBELL

Submitter : **Tammela Mason** **Date: 08/31/2007**

Organization : **Tammela Mason**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Tammela Mason

Submitter : **Rhonda Watson** **Date: 08/31/2007**

Organization : **Rhonda Watson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medieare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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P.O. Box 8018
Baltimore, MD 21244-8018

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Rhonda Watson

Submitter : **Robert Kranz** **Date: 08/31/2007**

Organization : **Robert Kranz**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Robert Kranz

Submitter : **Gale Moss** **Date: 08/31/2007**

Organization : **Gale Moss**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Gale Moss

Submitter : LANCE CANFIELD **Date: 08/31/2007**

Organization : LANCE CANFIELD

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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LANCE CANFIELD

Submitter : **Cathy Kranz** **Date: 08/31/2007**

Organization : **Cathy Kranz**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Cathy Kranz

Submitter : **Dr. Thenu Manikantan** **Date: 08/31/2007**

Organization : **Dr. Thenu Manikantan**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq. August 31, 2007
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Dr Thenu Manikantan

CMS-1385-P-14054

Submitter : **David Stephens** **Date: 08/31/2007**

Organization : **David Stephens**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

David Stephens

Submitter : **Dr. philip facquet III** **Date: 08/31/2007**

Organization : **Dr. philip facquet III**

Category : **Chiropractor**

Issue Areas/Comments

GENERAL

GENERAL

Docket: CMS-1385-P - Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies; Revisions to Payment Policies for Ambulance Services for CY 2008.

To eliminate a chiropractor's ability to order an x-ray study and have the lab paid for that service is nonsence. That measure will only cause a patient to pay more. It will also cause more DC's to own and operate additional x-ray units. The professional community can handle our referrals and take our x-rays...only politics would trash this relationship.

CMS-1385-P-14056

Submitter : Dr. KHURAM SIAL **Date:** 08/31/2007

Organization : TEMECULA PAIN MANAGEMENT GROUP

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14056-Attach-1.TXT

14056

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05	Interventional Pain Management Physicians

	(Non-Facility)	- 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Khuram Sial, M.D.
27720 JEFFERSON AVE, STE. 100B
TEMECULA< CA 92591

Submitter : Ms. RAMONICA SCOTT **Date:** 08/31/2007

Organization : HENDERSON STATE UNIVERSITY

Category : Other Health Care Professional

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
I am a certified athletic trainer working at a Division II university in Arkadelphia, Arkansas. I received my athletic training education from the University of Tulsa and continued my education by receiving a master s degree from Northwestern State University in 2005. I have been certified since November 2003. I am not currently working in a clinical or hospital setting but I want to have those settings as an option in the future. I feel that having athletic trainers in these settings is vital in the medical community.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Ramonica Scott, ATC/LAT

Submitter : **Michael Royce** **Date: 08/31/2007**

Organization : **Michael Royce**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Michael Royce

Submitter : **Mr. James Wilson** **Date: 08/31/2007**

Organization : **Illinois State University**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is James Wilson and I currently work as an Certified Athletic Trainer at Illinois State University. I am starting my second year of my master's degree and am working with the baseball and the swim team.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

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Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

James Wilson, ATC, CSCS

Submitter : Tina Stephens **Date:** 08/31/2007

Organization : Tina Stephens

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

CMS-1385-P-14061

Tina Stephens

Submitter : **Stephanie Royce** **Date: 08/31/2007**

Organization : **Stephanie Royce**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslic V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthcsia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Stephanie Royce

CMS-1385-P-14064

Submitter : Mr. Zubin Tantra **Date:** 08/31/2007

Organization : Lake County Physical Therapy LLC

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

please read attachment

CMS-1385-P-14064-Attach-1.RTF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : **Sharon Moss** **Date: 08/31/2007**

Organization : **Sharon Moss**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
Sharon Moss

Submitter : **Kristin Hook** **Date: 08/31/2007**

Organization : **Kristin Hook**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Kristin Hook

Submitter : **Poornachandran Manikantan** **Date: 08/31/2007**

Organization : **Poornachandran Manikantan**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq. August 31, 2007
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Dr Poornachandran Manikantan

Submitter : LARRY CLEMONS **Date:** 08/31/2007

Organization : LARRY CLEMONS

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
KAREN CANFIELD

Submitter : Jeff Lindsay **Date:** 08/31/2007

Organization : Jeff Lindsay

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Jeff Lindsay

Submitter : Janian Thurman **Date:** 08/31/2007

Organization : SDSU Fitness Clinic for Individuals w/ Dis.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

RE: Docket #1385-P Therapy Standards and Requirements, Physician Self-Referral Provisions

BRIEF INTRO ABOUT SELF: I am a Registered Kinesiotherapist and Lecturer at San Diego State University. I work as the Program Director for the Fitness Clinic for Individuals with Disabilities at SDSU, a clinic that assists community members with varying disabilities through their prescribed fitness programs. I hold a Masters degree in Public Health, Epidemiology.

I am writing today to voice my opposition to the proposed therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and other facilities proposed in Federal Register issue #1385-P. As a Kinesiotherapist, I would be excluded from providing physical medicine and rehabilitation services under these rules.

I am concerned that these proposed rules will create additional lack of access to quality health care for my patients. This is particularly important because my colleagues and I work with many wounded Veterans, an increasing number of whom are expected to receive services in the private market. These Medicare rules will have a detrimental effect on all commercial-pay patients because Medicare dictates much of health care business practices.

I believe these proposed changes to the Hospital Conditions of Participation have not received the proper and usual vetting. CMS has offered no reports as to why these changes are necessary. There have not been any reports that address the serious economic impact on Kinesiotherapists, projected increases in Medicare costs or patient quality, safety or access. What is driving these significant changes? Who is demanding these?

As a Kinesiotherapist, I am qualified to perform physical medicine and rehabilitation services. My education, clinical experience, and registered status insure that my patients receive quality health care. Hospital and other facility medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards and accepted practices.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the health care industry. It is irresponsible for CMS to further restrict PMR services and specialized professionals.

It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to reconsider these proposed rules. Leave medical judgments and staffing decisions to the professionals. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Jan Thurman, MPH, RKT

Submitter : **Connie Lindsay** **Date: 08/31/2007**

Organization : **Connie Lindsay**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Connie Lindsay

Submitter : **Richard Cooper** **Date: 08/31/2007**

Organization : **The Everett Clinic**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14072-Attach-1.PDF

14012

The Everett Clinic
For the whole you.

3901 Hoyt Avenue ■ Everett, WA 98201 ■ (425) 259-0966
www.everettclinic.com

August 31, 2007

Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8108

By Electronic Submission

Dear Mr. Kuhn:

Please accept the following comments regarding the proposed CMS 2008 Physician Services Fee Schedule Rules. The Everett Clinic is a 250 physician multi-specialty group practice located in Snohomish County, WA, 30 miles north of Seattle. We currently participate in the Physician Group Practice Demonstration Project sponsored by CMS. In that project we have been very focused on improving quality and cost of care to Medicare beneficiaries within our patient population. It is in that spirit of improvement that we are particularly interested in commenting on rule changes that negatively impact our ability to work collaboratively with our local hospital to create community benefit by sharing expensive health care resources and avoiding duplication.

We strongly believe CMS should not revise its historic position with regard to services furnished by physicians to hospitals "under arrangements" by amending the definition of "entity" under 42 CFR § 411.351. In addition, CMS should continue to allow unit-of-service (per click) payments in space and equipment leases, as long as the lease amounts are set at fair market value at the inception of the lease and do not change in any manner that takes into account referral patterns for designated health services.

Many organized independent medical groups have fostered good working relationships with hospitals that benefit the community through these types of arrangements. In our own community, we have recently forged a relationship with our local hospital and two other medical groups to create a state of the art regional cancer center. This center will allow Medicare beneficiaries to receive high quality, cost effective care in one setting. Physicians will daily collaborate with each other on case management of patients through case conferences and a shared electronic medical record. Patients will have access to the latest cancer treatment technology that wouldn't be possible without coordination of efforts.

For the physician groups to participate in this venture, we had to find an economic model that helped sustain a viable medical and surgical oncology practice. In that model, the physicians share in the investment of technology and equipment through a leasing company that leases the equipment back to the hospital where the cancer center is housed. There is independent utilization review of the procedures performed on this equipment and the lease rates are independently certified as being of fair market value.

This type of arrangement is contrasted with one where each physician group in the community buys duplicative cancer technology, competes directly with the hospital, and little collaboration among providers exists.

While we acknowledge that abuse does exist in some areas of the country with these so called, "per-click" leasing arrangements, we do not believe a blanket approach that outlaws what has been a long standing, legitimate way for physicians and hospitals to collaborate to offer coordinated, state of the art technology is in the best interest of the Medicare program or its beneficiaries.

Thank you for the opportunity to comment on this proposed rule change.

Sincerely,

Richard H. Cooper
Chief Executive Officer

cc: Representative Rick Larsen
American Medical Group Association

Submitter : **Melville Mercer** **Date: 08/31/2007**

Organization : **Melville Mercer**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medieare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Melville Mercer

Submitter : **Mr. Steve Chambers** **Date: 08/31/2007**

Organization : **Mr. Steve Chambers**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Submitter : LARRY CLEMONS

Organization : LARRY CLEMONS

Date: 08/31/2007

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
KAREN CANFIELD

CMS-1385-P-14076

Submitter : Melinda Mercer **Date:** 08/31/2007

Organization : Melinda Mercer

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Melinda Mercer

Submitter : **Loris Wiersig** **Date: 08/31/2007**

Organization : **Loris Wiersig**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Loris Wiersig

Submitter : **Mr. LARRY NOWICKI** **Date: 08/31/2007**

Organization : **SHAFER PHARMACY, INC**

Category : **Pharmacist**

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

My pharmacy currently FAX's refill authorizations to clinics and doctors of one of the largest HMO's in the area - that is the ONLY way to request refills for patients. Most of the clinics and doctors in the area have FAX software from their computers and approximately 80% of the prescriptions I receive are by FAX. To eliminate the exemption for computer generated facsimiles would cause a tremendous burden on my pharmacy and the way we do business. Thank you for letting me express my views.

Submitter : **Reginald Scott** **Date: 08/31/2007**

Organization : **Reginald Scott**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Reginald Scott

Submitter : Mr. Ben Johnston

Date: 08/31/2007

Organization : Focus On Therapeutic Outcomes Inc.

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

As the leading developer of quality and outcomes measures for outpatient rehabilitation therapy, Focus On Therapeutic Outcomes, Inc., (FOTO) is pleased to provide comments in response to the Notice of Proposed Rulemaking pertaining to the Medicare Physician Fee Schedule (PFS) as published in the Federal Register / Vol. 72, No. 133 / Thursday, July 12, 2007. We are commenting on several of the issuesin the attached letter.If there are questions, I can be reached at 865-740-1932.

Submitter : **Mrs. Janet Chambers** **Date: 08/31/2007**

Organization : **Mrs. Janet Chambers**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Submitter : **Kathryn Scott** **Date: 08/31/2007**

Organization : **Kathryn Scott**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Kathryn Scott

Submitter : **Don Maxwell** **Date: 08/31/2007**

Organization : **Don Maxwell**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Don Maxwell

Submitter : **Ms. Cate Brennan Lisak** **Date: 08/31/2007**

Organization : **Ms. Cate Brennan Lisak**

Category : **Individual**

Issue Areas/Comments

Impact

Impact

Aug. 31, 2007

Re: Docket ID CMS-1385-P

Dear Sir or Madam:

The therapy standards proposed by CMS in the Physician Fee Schedule will harm the patients of athletic trainers and create access problems. There is a strong possibility that with these Byzantine and onerous rules will, in fact, decrease the quality of services provided to Medicare beneficiaries. These CMS proposed rules are not supported by any objective reports or other rationale that has been made public.

As a 50-ish adult female, I personally used the services of an athletic trainer when I twisted my ankle when I simply stepped off a curb wrong in my morning exercise walk. The athletic trainer was fully qualified to assess, treat and rehabilitate my injury. I was pleased that I that I received a home rehab program, which reduced my cost and inconvenience.

I believe these will greatly rules will harm non-Medicare patients. Anytime Medicare makes a rule it eventually gets adopted in the private sector. Millions of secondary school and college students will lose access to services. Millions of seniors recovering from hip replacement and other orthopedic surgeries and conditions will lose access. Is this want Medicare intends?

These are unnecessary and unreasonable rules. I want to chose the best provider for me especially now that I have a Health Spending Account and that flexibility.

These whole therapy standards rules make no sense. I respectfully request that all rules past and present that restrict the ability of athletic trainers to lawfully practice their profession be reversed by CMS. Further, I recommend that the broadest possible panel including sports medicine consumers of physical medicine and rehabilitation services providers be established to review future therapy rules prior to such efforts to insert them into the Federal Register.

Sincerely,

Cate Brennan Lisak
Dallas Texas 75229

Therapy Standards and Requirements

Therapy Standards and Requirements

Aug. 31, 2007

Re: Docket ID CMS-1385-P

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Sincerely,

Catc Brennan Lisak
Dallas Texas 75229
Aug. 31, 2007

Submitter : **Jenna Singer** **Date: 08/31/2007**

Organization : **University of Illinois Athletic Training Program**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

I am a student at the University of Illinois in Urbana-Champaign in the Athletic Training Education Program.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jenna Singer

Submitter : **DON COBBS** **Date: 08/31/2007**

Organization : **DON COBBS**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Thank you for your consideration of this serious matter.
DON COBBS

Submitter : **Mr. Jack Chambers** **Date: 08/31/2007**

Organization : **Mr. Jack Chambers**

Category : **Individual**

Issue Areas/Comments

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Thank you for your consideration of this serious matter.

CMS-1385-P-14091

Submitter : Dr. Richard Gracer

Date: 08/31/2007

Organization : Gracer Medical Group

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

:4091

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : Alice Tiemann

Organization : Alice Tiemann

Date: 08/31/2007

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.
Alice Tiemann

Submitter : **Jennifer McKeown** **Date: 08/31/2007**

Organization : **Jennifer McKeown**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Jennifer McKeown

CMS-1385-P-14094

Submitter : **Connie Matthies** **Date: 08/31/2007**

Organization : **Connie Matthies**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Connie Matthies

Submitter : **Gisele Wilke** **Date: 08/31/2007**

Organization : **Gisele Wilke**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Gisele Wilke

Submitter : **WANEMA COBBS** **Date: 08/31/2007**

Organization : **WANEMA COBBS**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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WANEMA COBBS

Submitter : **Mr. Nicholas Chambers** **Date: 08/31/2007**

Organization : **Mr. Nicholas Chambers**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Submitter : Lori Fialkowski **Date:** 08/31/2007

Organization : Lori Fialkowski

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Lori Fialkowski

CMS-1385-P-14099

Submitter : Scott Wilke **Date: 08/31/2007**

Organization : Scott Wilke

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Scott Wilke

Submitter : **Scott Tiemann** **Date: 08/31/2007**

Organization : **Scott Tiemann**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Scott Tiemann

Submitter : **SAUNDRA COBBS** **Date: 08/31/2007**

Organization : **SAUNDRA COBBS**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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SAUNDRA COBBS

Submitter : **Mr. Neil Duval** **Date: 08/31/2007**

Organization : **Saint Anselm College**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Neil E. Duval and I am a Head Athletic Trainer at the collegiate level and President of the New Hampshire Athletie trainers Association. I have been a certified athletic trainer for roughly ten years. I have worked in a variety of settings ranging from collegiate levels Divison II an III, clinical/high school and graduate school instructor. I have been involved within my chosen profession at both the state and national levels in a variety of positions ranging from state association secretary to current state president. I have been following the CMS rulings closely for the past few years and would like to express my concern regarding the most recent events of CMS proposed rule changes to the way hospitals staff their outpatient clinics and other rehabilitation departments.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Neil E. Duval, ATC, NASM-PES
President- New Hampshire Athletic Trainers Association

Submitter : **Kent Woolard**

Organization : **Kent Woolard**

Date: 08/31/2007

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Kent Woolard

Submitter : KELLY COBBS **Date:** 08/31/2007

Organization : KELLY COBBS

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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KELLY COBBS

Submitter : **Mr. Gerald Chambers** **Date: 08/31/2007**

Organization : **Mr. Gerald Chambers**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Submitter : **Herman Luciani** **Date: 08/31/2007**

Organization : **Herman Luciani**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Herman Luciani

CMS-1385-P-14108

Submitter : **Bob Klein** **Date: 08/31/2007**

Organization : **Bob Klein**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Bob Klein

CMS-1385-P-14109

Submitter : **Dr. John Zepp** **Date: 08/31/2007**

Organization : **Hosp Univ of PA**

Category : **Physician**

Issue Areas/Comments

Coding-- Additional Codes From 5-Year Review

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Submitter : AMY COBBS **Date:** 08/31/2007

Organization : AMY COBBS

Category : Individual

Issue Areas/Comments

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Thank you for your consideration of this serious matter.
AMY COBBS

CMS-1385-P-14111

Submitter : David Young **Date: 08/31/2007**

Organization : David Young

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dcar Ms. Norwalk:

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Thank you for your consideration of this serious matter.

David Young

Submitter : Dr. Zeferrino Arroyo **Date:** 08/31/2007

Organization : Anesthesia Partners of Montana

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Sincerely,

Zeferino Arroyo

CMS-1385-P-14113

Submitter : **Marilyn Young** **Date: 08/31/2007**

Organization : **Marilyn Young**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Marilyn Young

Submitter : **Herman Luciani** **Date: 08/31/2007**

Organization : **Herman Luciani**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Mike Meier

Submitter : **Lois Klein** **Date: 08/31/2007**

Organization : **Lois Klein**

Category : **Individual**

Issue Areas/Comments

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Payment For Procedures And Services Provided In ASCs

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Lois Klein

Submitter : **John Aldridge** **Date: 08/31/2007**

Organization : **John Aldridge**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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John Aldridge

Submitter : **DAVIS COLE** **Date: 08/31/2007**

Organization : **DAVIS COLE**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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DAVIS COLE

Submitter : Gregory Gullo

Date: 08/31/2007

Organization : Gregory Gullo

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14118-Attach-1.DOC

14118

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05	Interventional Pain Management Physicians

	(Non-Facility)	- 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Gregory Gullo MD
Integrated Spine Care
24076 SE Stark St , Suite 320
Gresham, OR 97030

Submitter : **Jeanie Aldridge** **Date: 08/31/2007**

Organization : **Jeanie Aldridge**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Jeanie Aldridge

Submitter : Mrs. Lorraine Chambers **Date:** 08/31/2007

Organization : Mrs. Lorraine Chambers

Category : Individual

Issue Areas/Comments

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Submitter : **Ruth Leslie** **Date: 08/31/2007**

Organization : **Ruth Leslie**

Category : **Individual**

Issue Areas/Comments

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Payment For Procedures And Services Provided In ASCs

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Ruth Leslie

Submitter : AMANDA COLE **Date: 08/31/2007**

Organization : AMANDA COLE

Category : Individual

Issue Areas/Comments

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
AMANDA COLE

Submitter : **Scott Ames** **Date: 08/31/2007**

Organization : **Scott Ames**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Scott Ames

Submitter : **Dr. Coralee Van Egmond** **Date: 08/31/2007**

Organization : **International Chiropractors Association**

Category : **Chiropractor**

Issue Areas/Comments

Background

Background

CMS-1385-P. Technical Corrections
Comments from the
International Chiropractors Association

On behalf of the membership of the International Chiropractors Association (ICA), working to serve Medicare beneficiaries in all fifty states, we wish to take this opportunity to offer comment on changes proposed in CMS-1385-P. ICA is deeply concerned that the impact of provisions published in the Federal Register, (Proposed Rules: Diagnostie X-ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Conditions. Federal Register, July 12, 2007. Vol. 72, No. 133.), would be a disservice to ehiropractic provider and beneficiary alike, and should not be implemented.

These new rules would disrupt a functional, reasonable and above all, fiscally responsible approach to providing the diagnostic imaging procedures necessary to the delivery of safe, cffective chiropractic care to Medicare beneficiaries, without forcing those same beneficiaries to pay out of pocket for those diagnostic services. This ehangc would only servc to:

" Dcny doctors of chiropractic reasonablc access to an esscntial basic service vital to the detection of vertebral subluxation(s) and possible complicating factors.
" Drivc Mcdicarc beneficiaries away from the chiropractic care which is their care of choicc, to far more expensive specialist care, which is care of second choice.
" Impose what is, in effect, a chiropractic tax on Medicare beneficiaries by obliging them to pay out of pocket for what should be a routine covered servicc.
" Possibly forcc Mcdicare beneficiaries to decide not to seek the care they need because of the undue financial and practical burden this change would impose.
" Medicare bencficiarics are entitled to one drugless approach to health care, and this change would unfairly serve to drive more beneficiaries in a traditional medical, pharmaceutical-based direction, increasing costs and denying patient choice.

To change the current system, &which permits a physician who is not a treating physician to order and receive payment for an X-ray that is used by a chiropractor, is simply not sound public policy.

ICA strongly urges that this issue be reconsidered and that the proposed rule change be withdrawn.

Thank you for your attention and consideration.

Respcctfully Submitted,

Coralce Van Egmond, DC, FICA
Director of Professional Development

International Chiropractors Association
1110 North Glebe Road, Suite 650
Arlington, VA 22201

Submitter : **Joy Meier** **Date: 08/31/2007**

Organization : **Joy Meier**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Joy Meier

CMS-1385-P-14126

Submitter : Dr. William Nelson **Date:** 08/31/2007

Organization : NDCA

Category : Chiropractor

Issue Areas/Comments

Technical Corrections

Technical Corrections

Please see attachment.

CMS-1385-P-14126-Attach-1.DOC

19126

August 31, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: "TECHNICAL CORRECTIONS"

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

William Nelson, DC

Submitter : **Mrs. Nancy Hiller** **Date: 08/31/2007**

Organization : **Missoula Anesthesiology, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

Missoula Anesthesiology is a 28 physician anesthesia practice. We would like to voice our support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. It is fortunate that that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

Currently, Medicare payment for anesthesia services is $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. we are pleased that the Agency accepted this recommendation in its proposed rule, and we support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,
Nancy Hiller
Missoula Anesthesiology, PC

Submitter : **SUSAN CONWAY** **Date: 08/31/2007**

Organization : **SUSAN CONWAY**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
SUSAN CONWAY

Submitter : **Becca Gaines** **Date: 08/31/2007**

Organization : **Becca Gaines**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.
Becca Gaines

Submitter : JAMIE CONWAY **Date:** 08/31/2007

Organization : JAMIE CONWAY

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
JAMIE CONWAY

Submitter : **Mr. Joel Klunke** **Date: 08/31/2007**

Organization : **Mr. Joel Klunke**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
Joel Klunke CRNA____________________________
Name & Credential
13120 Independence_Ave______________________________
Address
Savage, MN 55378______________________________
City, State ZIP

CMS-1385-P-14132

Submitter : Hari Lu Ames

Date: 08/31/2007

Organization : Hari Lu Ames

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Hari Lu Ames

Submitter : RAMSEY CONWAY **Date: 08/31/2007**

Organization : RAMSEY CONWAY

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
RAMSEY CONWAY

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

Medicare Economic Index (MEI)

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Thank you for your consideration of this serious matter.

CMS-1385-P-14135

Submitter : **Mr. Jerry Krummel** **Date: 08/31/2007**

Organization : **State of Oregon, Legislative Assembly**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Please see Attachment.

CMS-1385-P-14135-Attach-1.DOC

#14135

August 31, 2007

Dear Sir or Madam:

I am State Representative Jerry Krummel, House District 26, Oregon House of Representatives. Additionally, I am a Certified Athletic Trainer. I have watched CMS over the years with a keen eye towards reducing health care costs for Oregonians and all Americans, and I am concerned CMS is missing the mark.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

As a State Representative I am concerned about the continual involvement of government that actually reduces access to healthcare for all Americans and Oregonians in particular. When we in government write rules, it should be with the goal in mind of increasing access to healthcare, not minimizing it. The proposed rules, in my opinion will reduce access. Further I am concerned with actions of the federal government negatively affecting states rights in the area of healthcare.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jerry Krummel, ATC

State Representative,

House District 26,

Submitter : **Meredith Ellis** **Date: 08/31/2007**

Organization : **Meredith Ellis**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Meredith Ellis

Submitter : **JOHN CONWAY** **Date: 08/31/2007**

Organization : **JOHN CONWAY**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.
JOHN CONWAY

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am an independent private practice physical therapist,who wishes to comment on the physician self referral and the in-office ancillary services exemption. My comments will highlight the abusive nature of POPTS and support PT services removal from permitted services, under the in-office ancillary exeption. I have practiced in the Central Virginia area for over 20 years. Until 2001, my practice had continued to receive many ortho(orthopaedic) referrals. This practice specializes in hand and upper extremity patients. In 2001; my hand therapists'(PT)patient load was 75% ortho referrals, which were primarily workers compensation(WC) patients. July 2007 referral statistics noted that this percentage had dropped to 15%. 2006 referral statistics noted 13% hand referrals, and 10% of the 13% were WC ortho referrals. From my perspective, this referral pattern is common to all POPTS, as they take the WC patient loads from other practices. The orthos do this because WC referrals are billed to a single payor; and there is more profit derived from WC referrals. With regards to WC hand referrals;it can be lucrative due to the splinting charges. I have seen POPTS splinting charges that are 70% higher than our comparative custom molded splints. My hand therapist has met numerous times with certain orthopedists to try to increase her hand patient census. She has known these orthos for more than ten years. She has been told by them, that they have been told by their younger partners and practice administrator,that they are to refer their WC patients to their POPTS.In addition; during the orthos monthly meeting; each ortho is given their monthly self referral data to see if they have been referring enough patients. After one meeting with a certain ortho; my hand therapist was given the impression that the practice administrator had told the orthos that they would have to continue to self refer lots of patients(especially WC); in order to pay for their new medical building; scheduled for completion in 2008. There is one Ortho group in this area; with their POPTS. Are they engaging in physical therapy referral patterns that promote quality care? As one of my students told me last summer; their need to succeed appears to be greed;which is an observation and not an accusation! There are better and more cost effective independent physical therapy providers in the Central Virginia area. Competing against a POPTS has been difficult; as the orthos unfairly control the referral patterns; keeping the patient load that will generate the most profit;and referring the least profitable(ie,MC)to other physical therapy practices. As long as the orthos continue to pay their lobbyists for access to elected officials, who vote in favor of POPTS legislation, the present status quo will exist! Thank-you for the opportunity to share my negative experiences pertaining to POPTS.

CMS-1385-P-14139

Submitter : Dr. mitchell cohn **Date:** 08/31/2007

Organization : northeastern anesthesia pc

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

It is truly time that Medicare abandon its ludicrous 1970s based fee schedule and substantially update its payment policies. There is no question that access to care is compromised on a daily basis for senior citizens as well as pushing physicians into a "volume" mentality that forces them to spend less time with their patients.

Submitter : MARIANNE COOKSEY **Date: 08/31/2007**

Organization : MARIANNE COOKSEY

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
MARIANNE COOKSEY

Submitter : **Richard Cramer** **Date: 08/31/2007**

Organization : **Thompson Health**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

My name is Trevor Cramer. I am a certified athletic trainer from Victor, NY. I work for Thompson Health's Sports Medicine Center. I have a Bachelor's Degree in Health Science from Lock Haven University of Pennsylvania.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-efficient treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clincs, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Richard Trevor Cramer, ATC
Senior Athletic Trainer
Thompson Health
Sports Medicine Center
3170 West St.
Canandaigua, NY 14424
585-396-6700

Submitter : **Lindsay Lucas** **Date: 08/31/2007**

Organization : **Lindsay Lucas**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Lindsay Lucas

Submitter : Mr. Gary Puryear **Date:** 08/31/2007

Organization : SRNA Union University

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

Please continue with the proposal to increase Medicare reimbursement for anesthesia services.

Submitter : **Dr. Paul Scott** **Date: 08/31/2007**

Organization : **Urology Associates of Mobile, P.A.**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14144-Attach-1.DOC

14144

Urology Associates of Mobile, P.A.
168 Mobile Infirmary Boulevard
Mobile, Alabama 36607

A. Greer Megginson, M.D.
G. Coleman Oswalt, M.D.
Charles F. White, Jr., M.D.
Dino N. Frangos, M.D.
S. Harbour Stephens, III, M.D.
Paul A. Scott, Sr., M.D.

August 30, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, Maryland

Dear Ladies and Gentlemen,

My name is Dr. Paul A. Scott, Sr. I am a urologist practicing in Mobile, Alabama in a private group practice. This letter is in addendum to the letter offered by my partner Charles White, M.D., dated August 21, 2007 on behalf of the entire practice. We are involved in a joint venture partnership providing lithotripsy services within Mobile and Baldwin counties in Alabama; however, we also provide service to patients in numerous rural counties in both Alabama and Mississippi.

Prior to the formation of our partnership, lithotripsy services were controlled by a for-profit hospital who determined whether or not a patient was offered treatment. Since their unit was a fixed unit, this limited geographically where a patient could have his or her treatment.

The proposed new regulations regarding physician fee schedules cause great concern to urologists, and threaten access to care for many of our patients.

Particularly of concern, regarding under-arrangement contracting, by sharing the services of our mobile lithotripsy equipment among several hospitals, this actually lowers costs. By providing mobile lithotripsy services, this provides access to services that smaller rural hospitals cannot afford. When the physicians own the equipment, we are more likely to remain up-to-date with technological advances in equipment, which allows patients access to this state-of-the-art therapy. Regarding concerns of over-utilization, with treatment of urinary stones, there is an easily identifiable diagnosis of a stone, which doesn't lend itself to the abuses of diagnostic procedures. The same argument can be made for provision of laser services for treatment of benign prostatic hypertrophy. These are not subjective issues, but objective findings.

Concerning per-procedure fee prohibition, hospitals potentially will not be willing to accept the risk of purchasing expensive new equipment, or engaging in fixed monthly leases where exact volume of cases cannot be predicted. This may be particularly true in low-volume rural hospitals. This will limit access to care. In addition, historically, Congress has wished to preserve per procedure fees in Stark legislation, and the proposed regulations would contradict this intent.

In conclusion, therapeutic joint venture partnerships, like ours in Mobile, Alabama, have provided greatly increased access to care, while reducing costs. Over-utilization is not a concern as there is an identifiable diagnosis to be treated. I feel that it would be a mistake to institute regulations that would limit the quality services that partnerships like ours provide to our patients.

Thank you for your consideration of this critically important issue.

Sincerely,

Paul Anthony Scott, Sr., M.D.

Submitter : Mr. Matthew Eyles **Date:** 08/31/2007

Organization : Wyeth Pharmaceuticals

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Wyeth Pharmaceuticals appreciates the opportunity to submit comments on the 2008 Medicare Physician Fee Schedule Proposed Rule. Our detailed comments are included in the attached document.

CMS-1385-P-14145-Attach-1.DOC

Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Matthew D. Eyles
Vice President
Public Policy
484 865 5132 tel
484 865 6420 fax

Wyeth

BY ELECTRONIC DELIVERY **http://www.cms.hhs.gov/eRulemaking**
#14145

August 31, 2007

Mr. Herbert Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1385-P ; Comments on the Proposed Physician Fee Schedule Rule for Calendar Year 2008

Dear Mr. Kuhn:

Wyeth Pharmaceuticals appreciates the opportunity to comment on the CMS proposed rule for the Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 (MPFS Proposed Rule). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research driven pharmaceutical and health care products companies with leading products in the areas of women's health care, infectious disease, gastrointestinal health, central nervous system, inflammation, transplantation, hemophilia, oncology, vaccines and nutritional products.

As a core principle, Wyeth believes it is important to ensure Medicare beneficiary access to clinically appropriate drugs and biologicals by adequately reimbursing healthcare providers for the costs of acquiring and administering these important therapies. In addition, we believe it is critical for rulemaking to occur through open and transparent processes. Many stakeholders—especially CMS—recognize the growing importance of transparency in the health care system. The 2008 MPFS Proposed Rule addresses a number of significant new issues. Our specific comments address the following issues:

- Average sales price (ASP): bundled price concessions, clotting factor furnishing fee updates, and widely available market prices and average manufacturer price threshold
- Drug compendia

ASP Issues
This section addresses the following ASP-related issues: bundled price concessions, clotting factor furnishing fee updates, and widely available market prices and average manufacturer price threshold.

Bundled Price Concessions
Wyeth believes that clear and consistent guidelines regarding the treatment of bundled price concessions are important to ensure accurate reporting of ASP data and recommends that CMS develop such guidelines through Notice of Proposed Rule Making (NPRM) procedures. Wyeth also suggests that CMS work with affected stakeholders to develop the most appropriate methodology to report bundled price concessions. Finally, we request that CMS delay implementation of the bundled price concession requirements for ASP reporting until the AMP provisions have been finalized.

Currently, CMS requires manufacturers to make reasonable assumptions in calculating ASPs for drugs and biologicals but provides no regulatory guidance on factoring bundled discounts into ASP calculations. CMS proposes to define a bundled arrangement as one in which any price concession "is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or some other performance requirement." [1] Performance requirements can include "the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, or prior purchases."[2]

Wyeth believes the proposed CMS definition of a bundled arrangement is too broad and open for interpretation. We request that CMS publish an NPRM in draft form and provide industry with a meaningful opportunity to comment on methodologies to guide manufacturers.

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[1] 72 Federal Register at 38150
[2] Id

CMS also proposes that manufacturers be required to "allocate the total value of all price concessions proportionately according to the dollar value of the units of each drug sold under a bundled arrangement."[3] Where multiple drugs are discounted, "the aggregate value of all discounts would be proportionately allocated across all drugs sold under the bundled arrangement."[4]

Again, the definition of a bundled arrangement is broad and ambiguous. For manufacturers to accurately and appropriately report any such arrangements, we encourage CMS to more clearly define what constitutes a bundled arrangement. Without further clarity on definitional and operational issues, it would be possible for manufacturers to make different assumptions in ASP calculations and reporting. As a result, CMS could inadvertently create an uneven competitive playing field with significant implications for Medicare beneficiary access.

Finally, CMS' proposed treatment of bundled sales under the MPFS Proposed Rule roughly parallels what has been proposed for Average Manufacturer Price (AMP) reporting under Medicaid.[5] CMS also notes that, while the agency will try to align ASP reporting requirements with those of AMP where appropriate, there will be differences in the two systems. Because the AMP rule has not yet been finalized, it is difficult for manufacturers to draw the necessary parallels regarding how bundled sales under the AMP rule may apply to ASP reporting. We request that CMS postpone the implementation of the bundled price concession requirements for ASP reporting until the AMP provisions have been appropriately defined.

Clotting Factor Furnishing Fee

Wyeth supports CMS' proposal to remove the clotting factor furnishing fee updates from the annual MPFS rulemaking process and instead issue future updates through program instruction.

At this time, the clotting factor furnishing fee is updated annually and equal to the fee for the previous year increased by the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending with June of

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[3] 72 Federal Register at 38150

[4] Id

[5] 71 Fed. Reg. 77174, 77176 (Dec. 22, 2006)

the previous year.[6] Since the annual June CPI information is not available when the proposed MPFS is published, CMS proposes to remove this annual update from the rulemaking process and issue future updates through program instructions.

Wyeth agrees with this new process as long as CMS continues to use the current CPI methodology for calculating the annual furnishing fee update. However, if CMS decides to change from the CPI methodology, CMS should do so only after following NPRM procedures that provide manufacturers and other affected stakeholders adequate opportunity to comment.

Widely Available Market Prices (WAMP) and Average Manufacturer Price (AMP) Threshold

Wyeth commends CMS for proposing to provide adequate notice to manufacturers prior to substituting WAMP or AMP for reimbursement purposes.

CMS proposes to continue to use a 5% threshold in determining whether WAMP or AMP should be substituted for ASP.[7] Manufacturers may experience complicated operational issues associated with potential payment substitutions—for example, potential new and additional data collection and reporting requirements. CMS recognizes these issues and intends to provide "adequate notice" to affected manufacturers of any WAMP or AMP substitutions. CMS also intends to develop a better understanding of the issues that may be related to certain drugs for which the WAMP and AMP may be lower than ASP over time. We commend CMS' proposal and request that the agency contact affected manufacturers and solicit their input on this process prior to a substitution of WAMP or AMP.

Drug Compendia

Wyeth is concerned with the lack of transparency regarding the processes for adding or removing specified drug compendia, compendia data collection, and subsequent Medicare coverage decisions. We recommend that CMS create clear

[6] 72 Federal Register at 38152
[7] Id

and consistent standards in these areas to ensure access by Medicare beneficiaries to anticancer therapies for medically accepted indications.

Medicare coverage under Part B for off-label uses of drugs and biologics in anticancer treatment is dictated by information provided in the CMS approved compendia.[8] To be considered a medically accepted indication, the statute requires that a use of a drug or biological be "supported by one or more citations" in one of the specified compendia.[9] In most cases, listing of an off-label use in a compendium ensures reimbursement, and Medicare contractors have discretion to allow coverage for off-label use of cancer treatments. When a drug or biological is used in treatment outside of a medically accepted indication provided by compendia, Medicare Part B payment will not be made for that drug for that specific use. The list of available compendia has changed since the inception of these anticancer drug provisions. Therefore, it is necessary for CMS to develop a mechanism to add new compendia to their approved list.

Three compendia are listed in the original statute: American Medical Association – Drug Evaluations (AMA-DE), the American Hospital Formulary Service Drug Information (AHFS-DI), and United States Pharmacopeia Drug Information (USP-DI). CMS proposes to modify the drug compendia selection process used to determine medically accepted indications because the AMA-DE is no longer published and the USP-DI has changed ownership to Thompson Micromedix. The AMA, along with cancer groups, physicians, manufacturers, and associations representing interested stakeholders have endorsed the National Comprehensive Cancer Network (NCCN) compendium to replace the discontinued AMA-DE compendium.

We encourage CMS to establish a formal process to add and remove compendia organizations from their approved list. Payers and carriers should have access to reliable sources of relevant scientific information—including compendia and peer-reviewed journals—before making a coverage determination. As part of this process, it will be important for CMS to address some questions to ensure the needs of Medicare beneficiaries and providers are met. For instance:

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[8] Section 1861(t)(2)(B) of the Social Security Act.

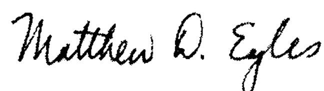
[9] Medicare Benefit Manual (pub 100-2) section 50.4.5

- Is there a minimum period of time a compendia remains on the list once it has been added to the list?
- What safeguards exist to assure uninterrupted coverage and reimbursement for beneficiaries when a drug was approved through one compendium that is subsequently changed or eliminated?
- What is the interplay between potentially new compendia coverage and clinical evidence from one of the peer reviewed medical publications previously deemed acceptable by CMS?

The proposed compendia changes affect a variety of stakeholders including oncology drug manufacturers, hospitals, and physicians but especially Medicare beneficiaries. Transparency and open communication is key to providing access to life-saving therapies and ensuring timely and appropriate reimbursement.

Conclusion
Wyeth appreciates the opportunity to comment on the MPFS Proposed Rule. We look forward to our continued work with CMS to ensure Medicare beneficiary access to vital therapies. If you have any questions about Wyeth's comments, please do not hesitate to contact me.

Sincerely,



Matthew D. Eyles

Submitter : **MIKE COOPER** **Date: 08/31/2007**

Organization : **MIKE COOPER**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
MIKE COOPER

Submitter : Dr. Karl Becker **Date:** 08/31/2007

Organization : Karl E. Becker, M.D., P.A.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment on CMS-1385-P

Submitter : **Jeff Glass** **Date: 08/31/2007**

Organization : **Jeff Glass**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
Jeff Glass

Submitter : **Date: 08/31/2007**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a certified athletic trainer who works in the Sports Medicine Department at the University of Wisconsin Hospital and Clinics in Madison, Wisconsin. I work as a physician extender, as well as provide medical coverage for various athletic events. However, I have provided rehabilative services for numerous individuals over the last 8 years. I received a B.S. from the University of Wisconsin-Madison and my Master's in Education from Auburn University in 2003. I have been a certified and licensed athletic trainer since 2001.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

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Sincerely,

Malinda Walker, M. Ed., ATC

Submitter : **TAMI COOPER** **Date: 08/31/2007**

Organization : **TAMI COOPER**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicarc and Medicaid Services
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Thank you for your consideration of this serious matter.
TAMI COOPER

Submitter : Lynnea Glass **Date:** 08/31/2007

Organization : Lynnea Glass

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Lynnea Glass

Submitter : **Ms. Rebecca Kurland** **Date: 08/31/2007**

Organization : **Rebecca J. Kurland, Attorney at Law**

Category : **Attorney/Law Firm**

Issue Areas/Comments

IDTF Issues

IDTF Issues

This is a comment to proposed Performance Standard 42 C.F.R. 433.10(g)(15), published at Federal Register Vol. 72, p. 38222, that the IDTF Does not share space, equipment, or staff or sublease its operations to another individual or organization.

It is respectfully requested that the final rule clarify this performance standard by adding at the end, who is a supplier with Medicare billing privileges. That is, the IDTF should not be subject to sanctions for failing to meet performance standards when it shares space and equipment with an individual or organization whose use of the space and equipment is wholly unrelated to the provision of medical imaging services to beneficiaries of the Program.

Developing technologies, such as functional MRI, rely on research and training activities conducted in the pursuit of knowledge, improvement of the technology and development of new means of using imaging to enhance health and learn about the workings of the human brain and organs. These activities are in the main conducted by nonprofit entities that are not Medicare suppliers and do not receive sufficient research support to maintain full-time operation of MRI and other technologically complex devices: Their scientific mission could be placed at risk if they could not enter into commercially reasonable arrangements to lease a portion of the equipment time and space to IDTFs to use for medical imaging.

In such arrangements, there is ready demarcation between patients receiving medical imaging services and research subjects or trainees. For example, sleep studies are conducted overnight, outside of standard business hours. The IDTF is a wholly separate entity from the research organization, with no affiliation or overlap of ownership. Therefore, the commingling that the Secretary rightly perceives as a significant risk to the Medicare Program is not present. There will be no impairment to or interference with the Secretary s ability to ensure that the IDTF meets and maintains all required performance standards. The arrangement should, of course, be documented in a manner that clearly sets out the IDTF s performance standards and does not permit the research or training entity to interfere with meeting those standards.

The clarification sought would allow legitimate and cost effective arrangements to continue without posing undue risk to the Secretary s ability to ensure the integrity of the Medicare Program and the compliance of IDTFs with performance standards integrally related to their provision of medical imaging services to beneficiaries.

Accordingly, it is respectfully requested that 42 C.F.R. 433.10(g)(15) published in the final rule, read as follows: Does not share space, equipment, or staff or sublease its operations to another individual or organization who is a supplier with Medicare billing privileges.

CMS-1385-P-14152-Attach-1.DOC

Submitter : **Dr. Stephen Watson** **Date: 08/31/2007**

Organization : **Innovative Pain Solutions**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. Weems:

I am a physician in private, solo, office practice in Springfield, Ohio. I practice interventional pain medicine 100% of my time. I am board certified in anesthesiology but am also certified by the American Board of Pain Medicine and now have finished the process to become board certified by the American Board of Interventional Pain Practice. I have been in solo office-practice for some eight or nine years. I have the pleasure of leasing a very nice but expensive office, a $200,000 fluoroscope, other electronic equipment worth $30,000, an electronic medical record system that cost $75,000 over the course of the last two years with multiple servers and computers to support its use. I have numerous employees in my practice to support my ability to see and care for employees. I live and work in Springfield which is a city of approximately 75,000 in Ohio between Columbus and Dayton. This is a moribund city having lost most all of its industrial backbone over the last 20 years. Our last remaining significant industry is Navistar. This truck producer has made loud hints suggesting that they will end production of their mid-size truck here in this city and move it to Texas or Mexico. They had 5,000 employees when I moved here in 1992 and now employ 1,300 employees. As you can imagine, my patient demographics include somewhere between 60 and 70% Medicare and Medicaid.

I appreciate the opportunity to comment on CMS-1385-P. I have reviewed the very complete letter that was put together by physicians with ASIPP. This letter explains everything very well. I do not, however, feel that it is worthwhile to just send a copy of the same letter to you. I want for you to hear from this individual physician and to learn about my real-world situation, not a rubber-stamp of anyone else.

I have read with increasing concern about the impending decrease in office-payment rates of 35% to 45% over the next 8 years. This certainly will be accompanied with the stated minimal 20% increase in expenses but more likely 40% to 50% increase in expenses. You need to know that at this time, I am receiving only enough salary on a month-to-month basis to barely pay my personal expenses. My wife and I live in the same 2,000 square foot home we have lived in for 15 years. We have taken one week of vacation this year and we stayed with friends that week. If the practice income were to go down even further, we really would not have any excess to even continue paying for our physician assistants, office staff, lease, ad infinitum. Clearly, decreasing the office-based reimbursement rates for interventional pain medicine will most-likely destroy my practice in this city. You need to know that I am the only truly interventional physician in this city. There are a number of others that are primarily anesthesiologists doing minor injections such as epidurals and facet blocks in the surgery centers of their hospitals in between operating room cases. None of those physicians, however, manage on a chronic basis Medicare and other patients who have severe pain problems and need ongoing pain medicine just to live out their daily lives. If I close my practice, those patients will have no one in this city who will be willing to deal with the pain process.

It is obvious that a majority of many of the more basic interventional procedures are being accomplished by anesthesiologists and PM&R physicians. These individuals who have very little to no practice expenses are absolutely draining the ability of true office-based physicians like myself from getting our practice expenses recognized by Medicare. There are also many interventionalists who still list themselves as anesthesiology primarily and this also skews the data. Please treat anesthesiologists who list interventional pain medicine as their secondary medical specialty in the same pool of those who list interventional medicine as their primary specialty. SWatson

Submitter : Mr. Alan Vitelli **Date:** 08/31/2007

Organization : North Park University

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

I am an athletic training student at North Park University in Chicago, Illinois. I am in my second year in the program here at school and have worked previously as a physical therapy aide under the direction of a certified athletic trainer. Upon completion of this program every student must pass a national certification exam to receive the ATC credentials.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients in the future.

As an athletic training student, I will be qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam will ensure that my patients receive quality health care. State law and hospital medical professionals will deem me qualified to perform these services and these proposed regulations attempt to circumvent those standards upon completion of my degree and national certification.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Alan Vitelli, Athletic Training Student

Submitter : **Jeff Maxwell** **Date: 08/31/2007**

Organization : **Jeff Maxwell**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Jeff Maxwell

Submitter : KELLY KAY **Date:** 08/31/2007

Organization : KELLY KAY

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
KELLY KAY

CMS-1385-P-14157

Submitter : Dr. Edwin Dodd

Date: 08/31/2007

Organization : Jackson Pain Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

14157

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

Submitter : Mrs. Frances Pena Hurlbut **Date:** 08/31/2007

Organization : The Urology Center, P.C.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attached Letter (Word Document)

CMS-1385-P-14158-Attach-1.DOC

14158

TO WHOM IT MAY CONCERN @ CMS:

On July 2, 2007, the Centers for Medicare and Medicaid Services ("**CMS**") issued proposed revisions to the Medicare payment policies under the physician fee schedule for calendar year 2008 (the "**2008 PFS**"). The 2008 PFS includes proposed changes to existing reassignment regulations and purchased test anti-markup regulations (collectively the "**Proposed Rules**").

The Proposed Rules are a substantial departure from the rules proposed last year by CMS in its 2007 PFS. Nevertheless, if finalized, the Proposed Rules will impact certain business arrangements utilized by some managed pathology laboratories. The purpose of this letter is to summarize the Proposed Rules as they relate to the provision of in-house pathology services, and to provide you with our perspective on the potential impact of the Proposed Rules on certain business arrangements routinely utilized by managed pathology laboratories.

The Social Security Act generally prohibits Medicare payment to anyone other than the Medicare beneficiary (the patient) or the physician or other person who performed the service for the beneficiary. This prohibition is found at 42 CFR § 424.80. This rule has exceptions known as "reassignment exceptions," which permit Medicare to make payment to an individual or entity other than the performing physician, provided the physician has appropriately "reassigned" his right to payment. One such exception, found at 42 CFR § 424.80(d), permits a physician to contractually reassign to a group practice the right to bill Medicare for services provided by the physician on the group's behalf. The Proposed Rules add certain requirements to this regulation which must be complied with by groups who bill for diagnostic tests pursuant to a contractual reassignment. It is pursuant to such a contractual reassignment that some managed pathology laboratories bill for services provided by their pathologists.

As amended, 42 CFR § 424.80 provides that if either the technical component ("**TC**") or the professional component ("**PC**") of a diagnostic test is billed by a physician or medical group pursuant to a contractual reassignment from a provider who is not a full time employee of the billing group, the following conditions must be met:

(i) the payment to the group, less applicable deductibles and coinsurance, may not exceed the lowest of: (1) the provider's net charge to the group, which must be determined without regard to any charge intended to cover the cost of equipment or space leased to the provider by the billing group payment that is made by the group to the physician; (2) the group's actual charge; or (3) the Medicare fee schedule payment for the service provided;

(ii) the group must identify the provider that performed the PC or the TC and indicate their net charge as a condition of reimbursement; and

(iii) in order to bill for the TC of a service, the group must directly perform the PC of the same service.

A second regulation, 42 CFR § 414.50, provides that if the TC of a diagnostic test was not performed by the billing physician and was not performed or supervised by a physician in the billing physician's group practice, Medicare payment is the lower of (i) the supplier's net charge, (ii) the billing group's actual charge, or (iii) the Medicare fee schedule payment. This is known as the "Anti-Markup Provision." The Anti-Markup Provision is intended to eliminate the opportunity for a group practice to profit by purchasing tests performed by other suppliers at a low price and then billing Medicare at a higher rate. The Proposed Rules amend this regulation by extending it to the PC of a diagnostic test that is either purchased by the billing group or billed by the billing group pursuant to a contractual reassignment. Both of these rules are intended to accomplish the same objectives.

The Proposed Rules are significant in a couple of respects. First, Medicare is limiting its payment to a group for the PC of a diagnostic test provided by an independent contractor physician to the amount of the payment the group makes to the physician. In calculating this payment, Medicare would not consider the cost of space, equipment, or other overhead necessary to permit the physician to provide the PC on the group's premises, despite the fact that the Stark Law requires that the physician perform these services on the group's premises. This does not prohibit a group from charging a physician for this overhead, but any such charge paid by the physician will lower the Medicare reimbursement to the group.

Essentially, this means that a group can no longer make a profit by utilizing a physician on a less than full time basis to provide the PC of Medicare reimbursed diagnostic tests on behalf of the group. It also means that the cost of overhead allocable to these services is now an unreimbursable cost of business to the group. While these limitations also apply to the TC of diagnostic tests, they will not affect the managed pathology laboratories because the TC in the managed laboratories is not performed by personnel who reassign their rights to bill Medicare. In our particular situation, we could not afford to hire a full time uropathologist and we would not have the volume to support such action. This would mean that only the very largest groups that would have the volume or could afford to do this. This also means that only the large groups could afford to render this type of care to their patients.

Second, the Proposed Rules provide that, in order to bill for the TC of a Medicare reimbursed diagnostic test, the group must directly perform the PC of the same service. This change will not affect managed laboratories, because those laboratories all bill for both the TC and PC of all tests, as a condition of Stark compliance. It is likely that this requirement will have a significant effect on other competing pathology delivery systems, particularly those in which a group practice provides its own TC and refers out the PC to independent pathologists who bill for the PC themselves.

Several previously considered rules were not proposed in this rulemaking. For example, there are no proposed rules addressing the size or location of a centralized building used for the provision of diagnostic tests. There is no proposed rule requiring that a centralized building contain on a permanent basis all of the equipment necessary to perform the diagnostic services it performed in that facility. And despite earlier consideration, there is no language in the Proposed Rules limiting their application to either pathology laboratories generally or specifically to pod labs. It appears managed pathology laboratories were successful in their efforts to ensure that the Proposed Rules evenhandedly addressed perceived abuses across the entire spectrum of diagnostic services.

We will also continue to work closely with CMS and Congressional leaders to present our case as to why the use of managed pathology laboratories provides superior urological pathology without any undue risk of program abuse. In our particular situation, we use a managed pathology laboratory model to send our pathology specimens, primarily because by using this particular laboratory model, our pathology specimens are interpreted by only uropathologist. This means that by only having a uropathologist preparing and interpreting our pathology specimens, we can detect possible problems sooner; therefore, we can offer appropriate treatment that much sooner to the patient, instead of having our pathology specimens prepared and interpreted by a general pathologist. In dealing with general pathologist, it may take more than one incident of Prostate biopsy before it is detected by a general pathologist. Possibly months could go by. Months, that when we are dealing with an aggressive Prostate cancer, could mean a life.

As Administrator of a group of 6 urologist in the New Haven area, as all medical groups throughout the country, it is becoming very difficult for physicians to be able to render good care with all of the "exceptions" and "rulings not only from CMS, but from managed care in general. We take pride in the quality of care that we render our patients and it is becoming very difficult to continue to do with all of the "reductions and "exceptions" that we face every year and still be able to cover our expenses. The decisions made by a few at CMS and by Congress can affect so many lives. Please review all of our concerns carefully and make sure that you fully understand the implications that your decision can have on physicians and the public's healthcare and welfare in general.

I hope this information helps you better understand how this proposal could affect our ability to render good medical care to our patients.

Sincerely,

Frances Peña Hurlbut

Frances Peña Hurlbut, MBA, CMPE

Submitter : **Dr. Roy Neeley**

Organization : **Dr. Roy Neeley**

Date: 08/31/2007

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.

Acting Administrator

Centers for Medicare and Medicaid Services

Attention: CMS-1385-P

P.O. Box 8018

Baltimore, MD 21244-8018

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations. Additionally, the majority of Medicare patients fall into a higher risk population with multiple illnesses and comorbidities, further complicating their care.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Roy Neeley, MD

Submitter : **Dr. Jeremy Scarlett** **Date: 08/31/2007**

Organization : **Dr. Jeremy Scarlett**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Sample Comment Letter:

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Jeremy A. Scarlett, MD

Submitter : **Ms. Christi Gates** **Date: 08/31/2007**

Organization : **NATA**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Aug. 31, 2007

Re: Docket ID CMS-1385-P

Dear Sir or Madam:

The therapy standards proposed by CMS in the Physician Fee Schedule will harm the patients of athletic trainers and create access problems. There is a strong possibility that with these Byzantine and onerous rules will, in fact, decrease the quality of services provided to Medicare beneficiaries. These CMS proposed rules are not supported by any objective reports or other rationale that has been made public.

I believe these will greatly rules will harm non-Medicare patients. Typically, when Medicare makes a rule it eventually gets adopted in the private sector. Millions of secondary school and college students will lose access to services critical to the safety of our children. In addition, millions of seniors recovering from hip replacement and other orthopedic surgeries and conditions will lose acccss. Is this want Medicare intends?

These are unnecessary and unreasonable rules. I want to chose the best provider for me.

These whole therapy standards rules make no sense. I respectfully request that all rules past and present that restrict the ability of athletic trainers to lawfully practice their profession be reversed by CMS. Further, I recommend that the broadest possible panel including sports medicine consumers of physical medicine and rehabilitation services providers be established to review future therapy rules prior to such efforts to insert them into the Federal Register.

Thank you,
Christi Gates

Submitter : **JENNIFER KAY** **Date: 08/31/2007**

Organization : **JENNIFER KAY**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
JENNIFER KAY

Submitter : **Dr. vijaya para** **Date: 08/31/2007**

Organization : **Monmouth Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.

Acting Administrator

Centers for Medicare and Medicaid Services

Attention: CMS-1385-P

P.O. Box 8018

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Thank you for your consideration of this serious matter.

Submitter : Kristi Maxwell **Date:** 08/31/2007

Organization : Kristi Maxwell

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Kristi Maxwell

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please see attached document

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

CMS-1385-P-14166

Submitter : TONY KENNEDY **Date:** 08/31/2007

Organization : TONY KENNEDY

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Thank you for your consideration of this serious matter.
TONY KENNEDY

Submitter : **Gina Postier** **Date: 08/31/2007**

Organization : **Gina Postier**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Gina Postier

Submitter : SHERYL KENNEDY **Date: 08/31/2007**

Organization : SHERYL KENNEDY

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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SHERYL KENNEDY

Submitter : **Lloyd Biby** **Date: 08/31/2007**

Organization : **Lloyd Biby**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Lloyd Biby

CMS-1385-P-14171

Submitter : Dr. Karl Becker

Date: 08/31/2007

Organization : Karl E. Becker, MD, PA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comment on CMS-1385-P

CMS-1385-P-14171-Attach-1.PDF

14171

Karl E. Becker, M.D., P.A.
11708 High Drive
Leawood, KS 66211-2226

913-345-1158 kbecker@kc.rr.com

August 31, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P—Anesthesia Coding (Part of 5-Year Review)

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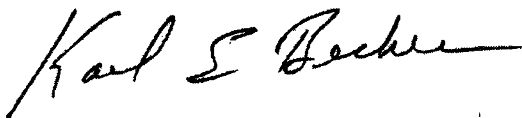
Thank you for your consideration of this serious matter.

Sincerely,



Karl E. Becker, M.D.

Submitter : **Jennifer Johnson** **Date: 08/31/2007**

Organization : **Jennifer Johnson**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Jennifer Johnson

Submitter : Yeonjoo Lee-Jones **Date:** 08/31/2007

Organization : Yeonjoo Lee-Jones

Category : Chiropractor

Issue Areas/Comments

GENERAL

GENERAL

This is in regards to reimbursement of radiology sevices when the referral was made by chiropractor to radiologist. It is imperative that we, chiropractors, should have direct access to x-rays as part of the diagnostic tool to provide proper care to medicare patients considering they fall in the highest risk of osteporosis and other bone related conditions. Medicare should first of all reimburse for x-rays taken by chiropractor to be most proper if any chiropractor wishes to do in office and there should not be any more huddles to jump to provide care. It is unnecessary for patients to go back to their primary while incurring another expense for the sake of x-ray referral, which will cost medicare more expense and at the same time medicare is trying save cost by proposing this change to elliminate the reimbursement seem to be out of line and illogical in any sense. Patients would have to wait longer for treatments just to satisfy medicare reqirements under this change and I don't belive public health care is designed to prevent people from utilizing it when it is necessary in a timely manner. I would like to know where this proposal originated, by which organization, and to what complishment government is expecting, if I may. It also seems that we are going back ward in providing healthcare by limiting access instead of expanding excess to what is patient's rights to begin with. It is astounding to me to watch abuses and overutilization of drugs and surgeries that drains most of our medicare dollars and there are not any decent proposal to regulate this however this proposal related to chipropractic referral, which has to be minute part of medicare spending, gets this much unwarranted attention in wrong direction. It almost felt to me as prejudice and discrimination against my profession that has served public over 100 hundred years.
Sincerely,

Yeonjoo Lee-Jones, D.C.

Submitter : Dr. David Schneider **Date:** 08/31/2007

Organization : American Society of Anesthesiologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Sincerely,

David Schneider, MD

Submitter : **Tommy Smith** **Date: 08/31/2007**

Organization : **Tommy Smith**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Tommy Smith

Submitter : **RICHARD KIELY** **Date: 08/31/2007**

Organization : **RICHARD KIELY**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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RICHARD KIELY

CMS-1385-P-14179

Submitter : **William Bailey** **Date: 08/31/2007**

Organization : **William Bailey**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

William Bailey

CMS-1385-P-14180

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please see attached document for comments

CMS-1385-P-14180-Attach-1.DOC

14180

Re: Removal of Physical Therapy Treatment from the In-Office Ancillary Services Exception.

From: (What should be the most relevant perspective,) "The Patient"

As a relatively active, intelligent person seeking proper guidance and professional input, I was enrolled in an exercise program at an outpatient physical therapy clinic owned by a physical therapist. This facility was recommended by a friend who experienced excellent results following knee surgery and subsequently participating in a step-down program. I was actually having some pain in my knee and mentioned it to my personal trainer at the facility during a training session. He immediately recruited one of the licensed physical therapists on staff to take a look. Following some questions and an impromptu consultation, he referred me for an orthopedic consultation. The P.T. had indicated my condition may require surgery, but a course of physical therapy may even prevent that from becoming necessary. He gave me the name of a physician he felt was "one of the best in the area when it comes to knees". I scheduled the consult.

The physical therapist was right. The doctor indicated surgery may be required, but physical therapy should be the first course of treatment. At that point I thought I would be going back to the physical therapy facility for treatment. Imagine my surprise when the doctor told me he would oversee my therapy in his office. I was confused. I even asked about therapy at the facility that referred me to him. He assured me I would be better served if he could keep a closer eye on my progress. Honestly, I pride myself on being an educated consumer, but I felt there were no options for me. I attended therapy at the doctor's office. It was busy. I only saw the doctor one time during therapy and that was at a scheduled appointment with him. It turns out, I was not even treated by a licensed physical therapist. I usually worked with an athletic trainer and sometimes an aide. My knee condition did not improve and after a second opinion, I proceeded with the surgery. It was performed by the original physician recommended by the physical therapist. Following surgery, a course of physical therapy was prescribed. As a result of my experience before surgery and my friend's exceptional rehab experience at the physical therapy facility, I expressed my interest in receiving treatment there. Again, my physician had concerns and felt my transition would be smoother under his supervision. I'm not a doctor or a therapist, I reluctantly acquiesced. Originally the doctor told me I would need to get into therapy almost immediately following surgery. When I attempted to schedule therapy, however, there were no available openings. Consequently, I did not get into therapy until 2 weeks following surgery. By the physical therapist's (on staff at the physician's office) own admission, or slip of the tongue, I should have gotten into therapy immediately and now I was having post-surgical problems as a direct result of waiting to get in.

You know the saying, "Fool me once, shame on you; Fool me twice, shame on me."

I stopped by the physical therapy facility where I had been training before surgery and found out I could have received therapy wherever I decided I wanted to go. All he had to

do was fill out a prescription. I unwittingly assumed the doctor would be acting in my best interest. I assumed from his strong "suggestions", this was not really my decision to make. I assumed many things and as a result, well, you probably know the saying about assuming too. I will not make that mistake again. I discontinued therapy at the physician's office, and began treatment at the physical therapy clinic immediately. Imagine my surprise again when I was treated or seen by a licensed physical therapist at every single visit. The treatment was more comprehensive, the care more hands-on and the facility was state of the art when in came to equipment. The environment felt more conducive to healing and they also focused on educating me about my condition and rehabilitation. I did have an interesting follow-up visit at the physician's office though.

During my 45 minute sentence in his waiting room, I read an interesting article about something called POPTS. Until then, I never even realized my orthopedic surgeon owned that part of the practice. He never mentioned that and, of course, I never asked. I wish I had been more informed from the very beginning.

Unfortunately, this is not an uncommon series of events for patients; It should be. Removing physical therapy services from the exceptions to the in-office ancillary services represents a powerful and viable solution.

You have, and perhaps even understand, the perspective of physical therapists as it relates to our concerns about the direction and livelihood of our profession. For me and my associates, those concerns pale in comparison to the rights and welfare of patients. As a health care professional (practicing P.T. for over 15 years), I fully recognize and appreciate people's vulnerability and trust when it comes to their physical rehabilitation. As a husband, father and patient, myself, I have been forced to trust my health care, and that of my family, to physicians. With my background and education, I feel, perhaps, more armed with knowledge than most. However, I want assurances there are no financial incentives for my health care providers to recommend or provide treatment for anything; therapy, medication, etc. In addition, I would like to know my insurance company and/or government has provisions to prevent such inherent conflicts of interest. I want the quality of my care and that of my loved ones in the hands of people who are truly concerned about *our* health, not *their* bottom line.

On my behalf and that of my associates, we thank you for a forum that affords us the opportunity to voice our concerns.

Submitter : **Laura Bailey** **Date: 08/31/2007**

Organization : **Laura Bailey**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Laura Bailey

Submitter : Tony Guinn

Date: 08/31/2007

Organization : Tony Guinn

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Tony Guinn

Submitter : **Lamonica Smith** **Date: 08/31/2007**

Organization : **Lamonica Smith**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
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When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Lamonica Smith

Submitter : JO KIELY **Date: 08/31/2007**

Organization : JO KIELY

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.
JO KIELY

Submitter : **Justin Postier** **Date: 08/31/2007**

Organization : **Justin Postier**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Justin Postier

Submitter : **Dr. Kara Zajac** **Date: 08/31/2007**

Organization : **Nature's Way Chiropractic Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore, Maryland 21244-8018

Re: TECHNICAL CORRECTIONS

The proposed rule dated July 12th contained an item under the technical corrections section calling for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non-treating provider and used by a Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any "red flags," or to also determine diagnosis and treatment options. X-rays may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

By limiting a Doctor of Chiropractic from referring for an X-ray study, the costs for patient care will go up significantly due to the necessity of a referral to another provider (orthopedist or rheumatologist, etc.) for duplicative evaluation prior to referral to the radiologist. With fixed incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, it is the patient that will suffer as result of this proposal.

I strongly urge you to table this proposal. These X-rays, if needed, are integral to the overall treatment plan of Medicare patients and, again, it is ultimately the patient that will suffer should this proposal become standing regulation.

Sincerely,

Dr. Kara Zajac

Submitter : **Jaison Wardrop** **Date: 08/31/2007**

Organization : **Avail Physical Therapy**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Jaison Wardrop, I work for Enloe Occupational Health as well as Avail Physical Therapy In Chico, California. I am a certified athletic trainer as well as an Exercise Physiologist. I provide vital healthcare coverage for a local high school in Chico. I hold an MA and as BS in Kinesiology with an emphasis in Athletic Training. I am a certified Athletic Trainer, meeting all standards and practices as required by NATABOC.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jaison Wardrop MA, ATC, EP

Submitter : **Leroy Crowl** **Date: 08/31/2007**

Organization : **Leroy Crowl**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Leroy Crowl

14189

CMS-1385-P-14189

Submitter : Mr. David Leigh

Organization : Marquette University

Category : Health Care Professional or Association

Date: 08/31/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14189-Attach-1.TXT

Dear Sir or Madam:

I am David Leigh a Certified Athletic Trainer that works at a University setting and have been an ATC for over 30 years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

David Leigh ATC

Submitter : **Wayne Gartner** **Date: 08/31/2007**

Organization : **Wayne Gartner**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Wayne Gartner

Submitter : **Robert Coon** **Date: 08/31/2007**

Organization : **Robert Coon**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Thank you for your consideration of this serious matter.

Robert Coon

Submitter : **Stephanie Coon** **Date: 08/31/2007**

Organization : **Stephanie Coon**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Stephanie Coon

Submitter : **Mrs. Kelly Capobianco** **Date: 08/31/2007**

Organization : **South Kent School**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

BRIEF INTRO ABOUT SELF ie. Where you work, what you do, education, certification, etc.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

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Sincerely,
Kelly S. Capobianco, BS, MS, ATC-L, CSCS

Submitter : **Camille Gartner** **Date: 08/31/2007**

Organization : **Camille Gartner**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Camille Gartner

Submitter : **Mrs. Lori Kozloski** **Date: 08/31/2007**

Organization : **GE Healthcare, Lunar**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14195-Attach-1.DOC

CMS-1385-P-14195-Attach-2.DOC

726 Heartland Trail
Madison, WI 53717

#14195 (attach #

September 10, 2007

Herb Kuhn, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1385-P Proposed Revisions to payment policies under the physician fee schedule and other Part B payment policies for CY 2008

Comments:

- **Practice Expense Inputs – CPT 77080**
- **Work RVU – CPT 77080**
- **Deficit Reduction Act**

Dear Mr. Kuhn:

GE Healthcare (GEHC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule regarding changes to the Medicare physician fee schedule CMS-1385-P. GEHC is a $15 billion unit of General Electric Company that is headquarters in the United Kingdom with expertise in medical imaging and information technologies, patient monitoring, life support systems, disease research, drug discovery, and biopharmaceuticals manufacturing technologies. Worldwide, GE Healthcare employs more than 43,000 people committed to serving healthcare professionals and their patients in more than 100 counties. Lunar, a division of GE Healthcare is a leading manufacturer of bone densitometry units and submits the following comments for consideration.

Comment: Practice Expense Inputs: CPT 77080 – Axial Bone Density Studies

We question the accuracy of the PE RVU formula after several attempts by various sources to include two CMS representatives to duplicate the .81 PE RVU for CPT 77080-Axial BMD, DXA as outlined in the CMS-1385-P PFS proposed rule it could not be duplicated. We contacted Rick Ensor who sent a detail worksheet with the calculation for determining the total PE RVU value. This worksheet showed the value of .85. ISCD received a similar worksheet from a different source with CMS that contained a few different line items within the calculation that showed a total value of .86. It was explained to us that there are rounding differences that would cause the variance. This would account only for a 1-point difference either way not a 5-point difference. When you take both worksheets and compare the direct and indirect cost, there were differences. After entering the same direct cost the variance is .15. ***It is important to note, that neither worksheet received from CMS matched the value listed in the proposed rule.***

CMS has a responsibility to ensure the formula's used to calculate the physician fee schedule is accurate and reproducible. We believe there is a significant flaw in the formula, therefore we request CMS to re-evaluate the formula.

We request CMS to revise the practice expense inputs for axial bone density studies to reflect differences in the factors: (1) type of equipment assigned to CPT 77080 & 77081, (2) the utilization rate assumption for these procedures; and (3) factors affecting the indirect cost assumptions. Discussion of each of these issues follows

Equipment Type – In 2006, GEHC and numerous other clinical societies provided comments to CMS-1321-P regarding the incorrect equipment type and cost used to calculate practice expense for DXA (77080 & 77081). In the final rule CMS-1321-FC published in December 1st (page 137), CMS advised they had revised CPT code 77080 & 77081 to fan beam technology with a cost of $85,000. In reviewing the 2007 input tables, however, the equipment type for both procedures were changed back to pencil beam technology. **For the following reasons, we urge CMS to once again revise the PE input data to reflect fan beam technology.**

1. The Lewin Group recently conducted a survey representing 8 specialties that provide DXA in an office-based setting with 163 completed surveys, 81% of the machines identified were fan beam with a cost of $85,000.

2. Results of the clinical society survey data conducted in 2006 of 453 physicians showed 93% of all bone densitometry units in use today were fan beam densitometers and 7% were pencil beam.

3. Our records show 90% of all systems sold from 2004-2006 were fan beam densitometers and 10% were pencil beam.

Indirect Percentages – With the implementation of the bottom up methodology, which uses the direct and indirect cost to calculate the PE RVU, it is clear what makes up the direct cost however, the indirect cost is unclear. To date we have been unable to determine how the indirect cost index was determined, how the specialty mix was derived and what specific inputs were used, therefore we request CMS to provide this information so that we may comment appropriately.

Utilization Rate – The utilization rate has a significant impact on direct cost of the PE RVU. Using the same utilization rate for all procedures can lead to significant payment inequities since utilization varies considerably by place of service and type of service (single use device versus multiple use devices).

The Lewin Group survey determined that the utilization rate for DXA in the non-facility setting was 12% and VFA was 6 %. ISCD on behalf of several national clinical societies whose members currently use DXA equipment conducted a study in 2006, which was submitted to CMS that included utilization information. Results of this study showed DXA utilization at a median range of 21% with the majority of systems sold to primary care physicians, rheumatologists, and endocrinologist. Based on CMS's own 2002 data information 70% of DXA scans were performed in an office-based setting, in which 60% were performed by non-radiologist. Place of service, equipment type (single use versus multiple use), type of service (preventative versus advanced technology), and operating hours should be used in the calculation of utilization. ***We implore CMS to consider alternative methods for calculating the utilization rate given the significant impact it has on the total PE RVU value for DXA.***

Comment: Work RVU – CPT 77080, Axial Bone Density Studies - We request CMS to reconsider the Work RVU for DXA by conducting an independent assessment of the survey data presented by the American College of Radiology (ACR) and International Society of Clinical Densitometry societies.

In the final rule of 2006, CMS accepted the RUC working group recommendation to lower the RVU to .20. This recommendation came from a working group comprised of six members in which only one member was knowledgeable about DXA. We strongly believe the survey data listed below should be considered and the

Work RVU be increased to .50 as detailed in the ISCD survey and/or at the very least increased to .30 as recommended by the ACR. ACR conducted a survey of 51 radiologists regarding the physician work component for DXA. The survey concluded that the Work RVU for DXA should remain at .30. Radiologist makes up 40% of physicians performing the DXA. ISCD surveyed 453 physicians currently performing DXA from multiple disciplines with results ranging from a low of .17 to a high of .76 with the median of .50. The multiple disciplines make up 60% of physicians performing DXA.

Comment: Deficit Reduction Act – GEHC request that CMS reevaluate and exclude DXA testing 77080 & 77081 from the provisions of the DRA for the following reasons:

The proposed rule references the definition of imaging services under Section 5102(b)(1) of the Deficit Reduction Act (DRA). In addition, it sets out the criteria and analysis to determine which imaging services will be included in order to implement the DRA as well as those imaging services that are to be exempt from the DRA's definition.

Under the DRA, imaging services are defined as "imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography". In the rule, CMS articulates the analysis that it will use to determine which CPT codes are to be included under the DRA definition, as well as those codes that are to be considered exempt from the law.

CMS states, "we believe that imaging services are those that provide visual information, thereby assisting in the diagnosis or treatment of illness or injury". CMS notes the following procedures as examples of exceptions to the definition of imaging services under the Act: bronchoscopy with or without fluoroscopic guidance and upper gastrointestinal endoscopy with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s). CMS articulates the rational for these exceptions: "In these cases, we are unable to clearly distinguish imaging from non-imaging services because, for example, *a specific procedure may or may not utilize an imaging modality, or the use of an imaging technology cannot be segregated from the performance of the main procedure." (Emphasis added).*

Therefore, applying this CMS analysis, CPT Code 77080 (DXA) should be excluded from the definition of imaging services in the diagnosis and treatment of osteoporosis. The DXA test uses equipment that produces a numerical value of bone mass (in units of gram/cm) which is compared to young normal controls to derive a T-score). This number is used to diagnose bone disease. Although the DXA equipment also generates an image, the image itself is not used to diagnose bone disease and therefore cannot be segregated from the main procedure, and should be excluded from the provision of the DRA.

Summary

Osteoporosis causes fractures in approximately half of women and one quarter of men. Over 20% of adults who sustain a hip fracture die within the following year and many more never regain independence. Annual direct health care costs for fracture care in the United States currently approximate $16.9 billion a year and are projected to exceed $25 billion by 2025. Despite the epidemic proportions of osteoporosis, the test used to diagnosis this ***preventable disease***, and hailed by the Surgeon General in 2004, as "one of the most significant advances in the last quarter century," is in danger of being eliminated from the woman's health care arsenal by Medicare payment policies. The test, DXA (Dual Energy X-Ray Absorptiometry) (CPT code 77080), and a companion procedure, VFA (Vertebral Fracture Assessment) (CPT code 77082) are critical for the diagnosis of osteoporosis and monitoring the response to treatment. The 40% reduction in the Medicare Physician Fee Schedule reimbursement for DXA in the non-facility setting (implemented in 2007 with the Deficit Reduction Act) has already caused some physicians to discontinue offering this vital service. By 2010, DXA reimbursement will have dropped 75%. With reimbursement below operating costs in 2010, this essential preventive service will largely disappear from the non-facility environment as over 90% of physicians have indicated that they will stop performing DXA studies by 2010.

While CMS has an obligation to review all comments received during the rule making process, we call on Medicare to carefully consider the requests contained in this document, as this particular payment policy will undermine the agency's preventive health care agenda as it relates to osteoporosis care. The Medicare Payment Advisory Committee (MedPAC) in their March 2007 report to Congress states;

"The Commission is concemed that differences in the profitability across physician services create financial incentives for physicians to favor fumishing some procedures and services over other, less profitable ones. In this environment, beneficiary access to relatively undervalued services-and to the providers that perform them—may be threatened. Misvalued services should be identified and payments corrected.... Also, revisiting the RBRVS may be needed to explore the possibility of including other factors—in addition to input costs—in the pricing of individual services."

Undervalued services create disincentives to provide such services to Medicare beneficiaries, thereby threatening access to important health care diagnostic and therapeutic interventions. We believe that the changes requested in our comment letter are necessary to support efforts to improve recognition of osteoporosis through increased DXA testing.

Sincerely,

Lori Kozloski,
GEHC, Lunar – Reimbursement Specialist

Enclosure: CMS PE RVU worksheets

14195
(attach # 2)

PROVIDED BY RICK ENSOR 08/23/2007

77080 tc'

DIRECT CALCULATION

	rate	time(min)
Clinical Labor	0.41	43
Total Clinical Labor (in dollars)		**17.63**

	price	quantity
Supplies	0.533	1
	0.307	1
	0.014	7
	0.938	
Total Supplies (in dollars)		**0.938**

Equipment cost_min=(1/(mins_yr*usage))*price*((intrate/(1-(1/((1+intrate)**life))))+maint)

minutes a year	150000	approx 48 hours a week, 52 weeks a year		
usage	0.5			
price 1	41000	Cost Min 1	0.175245	7.535539
price 2	2110	Cost Min 2	0.006184	0.012367
interest rate	0.11			
maintenance	0.05			
life 1	5			
life 2	10			
eqt 1	43			
eqt 2	2			

Total Equipment (in dollars) **7.548**

(1/(mins_yr*usage))*price
((intrate/(1-(1/((1+intrate)**life))))+maint)

Total Direct Dollars	**26.116**		
Direct Dollars Converted to RVUs	0.73	35.9848	37.8975
Direct Adjuster	0.654	34.135	
Direct RVUs Adjusted	**<u>0.47</u>**		

INDIRECT CALCULATION

Ind Pct*(Adj Direct RVU/Dir Pct)+Work RVU

Indirect Pct	0.629		
Direct Pct	0.371		
Direct RVU	0.47		
Clinical Labor RVU	0.34	Unadj Ind RVU	1.142489
Work RVU (adj by 0.90)	0	Adj Ind RVU	0.409011
indirect adj	0.358	Adj Ind RVU w/ PCI	0.374654
PCI Adjustment	0.916		

Indirect RVU w/ PCI **0.37**

PROVIDED TO ISCD 08/30/2007

Practice Expense Calculation for 77080

Clinical Labor

Radiologic Technologist

minutes	31	
rate per minute	$ 0.41	
		$ 12.71

Equipment

densitometry unit, fan beam, DXA (w-computer hardware & software)	$ 85,000	
Minutes per service	31	
Depreciation (years)	5	
Utilization Rate	0.5	
Maintainance	0.05	
		$ 9.87
solid water calibration check	$ 2,110	
Minutes per service	15	
Depreciation (years)	10	
Utilization Rate	0.5	
Maintainance	0.05	
		$ 0.08

Supplies

gown, patient; paper, laser printing (each sheet); pillow case	$ 0.86
Subtotal Direct Costs (Lab+Equip+Sup)	$ 23.51

Submitter : **Brent Amos** **Date: 08/31/2007**

Organization : **Brent Amos**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Brent Amos

Submitter : Joe Schroeder

Organization : Joe Schroeder

Date: 08/31/2007

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.
Joe Schroeder

CMS-1385-P-14198

Submitter : **Kathy Goff** **Date: 08/31/2007**

Organization : **Kathy Goff**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Kathy Goff

Submitter : **Leon Goff** **Date: 08/31/2007**

Organization : **Leon Goff**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Leon Goff

CMS-1385-P-14200

Submitter : **Mr. Brian Abraham** **Date: 08/31/2007**

Organization : **MedImmune**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1385-P-14200-Attach-1.PDF

14200

MedImmune

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Rule [CMS-1385-P]

Dear Acting Deputy Administrator Kuhn:

MedImmune is pleased to take this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule for the 2008 Medicare physician fee schedule (Proposed Rule).[1] MedImmune, the biologics unit of AstraZeneca, is committed to advancing science to develop better medicines that help people live healthier, longer, and more satisfying lives. We appreciate CMS's efforts to ensure beneficiary access to available medical technologies and treatments, particularly your commitment over the past couple of years to ensure that Medicare beneficiaries remain healthy by obtaining preventive treatment.

As the manufacturer of FluMist® (Influenza Virus Vaccine, Live, Intranasal), we share your concerns about stopping the spread of the influenza virus among the aged and disabled, as well as the US population at large. We greatly appreciate the agency's willingness to meet with us on August 16, 2007. These comments follow up on that discussion and serve to formally request that the agency increase the practice expense relative value units (PE RVUs) for the intranasal administration of influenza vaccine to the same level as the level for injected administration. This action would reflect additional non-physician staff time spent with patients and help to ensure that providers are able to make treatment decisions based on medical appropriateness rather than economic considerations. We firmly believe that equalizing payment rates will help ensure more children get immunized, thereby reducing the burden of influenza on society as a whole and on Medicare beneficiaries in particular. We urge you to make these changes in the final rule.

[1] 72 Fed. Reg. 38122 (July 12, 2007).

EQUALIZING PAYMENT RATES FOR INFLUENZA VACCINE ADMINISTRATION MAY REDUCE INFLUENZA RATES AMONG MEDICARE BENEFICIARIES

We believe that equivalent administration payment rates between the intranasal and injectable influenza vaccines will help increase influenza protection among children, which in turn may reduce influenza-related morbidity, mortality, and costs among Medicare beneficiaries. Each year, approximately 36,000 people die from influenza-related illnesses; there are more than 200,000 hospitalizations and more than 25 million physician visits, with Medicare-aged patients having the highest risk of complications and death from influenza.[2] However, the highest rates of influenza are seen in children and children also are most likely to spread the disease to others (including Medicare beneficiaries).[3] Those who are at risk for influenza tend to get vaccinated; however, those most likely to spread the virus – household contacts aged 2-17 years – are often not vaccinated.[4] At the same time, while the influenza vaccination rate among the elderly has increased, mortality from the disease has not decreased.[5] This leads to the conclusion that we should increase the influenza vaccination rate among the non-elderly population to protect the aged population of Medicare beneficiaries. This is where CMS can help without a significant financial commitment, but a simple change in policy.

BACKGROUND

This section of MedImmune's comments refers both to the Background section of the Proposed Rule and the background of our request.

Proposed Rule Background
As stated in this Proposed Rule, as well as in other previous proposed and final rules, CMS makes payment for physician services based on three major components: the physician work RVU (Work RVU), the PE RVU, and the malpractice expense RVU (MP RVU).[6] Our discussion of the payment for administration of vaccines will focus on the Work and PE RVUs. As Table 1 shows, the proposed payment rates for immunization administration vary widely between injected administration and intranasal administration.

---

[2] Death rate and hospitalizations from CDC, Influenza Fact Sheet at www.cdc.gov/flu/.keyfacts.htm; physician visits from Couch RB, *Ann Intern Med,* 2000; 133:992-998.
[3] Monto AS, et al. Epidemiol Infect. 1993; 110:145-160.
[4] CDC. *MMWR*. 2007;56:1-54.
[5] Simonsen L, et al. *Arch Intern Med.* 2005;165:265-272.
[6] 72 Fed.Reg. 38126.

Table 1. Vaccine Administration Relative Value Units, Proposed 2008

CPT Code	Description	Physician Work RVUs	Year 2008 Transitional Non-Fac PE RVUs	Malpractice RVUs	Total RVU
90465	Immuniz admin 1 inj w counsel < 8 yr	0.17	0.38	0.01	0.56
90466	Immuniz admin, addl inj w counsel, <8 yr	0.15	0.12	0.01	0.28
90467	Immuniz admin, intranasal w counsel, <8 yr	0.17	0.17	0.01	0.35
90468	Immuniz admin, each addl intranas w counsel, <8 yr	0.15	0.11	0.01	0.27
90471	Immuniz admin (inj)	0.17	0.38	0.01	0.56
90472	Immuniz admin, each addl (inj)	0.15	0.13	0.01	0.29
90473	Immuniz admin, intranas	0.17	0.18	0.01	0.36
90474	Immuniz admin, each addl intranasal	0.15	0.09	0.01	0.25

Source: CMS-1385-P, Addendum B at 72 Fed. Reg. 38341.

We believe the PE RVUs for intranasal administration are inappropriately low and should be equalized to the injectable immunization administration PE RVUs. When the codes last were reviewed in 2004, the differences in the PE RVUs were from direct inputs such as syringes, bandages, and swab-pads. As we will explain later in these comments, the physician community has found that there is a differential in clinical staff time with more time being devoted to intranasal administration than to injected immunization. We request that CMS equalize the RVUs by increasing the clinical staff input to a level that would bring the PE RVU of intranasal administration up to the level of injected administration. Specifically, we ask the agency to revise the values in Table 1 as follows:

Table 1 (REVISED). Vaccine Administration Relative Value Units, 2008

CPT Code	Description	Physician Work RVUs	Year 2008 Transitional Non-Fac PE RVUs	Malpractice RVUs	Total RVU
90465	Immuniz admin 1 inj w counsel < 8 yr	0.17	0.38	0.01	0.56
90466	Immuniz admin, addl inj w counsel, <8 yr	0.15	0.12	0.01	0.28
90467	**Immuniz admin, intranasal w counsel, <8 yr**	**0.17**	**0.38**	**0.01**	**0.56**
90468	**Immuniz admin, each addl intranas w counsel, <8 yr**	**0.15**	**0.12**	**0.01**	**0.28**
90471	Immuniz admin (inj)	0.17	0.38	0.01	0.56
90472	Immuniz admin, each addl (inj)	0.15	0.13	0.01	0.29
90473	**Immuniz admin, intranas**	**0.17**	**0.38**	**0.01**	**0.56**
90474	**Immuniz admin, each addl intranasal**	**0.15**	**0.13**	**0.01**	**0.29**

Background of our Request
Our comments on this Proposed Rule are the culmination of previous discussions, comments, and interactions between CMS and MedImmune on this topic. We greatly appreciate the open, ongoing dialog we have had with the agency on these important issues. We previously commented on this same disparity in the hospital outpatient department setting as part of the proposed rule on the Hospital Outpatient Prospective Payment System (HOPPS) for the 2006 Calendar Year (CMS-1501-P). As a result, CMS equalized the payment for all influenza immunization administrations by establishing a single payment rate under the code G0008.

This same code is proposed in the physician fee schedule for 2008 with a payment rate of $18.43.[7] As much as we would like this code and proposed rate to resolve the differential in payments, the intranasal influenza vaccine is administered primarily in the pediatric population, raising two issues. First, commercial payers and Medicaid agencies, those likely to cover the pediatric population, benchmark from Medicare's physician fee schedule, not HOPPS, so very few have captured CMS's adoption of G0008 in their systems. Second, these payers tend to benchmark from Current Procedural Terminology (CPT) codes, not the Level II Healthcare Common Procedure Coding System (HCPCS) codes, so they would be more likely to use only the CPT codes referring to administration of immunizations (90465-90474), not G0008.

As you will see in Table 2, studies have shown that the time burden is similar for both vaccines. We believe that when the codes for intranasal administration were reevaluated in 2004, there was not enough experience in the office to fully understand the amount of time necessary to explain the intranasal vaccine, as well as screen patients for eligibility to receive it. Now that physician offices have gained a few years of experience with this procedure, we have heard from representatives from both the American Medical Association (AMA) and American Academy of Pediatrics (AAP) that this issue is worth revisiting. In fact, we have encouraged the AAP to communicate with the Relative Value Update Committee (RUC) in support of equalizing payment for the codes.

Table 2. Time Burden for Vaccine Administration, by Method

Average time for administrations with values for all identified steps	Intranasal (minutes)[8]	Injectable (minutes)[9]
Explanation	1.0	0.5
Obtain & Prepare Vaccine	0.7	1.0
Administration	0.3	0.3
Clean-up	0.1	0.3
Summation of Average Times	2.1	2.1

*Does not include time for eligibility screening or charting.

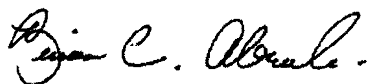
[7] 72 Fed.Reg. 38216, Table 26.
[8] Washington, ML, et al. Vaccine. 2005;23:4879.
[9] Szilagyi, PG, et al. Arch Ped Adol Med. 2003; 157:191.

Changing the RVU for Vaccine Administration
As noted in Table 1, there are significant differences in the PE RVUs between the injection codes (90465, 90466, 90471, and 90472) and the intranasal administration codes (90467, 90468, 90473, and 90474). In summary, we request that CMS increase the PE RVUs to reflect the additional non-physician staff time spent with patients explaining the burden of influenza, screening for eligibility, and discussing the safety and efficacy of the intranasal vaccine. This increase should net out to equal the PE RVUs of the injection codes, such that the total RVUs of the intranasal administration codes and the injection administration codes are equalized.

We firmly believe that equal payment rates will encourage providers to make treatment decisions based on medical appropriateness without the question of inequitable payment for services. There should be no sizable cost increase to Medicare as the intranasal influenza vaccine currently is indicated only for persons under the age of 50. There likely will be a decrease in Medicare costs due to lower influenza and pneumonia cases among the over 65 age group from the herd immunity benefit. Finally, by making these changes, CMS will improve public health by decreasing the influenza burden, thus decreasing hospitalization and mortality among the elderly.

Thank you for your repeated willingness to work with us on this important public health issue. If you have questions or would like additional information, please contact me at 301-398-4626 or abrahamb@medimmune.com.

Respectfully yours,



Brian C. Abraham
Associate Director, Reimbursement
MedImmune

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Please see attached document for relevant comments.
Thank you.

CMS-1385-P-14201-Attach-1.DOC

14201

Re: Removal of Physical Therapy Treatment from the In-Office Ancillary Services Exception.

From: (What should be the most relevant perspective,) "The Patient"

As a relatively active, intelligent person seeking proper guidance and professional input, I was enrolled in an exercise program at an outpatient physical therapy clinic owned by a physical therapist. This facility was recommended by a friend who experienced excellent results following knee surgery and subsequently participating in a step-down program. I was actually having some pain in my knee and mentioned it to my personal trainer at the facility during a training session. He immediately recruited one of the licensed physical therapists on staff to take a look. Following some questions and an impromptu consultation, he referred me for an orthopedic consultation. The P.T. had indicated my condition may require surgery, but a course of physical therapy may even prevent that from becoming necessary. He gave me the name of a physician he felt was "one of the best in the area when it comes to knees". I scheduled the consult.

The physical therapist was right. The doctor indicated surgery may be required, but physical therapy should be the first course of treatment. At that point I thought I would be going back to the physical therapy facility for treatment. Imagine my surprise when the doctor told me he would oversee my therapy in his office. I was confused. I even asked about therapy at the facility that referred me to him. He assured me I would be better served if he could keep a closer eye on my progress. Honestly, I pride myself on being an educated consumer, but I felt there were no options for me. I attended therapy at the doctor's office. It was busy. I only saw the doctor one time during therapy and that was at a scheduled appointment with him. It turns out, I was not even treated by a licensed physical therapist. I usually worked with an athletic trainer and sometimes an aide. My knee condition did not improve and after a second opinion, I proceeded with the surgery. It was performed by the original physician recommended by the physical therapist. Following surgery, a course of physical therapy was prescribed. As a result of my experience before surgery and my friend's exceptional rehab experience at the physical therapy facility, I expressed my interest in receiving treatment there. Again, my physician had concerns and felt my transition would be smoother under his supervision. I'm not a doctor or a therapist, I reluctantly acquiesced. Originally the doctor told me I would need to get into therapy almost immediately following surgery. When I attempted to schedule therapy, however, there were no available openings. Consequently, I did not get into therapy until 2 weeks following surgery. By the physical therapist's (on staff at the physician's office) own admission, or slip of the tongue, I should have gotten into therapy immediately and now I was having post-surgical problems as a direct result of waiting to get in.

You know the saying, "Fool me once, shame on you; Fool me twice, shame on me."

I stopped by the physical therapy facility where I had been training before surgery and found out I could have received therapy wherever I decided I wanted to go. All he had to

do was fill out a prescription. I unwittingly assumed the doctor would be acting in my best interest. I assumed from his strong "suggestions", this was not really my decision to make. I assumed many things and as a result, well, you probably know the saying about assuming too. I will not make that mistake again. I discontinued therapy at the physician's office, and began treatment at the physical therapy clinic immediately. Imagine my surprise again when I was treated or seen by a licensed physical therapist at every single visit. The treatment was more comprehensive, the care more hands-on and the facility was state of the art when in came to equipment. The environment felt more conducive to healing and they also focused on educating me about my condition and rehabilitation. I did have an interesting follow-up visit at the physician's office though.

During my 45 minute sentence in his waiting room, I read an interesting article about something called POPTS. Until then, I never even realized my orthopedic surgeon owned that part of the practice. He never mentioned that and, of course, I never asked. I wish I had been more informed from the very beginning.

Unfortunately, this is not an uncommon series of events for patients; It should be. Removing physical therapy services from the exceptions to the in-office ancillary services represents a powerful and viable solution.

You have, and perhaps even understand, the perspective of physical therapists as it relates to our concerns about the direction and livelihood of our profession. For me and my associates, those concerns pale in comparison to the rights and welfare of patients. As a health care professional (practicing P.T. for over 15 years), I fully recognize and appreciate people's vulnerability and trust when it comes to their physical rehabilitation. As a husband, father and patient, myself, I have been forced to trust my health care, and that of my family, to physicians. With my background and education, I feel, perhaps, more armed with knowledge than most. However, I want assurances there are no financial incentives for my health care providers to recommend or provide treatment for anything; therapy, medication, etc. In addition, I would like to know my insurance company and/or government has provisions to prevent such inherent conflicts of interest. I want the quality of my care and that of my loved ones in the hands of people who are truly concerned about *our* health, not *their* bottom line.

On my behalf and that of my associates, we thank you for a forum that affords us the opportunity to voice our concerns.

Submitter : Jeri Ramey

Organization : Jeri Ramey

Date: 08/31/2007

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Jeri Ramey

Submitter : **Dr. Brenda Bucklin** **Date: 08/31/2007**

Organization : **Univ. of CO Health Sciences Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Sincerely yours,
Brenda A. Bucklin, M.D.
Professor of Anesthesiology
University of Colorado Health Sciences Center

CMS-1385-P-14204

Submitter : **Brent Amos** **Date: 08/31/2007**

Organization : **Brent Amos**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Brent Amos

Submitter : **Robert Hildebrand** **Date: 08/31/2007**

Organization : **Robert Hildebrand**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Robert Hildebrand

Submitter : **JACK KIMBLER** **Date: 08/31/2007**

Organization : **JACK KIMBLER**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
BRAD KIMBLER

Submitter : **Dinah Hildebrand**
Organization : **Dinah Hildebrand**

Date: 08/31/2007

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Dinah Hildebrand

Submitter : **Terry Jenkins** **Date: 08/31/2007**

Organization : **Terry Jenkins**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Terry Jenkins

CMS-1385-P-14210

Submitter : **Vernon Jenkins** **Date: 08/31/2007**

Organization : **Vernon Jenkins**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Vernon Jenkins

CMS-1385-P-14211

Submitter : **Sheila Amos** **Date: 08/31/2007**

Organization : **Sheila Amos**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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Sheila Amos

Submitter : **Harold Frieze** **Date: 08/31/2007**

Organization : **Harold Frieze**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Thank you for your consideration of this serious matter.

Harold Frieze

Submitter : Mr. Travis Mattern **Date:** 08/31/2007

Organization : AANA

Category : Other Practitioner

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:

As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.

This increase in Medicare payment is important for several reasons.

ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.

ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.

ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.

Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).

America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.

Sincerely,
Travis Mattern, MS CRNA________________________
Name & Credential
1580 3rd st east________________________
Address
West Fargo, ND 58078________________________
City, State ZIP

Submitter : **Violet Frieze** **Date: 08/31/2007**

Organization : **Violet Frieze**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Violet Frieze

CMS-1385-P-14217

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Due to error messages, I am not certain this has gone through. If it is a duplicate, I apologize for the copy. Please see the attached.
Thank you.

CMS-1385-P-14217-Attach-1.DOC

Re: Removal of Physical Therapy Treatment from the In-Office Ancillary Services Exception.

From: (What should be the most relevant perspective,) "The Patient"

As a relatively active, intelligent person seeking proper guidance and professional input, I was enrolled in an exercise program at an outpatient physical therapy clinic owned by a physical therapist. This facility was recommended by a friend who experienced excellent results following knee surgery and subsequently participating in a step-down program. I was actually having some pain in my knee and mentioned it to my personal trainer at the facility during a training session. He immediately recruited one of the licensed physical therapists on staff to take a look. Following some questions and an impromptu consultation, he referred me for an orthopedic consultation. The P.T. had indicated my condition may require surgery, but a course of physical therapy may even prevent that from becoming necessary. He gave me the name of a physician he felt was "one of the best in the area when it comes to knees". I scheduled the consult.

The physical therapist was right. The doctor indicated surgery may be required, but physical therapy should be the first course of treatment. At that point I thought I would be going back to the physical therapy facility for treatment. Imagine my surprise when the doctor told me he would oversee my therapy in his office. I was confused. I even asked about therapy at the facility that referred me to him. He assured me I would be better served if he could keep a closer eye on my progress. Honestly, I pride myself on being an educated consumer, but I felt there were no options for me. I attended therapy at the doctor's office. It was busy. I only saw the doctor one time during therapy and that was at a scheduled appointment with him. It turns out, I was not even treated by a licensed physical therapist. I usually worked with an athletic trainer and sometimes an aide. My knee condition did not improve and after a second opinion, I proceeded with the surgery. It was performed by the original physician recommended by the physical therapist. Following surgery, a course of physical therapy was prescribed. As a result of my experience before surgery and my friend's exceptional rehab experience at the physical therapy facility, I expressed my interest in receiving treatment there. Again, my physician had concerns and felt my transition would be smoother under his supervision. I'm not a doctor or a therapist, I reluctantly acquiesced. Originally the doctor told me I would need to get into therapy almost immediately following surgery. When I attempted to schedule therapy, however, there were no available openings. Consequently, I did not get into therapy until 2 weeks following surgery. By the physical therapist's (on staff at the physician's office) own admission, or slip of the tongue, I should have gotten into therapy immediately and now I was having post-surgical problems as a direct result of waiting to get in.

You know the saying, "Fool me once, shame on you; Fool me twice, shame on me."

I stopped by the physical therapy facility where I had been training before surgery and found out I could have received therapy wherever I decided I wanted to go. All he had to

do was fill out a prescription. I unwittingly assumed the doctor would be acting in my best interest. I assumed from his strong "suggestions", this was not really my decision to make. I assumed many things and as a result, well, you probably know the saying about assuming too. I will not make that mistake again. I discontinued therapy at the physician's office, and began treatment at the physical therapy clinic immediately. Imagine my surprise again when I was treated or seen by a licensed physical therapist at every single visit. The treatment was more comprehensive, the care more hands-on and the facility was state of the art when in came to equipment. The environment felt more conducive to healing and they also focused on educating me about my condition and rehabilitation. I did have an interesting follow-up visit at the physician's office though.

During my 45 minute sentence in his waiting room, I read an interesting article about something called POPTS. Until then, I never even realized my orthopedic surgeon owned that part of the practice. He never mentioned that and, of course, I never asked. I wish I had been more informed from the very beginning.

Unfortunately, this is not an uncommon series of events for patients; It should be. Removing physical therapy services from the exceptions to the in-office ancillary services represents a powerful and viable solution.

You have, and perhaps even understand, the perspective of physical therapists as it relates to our concerns about the direction and livelihood of our profession. For me and my associates, those concerns pale in comparison to the rights and welfare of patients. As a health care professional (practicing P.T. for over 15 years), I fully recognize and appreciate people's vulnerability and trust when it comes to their physical rehabilitation. As a husband, father and patient, myself, I have been forced to trust my health care, and that of my family, to physicians. With my background and education, I feel, perhaps, more armed with knowledge than most. However, I want assurances there are no financial incentives for my health care providers to recommend or provide treatment for anything; therapy, medication, etc. In addition, I would like to know my insurance company and/or government has provisions to prevent such inherent conflicts of interest. I want the quality of my care and that of my loved ones in the hands of people who are truly concerned about *our* health, not *their* bottom line.

On my behalf and that of my associates, we thank you for a forum that affords us the opportunity to voice our concerns.

Submitter : **Mrs. Amber Mathis** **Date: 08/31/2007**

Organization : **Mrs. Amber Mathis**

Category : **Other Practitioner**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,

Amber Mathis, RN, BSN, SRNA
199 Dyersburg Hwy
Trenton, TN 38382

Submitter : **James Beeler** **Date: 08/31/2007**

Organization : **James Beeler**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

James Beeler

Submitter : Robin Clavier

Date: 08/31/2007

Organization : Robin Clavier

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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Robin Clavier

Submitter : **Bradley Lambrecht** **Date: 08/31/2007**

Organization : **Bradley Lambrecht**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Bradley Lambrecht

CMS-1385-P-14223

Submitter : **Dan Willard** **Date: 08/31/2007**

Organization : **Dan Willard**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Baltimore, MD 21244-8018

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Dan Willard

Submitter : **Victor Neal** **Date: 08/31/2007**

Organization : **Victor Neal**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Victor Neal

Submitter : **Sunny Lambrecht** **Date: 08/31/2007**

Organization : **Sunny Lambrecht**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Sunny Lambrecht

Submitter : **Mary Neal** **Date: 08/31/2007**

Organization : **Mary Neal**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Mary Neal

Submitter : **Evelyn Schroeder** **Date: 08/31/2007**

Organization : **Evelyn Schroeder**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Evelyn Schroeder

CMS-1385-P-14228

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

As a result of multiple error messages I was unsure if my submission went through. If this is a copy, I apologize for the inconvenience.
Thank you.

CMS-1385-P-14228-Attach-1.DOC

14228

Date: August 29, 2007
Re: In-Office Ancillary Services Exception
Abolish the Stark Referral Loophole

As a physical therapist in practice for over 15 years, my worst fears about this exception have been realized. Nearly 10 years ago, I went into private practice to provide the quality of physical therapy care patients deserve and should expect. As a result of my efforts, I now serve several communities where a number of my clinics are located. Each facility is jointly owned and operated by a physical therapist. As therapists, we care about our patients and yes, we have a vested interest in their rehabilitative outcome; personally, professionally and financially. Consequently, we reap the rewards of a successful practice, as word-of-mouth referrals continue to bring patients to our facilities. When you provide a quality of hands-on care, where patients feel listened to and are seen by a licensed physical therapist at each visit, they come back and they tell their family and friends.

My business is not my concern. Patient care is. Let's face it, the original provision was mandated to dodge the inherent risk of physicians profiting from referrals of any kind. Perfect, until the exceptions were put in place for various services, including physical therapy. I can only speak to *this* exception because of my direct and personal experience. By allowing physicians to refer and bill patients and their carriers for physical therapy treatment in their (physician-owned) facilities, a fertile ground has been laid for fraud, abuse and inadequate patient care. As a provider of these services, I and every one of my partners and employees have encountered the drawbacks and consequences of this exception. That fertile ground has propagated into a flourishing garden of over-utilized, over-charged services and an inexcusable level of patient care.

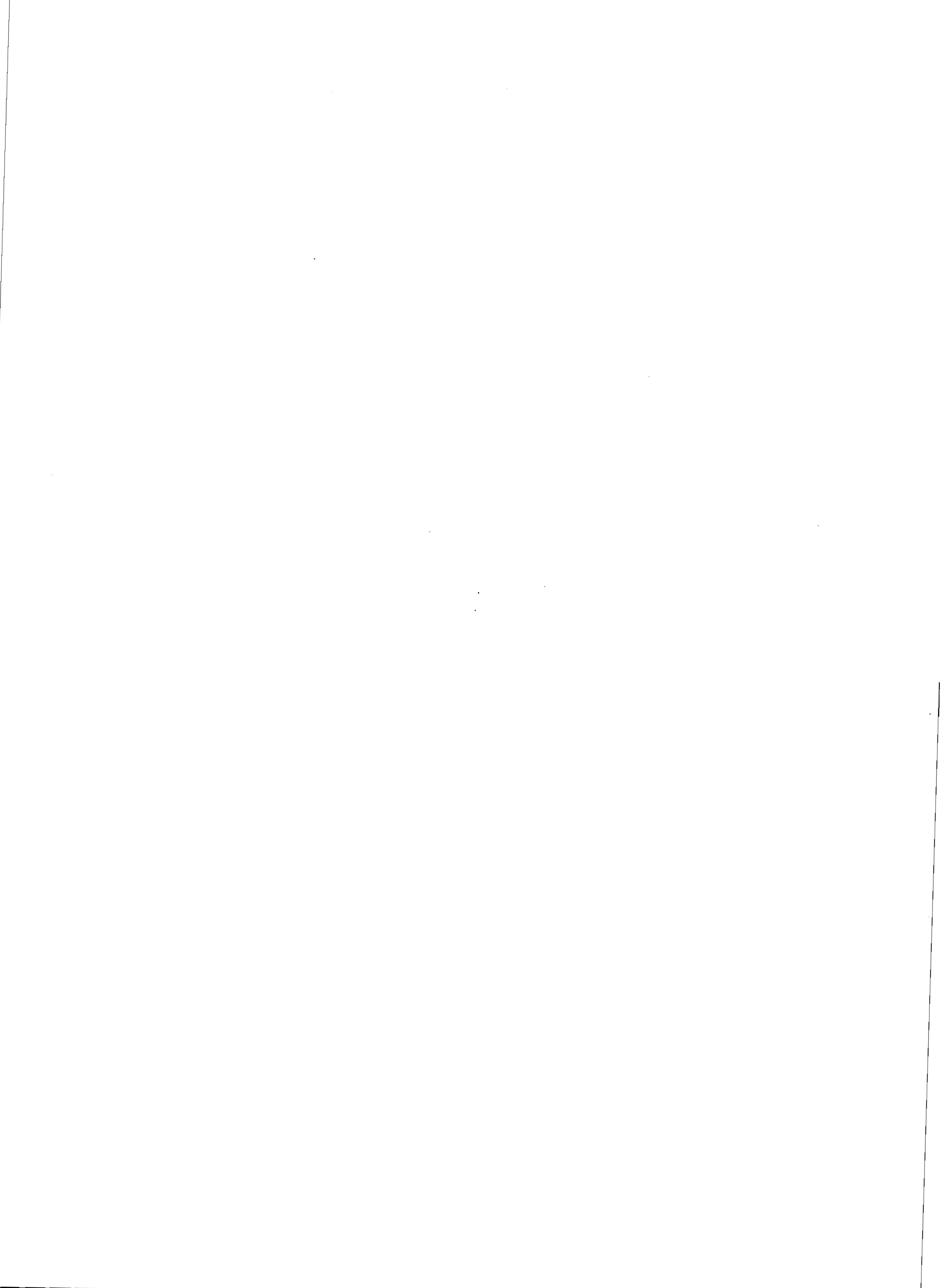
You have seen the studies and reviewed the statistics; perhaps they bear repeating. A study conducted in 1992 by the New England Journal of Medicine found POPTS generated more charges and higher utilization than independent rehabilitation facilities. In addition, elevated costs were associated with physical therapy care under the CA workers compensation program in POPTS. Another revealing study established that physicians initiated physical therapy 2.3 times more often when referring in-house than before they opened their own PT facilities. Suddenly their patients' need for therapy more than doubled!? The financial incentive behind this overwhelming increase seems obvious.

I know we provide every patient that walks through our doors with the best quality care, state of the art equipment and an environment that encourages proactive healing and education. I also know, based on feedback from patients and the aforementioned statistics, this level of care is not provided in POPTS. After all, what is their motivation? Care is often compromised and over prescribed. Regardless of rehab results and/or patient satisfaction of services, a physician has the luxury of a never-ending built-in referral base, their own patients. Herein lies, yet another, conflict of interest. In 1991, Florida Health Care Costs Containment Board found both licensed and non-licensed therapy workers spent less time with each patient in POPTS, resulting in reduced levels of care for all patients. I have personally spoken to patients who tell me they only saw a physical therapist once or twice, usually working with a trainer or aide throughout treatment (at POPTS facilities).

Our profession will survive these setbacks, but what happens to the patients stuck in the middle? Patients who truly trust their physicians to make altruistic recommendations about their health care; Patients who believe the choice is not really theirs to make; Patients who are often unaware their physicians financially benefit from their physical therapy care; Patients who trust their insurance carriers and government to protect them from conflicts of interest. That is my concern.

I do hope these points and other related studies will be taken into consideration when making the final decision about the application of this exception to physical therapy services. I want to restate the real victims in all of this, the patients. In order to provide the best quality of care, the only option is to remove the proverbial dangling carrot. If it does not exist, there is no temptation to sneak it and no opportunity to abuse it.

In sincere appreciation for this forum to submit my perspective and that of my colleagues.



Submitter : **Miss. Jessica Humbach** **Date: 08/31/2007**

Organization : **University of Illinois- Champaign-Urbana**

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Jessica Humbach and I am a student at the University of Illinois in Champaign-Urbana. I am currently in my fourth semester in the Athletic Training Education Program.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

Following certification as an athletic trainer, I will be qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients will receive quality health care. Upon completion and certification, state law and hospital medical professionals will have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Jessica Humbach

Submitter : **Leslie Taylor** **Date: 08/31/2007**

Organization : **Leslie Taylor**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Leslie Taylor

CMS-1385-P-14231

Submitter : **Jennifer Willard** **Date: 08/31/2007**

Organization : **Jennifer Willard**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Centers for Medicare and Medicaid Services
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Jennifer Willard

Submitter : **Eric Nolan** **Date: 08/31/2007**

Organization : **Eric Nolan**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Eric Nolan

CMS-1385-P-14233

Submitter : Lori Nolan **Date: 08/31/2007**

Organization : Lori Nolan

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Lori Nolan

Submitter : **Dr. Chee-Hahn Hung** **Date: 08/31/2007**

Organization : **Dr. Chee-Hahn Hung**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1385-P-14234-Attach-1.RTF

CMS-1385-P-14234-Attach-2.RTF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951..

CMS-1385-P-14235

Submitter : Johnny Siler **Date:** 08/31/2007

Organization : Johnny Siler

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.
Johnny Siler

Submitter : **Michael Dore** **Date: 08/31/2007**

Organization : **Michael Dore**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Thank you for your consideration of this serious matter.

Michael Guest

Submitter : **Lisa Moehrle** **Date: 08/31/2007**

Organization : **Lisa Moehrle**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Lisa Moehrle

Submitter : Mr. Ralph Holte **Date:** 08/31/2007

Organization : AANA

Category : Other Practitioner

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
__Ralph Holte, CRNA__________________________
Name & Credential
3101 Bohnet Blvd. N.__________________________
Address
__Fargo, ND 58102__________________________
City, State ZIP

Submitter : **Glenda Conn** **Date: 08/31/2007**

Organization : **Glenda Conn**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Glenda Conn

Submitter : **Ms. susan smith** **Date: 08/31/2007**

Organization : **PROFESSIONAL ANESTHESIA SERVICE**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

I work for Professional Anesthesia Service, and I think this is a field that is long due for an increase in a fee schedule.

Submitter : **T Potter** **Date: 08/31/2007**

Organization : **UAB**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Teri Potter

Submitter : **Sheila Murray** **Date: 08/31/2007**

Organization : **Sheila Murray**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Sheila Murray

CMS-1385-P-14243

Submitter : Darryl Payton **Date:** 08/31/2007

Organization : Darryl Payton

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Darryl Payton

Submitter : **JENNIFER KIMBROUGH** **Date: 08/31/2007**

Organization : **JENNIFER KIMBROUGH**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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JENNIFER KIMBROUGH

Submitter : **Martha Siler** **Date: 08/31/2007**

Organization : **Martha Siler**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.
Martha Siler

Submitter : **Brandi Lane** **Date: 08/31/2007**

Organization : **Brandi Lane**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Scrvices
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Rc: CMS-1385-P
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Thank you for your consideration of this serious matter.

Brandi Lane

CMS-1385-P-14247

Submitter : Dr. Stephen Watson **Date:** 08/31/2007

Organization : Innovative Pain Solutions

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Mr. Weems,

I apologize but I ran out of room to finish my letter. This is the final part of my comments. I appreciate your reading my letter.

I am an active implanter of stimulators. I stopped implanting pumps because of multiple factors among which was atrocious reimbursement to the point of losing money just to refill a pump on a monthly basis. There really needs to be a national policy that will allow for physicians to make enough money for the time, effort, risk and expertise to be worth utilizing this technology. As an example, my filling a pump with a mixture of medications and being reimbursed for the exact cost of the medications along with the refill fee of approximately $50 is a loss. If I have to do the refill, I am kept from even seeing return patients and bringing in more than the $50. I certainly may very well have to forgo doing another interventional procedure and therefore lose that revenue. In light of the $3,500 lease payment monthly for my fluoroscope (OEC 9800 MD), I cannot make this payment doing pump refills. Even worse, I know that eventually each one of my remaining pump patients will come to the office one day in the future. Their pump alarm will be sounding and I will know that I have less than 6 weeks to replace the pump or it will fail completely and the patient will lose their infusion possibly endangering their very life. I then have to schedule operating room time in a hospital and clear basically several hours of my schedule in my office so that I can drive to the hospital, do the paperwork, do the procedure, finish the paperwork and get back to my office. The professional component of replacing that intrathecal pump in no way makes up the revenue loss from not doing procedures in my office. In otherwords, I can not and will not implant any more pumps in patients, especially Medicare, because the ongoing reimbursement is actually typically a loss and the eventual replacement of the pump just destroys my revenue stream. Something must be done!

Please incorporate the updated practice expense data from physician practice surveys in future rule-making. Obviously, I am just one isolated physician. I doubt, however, that my situation is unique. If you fail to do this, people like myself will have to leave this specialty practice over the next several years.

Please fix the SGR formula. As I just stated, the impending decrease in office reimbursement rates over the next 8 years will, if enacted, destroy my ability to bring in enough money to pay the bills. If I leave this practice, the only physicians left in this community will be anesthesiologists and PM&R physicians who will not keep Medicare and Medicaid patients in their practice who just need ongoing prescriptions for pain control. That is a fact of life. If you desire to see that come about, keep SGR as it is.

Thank you for taking your time and your staff's time to read my letters. This information has come from my heart. This is not a "canned" letter that I simply signed and forwarded. I am absolutely earnest in my comments and what I have told you will transpire here in Springfield if you do not alter the present course of Medicare. I would be very happy to respond in any way to a telephone call, letter, e-mail or whatever. Please let me help if there is anything that I can do for you.

Sincerely,

Stephen David Watson, M.D., Ph.D.
937-405-8087 Cell phone
937-323-3900 Office phone
swatson@chronicpainmgmt.com

Submitter : **Karen Mann** **Date: 08/31/2007**

Organization : **Self**

Category : **Individual**

Issue Areas/Comments .

GENERAL

GENERAL

Re: CMS-1385-P

Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Submitter : **Dr. Fred Davis** **Date: 08/31/2007**

Organization : **Lahey Clinic**

Category : **Physician**

Issue Areas/Comments

Medicare Economic Index (MEI)

Medicare Economic Index (MEI)

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Submitter : **Jim Murray** **Date: 08/31/2007**

Organization : **Jim Murray**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Jim Murray

Submitter : **RICK LEATH** **Date: 08/31/2007**

Organization : **RICK LEATH**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.
RICK LEATH

Submitter : **Trisha Eshelman** **Date: 08/31/2007**

Organization : **Trisha Eshelman**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Trisha Eshelman

Submitter : **Jana Biedniak** **Date: 08/31/2007**

Organization : **Jana Biedniak**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Jana Biedniak

Submitter : **Bill Knight** **Date: 08/31/2007**

Organization : **Bill Knight**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Bill Knight

CMS-1385-P-14257

Submitter : **Ike Glass** **Date: 08/31/2007**

Organization : **Ike Glass**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Ike Glass

Submitter : **Richard Foutch** **Date: 08/31/2007**

Organization : **Richard Foutch**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Richard Foutch

CMS-1385-P-14259

Submitter : Anna Lee Underwood **Date:** 08/31/2007

Organization : Anna Lee Underwood

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your considcration of this serious matter.

Anna Lce Undcrwood

CMS-1385-P-14260

Submitter : Angela Smith

Organization : Angela Smith

Category : Individual

Issue Areas/Comments

Date: 08/31/2007

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Angela Smith

Submitter : **JAN LEATH** **Date: 08/31/2007**

Organization : **JAN LEATH**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Thank you for your consideration of this serious matter.
JAN LEATH

CMS-1385-P-14262

Submitter : Carl Stevenson **Date:** 08/31/2007

Organization : Carl Stevenson

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Carl Stevenson

Submitter : **Gloria Dickens**

Date: 08/31/2007

Organization : **Gloria Dickens**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.

Gloria Dickens

Submitter : **Mary Beth Glass** **Date: 08/31/2007**

Organization : **Mary Beth Glass**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Mary Beth Glass

Submitter : **Dr. Michael Stretanski** **Date: 08/31/2007**

Organization : **Interventional Spine**

Category : **Physician**

Issue Areas/Comments

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Coding--Multiple Procedure Payment Reduction for Mohs Surgery

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Wcems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008 (the Proposed Rule) published in the Federal Register on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.
There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the all physicians crosswalk. This, however, did not relieve the continued underpayment of interventional pain servicees and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries access.

The current practice expense methodology does not aceurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as interventional pain physicians for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

CMS should treat Physical Medicine & Rehabilitation Medicine (PM&R) physicians who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to all physicians for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional

CMS-1385-P-14265-Attach-1.WPD

CMS-1385-P-14265-Attach-2.TXT

#14265

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

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This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain

services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding

pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Michael F. Stretanski, DO
Director, Interventional Spine & Pain Rehabilitation, ltd
Fellowship Director, ISPRoC

Submitter : **Betty Stevenson** **Date: 08/31/2007**

Organization : **Betty Stevenson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Betty Stevenson

Submitter : **Charles Dickens** **Date: 08/31/2007**

Organization : **Charles Dickens**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Charles Dickens

CMS-1385-P-14268

Submitter : **Dr. Neal Birnbaum** **Date: 08/31/2007**

Organization : **American College of Rheumatology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Comment letter specifies header before paragraph.

CMS-1385-P-14268-Attach-1.PDF

AMERICAN COLLEGE OF RHEUMATOLOGY
EDUCATION • TREATMENT • RESEARCH

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#14268

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Subject: CMS-1385-P Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008

Dear Mr. Kuhn:

The American College of Rheumatology appreciates the opportunity to comment on the Centers for Medicare & Medicaid Proposed Notice on the revisions to Medicare payment policies under the physician Payment Schedule for calendar year 2008.

Budget Neutrality/Five-Year Review Work Adjuster (Section: Background)

In this Proposed Rule, CMS announces that the Five-Year Review Work Adjuster will increase from -10.1% to -11.8%. The proposed changes from the 5-year review are requiring that CMS make adjustments to comply with the Omnibus Budget Reconciliation Act of 1989 and its demand for budget neutrality. The proposed rule suggests that the adjustment be made to the work RVUs instead of the conversion factor. Historically, CMS has made different attempts to achieve budget neutrality. It seems that adding another step to an already complex equation will create more confusion than if CMS applied the adjustment to the conversion factor. Therefore, ACR would like to encourage CMS, again this year, to make an adjustment to the conversion factor as it has done since 1998.

Dual Energy X-Ray Absorptiometry (DEXA) (Section: Resource-Based PE RVUs)

The ACR applauds CMS's decision to accept the PERC's recommendations regarding practice expense for DEXA studies. The ACR continues to be concerned about the large decrease in reimbursement that DEXA studies will have as the new practice expense calculation is fully implemented. I encourage CMS to study the calculation and determine what portion of the calculation is causing the large decrease for this one study. It is extremely concerning as DEXA's are considered the gold standard for determining if an individual is at risk for osteoporosis. If the reimbursement is not appropriate, fewer physicians will provide and/or recommend the study to their patients placing the patients at risk. Therefore, I hope that CMS will continue to work with physicians on this issue.

Payment for IVIG add-on Code for Preadmission Related Services (Section: Coding- Payment IVIG)

Intravenous immune globulin is given to very sick patients and is seen by the patients as lifesaving. Unfortunately, in the past few years there have been problems with shortages and appropriate reimbursement. Appropriate reimbursement continues to be a problem and many physicians are forced to send patients to outpatient hospital departments for treatment. Although there continues to be problems with IVIG administration, the ACR is hopeful that the preadministration code that has been created will assist physicians in providing for these very sick patients. This is beneficial to both the physician and the patient. The patients receiving IVIG deserve to have continuity of care as they battle their diseases.

Averages Sales Price (ASP) (Section: ASP Issues)

ASP payments are submitted by the manufacturers not later than 30 days after the end of a quarter. CMS then has until the next quarter to update the figures. Physicians are therefore forced to deal with price changes for approximately 6 months until CMS has been able to update the figures. This is a burden to rheumatologists in small practices when patients are using expensive drugs. With current technology, ASP should only have a lag time of 2-3 months at most. The ACR would like to encourage CMS to accelerate the ASP disclosure rate.

Physician Quality Reporting Initiative (Section: PQRI)

The ACR agrees that physicians should have the ability to voluntarily measure their quality on an individual basis. Therefore, the ACR was pleased to see that CMS was adding "Disease Modifying Anti-rheumatic Drug Therapy in Rheumatoid Arthritis" as one of the quality measures for 2008. However, the ACR does not believe that physicians should be reimbursed based on performance or receive ratings based on insurance company chart review. The ACR believes the PQRI system should be a voluntary system so physicians may measure themselves against other physicians to improve quality.

Addressing a Mechanism for Submission of Data on Quality Measures via Medical Registry or Electronic Health Record (Section: PQRI)

The ACR supports the concept of reporting quality measures via a medical registry or electronic health record. It is important that when these assistive devices are developed they are truly assistive and not an administrative burden for the physician. The ACR is in the process of developing a medical registry and would be interested in discussing the opportunity to be a pilot study group for CMS.

Physician Assistance and Quality Initiative Fund (Section: TRHCA-Section 101(d) PAQI)

TRHCA developed a fund in the amount of $1.35 billion to be used for physician payment and quality improvement initiatives. The proposed rule states that CMS would like to use the funds to continue the PQRI quality payments. ACR believes that when physicians are facing a 10% payment decrease in 2008, the appropriate use for the funds would be to use them to "buy-down" the decrease in the conversion factor. MedPAC also recommended that the $1.35 billion fund be used for the conversion factor update in its report to Congress. Additionally, the ACR is concerned that if the fund is used to

continue payments for PQRI it would unfairly benefit physicians that have reportable measures. There are a several specialties that have few or no measures to report. Therefore, the PAQI fund would be

split amongst the physicians that have the ability to report instead of benefiting all physicians. Based on the information available in TRHCA, it was clear that the writers intended to provide some relief for the expected shortfall in the conversion. Therefore, the ACR encourages CMS to rethink their decision in using the fund for a subset of physicians that report quality.

Thank you for the opportunity to provide comment on these important issues. The ACR looks forward to continuing working with CMS on these issues. Please feel free to contact me if you have additional questions.

Sincerely,

Neal Birnbaum, MD
President, American College of Rheumatology

Submitter : **Doug Smith** **Date: 08/31/2007**

Organization : **Doug Smith**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Doug Smith

Submitter : JIM LEE **Date: 08/31/2007**

Organization : JIM LEE

Category : Individual

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JIM LEE

Submitter : **Robert Houston** **Date: 08/31/2007**

Organization : **Robert Houston**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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Robert Houston

CMS-1385-P-14272

Submitter : **Chris Zehder** **Date: 08/31/2007**

Organization : **Chris Zehder**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Chris Zehder

Submitter : **Ann Houston** **Date: 08/31/2007**

Organization : **Ann Houston**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Centers for Medicare and Medicaid Services
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Ann Houston

Submitter : **Ron Delamarter** **Date: 08/31/2007**

Organization : **Ron Delamarter**

Category : **Individual**

Issue Areas/Comments

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Ron Delamarter

CMS-1385-P-14276

Submitter : **Stephen Campbell** **Date: 08/31/2007**

Organization : **Stephen Campbell**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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Baltimore, MD 21244-8018

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Stephen Campbell

Submitter : **Teresa Foutch** **Date: 08/31/2007**

Organization : **Teresa Foutch**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Teresa Foutch

Submitter : **Colleen Smith** **Date: 08/31/2007**

Organization : **Colleen Smith**

Category : **Individual**

Issue Areas/Comments

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Thank you for your consideration of this serious matter.
Colleen Smith

Submitter : **Nancy Campbell** **Date: 08/31/2007**

Organization : **Nancy Campbell**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Submitter : **Stella Starkey** **Date: 08/31/2007**

Organization : **Stella Starkey**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Stella Starkey

CMS-1385-P-14281

Submitter : Dr. Laurie Maysick

Date: 08/31/2007

Organization : Dr. Laurie Maysick

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Plea... note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **JEAN LEGER** **Date: 08/31/2007**

Organization : **JEAN LEGER**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Submitter : **Renae Delamarter** **Date: 08/31/2007**

Organization : **Renae Delamarter**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Renae Delamarter

Submitter : **Charolotte Bacon** **Date: 08/31/2007**

Organization : **Charolotte Bacon**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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Charlotte Bacon

Submitter : **Christy Zehder**

Organization : **Christy Zehder**

Date: 08/31/2007

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Christy Zehder

Submitter : **PATTY LEGER** **Date: 08/31/2007**

Organization : **PATTY LEGER**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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PATTY LEGER

Submitter : **Brenda Rutherford** **Date: 08/31/2007**

Organization : **Brenda Rutherford**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Brenda Rutherford

CMS-1385-P-14290

Submitter : Dr. MICHAEL STRETANSKI **Date:** 08/31/2007

Organization : INTERVENTIONAL SPINE AND PAIN

Category : Physician

Issue Areas/Comments

Impact

Impact

SEE LETTER

CMS-1385-P-14290-Attach-1.DOC

1129c

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat Physical Medicine & Rehabilitation Medicine (PM&R) physicians who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain

services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding

pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Michael F. Stretanski, DO
Director, Interventional Spine & Pain Rehabilitation, ltd
Fellowship Director, ISPRoC

Submitter : Mike Mewbourn **Date:** 08/31/2007

Organization : Mike Mewbourn

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Mike Mewbourn

Submitter : **Bill Collier** **Date: 08/31/2007**

Organization : **Bill Collier**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Bill Collier

Submitter : **Mary Young** **Date: 08/31/2007**

Organization : **Mary Young**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Mary Young

Submitter : **James Rutherford** **Date: 08/31/2007**

Organization : **James Rutherford**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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James Rutherford

Submitter : **ERIC LEWIS** **Date: 08/31/2007**

Organization : **ERIC LEWIS**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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ERIC LEWIS

Submitter : **Jane Ellen White** **Date: 08/31/2007**

Organization : **Jane Ellen White**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Jane Ellen White

Submitter : **Susan Ross** **Date: 08/31/2007**

Organization : **Susan Ross**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Susan Ross

Submitter : **Debbie Mewbourn** **Date: 08/31/2007**

Organization : **Debbie Mewbourn**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Debbie Mewbourn

CMS-1385-P-14300

Submitter : **Susan Collier** **Date: 08/31/2007**

Organization : **Susan Collier**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Centers for Medicare and Medicaid Services
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Baltimore, MD 21244-8018

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Susan Collier

Submitter : **Ron White** **Date: 08/31/2007**

Organization : **Ron White**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Ron White

Submitter : **Kenneth Snider** **Date: 08/31/2007**

Organization : **Kenneth Snider**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Kenneth Snider

Submitter : **Karen Edwards**

Date: 08/31/2007

Organization : **Karen Edwards**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Karen Edwards

CMS-1385-P-14304

Submitter : **Laurie Maysick** **Date: 08/31/2007**

Organization : **Laurie Maysick**

Category : **Physician**

Issue Areas/Comments

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Submitter : **RONNIE LLOYD** **Date: 08/31/2007**

Organization : **RONNIE LLOYD**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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RONNIE LLOYD

Submitter : **Dr. Jolene Henning** **Date: 08/31/2007**

Organization : **UNCG**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:
I am a certified athletic trainer and the director of the graduate athletic training program at the University of North Carolina at Greensboro. I am charged with educating future professionals in the athletic training profession.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,
Jolene M. Henning, EdD, ATC

Submitter : **Shelli Shaffer** **Date: 08/31/2007**

Organization : **Shelli Shaffer**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Shelli Shaffer

Submitter : **Marc Edwards** **Date: 08/31/2007**

Organization : **Marc Edwards**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Marc Edwards

Submitter : **Brant Fricker** **Date: 08/31/2007**

Organization : **Brant Fricker**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Brant Fricker

Submitter : **Mickie Smith** **Date: 08/31/2007**

Organization : **Mickie Smith**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Mickie Smith

Submitter : **Matt Weller** **Date: 08/31/2007**

Organization : **Matt Weller**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Centers for Medicare and Medicaid Scrvices
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Thank you for your consideration of this serious matter.

Matt Weller

Submitter : **GLORIA LLOYD** **Date: 08/31/2007**

Organization : **GLORIA LLOYD**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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GLORIA LLOYD

Submitter : Vicky Snider **Date: 08/31/2007**

Organization : Vicky Snider

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Vicky Snider

14315

Southern Pines Physical Therapy, LLC
210 South Bennett Street
Southern Pines NC 2838
910 692-8269 Fax: 910 692-8479

physical therapy for life

August 30, 2007

Mr. Kerry N. Weems
Administrator- Designate
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1385-P
PO Box 8018
Baltimore MD 21244-8018

RE: Medicare Program; Proposed Revisions to Payment Policies under Physician Fee Schedule, and Other part B Payment Policies for CY 2008; Proposed Rule
Limited

Dear Sir:

I am writing to support tighter control for in-office ancillary services for physical therapy. I have been a private practicing physical therapist in my community for 25 years. Over the years physician self referral has been on the horizon but prior interpretations of the Stark Laws have discouraged the development of these programs in my community. Not so any more. Recent interpretation has encouraged the development of a large in-office physical therapy program as an ancillary service in our local surgical clinic. The importance of the size of this program is significant when it is noted that only 4 surgeons in our community are **not** included in this surgical clinic.

Last year the surgical clinic opened their in-office physical therapy program. Prior to that time they represented 25 percent of our patient referrals. Our referrals immediately dropped to none. Since that time our referrals have gradually increased and they represent about 10 percent of our patients. Interestingly it has been two categories of patients that we now see from this clinic. First are the patients we have seen previously and request to come see us and second are patients who have been unsuccessful in their care at the physician's facility. For our Medicare patients with the rehabilitation cap this can be a problem.

When the physician's physical therapy program was being developed we had a visit from one of the physicians. He was apologetic about their plans because as he told us "..access and quality are not a problem" in regards to available physical therapy services. The problem rested with the fact that they had a new large building and "need to use the space". We requested consideration for the opportunity to lease their space. We were then informed that a contractual company had proposed $375,000 in profit with an in-house physical therapy program. Clearly we could not compete.

A few things to note since the opening of the physicians physical therapy services:

Our relationship with this group of physicians has remained open and communicative regarding the care of their patients. We have never found it necessary to have direct supervision to care for their patients.

We have not filled a vacant physical therapy position that came available this spring. We no longer have the patient volume to support the position. I understand that the local hospital has had similar response to the direction of physical therapy referrals. Yet the physician's clinic has continued to recruit staff.

My examples above outline changes in our practice since the development of this physician owned physical therapy services in our small community. My concerns continue to increase as more reports of unnecessary or substandard care are brought to my attention. With the current Medicare Cap, I fear that necessary treatment be denied as reimbursement is not available. Tighter restrictions must be made regarding the in-office ancillary services for physical therapy. Based on my experience, I believe that Referral For Profit put the motivation on generating revenues and not on delivering patient care.

Thank you for the opportunity to provide my comments. I may be reached at the above address if further discussion is requested.

Sincerely,

Sue Stovall PT DPT
Partner
Southern Pines Physical Therapy

Submitter : **Mr. Michael Heidt** **Date: 08/31/2007**

Organization : **Aurora Health Care**

Category : **Other Health Care Provider**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:
My name is Mike Heidt, and I am the manager of Rehabilitation Services for Aurora Medical Center in Manitowoc County. As a manager of therapy services in a rural area, I can attest first hand that the current shortage of qualified health care workers is quickly reaching pandemic levels. The proposed changes to 1385-P will only speed this process into an epidemic.
I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.
While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.
As a licensed athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, national certification, and state licensure ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.
The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. Athletic Trainers, in most settings do not provide substantial healthcare services to Medicare patients; however, most insurance companies reflect CMS rules, so by imposing limits that are meant to only affect Medicare beneficiaries, in essence effect and limit many cost-effective patient options. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.
Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.
Sincerely,

Mike Heidt, ATC
Manager of Rehab Services
Aurora Medical Center, Manitowoc County
5000 Memorial Drive
Two Rivers, WI 54241
Michael.heidt@aurora.org

Submitter : **Jess Caine** **Date: 08/31/2007**

Organization : **Excel Sports and Physical Therapy**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is Jess Caine and I'm an athletic trainer currently working out the St. Louis area.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

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Sincerely,

Jess Caine, ATC, EMT-B

Submitter : **Randy Smith** **Date: 08/31/2007**

Organization : **Randy Smith**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Lcslie V. Norwalk, Esq.
Acting Administrator
Ccnters for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Randy Smith

CMS-1385-P-14319

Submitter : Richard Bridwell **Date:** 08/31/2007

Organization : Richard Bridwell

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Richard Bridwell

Submitter : **Mr. james horvath** **Date: 08/31/2007**

Organization : **Steel City Anesthesia, LLC**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

CMS has turned our senior citizens into undesirable patients. After many years of contribution into the system, they have been reduced to the equivalent of not just 'no pays', but actually an expense to our companies. When a 65 year old Senator goes to the hospital for open heart surgery it cost the anesthesia company money to put them asleep for the procedurc. THAT' HOW LITTLE CMS PAYS'. When a street thug, who has never contributed to the system, gets shot in the chest during a drug deal, fiscal outcome is the same for your anesthesia company. This is what CMS has reduced our seniors too, respectable Senators are not any different than our street thug patients. Congratulations CMS.

Submitter : **Kelly Wilson** **Date: 08/31/2007**

Organization : **Kelly Wilson**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Centers for Medicarc and Mcdicaid Scrvices
Attention: CMS-1385-P
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Kelly Wilson

Submitter : **Judy Bridwell** **Date: 08/31/2007**

Organization : **Judy Bridwell**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Judy Bridwell

Submitter : **ANDREA LYLES** **Date: 08/31/2007**

Organization : **ANDREA LYLES**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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ANDREA LYLES

CMS-1385-P-14324

Submitter : **Katherine McGranahan** **Date: 08/31/2007**

Organization : **Katherine McGranahan**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
Baltimore, MD 21244-8018

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Katherine McGranahan

Submitter : **Dr. Ari Brunschwig** **Date: 08/31/2007**

Organization : **Dr. Ari Brunschwig**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Rc: CMS-1385-P

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Thank you for your consideration of this serious matter.

Ari Brunschwig M.D.

Submitter : **Margrette Vo** **Date: 08/31/2007**

Organization : **Margrette Vo**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Margrette Vo

Submitter : **Lawrence McGranahan** **Date: 08/31/2007**

Organization : **Lawrence McGranahan**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Rcview)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Lawrence McGranahan

Submitter : **Dr. Ryan Cortez** **Date: 08/31/2007**

Organization : **West Georgia Anesthesia Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Submitter : **Jack Spear** **Date: 08/31/2007**

Organization : **Jack Spear**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.
Jack Spear

Submitter : **Ted Wenger** **Date: 08/31/2007**

Organization : **Ted Wenger**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Ted Wenger

Submitter : JEFF LYLES **Date: 08/31/2007**

Organization : JEFF LYLES

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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JEFF LYLES

Submitter : **Miss. Melinda Compton** **Date: 08/31/2007**

Organization : **Miss. Melinda Compton**

Category : **Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Melinda Compton

Submitter : **Charles Powell** **Date: 08/31/2007**

Organization : **Northeast Georgia Heart Center**

Category : **Physician**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

An underarrangement contract was contemplated for the benefit of the NE GA community to combine existing diagnostic services and to expand to cardiac CT and additional cath labs with the local hospital rather than duplieating services. This would likely save CMS money, not create proliferation of testing. It certainly had the support of the community and would continue to have such support if the proposed inclusion of underarrangements as a Stark prohibited arrangement occurs. Please note our opposition to restricting underarrangement deals between hospitals and physicians.

Submitter : **Gary Stogsdill** **Date: 08/31/2007**

Organization : **Gary Stogsdill**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Gary Stogsdill

Submitter : **Mr. Jeff Zarling** **Date: 08/31/2007**

Organization : **aana**

Category : **Other Practitioner**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
_Jeff Zarling crna________________________________
Name & Credential
___812 orchard park drive______________________________
Address
__Fargo nd 58104______________________________
City, State ZIP

Submitter : Sam Farr

Date: 08/31/2007

Organization : U.S. House of Representatives

Category : Congressional

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

See attached letter.

CMS-1385-P-14336-Attach-1.DOC

1556

SAM FARR
17TH DISTRICT, CALIFORNIA

COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEES:
AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES
HOMELAND SECURITY
MILITARY CONSTRUCTION, VETERANS' AFFAIRS, AND RELATED AGENCIES
CO-CHAIR, CONGRESSIONAL ORGANIC CAUCUS
CO-CHAIR, CONGRESSIONAL TRAVEL AND TOURISM CAUCUS
CO-CHAIR, HOUSE OCEANS CAUCUS

Congress of the United States
House of Representatives
Washington, DC 20515–0517

1221 LONGWORTH HOUSE OFFICE BUILDING
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ROOM 318
SANTA CRUZ, CA 95060
(831) 429–1976

www.farr.house.gov

August 31, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

File code: CMS-1385-P
Re: GPCI

Dear CMS:

I write today to comment on the proposed rule as noticed in the July 12, 2007 *Federal Register* regarding geographic practice cost index (GPCI) matters. I urge the CMS to redefine Physician Payment localities in California as precisely as possible based on the most accurate data available using a consistent and appropriate methodology to do so.

It is no secret that CMS has erroneously designated a number of counties in California as "Rest of California" otherwise known as Locality 99 when their GAFs clearly make them eligible for separation out of Locality 99 and into a new locality per CMS' own rules. That CMS has failed to do so demands correction. Thankfully, CMS in its proposed rules for Physician Reimbursement for CY2008 has offered three options to correct the GPCI oversight.

For years CMS has acknowledged that a number of California counties – Santa Cruz, Monterey, and Santa Barbara, and San Diego, to name just a few – have GAFs far above CMS' 5% threshold that define when a county deserves its own locality calculation. The consequences of not implementing locality reform for these counties have been enormous. For example Santa Cruz County doctors are paid the lowest rate ("Rest of California) while neighboring doctors in Santa Clara County are paid at one of the highest rates. The disparity between the two counties is the greatest in the entire United States. Even common sense tells us that such situations are not defensible. Besides driving doctors away from the Medicare system, this erroneous CMS payment policy has created access issues for local seniors, compounding the problem.

I support Option Three because it uses the 5% iterative methodology that CMS used to reconfigure localities in 1996. However, in order to promulgate a rule that is honest and fair I offer suggestions to modify Option Three in order to make it more accurate and precise.

As you know, shortly after the July 12 *Register* notice, the GAO published a report on CMS' locality designations and GPCI calculations and found that CMS over time has revised localities

under a variety of different approaches and never uniformly. Unfortunately, Option Three as published in the July 12 *Register* suffers from this inconsistency.

The *Register* text accompanying the GPCI update provisions states that "The geographic adjustment factors (GAFs) for more than 90 percent of counties are developed using proxies based on larger geographic areas" (page 38139). Using the same census data as CMS, the GAO was able to calculate individual work and practice expense GPCIs for 1091 counties that were part of a metropolitan statistical area (MAS) (GAO-07-446, page 46). However, there seems to be a discrepancy – a significant one – in the GAF for San Benito County, California between what the CMS says the GAF is and therefore into which locality San Benito falls, and what the GAO says the GAF is for San Benito and into which locality it falls. GAO gives San Benito a GAF of 1.081 (page 54 of GAO report 07-446) while CMS gives San Benito a GAF of .971 (page 38142 of the *Register*). This discrepancy cannot be explained by differences in rent indices and/or malpractice GPCIs.

It would seem that CMS used the wrong MSA-derived census data. San Benito County resides in the San Jose (CA) MSA, not California Non-Metropolitan Areas as suggested by the CMS GAF.

Consequently, though Option Three provides the fairest methodology for redesignating physician payment localities, it uses the wrong data to do so. I wonder, too, if this is the reason that CMS lists the GAF for Monterey and Santa Cruz counties in Option Three as being different from those counties' GAFs as listed in Options One and Two? If CMS intends to promulgate Option Three, or any option for that matter, it should do so using data that is appropriate, accurate and without doubt. It is simply wrong to write rules that use faulty data.

I am too painfully aware of the budget sensitivity of promulgating one of these options. However, it is my belief that the Secretary has sufficient discretionary powers that could ameliorate any offsetting cuts to Locality 99 that would otherwise occur. It is also my belief that had CMS acted more promptly in addressing this issue it would not be at crisis level today. Nonetheless, failing to act only exacerbates the problem. Action today is imperative – but action that is based on real data and the correct methodology.

Thank you for the chance to comment on this proposed rule. I hope you will give these comments serious consideration and do what is fairest for the California doctors and Medicare beneficiaries.

Sincerely,

SAM FARR
Member of Congress

SF/rsd

Submitter : **Roseanne Abrogar** **Date: 08/31/2007**

Organization : **Roseanne Abrogar**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

roseanne Abrogar

CMS-1385-P-14338

Submitter : Linda Stogsdill **Date:** 08/31/2007

Organization : Linda Stogsdill

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Thank you for your consideration of this serious matter.

Linda Stogsdill

CMS-1385-P-14339

Submitter : Cuong Hoang **Date:** 08/31/2007

Organization : Cuong Hoang

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Cuong Hoang

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am an office manager for a privately owned, small business physical therapy office. I have serious concerns over the number of patients I see that have sought physical therapy elsewhere because it was physician recommended. One of our current patients, who were a former patient, was told by her physician to go elsewhere for physical therapy even though she wanted to return to our clinic, which she eventually did. I believe this is unfair, especially to privately owned practices.

I urge the Federal Government to close the loophole in the Stark physical self-referral law and protect physical therapy services as Congress originally intended.

I also believe physical therapy services should be included in the in-office ancillary services exception.

Thank you for your time and consideration in this matter.

Sincerely,

Kathleen Sturtevant
Office Manager
Peak Performance Physical Therapy &
Sports Medicine, Inc.

Submitter : **JORDAN LYLES** **Date: 08/31/2007**

Organization : **JORDAN LYLES**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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JORDAN LYLES

Submitter : Mrs. Mary Presson **Date:** 08/31/2007

Organization : American Association of Nurse Anesthetists

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

Dear CMC Committee,
I have been a Certified Registered Nurse Anesthetist for 37 years and now need your help. We need the support of your committee to boost the proposal to increase the value of anesthesia work by 32% and increase the anesthesia conversion factor by 15% in 2008. This will ensure that all Medicare beneficiaries will continue to receive needed anesthesia services. As only one of 36,000 CRNA's serving Medicare beneficiaries serving our great America, we need this proposal(CMS-1385-P Background, Impact, Anesthesia Services) to be approved. Remember, CRNA's provide 27 million anesthetics annually in this great USA and are the predominant anesthesia provider to rural and underserved Americans...plus our dominance within all branches of our military. Thank you in advance for your support, M.E. Presson CRNA Conway, South Carolina

Submitter : **Angela Fricker** **Date: 08/31/2007**

Organization : **Angela Fricker**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthcsia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
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Angela Fricker

Submitter : **Jennifer McNabb** **Date: 08/31/2007**

Organization : **Jennifer McNabb**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Thank you for your consideration of this serious matter.

Jennifer McNabb

Submitter : **Jana Falconer** **Date: 08/31/2007**

Organization : **Jana Falconer**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Jana Falconer

CMS-1385-P-14346

Submitter : **Randy Compton** **Date: 08/31/2007**

Organization : **Randy Compton**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Thank you for your consideration of this serious matter.
Randy Compton

Submitter : **Nancy Spear**

Organization : **Nancy Spear**

Date: 08/31/2007

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Thank you for your consideration of this serious matter.
Nancy Spear

CMS-1385-P-14348

Submitter : **Ms. Sherrie Springer** **Date: 08/31/2007**

Organization : **Univ of Michigan MedSport**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

I have been a certified athletic trainer for the past twenty six years. For the past fifteen years, I have worked for the University of Michigan Hospital's MedSport outpatient physical therapy clinic in Ann Arbor, Michigan. In our setting, I work with a team of health care professionals to provide our patients with the best possible care and rehabilitation. It has been my experience that our patients are extremely pleased with the care they receive from myself as well as the other certified athletic trainers on our staff.

I received my Bachelor of Science degree in Health and Safety Education, Athletic Training and Biology at Indiana University in Bloomington in 1980. I completed my Master of Science degree in Athletic Training at the University of Arizona in Tucson, Arizona in 1981. I passed the National Athletic Trainers Association Board of Certification's national certifying exam also in 1981. In addition, in the State of Michigan, our governor, Jennifer Granholm, recently passed a bill for licensure of athletic trainers to ensure the quality of care for all patients.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day to day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

I appreciate your time and consideration.

Sincerely,

Sherrie L. Springer, MS, ATC
Certified Athletic Trainer
14211 HayRake Hollow
Chelsea, MI 48118
Home (734) 475-2908
Work (734) 930-7400

Submitter : **BILL MASSEY** **Date: 08/31/2007**

Organization : **BILL MASSEY**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
BILL MASSEY

Submitter : **Katie Compton** **Date: 08/31/2007**

Organization : **Katie Compton**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Katie Compton

Submitter : **Cindy Varela** **Date: 08/31/2007**

Organization : **Cindy Varela**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Cindy Varela

Submitter : **Brazil Varela** **Date: 08/31/2007**

Organization : **Brazil Varela**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Brazil Varela

Submitter : **Eric Steele** **Date: 08/31/2007**

Organization : **Eric Steele**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Eric Steele

Submitter : MENDY MASSEY **Date:** 08/31/2007

Organization : MENDY MASSEY

Category : Individual

Issue Areas/Comments

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MENDY MASSEY

Submitter : **Amy Compton** **Date: 08/31/2007**

Organization : **Amy Compton**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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Amy Compton

Submitter : **Kristi Beaver** **Date: 08/31/2007**

Organization : **Kristi Beaver**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Kristi Beaver

Submitter : **Gary Beaver** **Date: 08/31/2007**

Organization : **Gary Beaver**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Gary Beaver

Submitter : **BO MATTHEWS** **Date: 08/31/2007**

Organization : **BO MATTHEWS**

Category : **Individual**

Issue Areas/Comments

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
BO MATTHEWS

Submitter : **Kari Steele** **Date: 08/31/2007**

Organization : **Kari Steele**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.
Kari Steele

Submitter : **Doug Brownen** **Date: 08/31/2007**

Organization : **Doug Brownen**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.
Doug Brownen

Submitter : **Mr. Tony Anteau** **Date: 08/31/2007**

Organization : **Medcorp, Inc.**

Category : **Private Industry**

Issue Areas/Comments

Ambulance Services

Ambulance Services

Herb Kuhn
Acting Deputy Administrator
Centers for Medciare and Medicaid Services
Department of Health and Human Services
P.O.Box 8018
Baltimore, Maryland 21244-8018

Re: CMS-1385-P: "Geographical Price Cost Indices"

Dear Mr. Kuhn:

MedCorp, Inc. is a privately held Emergency Medical Services organization based in the State of Ohio. We provide service in Ohio, Michigan, Indiana, Kentucky, and West Virginia. Our organization is strongly opposed to any reductions in Medicare reimbursement for ambulance service providers as currently outlined in Proposed Rule CMS-1385-P. Any such reductions in reimbursement would have the unintended consequence of adversely affecting the availability and access to lifesaving emergency medical care of the residents in our service areas.

While we recognize the statutory requirements for CMS to update the GPCI, any reductions in reimbursement would be in direct contradiction to the findings of the May 2007 Government Accountability Office (GAO) report entitled "Ambulance Providers: Costs and Expected Medicare Margins Vary Greatly" (GAO-07-383) which determined that Medicare already reimburses ambulance providers on average 6% below their costs of providing services and 17% for providers in super rural areas. MedCorp would be greatly impacted in its ability to continue performing its vital lifesaving services with the proposed reductions in Medicare reimbursement for our services.

The GAO recommended that CMS monitor the utilization of ambulance transports to ensure that negative Medicare reimbursement does not impact beneficiary access to ambulance services. We believe a major disruption of service will occur on a national basis relative to ambulance services being able to remain viable with these proposed reductions in Medicare reimbursement.

We implore CMS to take this into consideration as it finalizes the Proposed Rule and alleviate any harmful impact these changes in the GPCI will have on providers, especially in a time when proposed INCREASES, not decreases, in reimbursement are so deperately needed.

Thank you for your consideration of these comments.

Sincerely,

Tony Anteau
Executive Vice President
MedCorp, Inc.

Submitter : **Mr. Scott Andrews** **Date: 08/31/2007**

Organization : **Wellness Coaches USA**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am an Athletic Trainer writing to you because of my concern about the proposed revivions to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

The oversight board of the department of public health in Massachusetts and Rhode Island has deemed the athletic training profession important enough to the public to issue a license and monitor those professional practising in state. I, like most of my colleagues, have earned an advanced degree allowing me to care for the orthopedic and other health needs of the active population.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,

Scott Andrews, MSS, LAT

CMS-1385-P-14364

Submitter : **James Horvath** **Date: 08/31/2007**

Organization : **Steel City Anesthesia**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

I don't understand why all of our groups, AANA, AAA, your Assembly, politically exploit the fact that this low reimbursement discriminates against our elderly. It makes them a fiscally undesirable patient. What politician would want to be responsible for such an accusation?

Submitter : **SU MATTHEWS** **Date: 08/31/2007**

Organization : **SU MATTHEWS**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
SU MATTHEWS

Submitter : **JoVanna Eisenbarth** **Date: 08/31/2007**

Organization : **JoVanna Eisenbarth**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.

JoVanna Eisenbarth

Submitter : **Charles Powell** **Date: 08/31/2007**

Organization : **NE GA Heart Center**

Category : **Physician**

Issue Areas/Comments

Resource-Based PE RVUs

Resource-Based PE RVUs

NE GA Heart Center supports the position conveyed by the Cardiology Advocacy Alliance to leave the utilization rate for equipment for echo and nuclear services at 50%. We are opposed to the bundling of 93325 into one code for each as time and effort is used to obtain this portion of the study by the tech and additional reading time and effort is necessary for the physician.

Submitter : **Joseph Tata** **Date: 08/31/2007**

Organization : **Joseph Tata**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Thank you for your consideration of this serious matter.

Joseph Tata

CMS-1385-P-14369

Submitter : **Ms. Anne Canfield** **Date: 08/31/2007**

Organization : **Rx Benefits Coalition**

Category : **Other Association**

Issue Areas/Comments

Proposed Elimination of Exemption for Computer-Generated Facsimiles

Proposed Elimination of Exemption for Computer-Generated Facsimiles

See Attachment.

CMS-1385-P-14369-Attach-1.DOC

#14369

Rx BENEFITS COALITION

Safety + Affordability + Innovation

September 10, 2007

Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: File Code CMS-1385-P

PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

The Rx Benefits Coalition (RxBC) appreciates the opportunity to submit its views concerning the Centers for Medicare & Medicare Services ("CMS") proposed rule ("NPRM") addressing, among other things, the proposed elimination of the exemption for computer-generated facsimile transmissions from the National Council for Prescription Drug Programs ("NCPDP") SCRIPT standard for transmitting prescription and certain prescription-related information for Medicare Part D eligible individuals. *See* 72 Fed. Reg. 38122 (July 12, 2007.).

RxBC represents a diverse group of employers and other payors and providers of prescription drug benefits and services committed to ensuring that consumers have access to safe and affordable prescription drug services through the use of proven market-based innovations in pharmaceutical care. One of those innovations is electronic prescribing ("e-prescribing"). RxBC is a strong advocate of e-prescribing, both in the Part D program and across all other venues in which drugs are prescribed and administered, because it enhances safety by reducing errors and reduces costs by making the information the prescriber and pharmacy need – such as medical history, formularies, prior authorization, step therapy, co-pays, deductibles -- immediately available for their use when prescribing a drug and filling a prescription.

RxBC appreciates and has supported efforts by CMS to accelerate the adoption of e-prescribing by approving "foundation standards" ahead of the April 1, 2008 date on which the Secretary was required to issue final e-prescribing standards under the Medicare Modernization Act of 2003 ("MMA"). We also support continuing efforts by CMS to encourage prescribers and pharmacies to adopt e-prescribing capability,

101 Constitution Ave., NW; 9th Floor West; Washington, DC 20001
Phone: (202) 742-4370 Fax: (202) 403-3926
www.rxbc.org

including the current proposal to eliminate the exemption for computer-generated faxes for prescribers that use software that is capable of generating SCRIPT transactions ("SCRIPT-compliant software") and prescribers that use legacy software that cannot generate SCRIPT transactions ("legacy prescribers"). We do recommend a later effective date than proposed in the NPRM for eliminating the exemption for legacy prescribers. It is unclear whether CMS's proposal would also eliminate the exemption for pharmacies communicating with SCRIPT-compliant prescribers. If it does, RxBC has concerns that are discussed in greater detail later in this comment letter.

1. Elimination of Exemption for Prescribers Using SCRIPT-Compliant Systems

RxBC supports the elimination of the exemption for computer generated faxes for prescribers that use SCRIPT-compliant software because we do not believe that eliminating the exemption will impose economic or workflow burdens on the prescribers that will cause them to revert to writing paper prescriptions.

- For those prescribers capable of generating Script transactions but are not doing so and are instead communicating with pharmacies through computer generated faxes, the cost of converting to SCRIPT transactions should be minimal. As CMS noted in the preamble to the NPRM: "the costs to convert to e-prescribing using NCPDP SCRIPT for these prescribers would in most cases be included in the annual maintenance fee they pay their software vendor."[1]

- Most SCRIPT-compliant software converts a SCRIPT transaction into a computer generated fax for those pharmacies using legacy software. Prescribers required to generate SCRIPT transactions will still be able to communicate with pharmacies with legacy systems so their workflow will not be interrupted.[2]

- The information the prescriber with SCRIPT-compliant software is required to input for a SCRIPT transaction versus a computer generated fax transaction and the method of inputting that information is essentially the same. There should be no disruption in the prescriber's workflow resulting from the need to learn a new procedure for SCRIPT transactions.

RxBC also believes that as these prescribers move to utilizing SCRIPT transactions as the result of elimination of the computer generated fax exemption they will become comfortable with and recognize the benefits of the SCRIPT transaction and advise their colleagues to acquire SCRIPT-compliant software.

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[1] 72 Fed. Reg. at 38195 (July 12, 2007)

[2] We have assumed for purposes of our analysis that prescribers transmitting prescriptions in NCPDP SCRIPT format could, under the CMS proposal, continue to utilize the software feature that converts a SCRIPT transaction into a computer generated fax for pharmacies using legacy software. If that is not the case and the proposal contemplates that the conversion feature in the software is to be disabled so legacy pharmacies can no longer receive a computer generated fax, a number of concerns arise which are discussed in greater detail on page 4 of this comment letter under "Elimination of Exemption for Pharmacies Communicating With SCRIPT-Compliant Prescribers."

Because elimination of the computer-generated fax exemption should not impose economic or workflow burdens on prescribers with SCRIPT-compliant software, RxBC believes the proposal to eliminate the exception "1 year after the effective date of the CY 2008 PFS final rule"[3] is reasonable.

2. Elimination of Exemption for Prescribers Using Legacy Systems

RxBC recognizes that eliminating the computer generated fax exemption for prescribers using legacy systems will have a greater impact them than on prescribers using SCRIPT-compliant systems because the cost to legacy prescribers of purchasing and installing SCRIPT-compliant software and the disruption to workflow while the prescribers learn how to use the software. CMS in the preamble to its final rule on e-prescribing noted that a prescriber using a legacy system:

> ". . . is merely using word processing software and the computer's fax capabilities in lieu of faxing paper. Requiring these prescribers to convert to e-prescribing using the foundation standards would likely result in their simply reverting to faxing paper. Consequently, requiring these entities to comply with the NCPDP SCRIPT Standard would force the vast majority of them to revert to paper faxes, and, thus, it would impose a significant burden on those entities presently using computer-generated faxing, and would be counterproductive to achieving standardized use of non-fax electronic data interchange for prescribing."[4]

However, it's important to recognize the context in which the final e-prescribing rule was issued on November 7, 2005. On that date, it was less than two months to the date on which the Medicare Part D program would become effective. Had the legacy prescribers not received a computer generated fax exemption, we concur with CMS that a "vast majority of them [would have] reverted to paper faxes." The legacy prescribers, many of whom would have had little or no experience in the area of SCRIPT transactions, would not have had ample time in that two month period to become comfortable with the provisions of the final e-prescribing rule or to make decision on whether an investment in a SCRIPT compliant system with its resulting workflow disruptions was in the best interest of their practice.

In the intervening two years since the final e-prescribing rule, we believe many legacy prescribers have been introduced, often by their colleagues, to the benefits of SCRIPT-compliant software, including the availability of a patient's medical history, the formulary and prior authorization of a patient's drug benefit, and the reduction in errors that can result both from the availability of the patient's medical history and the transmission of a prescription utilizing the SCRIPT standard. RxBC believes that knowledge of these benefits, coupled with the fact that the foundation standards have been adopted and that the remaining e-prescribing standards will become effective by April 1, 2009, will provide most legacy prescribers the necessary comfort level to acquire SCRIPT-compliant software when the computer-generated fax exemption is no longer available to them.

[3] 72 Fed. Reg. at 38196

[4] 70 Fed. Reg. 67571 (Nov. 7, 2005)

CMS noted in the preamble that "since January 2006, we have seen little reduction in the use of computer-generated fax technology."[5] This would suggest that legacy prescribers should be given ample time to move to SCRIPT-compliant software and to SCRIPT transactions. RxBC believes most legacy prescribers will make the move, rather than revert to paper faxes. We also believe that the more accommodative the final rule is to legacy prescribers the greater the number of them that will move to SCRIPT-compliant software. RxBC recommends that the effective date on which the computer-generated fax exemption should no longer be available to legacy prescribers should be April 1, 2009.

3. Elimination of Exemption for Pharmacies Communicating With SCRIPT-Compliant Prescribers

The NPRM observes that "SureScripts reports that all chain drug stores and 20 percent of independent pharmacies are capable of sending out and receiving SCRIPT transactions."[6] We are advised that most of the independent pharmacies that are not capable of sending or receiving SCRIPT transactions do have computer generated fax capability and that it is an important means of communicating with SCRIPT-compliant prescribers.

(a) Sending Computer Generated Faxes to Pharmacies

We noted earlier in footnote 2 our assumption that under the CMS proposal, a SCRIPT transaction originated by a prescriber could be converted to a computer generated fax so it could be received by a pharmacy that is not capable of receiving the SCRIPT transaction. If that assumption is incorrect, prescribers will not be able to communicate electronically with the 80 percent of independent pharmacies that cannot receive SCRIPT transactions with the result that communication between prescribers and these pharmacies will be in the form of written prescriptions and paper faxes with the attendant increase in errors resulting from such communications.

(b) Receiving Computer Generated Faxes from Pharmacies

The same results accrue if SCRIPT-compliant prescribers are not permitted under the CMS proposal to accept computer-generated faxes from those pharmacies. If the pharmacies are required to communicate with the prescriber in writing or by paper fax with respect to inquiries on prescriptions received from the prescriber or refill requests, the possibility of error increases and the margin of patient safety decreases.

(c) Elimination of Exemption Will Not Encourage Pharmacies to Become SCRIPT-Compliant

Prohibiting pharmacies from receiving or sending computer generated faxes from or to SCRIPT-compliant prescribers is unlikely to encourage them to acquire the capability needed to receive and send SCRIPT-compliant transactions. In an environment in which

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[5] 72 Fed. Reg. 38195

[6] Id.

independent pharmacies are seeking relief from Congress for oncoming changes to reimbursement rates under Medicaid and perceive increasing competition from retail pharmacies, most independent pharmacies will see little or no economic sense in incurring the cost of acquisition and installation SCRIPT-compliant software as well as the per transaction fees charged by most vendors for SCRIPT transactions.

In addition, prohibiting independent pharmacies from communicating with SCRIPT-compliant prescribers by computer-generated fax may discourage prescribers with SCRIPT-compliant software from moving to SCRIPT transactions if the volume of activity between prescribers and these independent pharmacies is sizable.

(d) Final Rule Should Not Eliminate Exemption for Pharmacies Communicating With SCRIPT-Compliant Prescribers

For the reasons discussed in (a) through (c) above, RxBC recommends that CMS delay issuing a rule eliminating the computer-generated fax exemption for pharmacies communicating with SCRIPT-compliant prescribers until the nationwide infrastructure supporting EHR systems has been put into place. Once the infrastructure is in place, these pharmacies can better ascertain whether prescribers that are not SCRIPT compliant plan to acquire an EHR system with SCRIPT-compliant software and convert to SCRIPT transactions. Based on that information, pharmacies can make a reasonable economic judgment as to whether it is worthwhile to take the necessary steps to enter into SCRIPT transactions.

(e) Timing

If CMS determines that the final rule should require that SCRIPT-compliant prescribers may not send or receive computer-generated faxes from or to pharmacies that are not SCRIPT compliant, RxBC strongly recommends that this requirement be delayed beyond the proposed effective date. For the reasons stated above, requiring compliance within that timeframe will cause independent pharmacies that are not SCRIPT compliant to revert to paper. In addition, as noted earlier, if a sufficient number of independent pharmacies revert to paper it may discourage prescribers with SCRIPT-compliant software from moving to SCRIPT transactions and legacy prescribers from acquiring SCRIPT-compliant software.

If CMS decides to eliminate the computer-generated fax exemption for pharmacies pursuant to the final rule, RxBC recommends that the effective date for elimination be no earlier than April 1, 2009, the date on which the final e-prescribing standards become effective. Moving the effective date to April 1, 2009, will allow pharmacies that are not SCRIPT compliant to determine the parameters of a comprehensive e-prescribing system and whether they are comfortable with those parameters. It will also permit them to ascertain whether legacy prescribers are converting to SCRIPT-compliant software and whether prescribers with the software intend to send prescriptions as SCRIPT transactions. With that information, those pharmacies can determine whether, given the coming repeal of the computer-generated fax exemption on April 1, 2009, it is in their best interest to become SCRIPT compliant.

4. Use of Computer-Generated Faxes During Temporary Communications Failures

RxBC recommends that the final rule recognize the possibility of temporary communications failures, such as connectivity failures or temporary outages of the prescriber's or pharmacy's computer or management systems, which could preclude the creation or transmission of SCRIPT transactions. During such failures, prescribers and pharmacies should be permitted to communicate via computer-generated faxes.

5. Tipping Point

For all of the reasons discussed above, RxBC does not believe that adoption of the CMS proposal to eliminate the computer-generated fax exemption will create a "tipping point" that causes independent pharmacies to adopt e-prescribing as suggested in the NPRM.[7] Instead, there are two broad initiatives that HHS and CMS should undertake to assure the success of e-prescribing.

First, CMS should implement comprehensive, uniform nationwide standards which would ensure interoperability. CMS's final e-prescribing rule did not accomplish this goal. In addition, these standards need to apply to prescriptions for controlled substances.[8] Unfortunately, CMS's final e-prescribing rule issued in 2005 created a "51st standard" that was limited to prescriptions for Part D drugs for Medicare beneficiaries. All other prescriptions, including those reimbursed by Medicaid, employer-provided plans, or self paid by individual patients are subject to the requirements imposed by the state or states in which the transaction occurs.

While the states and technology vendors have worked jointly in an attempt to accommodate the varying requirements by each state and the federal Medicare standards in an effort to facilitate e-prescribing, the absence of nationwide standards, applicable to all prescriptions, has resulted in inefficiencies and has driven up the costs of e-prescribing technology.

Second, in order to foster e-prescribing, CMS and HHS/OIG should revisit their rules with regard to the physician self-referral prohibitions and to the safe-harbors for the anti-kickback laws, respectively. Specifically, the current rules should be modified to more broadly facilitate the donation of technology systems to physicians and other health care providers. While physicians stand at the center of the relationship between the patient and other healthcare providers and payors, including hospitals, pharmacies, laboratories, and health insurers, the individual physician has little economic interest in adopting expensive technologies for e-prescribing and electronic health records because the economic benefits are dispersed throughout the health care system and do not accrue to the physicians as a direct financial incentive.

[7] Id.

[8] While we understand that this is outside of the purview of CMS, we nonetheless encourage CMS to continue to work with the Drug Enforcement Administration and the Department of Justice to resolve this impediment to a comprehensive and uniform e-prescribing system.

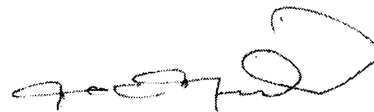
This barrier to incentivizing physician adoption could be overcome by allowing those with the financial capability and interest to more readily underwrite the cost of its implementation. Until the appropriate alignment of costs and benefits is allowed to occur in the health care marketplace, the hope of technological transformation of the health care system will remain unrealized.

We thank you for the opportunity to submit comments on the proposed rule to eliminate the computer-generated fax exemption RxBC supports CMS's ongoing efforts to encourage prescribers and pharmacies to move to true e-prescribing. We encourage CMS to move forward with the proposed rule incorporating the recommendations we have made herein.

Please do not hesitate to contact RxBC if you have further questions or require clarification.

Thank you.

Sincerely,



Anne C. Canfield
Executive Director

Submitter : **Richard Stone** **Date: 08/31/2007**

Organization : **Richard Stone**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

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LesV. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Richard Stone

Submitter : **Carsten Eisenbarth** **Date: 08/31/2007**

Organization : **Carsten Eisenbarth**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Carsten Eisenbarth

CMS-1385-P-14372

Submitter : Dennis Braggs

Date: 08/31/2007

Organization : Dennis Braggs

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Dennis Braggs

Submitter : **Nooria Tata** **Date: 08/31/2007**

Organization : **Nooria Tata**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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Nooria Tata

Submitter : DAN MCCARTNEY **Date: 08/31/2007**

Organization : DAN MCCARTNEY

Category : **Health Care Professional or Association**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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DAN MCCARTNEY

Submitter : **Margaret Bartlett** **Date: 08/31/2007**

Organization : **Margaret Bartlett**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
Baltimore, MD 21244-8018

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Margaret Bartlett

Submitter : **Patricia Bartlett** **Date: 08/31/2007**

Organization : **Patricia Bartlett**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Baltimore, MD 21244-8018

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Patricia Bartlett

Submitter : **John Bartlett** **Date: 08/31/2007**

Organization : **John Bartlett**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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P.O. Box 8018
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John Bartlett

Submitter : **Carissa Vandagriff** **Date: 08/31/2007**

Organization : **Carissa Vandagriff**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Aeting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Carissa Vandagriff

CMS-1385-P-14380

Submitter : Joyce Stone **Date:** 08/31/2007

Organization : Joyce Stone

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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Joyce Stone

Submitter : **Lorri Thomas** **Date: 08/31/2007**

Organization : **Lorri Thomas**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Lorri Thomas

CMS-1385-P-14382

Submitter : **Ralph Bruton** **Date: 08/31/2007**

Organization : **Ralph Bruton**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Ralph Bruton

Submitter : **Floyd Vandagriff** **Date: 08/31/2007**

Organization : **Floyd Vandagriff**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Floyd Vandagriff

Submitter : **Dorothy Bruton** **Date: 08/31/2007**

Organization : **Dorothy Bruton**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Dorothy Bruton

Submitter : **Jason Bashforth** **Date: 08/31/2007**

Organization : **Jason Bashforth**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Jason Bashforth

Submitter : **Robert Rose** **Date: 08/31/2007**

Organization : **Robert Rose**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Robert Rose

CMS-1385-P-14388

Submitter : Ms. Rebecca DeCourcey **Date:** 08/31/2007

Organization : NA

Category : Individual

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Aug. 31, 2007

Re: Docket ID CMS-1385-P

Dear Sir or Madam:

The therapy standards proposed by CMS in the Physician Fee Schedule will harm the patients of athletic trainers and create access problems. There is a strong possibility that with these Byzantine and onerous rules will, in fact, decrease the quality of services provided to Medicare beneficiaries. These CMS proposed rules are not supported by any objective reports or other rationale that has been made public.

As a young and active individual, I grew up using athletic training services as a student athlete. In fact, it was a certified athletic trainer that helped me to recover after a serious hip injury sustained during high school cross country. Because of the services provided by a certified athletic trainer, I am healthy and able to run marathons on a regular basis. I hope to continue to remain active into my old age. The thought that this CMS ruling could limit my access to services provided by certified athletic trainers, is very discouraging. I know first hand, the abilities, knowledge and skills that athletic trainers have and they are my first choice when seeking scrvices for musculoskelctal injuries and illnesses. If you ask me, or any of my friends, I know that everyone will tell you that every athletic trainer they have worked with was fully qualified to assess, treat and rehabilitate their injuries.

I believe these new rules will greatly harm non-Medicare patients like myself. Anytime Medicare makes a rule it eventually gets adopted in the private sector. Millions of secondary school and college students will lose access to services. Millions of seniors recovering from hip replacement and other orthopedic surgeries and conditions will lose access. Is this want Medicare intends?

These are unnecessary and unreasonable rules. I want to choose the best provider for me especially now that I have a Health Spending Account and that flexibility.

These new therapy standards and rules do not make much sense. I respectfully request that CMS considers reversing all rules, past and present, that restrict the ability of athletic trainers to lawfully practice their profession.

Sincerely,

Rebecca DeCourcey

Submitter : **John Martin** **Date: 08/31/2007**

Organization : **John Martin**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

John Martin

Submitter : **Brad Thomas** **Date: 08/31/2007**

Organization : **Brad Thomas**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Brad Thomas

Submitter : **Raenalle DeGidio** **Date: 08/31/2007**

Organization : **Raenalle DeGidio**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Raenalle Degidio

CMS-1385-P-14392

Submitter : **Ms. Sherrie Springer** **Date: 08/31/2007**

Organization : **University of Michigan MedSport**

Category : **Other Health Care Professional**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P. I have been a certified athletic trainer for the past twenty six years. For the past fifteen years, I have worked for the University of Michigan Hospital's MedSport outpatient physical therapy clinic in Ann Arbor, Michigan. In our setting, I work with a team of health care professionals to provide our patients with the best possible care and rehabilitation. It has been my experience that our patients are extremely pleased with the care they receive from myself as well as the other certified athletic trainers on our staff. I received my Bachelor of Science degree in Health and Safety Education, Athletic Training and Biology at Indiana University in Bloomington in 1980. I completed my Master of Science degree in Athletic Training at the University of Arizona in Tucson, Arizona in 1981. I passed the National Athletic Trainers Association Board of Certification's national certifying exam also in 1981. In addition, in the State of Michigan, our governor, Jennifer Granholm, recently passed a bill for licensure of athletic trainers to ensure the quality of care for all patients. While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients, family and friends. As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards. I am also concerned about the potential job loss and economic impact for a very capable group of health care professionals, namely certified athletic trainers. The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available. Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day to day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility. I appreciate your time and consideration. Sincerely, Sherrie L. Springer, MS, ATC Certified Athletic Trainer 14211 HayRake Hollow Chelsea, MI 48118 Home (734) 475-2908 Work (734) 930-7400

Submitter : **Dr. Hans Hansen** **Date: 08/31/2007**

Organization : **Dr. Hans Hansen**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Attachment

EPARTMENT OF HEALTH AND HUMAN SERVICES
ENTERS FOR MEDICARE AND MEDICAID SERIVICES
FFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

lea:: note: We did not receive the attachment that was cited in his comment. We are not able to receive attachments that have been repared in excel or zip files. Also, the commenter must click the ellow "Attach File" button to forward the attachment.

lease direct your questions or comments to 1 800 743-3951..

Submitter : **Eloise Martin** **Date: 08/31/2007**

Organization : **Eloise Martin**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Eloise Martin

Submitter : **Joe Carrier** **Date: 08/31/2007**

Organization : **Joe Carrier**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Joe Carrier

CMS-1385-P-14396

Submitter : **Kari Sturtevant** **Date: 08/31/2007**

Organization : **Peak Performance**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am the owner and physical therapist of an independent, private physical therapy office. I have a series of concerns regarding referral for profit physician/physical therapist relationships. I believe that these relationships are unethical.

A number of our previous patients have been forced to receive additional physical therapy services in their physician s office because their physician strongly encouraged them to do so. Our practice is known to be one of the best in the area, so quality of care was certainly not the issue. These arrangements are harmful to patients since they don t receive the best care possible. Small business owners suffer as well. Regardless of how effective and efficient our services are, the physician that profits from self referral will not refer out of his/her system.

I urge the Federal Government to close the loophole in the Stark physical self-referral law and protect physical therapy services as Congress originally intended.

I also believe physical therapy services should be included in the in-office ancillary services exception.

Thank you for your time and consideration in this matter.

Sincerely,

Kari Sturtevant
Physical Therapist and Owner
Peak Performance Physical Therapy &
Sports Medicine, Inc.

Submitter : **Michelle Spurling** **Date: 08/31/2007**

Organization : **Michelle Spurling**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Michelle Spurling

Submitter : **LOIS MCCARTNEY** **Date: 08/31/2007**

Organization : **LOIS MCCARTNEY**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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LOIS MCCARTNEY

Submitter : **Shanda Jackson** **Date: 08/31/2007**

Organization : **Shanda Jackson**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

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Acting Administrator
Centers for Medicare and Medicaid Services
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Shanda Jackson

Submitter : **Dale Hottel** **Date: 08/31/2007**

Organization : **Dale Hottel**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Dale Hottel

CMS-1385-P-14401

Submitter : John Spurling **Date:** 08/31/2007

Organization : John Spurling

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

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John Spurling

Submitter : **Gretchen Bashforth** **Date: 08/31/2007**

Organization : **Gretchen Bashforth**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
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Gretchen Bashforth

Submitter : **Donald Wood** **Date: 08/31/2007**

Organization : **Donald Wood**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Donald Wood

Submitter : **Darlene Hottel** **Date: 08/31/2007**

Organization : **Darlene Hottel**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Darlene Hottel

Submitter : Dr. Marc Valley

Date: 08/31/2007

Organization : Dr. Marc Valley

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment

CMS-1385-P-14405-Attach-1.DOC

1/4/05

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. **CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.**

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05	Interventional Pain Management Physicians

	(Non-Facility)	- 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge

CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Marc A. Valley, MD, MS
Medical Director, Southeastern Pain Management Center
3183 West State Street, Suite 1101
Bristol, Tennessee 37620

Submitter : **Tammy Wood** **Date: 08/31/2007**

Organization : **Tammy Wood**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Tammy Wood

CMS-1385-P-14407

Submitter : JOE MCKENZIE **Date:** 08/31/2007

Organization : JOE MCKENZIE

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
JOE MCKENZIE

CMS-1385-P-14408

Submitter : Wayne Hyams **Date:** 08/31/2007

Organization : Wayne Hyams

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Wayne Hyams

Submitter : **Delbert Heskett** **Date: 08/31/2007**

Organization : **Delbert Heskett**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Delbert Heskett

CMS-1385-P-14410

Submitter : **Yvonne Hyams** **Date: 08/31/2007**

Organization : **Yvonne Hyams**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Yvonne Hyams

Submitter : **Dr. James Sparrow** **Date: 08/31/2007**

Organization : **Dr. James Sparrow**

Category : **Physician**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

James Sparrow, MD
Assistant Professor Of Anesthesiology
UAB Hospital Birmingham, AL
205-531-6993

Submitter : **Geneva Heskett** **Date: 08/31/2007**

Organization : **Geneva Heskett**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Geneva Heskett

Submitter : **Rick Castleberry** **Date: 08/31/2007**

Organization : **Rick Castleberry**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Rick Castleberry

Submitter : Ken Jackson **Date:** 08/31/2007

Organization : Ken Jackson

Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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Thank you for your consideration of this serious matter.
Ken Jackson

Submitter : **Catherine Thompson** **Date: 08/31/2007**

Organization : **Catherine Thompson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
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Thank you for your consideration of this serious matter.

Catherine Thompson

Submitter : **Mrs. Susan Thompson** **Date: 08/31/2007**

Organization : **San Benito County California**

Category : **Local Government**

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

San Benito County California is a regional neighbor and shares jurisdictional boarders with the counties of Monterey and Santa Cruz. As such we share many regional health care physicians and practices. Medicare physician fees in our geographic region are in dire need of adjustment to recognize the high cost of providing services here.

It is our belief that Option 3-revision to payment localities of the proposed rule is the most equitable and best option for California, but its calculation is faulty. If properly computed San Benito would qualify to be moved into the same locality as Monterey. The data that should be used to correctly calculate adjustments is the information unearthed by the General Accounting Office in its June Report.

Please review this data and it will be apparent that our needs in San Benito County are equally significant to our neighbor counties.

Our small (57,000 population) agricultural county is already underserved by medical professionals and our residents must not loose ground do to inaccruate computations of the GPCIs.

Submitter : **Lawrence Thompson** **Date: 08/31/2007**

Organization : **Lawrence Thompson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Lawrence Thompson

CMS-1385-P-14418

Submitter : **Preston Moorad** **Date: 08/31/2007**

Organization : **Preston Moorad**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Preston Moorad

Submitter : Dr. Thomas Nieradka **Date:** 08/31/2007

Organization : Dr. Thomas Nieradka

Category : Chiropractor

Issue Areas/Comments

GENERAL

GENERAL

Re Technical corrections
The proposed rule dated July 12 calls for the current regulation that permits a beneficiary to be reimbursed by Medicare for an X-ray taken by a non treating provider and used by A Doctor of Chiropractic to determine a subluxation, be eliminated. I am writing in strong opposition to this proposal.

While subluxation does not need to be detected by an X-ray, in some cases the patient clinically will require an X-ray to identify a subluxation or to rule out any red flags, or to also determine diagnosis and treatment options. X-ray may also be required to help determine the need for further diagnostic testing, i.e. MRI or for a referral to the appropriate specialist.

by limiting A Doctor of Chiropractic from referring for an X-ray study, the costs for the patient care will go up significantly due to the necessity of a referral to another provider(orthopedist or rheumatoloist,etc.) for duplicative evaluation prior to referral to the radiologist. With fixes incomes and limited resources seniors may choose to forgo X-rays and thus needed treatment. If treatment is delayed illnesses that could be life threatening may not be discovered. Simply put, itis the patient that will suffer as a result of this proposal.

I strongly urge you to table this proposal. These X-rays if needed, are integral to the overall treatment plan of Medicare patients and, it is ultimately the patient that will suffer should this proposal become standing regulation

Sincerely,

Dr. Thomas D. Nieradka
Midland Chiropractic Center

CMS-1385-P-14420

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14420-Attach-1.PDF

14920

August 30, 2007

K. WOODHOUSE'S DIRECT NUMBER: (317) 236-2154
DIRECT FAX: (317) 592-4798
INTERNET: Kevin.Woodhouse@icemiller.com

T. SMITH'S DIRECT NUMBER: (317) 236-2482
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INTERNET: Taryn.Smith@icemiller.com

Submitted Electronically

Acting Administrator Leslie Norwalk
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

Attn: File Code CMS-1385-P

Re: ***Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008 Payment Rates; Proposed Rule***

Dear Administrator Norwalk:

We are writing on behalf of our client, a large, multi-specialty physician group ("Group"). We appreciate the opportunity to provide CMS with the Group's comments on the proposed changes to the Physician Fee Schedule for Calendar Year 2008 Payment Rates ("Proposed Rule") and their effects on the Group.

Effects of Proposed Revisions Generally

In the Proposed Rule, CMS proposes a 9.9% across-the-board cut in physician payment rates. The Group strongly opposes the payment cuts as proposed by CMS. The Group believes that the changes in the Proposed Rule will most dramatically affect and further disadvantage private practice physician groups to the benefit of hospital system providers.

Physician reimbursement is already steadily declining and is not keeping pace with the increasing practice overhead expenses of providing care. For generations, the independent physician group has been the stalwart of the health care delivery system in this country. However, continued reimbursement cuts and further restriction of the medical services a private practice physician can provide, as contemplated by the Proposed Rule, will make the independent physician provider a dying breed in many parts of the country. The Group believes that private practice physician groups cannot afford to be further disadvantaged to the benefit of hospital system providers who enjoy higher reimbursement for similar services and, in many

instances, the financial benefit of tax-exempt status. The Group believes that if the payment cuts in the Proposed Rule are finalized, healthcare costs will be driven up overall as patients are pushed into hospital-owned facilities, emergency rooms, and urgent care facilities for routine medical care, which are often paid at higher reimbursement rates than physician-owned facilities.

The Group further believes that hospitals are also advantaged by the wide latitude they enjoy to create built-in referral relationships by employing physicians. Hospitals are hiring physicians at an alarming rate in an effort to lock up referral streams, thereby generating millions of dollars in referrals from employed doctors. A recent study by a national physician search and consulting firm found that an employed physician generates approximately $1.5 million dollars in revenue for the affiliated hospital. If the "indirect" referred business is also taken into account that number jumps to between $4 and $5 million dollars in revenue annually. As a result, the Group believes that hospitals can often pay doctors at higher rates than a private physician group. Private practice groups are doubly squeezed. Private practice groups have to compete with inflated hospital salaries to attract new and replacement physicians and changes in the regulatory environment are narrowing the services a non-hospital employed physician can provide to his/her patients, making it harder for independent private practice groups to find and retain physicians. The Group believes that this will be the death knoll of the primary care physician. The Group urges CMS not to finalize the proposed changes.

Anti-Markup Rule

In the Proposed Rule, CMS is proposing to expand the Anti-Markup Rule to the technical and professional component services whether they are "purchased interpretations" or provided under reassignment, unless the performing supplier is a full-time employee of the billing entity. Additionally, CMS is proposing to exclude from the "net charge" that can be passed through to Medicare any amount attributable to rent or similar charges paid by the supplier to the billing entity for space or equipment related to the provision of the interpretations.

The Group is very concerned about limiting mark-ups of purchased interpretations or interpretations and professional services provided under reassignment to a group's full-time employees. The Group believes that this ignores the reality of many situations where, due to geographical limitations, the only feasible way for an independent private practice group to get services from a physician at all is to bring the physician in as a part-time employee or independent contractor of the group and provide the office and support for the part-time or independent contractor physician. These physicians' services are integral to the Group and in order for the Group to continue to be able to make these services available to its patients, the Group must be able to bill for what it pays the independent contractor physician taking into account billing and related direct costs of providing these professional services. However, the Group believes that there should still be a requirement that the physician be in the Group's space and using the Group's equipment and staff when providing services to the Group.

In-Office Ancillary Exception

Generally

The Group is urging CMS to make no further revisions to the In-Office Ancillary Exception. The Group feels that further restrictions in the In-Office Ancillary Exception could decimate private practice clinics that offer a wide range of services or one-stop services for their patients. The immediate and direct effect of a change to the in-office ancillary exception would be to drive more primary and specialty care doctors out of a private practice physician model and into hospital-employed practice models, thereby limiting patient access to care, significantly increasing cost to the overall healthcare system, and stifling competition.

The Group urges that if CMS has concerns related to the in-office ancillary exception, the focus should be on quality measures and meeting national accreditation standards, not on ultimate ownership. If the physician practice owns the equipment, employs the staff, provides the space and meets quality standards, it should be treated no differently than any other provider.

Centralized Building

In the Proposed Rule, CMS asked whether, and if so, how CMS should change the definition of "same building" and "centralized building."

The Group believes that there are already stringent requirements for what constitutes a "centralized building" for purposes of the in-office ancillary exception and no further changes should be made. The Group further believes that doctors should be encouraged to avoid duplication of equipment and services by continuing to be allowed to share in-office ancillaries if they are all under one roof, whether this is by means of a block time lease or through shared expenses. To restrict otherwise would encourage duplication of services, stifle competition, limit patient access, and drive patients to hospital-owned facilities which typically cost more than their physician-owned equivalents.

Ownership by Non-Specialists

In the Proposed Rule, CMS asked whether non-specialist physicians should be able to use the exception to refer patients for specialized services that will be performed on equipment owned by non-specialist physicians.

The Group believes that this request ignores the reality of multi-specialty groups. It assumes that groups are either all primary care physicians or all physicians from one specialty. The Group believes that if the service is within the physician's scope of practice and licensure, there should be no restrictions other than quality measures. If the physician practice owns the equipment, employs the staff, provides the space and meets quality standards, they should be treated no differently than any other provider.

Services Performed "Under Arrangements"

The Stark regulations prohibit a physician from making referrals for designated health services ("DHS") to an entity with which the physician has a financial relationship and prohibits the entity from billing Medicare for such DHS unless an exception applies. In an "under arrangements" relationship, an outside supplier furnishes the services and the hospital bills for the services, thus the outside supplier is not an "entity" for purposes of Stark Law. The only entity submitting a claim to Medicare is the hospital.

The Group urges CMS to make no change to the definition of entity. Many "under arrangements" relationships have existed for many years and benefit both the hospital and the patient. The hospital is able to secure services that it otherwise could not efficiently provide and instead allows the hospital to contract with an outside supplier, often an expert in these services, to provide the services to the hospital's patients. The Group believes that CMS should preserve the "under arrangements" relationship for situations where a physician or his/her group practice has the expertise to provide a service that the hospital does not have at all or does not have in a particular locality versus the situation where the hospital parcels out an existing hospital service to various unrelated physicians and flips the hospital service to an "under arrangement" relationship.

Additionally, not all "under arrangements" relationships result in higher Medicare reimbursement levels. The Group urges CMS to address any incentives due to differences in reimbursement levels between physician fee schedule and hospital outpatient prospective payment system (HOPPS) by eliminating those differences in reimbursement rather than revising the definition of "entity." This would then allow patients to continue to utilize the most convenient, appropriate location for required services.

Finally, the Group cannot stress enough the drastic and inequitable impact that implementation of the proposed changes would have on the future going-concern of a private practice physician model to the benefit of hospital system providers. As mentioned above, the independent physician group has been the stalwart of the health care delivery system in this country for generations. Continued reimbursement cuts and the increasing cost of providing medical care, compounded by layers of regulations that restrict the medical services that physicians can provide, have made the private practice physician a dying breed in many parts of the country. Independent physician groups cannot be further disadvantaged to the benefit of hospital system providers who enjoy special privileges of significantly higher reimbursement for similar services, wide latitude to create built-in referral relationships by employing physicians and, in many instances, the financial benefit of tax-exempt status. If implemented, the Group strongly believes that the proposed changes in the Proposed Rule will increase healthcare costs while also limiting patient access to care and stifling competition.

Again, the Group appreciates the opportunity to comment on the Medicare Physician Fee Schedule 2008 Proposed Rule and looks forward to continuing to work cooperatively with CMS

in order to address these important issues in an equitable manner. Please do not hesitate to contact us if you have any questions about these comments and recommendations.

Respectfully submitted,

Ice Miller LLP

Kevin C. Woodhouse

Taryn E. Smith

KCW:TES:lll

I/2003865.3

Submitter : **Nelson Strother** **Date: 08/31/2007**

Organization : **Nelson Strother**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Nelson Strother

Submitter : **Mrs. Laura Husak** **Date: 08/31/2007**

Organization : **DBE, inc dba Hendersonville Sports Medicine**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

I am a co-owner of an outpatient physical therapy and sports medicine clinic. My partner and I are both certified, licensed athletic trainers and have been serving our profession for a combined 40 years. We employee 5 physical therapists, 2 physical therapist assistants and 2 ATC/L other than ourselves. These ATCs work primarily in the high schools (at no cost to the schools) to provide quality care to their athletes. They also act as aids in the clinic intermittently. It would be a huge loss to our patients to loose such an important part of their treatment team.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Submitter : **Sean Jackson** **Date: 08/31/2007**

Organization : **Sean Jackson**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.
Sean Jackson

Submitter : **Leslie Strother** **Date: 08/31/2007**

Organization : **Leslie Strother**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Leslie Strother

CMS-1385-P-14426

Submitter : **Angela Moorad** **Date: 08/31/2007**

Organization : **Angela Moorad**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Centers for Medicare and Medicaid Services
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P.O. Box 8018
Baltimore, MD 21244-8018

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Angela Moorad

CMS-1385-P-14427

Submitter : **George Lesikar** **Date: 08/31/2007**

Organization : **George Lesikar**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

George Lesikar

Submitter : **Dr. Kathleen Cumbest** **Date: 08/31/2007**

Organization : **Dr. Kathleen Cumbest**

Category : **Physician**

Issue Areas/Comments

GENERAL

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Thank you for your consideration of this serious matter.

Kathleen Cumbest, MD
Birmingham, AL

Submitter : **Jerri Lesikar** **Date: 08/31/2007**

Organization : **Jerri Lesikar**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Ageney is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly duc to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia serviees stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Jerri Lesikar

Submitter : **Bob Steves** **Date: 08/31/2007**

Organization : **Bob Steves**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
Bob Steves

CMS-1385-P-14431

Submitter : **Sasa Jackson** **Date: 08/31/2007**

Organization : **Sasa Jackson**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Sasa Jackson

CMS-1385-P-14432

Submitter : **Alex Himaya** **Date: 08/31/2007**

Organization : **Alex Himaya**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Serviccs
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Aeting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Alex Himaya

Submitter : Mrs. Cynthia Ransburg-Brown

Date: 08/31/2007

Organization : Sirote

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1385-P-14433-Attach-1.DOC

THOMAS A. ANSLEY
HAROLD I. APOLINSKY
JOHN BAGGETTE
KATHERINE N. BARR
S. TRAVIS BARTEE
ROBERT R. BAUGH
ROBIN L. BEARDSLEY
CHRISTOPHER S. BERDY
JOSEPH S. BLUESTEIN
CHRISTOPHER A. BOTTCHER
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C. BRANDON BROWNING
JOHN P. BURBACH
DANIEL J. BURNICK
TIMOTHY A. BUSH
JULIAN D. BUTLER
W. TODD CARLISLE
JAMES B. CARLSON
JOHN GREGORY CARWIE
FRED L. COFFEY, JR.
RICHARD COHN
STEPHEN G. COLLINS
JOHN H. COOPER
KRISTEN S. CROSS
R. RYAN DAUGHERTY
J. MASON DAVIS, JR.
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KARL B. FRIEDMAN
EDWARD M. FRIEND, III
RUSSELL CARTER GACHE'
STEPHEN R. GEISLER
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PETER J. HARDIN
JACK E. HELD
JERRY E. HELD
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JOHN M. HUNTER
ELIZABETH H. HUTCHINS
DONALD E. JOHNSON
SHIRLEY M. JUSTICE
RONALD A. LEVITT
ALLISON REID LUMBATIS
MICHAEL B. MADDOX
JAY G. MAPLES
MELINDA M. MATHEWS
J. RUSHTON McCLEES
KERRY P. McINERNEY
DAVID R. MELLON
JEFFREY G. MILLER
RICHARD L. MORRIS
T. JULIAN MOTES
J. SANFORD MULLINS, III
GEORGE M. NEAL, JR.
RODNEY E. NOLEN

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CYNTHIA RANSBURG-BROWN
C. LEE REEVES
MATTHEW B. REEVES
J. JEFFERY RICH
JOE H. RITCH
JOSEPH T. RITCHEY
KELLI F. ROBINSON
MAURICE L. SHEVIN
J. SCOTT SIMS
BRADLEY J. SKLAR
ANTHONY R. SMITH
KYLE T. SMITH
RODERIC G. STEAKLEY
CRAIG M. STEPHENS
JUDITH F. TODD
THOMAS G. TUTTEN, JR.
GEORGE M. VAN TASSEL, JR.
JAMES E. VANN
JAMES S. WILLIAMS
CATHERINE L. WILSON
DAVID M. WOOLDRIDGE
DONALD M. WRIGHT
PETER M. WRIGHT

REGISTERED PATENT ATTORNEYS:
C. BRANDON BROWNING
RUSSELL CARTER GACHE'
J. JEFFERY RICH

OF COUNSEL:
JULIE W. JORDAN
LEIGH A. KAYLOR
STUART LEACH
COLLEEN McCULLOUGH
WANDA S. McNEIL
JOEL A. MENDLER
DIANE C. MURRAY
DAVID M. O'BRIEN
MICHAEL R. PILLSBURY
GINNY COCHRAN RUTLEDGE
JAMES R. STURDIVANT
JEFF G. UNDERWOOD
VICTOR S. VASILE
SANDRA L. VINIK
CAROLINE E. WALKER
SUSANNAH R. WALKER
CYNTHIA W. WILLIAMS

MORRIS K. SIROTE (1909-1994)
JAMES L. PERMUTT (1910-2005)
E. M. FRIEND, JR. (1912-1995)
WILLIAM G. WEST, JR. (1922-1975)
MAYER U. NEWFIELD (1905-2000)

September 14, 2007

VIA OVERNIGHT DELIVERY

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **CMS-1385-P**
Physician Self-Referral Provisions
In-Office Ancillary Services Exception

Dear Sir/Madam:

We represent individual physicians, physician group practices, physical therapists, facilities, freestanding ambulatory surgery centers, institutions and a number of associations and networks comprised of physicians and physician-related entities and joint ventures. We submit these comments on their behalf in response to **File Code CMS-1385-P**, *Medicare Program; Proposed Regulations to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008* published in 72 Federal Register 38122 on July 12, 2007 ("Regulations").

In particular, this comment addresses the proposed changes to the **Physician Self-Referral Provisions: In-Office Ancillary Services Exception**. According to the regulatory preamble, CMS, and certain comments to the Phase I and Phase II physician self-referral rules, indicate that the In-Office Ancillary Services Exception is susceptible to abuse. CMS also states that it has received "hundreds of letters from physical therapists and occupational therapists stating [that] the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices." Unfortunately, however, CMS fails to cite any of the arguments raised in those letters or to elaborate on its "concerns."[1]

[1] **We specifically request that CMS elaborate its concerns in this area and acknowledge that the numbers of letters received on a subject are not always indicative of the gravity of the issue or the need for correction.**

Instead, CMS has requested comments on "whether certain services should not qualify for the exception." As an example, CMS specifically mentions "any therapy services that are **not** provided on an "incident to" basis and services that are **not** needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment."

Previously, the **Phase II Regulatory Preamble** included specific inquires from physical therapists and a professional association representing physical and occupational therapists. In response to their inquiries, CMS responded that the Stark rules are not the "appropriate vehicle" for the changes proposed by the therapists and the professional association. 69 Federal Register at 16071 - 16072. We agree and submit now, more than three years later, that the Stark Law and its regulations are still **not** the "appropriate vehicle" for the changes sought by these groups. This is essentially a "turf battle" being waged by private practice physical therapists against POPTS at the state and now, federal, level, which is being pursued with an anti-competitive purpose against physician-owned physical therapy services.

If the In-Office Ancillary Services Exception is limited to only those physical therapy services that are provided as "incident to," CMS will be using the Stark Law in a manner for which it was never intended - that is - (1) to change the physician supervision requirements for therapy services provided in private physician offices[2]; and (2) to restrict access to therapy services. The Stark Law is intended to restrict physician referrals to entities with which the physician has a financial relationship that does not meet an applicable statutory or regulatory exception. The Stark Law does not, and should not, alter Medicare billing, claims submission or physician supervision policies and requirements, but must work within those stringent policies to effectuate its purpose.

The concerns raised by CMS regarding "non-incident to" therapy services provided in physician offices is unwarranted. Many physicians, especially those specializing in orthopaedics, occupational medicine, and physical medicine and rehabilitation services, are keenly aware of the continuity of care and successful medical outcomes resulting from an interdisciplinary team approach to surgery, therapy, rehabilitation, and recovery. Physician office practices have engaged or employed therapists to provide therapy services within the physician office environment for many years. Such practices, referred as a POPTS, must, and do, comply with very strict federal laws and regulations, which prevent any improper relationships, overutilization of services or performance of unnecessary services.

POPTS provides continuous oversight and overall physician supervision, which reduces cost to the Medicare Program.[3] It is far superior to situations where the physician only receives periodic, delayed reports of the patient's progress. POPTS focus on a team approach for the delivery of health care services within a physician group practice that is more convenient for the patient, who is always free to choose his or her therapy provider, and is consistent with current Medicare billing rules and the In-Office Ancillary Services Exception.

Indeed, this effort reflects an ongoing attempt by physical therapists in private practice and national and state physical therapy associations to eliminate competition from physician-employed physical therapists and Physician-Owned PT Services ("POPTS").

[2] The In-Office Ancillary Services Exception follows the Medicare physician supervision requirements. Consequently, whatever level of physician supervision is required for Medicare billing purposes is the same level of physician supervision required when those services are provided (and protected) under the In-Office Ancillary Services Exception.

[3] The continuous physician oversight and supervision reduces cost to the Medicare Program because the treating physician is continually aware of the patient's improvement and can modify the therapy regimen as necessary at each visit.

Current Medicare billing rules require a physician order before physical therapy services may be provided to Medicare beneficiaries. Medicare billing rules also permit a physician to provide physical therapy services or to hire a PT to provide therapy services in-office to the physician practice patients, provided all of the applicable billing rules are met, and the individual providing the physical therapy services is appropriately qualified and meets specific Medicare requirements. Nothing in the Stark statute or regulations prohibits physicians from providing therapy services as a core component of a physician's practice so long as such services are "not essentially a separate business enterprise.[4]" 69 Federal Register 16074. Attempts to modify the In-Office Ancillary Services Exception to prevent physician office physical therapy services is an unwarranted intrusion into physician practices and significantly impairs a physician's right to practice medicine.

Often times, ancillary services are ordered by a physician at one visit, but provided to the patient on a subsequent visit to the physician's office. The separate patient encounter may not require a direct encounter with the physician, and may not be required for Medicare billing purposes. These types of visits occur routinely in physician offices and may involve all types of ancillary services, not just physical and occupational therapy services. We strongly urge CMS **not** to implement changes to the In-Office Ancillary Services Exception that would restrict access to physical therapy services provided in physician offices when those services are provided by qualified therapists and when those services are not provided as "incident to" services.

We encourage CMS to share its "concerns" with the POPTS community for specific feedback before any decision regarding changes to the exception are implemented that would result in restricted patient access to Physician-Owned Physical Therapy Services.

Sincerely,

Lenora

Lenora W. Pate
FOR THE FIRM

Cynthia

Cynthia Ransburg-Brown
FOR THE FIRM

LWP/CRB/cm

---

[4] **Most physician group practices, which offer therapy services as an ancillary service to their patients, generally do not accept PT referrals from physicians who are not a part of the physician office practice. Consequently, a "separate business enterprise" is rarely an issue.**

Submitter : **Mr. Joseph Greene** **Date: 08/31/2007**

Organization : **University of Wisconsin Hospital**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

To Whom it May Concern,

My name is Joseph Greene and I am the Supervisor of Athletic Training Services for UW Health Sports Medicine at the University of Wisconsin Hospital. Additionally, I represent nearly 1000 athletic trainers in the State of Wisconsin as I am the President of the Wisconsin Athletic Trainers'Association, Inc. As part of my job, I also work to represent the employment of the 35 athletic trainers within our hospital that function in multiple roles. This includes the provision of rehabilitation services.

In my Supervisory role, I oversee the work of athletic trainers in multiple capacities and I have significant concerns about how the proposed rule changes could potentially affect the access of our active population to rehabilitation services. The rule changes could work to limit the choices of patients to a small number of qualified rehabilitation providers. There are many other qualified providers whom are safe and effective providers.

As an athletic trainer in Wisconsin, we are Licensed in the State of Wisconsin and Certified nationally. Our state practice act allows us to treat and rehabilitate active individuals of all types. Why should age or desired activity level dictate who a provider can see if the respective professional is trained properly?

I continually see that we have a shortage of access and allied health providers in this country. Yet these proposed changes work to restrict access further. They would also work to keep an athletic trainer in Wisconsin from practicing under their practice act.

Specifically, I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

While I am concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting, I am more concerned that these proposed rules will create additional lack of access to quality health care for my patients.

As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. State law and hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill therapy positions is widely known throughout the industry. It is irresponsible for CMS, which is supposed to be concerned with the health of Americans, especially those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage the CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

Sincerely,
Joseph Greene

Supervisor of Athletic Training Services
UW Health Sports Medicine
621 Science Drive
Madison, WI 53711
608-265-8382
608-220-6196 (Mobile)
608-265-8340 (FAX)
jgreene@uwhealth.org
www.uwsportsmedicine.org

CMS-1385-P-14435

Submitter : Dr. Sarah Ross **Date:** 08/31/2007

Organization : Dr. Sarah Ross

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter. Sarah Ross, MD, Birmingham, AL

Submitter : **Mr. Paul Renner** **Date: 08/31/2007**

Organization : **Fernandez-Renner-Scaia Physical Therapy Clinic**

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I am a licensed physical therapist who practices in Canton, Ohio. I am attaching a document regarding the Physician Self-Referral Provisions.

CMS-1385-P-14436-Attach-1.DOC

14436

FERNANDEZ-RENNER-SCAIA
PHYSICAL THERAPY CLINIC, INC.

August 30, 2007

Mr. Kerry N. Weems, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Physician Self-Referral Issues

Dear Mr. Weems:

I am a licensed physical therapist who practices in Canton, Ohio. I was licensed in 1976, and have been in a private physical therapy practice since 1981. The purpose of this letter is to comment on Medicare reimbursement for physical therapy services provided in a physician-owned physical therapy setting. Even with the most well-intentioned motive, I find it unethical for a physician to have an ownership interest in a for-profit physical therapy clinic. In my conversations with various physicians, it is clear that they are opening physical therapy centers in an effort to earn more money. I have had patients who were previously seen in physician-owned clinics, and they were clearly directed to go to that clinic without being informed that they have a choice in the matter. Additionally, these same patients frequently comment that the services rendered at our clinic (owned by physical therapists) were significantly more efficacious, allowing them to meet the treatment goals sooner.

Our clinic has seen a significant reduction in Medicare patients from those physicians who own physical therapy services. It would be interesting to compare the costs, numbers of treatments, and outcomes between our clinic and those of a physician-owned clinic.

I feel that it is in the best interest of Medicare patients and the Medicare program to remove physical therapy from the list of "in-office ancillary services" that physicians are permitted to provide.

Sincerely,

Paul Renner, P. T.

2405 FULTON ROAD N.W. – CANTON, OHIO 44709 – (330) 452-0049

Submitter : **Glenda Steves** **Date: 08/31/2007**

Organization : **Glenda Steves**

Category : **Individual**

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

LesV. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
Glenda Steves

Submitter : **Debra Jones** **Date: 08/31/2007**

Organization : **Debra Jones**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Debra Jones

Submitter : Delores A. Emerson **Date: 08/31/2007**

Organization : Delores A. Emerson

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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Thank you for your consideration of this serious matter.

Delores A. Emerson

Submitter : **Glen Jones** **Date: 08/31/2007**

Organization : **Glen Jones**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Glen Jones

Submitter : **Mrs. Linda Tilley** **Date: 08/31/2007**

Organization : **Mrs. Linda Tilley**

Category : **Individual**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

Dear Sir or Madam:

Changes to the therapy standards proposed by CMS in the Physician Fee Schedule will be harmful for all users of the healthcare system in this country. For non-medicare patients, I fear that insurance companies would consider following similar rules. The licensed physician should be making decisions on how, when and what licensed healthcare provider should be used in a given situation.

As baby boomers retire and become eligible for Medicare the pool of providers will be stretched beyond it's current limits. Making the provider pool smaller will cause a crisis. The proposed changes would be harmful to Medicare patients by causing physical, health, emotional and financial strain.

As a member of the Baby Boom generation facing Medicare eligibility in the next few years, I am terrified of the proposed rule changes. If I am injured or ill I want my physician to refer me to the service provider of his or her choice. Limiting my access to qualified providers is outrageous and completely unacceptable.

Please remove the restrictions from the standards out of consideration of the patients that will be adversely affected.

Respectfully,
Linda Tilley

Submitter : **Mr. JOHN LOPEZ** **Date: 08/31/2007**

Organization : **MARYLAND SPORTS & INDUSTRAIL MEDICINE SERVICES**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

My name is John Lopez and I am a certified athletic trainer in Maryland. I have been practicing since 1971. I have managed out patient physical therapy clinics in Maryland for over 21 years.

I am writing today to voice my opposition to the therapy standards and requirements in regards to the staffing provisions for rehabilitation in hospitals and facilities proposed in 1385-P.

I am extremly concerned that these proposed changes to the hospital Conditions of Participation have not received the proper and usual vetting! More importantly, I am extremely concerned that these proposed rules will create additional lack of access to quality health care for all patients.

I have two elderly parents (88 & 89 yo.)that currently have multiple medical conditions and have been in and out if the hospital, nursing home, and assisited living center for the last several years. While my Sister and I would like to have them both at home with a care giver, it has become increasingly more difficult for us to provide a consisitent level of care for them that will not cause them to endure anymore trips to the hospital. Accordingly everytime they do have to return to the hospital they encounter serious shortages in staffing in receiving physical therapy services.

There is currently a national shortage of PTs in many hospitals and private practices. As an athletic trainer, I am qualified to perform physical medicine and rehabilitation services, which you know is not the same as physical therapy. My education, clinical experience, and national certification exam ensure that my patients receive quality health care. In many parts of the country, hospital medical professionals have deemed me qualified to perform these services and these proposed regulations attempt to circumvent those standards.

The lack of access and workforce shortage to fill many health care positions is widely known throughout our industry. It is irresponsible for CMS, which is supposed to be concerned with the health of all Americans, especially the ederly and frail as well as those in rural areas, to further restrict their ability to receive those services. The flexible current standards of staffing in hospitals and other rehabilitation facilities are pertinent in ensuring patients receive the best, most cost-effective treatment available.

Since CMS seems to have come to these proposed changes without clinical or financial justification, I would strongly encourage CMS to consider the recommendations of those professionals that are tasked with overseeing the day-to-day health care needs of their patients. I respectfully request that you withdraw the proposed changes related to hospitals, rural clinics, and any Medicare Part A or B hospital or rehabilitation facility.

I can no longer continue to see the plight of my parents being endured by many of our American senior ctizens! Make access to qualified medical services more avaialbe not more difficult to access!

Sincerely,

John R. Lopez ATC.
2470 Twin Knolls Circle Drive
Reisterstown , MD 21136
loghome@erols.com
410-239-6820

Submitter : **Dr. Scott Klein** **Date: 08/31/2007**

Organization : **Dr. Scott Klein**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Sec Attachment

CMS-1385-P-14443-Attach-1.DOC

14-143

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

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Thank you for your consideration of this serious matter.

Submitter : **Charles Emerson** **Date: 08/31/2007**

Organization : **Charles Emerson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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charles Emerson

Submitter : **Victor Foutch** **Date: 08/31/2007**

Organization : **Victor Foutch**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Victor Foutch

Submitter : **Janet Foutch** **Date: 08/31/2007**

Organization : **Janet Foutch**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Leslie V. Norwalk, Esq.
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Centers for Medicare and Medicaid Services
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P.O. Box 8018
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Janet Foutch

Submitter : **David Paulson** **Date: 08/31/2007**

Organization : **David Paulson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
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Baltimore, MD 21244-8018

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David Paulson

Submitter : **Dr. Brian Weaver** **Date: 08/31/2007**

Organization : **UPHS**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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CMS-1385-P-14449

Submitter : Melanie Page **Date:** 08/31/2007

Organization : Melanie Page

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Melanie Page

Submitter : **Mary Ann Wagner** **Date: 08/31/2007**

Organization : **National Association of Chain Drug Stores**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14450-Attach-1.PDF

11450

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

August 31, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P: 42 CFR Parts 409, 410 et al. Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile Transmissions.

Dear Sir/Madam:

NACDS represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 37,000 pharmacies, employ 114,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of nearly $700 billion. We appreciate the opportunity to comment on proposed rules related to reimbursement for Part B drugs and supplying and dispensing fees, the potential elimination of the e-prescribing exemption for computer-generated facsimile transmissions, and the mandatory reporting of anemia quality indicators.

I. AVERAGE SALES PRICE (ASP) ISSUES

NACDS is concerned that the proposed rule: (1) does not increase supplying or dispensing fees for Part B drugs to help offset low reimbursements under the ASP, and administrative costs incurred in Medicare Part B claim submission; and (2) reduces reimbursement to the lesser of widely available market price (WAMP) or 103 percent of average manufacturer's price (AMP) if the ASP exceeds the AMP or the WAMP by five percent or more. As discussed later in our comments, community retail pharmacies face unique economic and administrative challenges in serving Medicare Part B patients, which must be considered by CMS in setting reimbursement policies.

NACDS, however, supports the proposed rule's clarification that, in deducting price concessions from ASP calculation, manufacturers must allocate price concessions on all drugs sold under a bundled arrangement to proportionately account for the dollar value of the units of each drug sold under the bundled agreement.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

Increase in Supplying and Dispensing Fees is a Logical Outgrowth of the Proposed Rule

Our request to increase supplying and dispensing fees is a logical outgrowth of CMS' proposal to update Part B payment policies. With its proposal, CMS intends to "ensure that its payment policies are updated to reflect changes in medical practice and the relative value of services." Nevertheless, despite increasing costs in billing for Medicare Part B services, CMS has not updated supplying and dispensing fees since 2005. Further, as supplying and dispensing fees are critical components of Part B drug coverage, it follows that CMS has the ability to consider an increase in supplying and dispensing fees despite its absence in the proposal.

Proposed Part B Rule Does Not Increase Supplying or Dispensing Fees for Part B Drugs

NACDS strongly urges that Part B drug supplying and dispensing fees be increased for CY2008 to help offset low reimbursement amounts realized under the ASP method, and administrative costs associated with Part B claims. ASP is retrospectively determined and bases reimbursement on pricing information that is out of date by several months. Calculation of ASP also fails to omit rebates offered to Pharmacy Benefit Managers (PBMs), customary prompt pay cash discounts extended to wholesalers, payments for pharmaceutical returns and related service fees, and free goods that are contingent on purchase requirements. These offsets are not received by pharmacies and therefore their inclusion in ASP benchmark used to reimburse pharmacies creates severe economic injuries.

CMS' failure to increase supplying and dispensing fees results in community pharmacies' reimbursement falling below the actual cost to dispense Part B prescriptions. Administrative costs incurred by pharmacies to participate in Part B remain costly and burdensome. At the same time, pharmacists' and pharmacy staffs' salaries continue to increase. In such precarious financial situations, Medicare beneficiaries may face difficulties in gaining access to their drugs if community pharmacies were forced to close due to the financial impact. The amount of supplying and dispensing fees established by CMS is critical in ensuring that pharmacies are compensated for the losses sustained from ASP-based product reimbursement, and to compensate for Medicare Part B's unusually burdensome billing.

Challenges Facing Pharmacies in Serving Medicare Part B Patients

Medicare payment policies should be designed to ensure that beneficiaries have access to Part B covered drugs. Every year, millions of Medicare beneficiaries choose to receive their Part B drugs from their community retail pharmacies. Despite the reliance beneficiaries have on community retail pharmacies, many aspects of the Part B reimbursement policies create economic and administrative challenges to pharmacies while serving their patients. A brief examination of some of these challenges follows.

Low reimbursement: Pharmacies are negatively impacted by the Part B drug reimbursement system, which bases reimbursement for a drug on the HCPCS code and not the drug's NDC number. HCPCS codes reimburse every product, whether brand or generic, listed under a particular code at the same reimbursement amount. Consider, for example, a prescription for a covered Part B brand name drug for which a generic drug is also available. Generic substitution laws in most states would preclude the pharmacist from dispensing the less expensive product – i.e. the generic – if the physician prescribes as "Brand Medically Necessary." The pharmacy is forced to dispense the brand name but is nevertheless reimbursed at the generic blended rate due to the HCPCS code billing. In these cases, by participating in the Medicare program, pharmacies are required to dispense brand name drugs at a loss.

Other pharmacy practice settings, such as Part B mail order facilities, stock only a specific formulary of drugs and do not deviate from their formulary. If a prescribed product is not in their formulary, they will call the physician and obtain an order for a formulary product. Retail pharmacies can not operate in this fashion since they stock all brand name products and must dispense the product as prescribed. The HCPCS based reimbursement method continues to underpay pharmacies when serving Medicare patients.

Lengthy claims process: The claims process in Medicare Part B is unusually long. Each group of Part B drug has different coverage and billing issues that must be resolved before a pharmacy can submit a "clean" claim to the DMERC. The extent of the additional time involved depends on the category of drug and the willingness of the physician to work with the pharmacy in providing the information necessary for billing. Further, with traditional, non-Medicare claims, pharmacies know instantly whether the claim is adjudicated, and the amount that the pharmacy will be paid. With Part B claims, pharmacies often have to provide services knowing that the claims process will be long and complex.

High rejection of claims: Even with "clean claims" submitted to the DMERC, Medicare Part B has a higher rejection rate than traditional third party prescription plans because of the lack of an online claims adjudication system. As a result, pharmacies incur significant amounts of "bad debt" in Medicare Part B compared to other third parties.

Delays in payment: Medicare Part B takes more time to pay pharmacies than traditional third party payers, tying up the pharmacies' cash flow for extended periods of time. This is especially true in the case of expensive immunosuppressive drugs. Because of the higher number of claim rejections in Medicare Part B and the longer time it takes to pay Medicare claims on average, a pharmacy may have dispensed several expensive Part B drugs to a Medicare beneficiary before the pharmacy gets any assurance that it will be reimbursed for the initial Part B claim submitted.

NACDS urges CMS to consider these unique challenges community retail pharmacies face in filling Part B prescriptions. Medicare beneficiaries' access to their local pharmacy must

be protected by implementing policies that maximize economic and administrative efficiencies in serving Part B patients.

CMS Should Not Require Reimbursement at the Lesser of WAMP or 103 percent of AMP Where ASP is Higher, as Proposed by § 414.904(d)(3)

NACDS is concerned that CMS' proposal to reimburse Part B drugs at the lower of WAMP or 103 percent of AMP where ASP is higher by five percent or more will create serious economic harm to pharmacy. In its current form, CMS' definition of AMP is problematic because it results in AMP values that do not reflect prices at which retail pharmacies purchase medications. Particularly, AMP includes sales to entities that are able to obtain drugs at prices that are lower than the prices paid by retail pharmacies. AMP also includes rebates and discounts that are not offered to retail pharmacies. For example, AMP includes sales and rebates offered to PBMs for their mail order pharmacies. Clearly, AMP prices are not reflective of retail pharmacies' acquisition costs.

AMP is unproven as a reliable reimbursement benchmark and poses a tremendous threat to community pharmacy. Even the Government Accountability Office (GAO) has concerns about the appropriateness of AMP as a reimbursement benchmark. GAO has estimated that Medicaid reimbursements based on AMP will be 36 percent below pharmacies' acquisition costs. Further, the lag time between reporting of AMP data and its use in reimbursement will cause pharmacy reimbursement to be based on outdated pricing information. Reliance on AMP as a basis for pharmacy reimbursement for Part B will reimburse pharmacies for less than their costs, and no provider should be asked to participate in Part B at a loss.

The use of WAMP as a reimbursement benchmark where ASP is higher also creates significant issues for community pharmacy. The definition of WAMP is problematic in that it also includes sales and discounts that are not extended to community retail pharmacies. The cost of purchasing Part B drugs by retail pharmacies is much higher than other entities. CMS' use of WAMP as a reimbursement benchmark where ASP is higher will also require pharmacies to participate in Part B at a loss.

Any reimbursement policy utilized by CMS should consider the unique costs retail pharmacies incur in filling Medicare Part B prescriptions. Claims processing under Medicare Part B remains challenging, despite the recent streamlining in the billing process. It is still more expensive for the retail pharmacy to bill Medicare Part B than any other third party. Administrative errors caused by the confusing Medicare billing procedures account for numerous denials in coverage and often result in costs that pharmacies are forced to absorb. Many pharmacies have hired additional personnel to handle the extra burden of preparing Part B claims for submission.

For these reasons, the agency should not further threaten pharmacies' financial position by paying the lower of WAMP or 103 percent of AMP where the ASP is higher by five percent or more. In fact, given the costs associated with dispensing Part B drugs, the agency is urged to increase supplying and dispensing fees for part B drugs and figure out ways to accurately reimburse pharmacies for their services.

> *NACDS supports the proposed rule's clarification that, in deducting price concessions from ASP calculation, manufacturers must allocate price concessions on all drugs sold under a bundled arrangement to proportionately account for the dollar value of the units of each drug sold under the bundled agreement.*

As discussed earlier, Medicare's reimbursement for pharmacy services do not accurately reflect the cost of obtaining and dispensing Part B drugs. Community pharmacy would realize reimbursement that reflects the true cost of doing business if other reimbursement benchmarks were used. Until then, CMS must ensure that whatever benchmark is used reflects pharmacies' true cost of obtaining and dispensing Part B drugs. While NACDS does not support the use of ASP as a benchmark for reimbursement, we are encouraged with CMS' proposal in § 414.804(a)(2)(iii) to make ASP calculation more clear by filtering price concessions that may not include concessions for Part B drugs.

II. PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES

NACDS is eager to see true e-prescribing become commonplace. Computer to computer electronic prescribing has many benefits and efficiencies for the prescriber, pharmacy, and patient. Numerous studies show that e-prescribing is associated with reduced medication errors, the use of more cost-effective medications such as generics, improved patient compliance, and other savings and benefits.

Although we support widespread adoption of true electronic prescribing as soon as reasonably possible, we have some concerns with CMS' proposed changes to § 423.160. We have summarized our concerns in bullet points below, followed by a more detailed discussion and draft rule language for CMS to consider.

We ask that CMS:

- Not completely eliminate the electronic facsimile exemption, but to continue to take a step-wise approach and to eliminate the exemption for prescribers and dispensers who have the functionality to engage in NCPDP SCRIPT-compliant transactions, but may not be using this functionality;
- Allow those who adopt NCPDP SCRIPT-compliant functionality after the effective date of the rule one year after such adoption to comply with the SCRIPT standard;

- Allow the electronic facsimile exemption to remain for prescribers and dispensers who cannot comply with NCPDP SCRIPT for reasons beyond their control;
- Recognize that pharmacies cannot enforce the rule upon prescribers, and should not be penalized for prescriber non-compliance;
- Address concerns that pharmacies have about liability under the proposed rules; and
- Amend the rule's effective date to harmonize with the effective date of MMA-mandated e-prescribing standards: April 1, 2009.

Step-wise Approach

We ask that CMS continue to take a step-wise approach to e-prescribing regulatory requirements. Rather than remove the exemption for all electronically generated faxed prescriptions, we ask that CMS narrow the exemption to eliminate the exemption for prescribers and dispensers who have the ability to generate NCPDP SCRIPT transactions. Many prescribers and dispensers have the ability to convert to true electronic prescribing without changing their workflow and without significant expense. Any required upgrade is often included in the costs that the prescriber or dispenser has already paid. Any additional costs should be minimal.

The costs for other prescribers and dispensers could, however, be significant if CMS were to eliminate completely the electronic facsimile exemption. Because these prescribers and dispensers do not currently have the functionality to engage in true e-prescribing, to force them to adopt this functionality would be disruptive to their workflow and/or require them to expend significant time and money toward such adoption. We believe that most of them would revert to paper and oral communication, thus erasing any gains made toward the adoption of true e-prescribing. These prescribers and dispensers include those who use software such as a word processing program that creates and sends a transmission that results in a paper prescription or response at the receiving end, and do not otherwise have true e-prescribing capabilities.

One-year Phase-in for Adopters after Effective Date: For prescribers and dispensers who move to adopt true e-prescribing after the effective date of the proposed rule, we ask that CMS allow a transition period of one year after they adopt the necessary technology, application, system, or software. This would allow for workflow changes, training, and the resolution of any technical glitches that might occur.

SCRIPT Noncompliance for Reasons Beyond Control

DEA regulations prohibit the e-prescribing of a prescription for a controlled substance. This prohibition acts as a tremendous barrier to prescriber adoption of e-prescribing. As currently written, CMS' proposed rule would exacerbate the problems caused by this prohibition. If prescribers could use neither electronic prescribing (because of DEA regulations) nor computer-generated faxes (because of the CMS proposed rule) for

controlled substance prescriptions, then many prescribers would have to revert to using traditional facsimile machines or paper and oral prescriptions for controlled substances. For these reasons, until such time that DEA amends its regulations to allow for the electronic prescribing of controlled substances, we believe that prescribers and dispensers need to retain the ability to use computer-generated facsimiles to send and receive prescriptions for controlled substances. In fact, this policy should apply in any circumstance in which a prescriber or dispenser is prohibited from complying with the NCPDP SCRIPT standard for reasons beyond their control.

Computer-generated Facsimile as Back-up: Similarly, prescribers and dispensers need secure alternative forms of communication in the event of temporary system failures, which will occur occasionally due to power failures and routine maintenance. In these circumstances, computer-generated faxing may provide the most safe and efficient alternative to true e-prescribing. Therefore, we ask that the computer-generated facsimile exemption remain for prescribers and dispensers during temporary communication failures.

Pharmacies Cannot Enforce Requirements

CMS must recognize that it will be very difficult, if not impossible, for a pharmacy to tell the difference between a facsimile that originated from a facsimile machine and one that originated electronically. CMS cannot hold pharmacies responsible for enforcing the requirements of the rule on prescribers. Community pharmacies cannot be forced to turn away patients with prescriptions from non-compliant prescribers.

CMS cannot allow for the recoupment of prescription claims after pharmacies filled them in good faith only to find out, after the fact, that the prescription violated the CMS regulation. Community pharmacies should not be penalized for prescriber non-compliance.

Similarly, any NCPDP SCRIPT enabled sending entity, such as a pharmacy, should be able to send a computer generated facsimile if the receiving entity is not capable of receiving an NCPDP SCRIPT message, and the pharmacy believes that a computer generated facsimile is the best and most efficient way to send the prescription message. Of course, if both the pharmacy and the prescriber are capable of communicating with the NCPDP SCRIPT standard, then they should do so (unless another exemption applies).

Concerns about Liability on Pharmacies

Prescriptions transmitted before the compliance deadline but filled or refilled after the compliance deadline should not be subject to the rule. We ask that CMS clarify this point. Otherwise, pharmacies would be forced to obtain new prescriptions for patients after the rule's effective date. Finally, we ask that CMS advise states that the dispensing of a prescription transmitted in a noncompliant manner should not be considered a

violation of either federal or state false claims acts. The proposed rule is designed to foster the adoption of true e-prescribing, not to increase the potential legal liability of pharmacies. However, we are concerned that additional litigation against pharmacies could be encouraged by allowing the dispensing of a prescription transmitted in a noncompliant manner to be deemed fraud and abuse. This could increase Medicare program participation costs for pharmacies and could potentially discourage pharmacy participation in the program.

Implementation Timetable

The effective date of this proposed rule is problematic, due to the fact that the industry is working on an implementation timetable built around the requirements of e-prescribing standards adoption spelled out in the Medicare Modernization Act of 2003 (MMA) and associated rules. The MMA requires that providers who write prescriptions electronically use the final standards that are in effect when they conduct e-prescribing transactions as of April 1, 2009. We are concerned that prescribers will be confused if the effective date of the electronic facsimile exemption is January 1, 2009. Therefore, rather than the January 1, 2009 date, we recommend that the effective date of this proposed rule be April 1, 2009, when the MMA e-prescribing standards will be required.

We have taken the liberty to draft language that we believe captures the intent of the changes suggested above, and we encourage CMS to revise the facsimile exemption so as not to eliminate the exemption in its entirety, but rather to eliminate the exemption for those prescribers/dispensers who today have, or in the future will have, purchased or licensed software that is capable of sending prescriptions messages through true electronic means in compliance with the NCPDP SCRIPT Standard. Our proposed language is as follows:

§ 423.160(a)(3(i) Entities transmitting prescriptions or prescription related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information in the following circumstances:

1. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) does not own, license, or otherwise use software that has or had the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the NCPDP SCRIPT Standard, whether on the version that the prescriber/dispenser is currently using or another version of such software.*

    a. *This exemption shall not apply to prescribers/dispensers sending a transaction listed at Section 423.160(b)(1)(i) through (xii) who own, license, or otherwise use software that has or had the*

capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated], to send and receive transactions compliant with the NCPDP SCRIPT Standard, but who has not upgraded to the version that is compliant with the NCPDP SCRIPT Standard and/or has not activated that functionality.

b. *In addition, in the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) owns, licenses, or otherwise uses software that does not have or did not have the capability, as of the date of the promulgation of this rule [i.e., insert date rule promulgated] to send and receive transactions compliant with the NCPDP SCRIPT Standard, but such software becomes capable to send and receive transactions compliant with the NCPDP SCRIPT Standard at any time after [insert date rule promulgated], then this exemption shall not apply with respect to such software twelve months after such software becomes capable to send and receive transactions compliant with the NCPDP SCRIPT Standard.*

2. *In the event that the prescriber/dispenser sending a transaction listed at Section 423.160(b)(1)(i) through (xii) is sending the transaction to a dispenser/prescriber who does not own, license, or otherwise use software that has the capability to receive transactions compliant with the NCPDP SCRIPT Standard.*

3. *In the event any applicable law or regulation would prohibit the electronic transmission of the prescription and prescription related information using the NCPDP SCRIPT Standard.*

4. *In the event there is a temporary communications failure, whether technological or otherwise, that would prohibit the electronic transmission of the transactions listed at Section 423.160(b)(1)(i) through (xii) using the NCPDP SCRIPT Standard. Such temporary communications failures include, by way of example and not limitation, power outages, connectivity failures, or temporary outages of the either the prescriber's or dispenser's computer or management systems.*

5. *Information transmitted in a manner that is compliant with this rule at the time of its transmission shall remain compliant with this rule for the purposes of this rule even if such information or transmission would otherwise become noncompliant at a future date.*

We support CMS' proposal to foster further adoption of true e-prescribing, and we urge CMS to move forward with the proposed rule, incorporating the recommendations we have provided above.

III. TRHCA—SECTION 110: ANEMIA QUALITY INDICATORS

The proposed rule, § 414.707(c), would require, effective January 1, 2008, payment request for anti-anemia drugs furnished to treat anemia resulting from cancer treatment to contain the beneficiaries most recent hemoglobin or hematocrit levels.

We request that there be a clarification to this rule clearly exempting retail pharmacies from this requirement. Cancer patients seeking prescription drugs are very ill and do not always furnish this information to the pharmacist. NACDS believes that physicians are in the best position to furnish information regarding a patient's hemoglobin or hematocrit levels to the CMS at the time of prescribing.

If CMS chooses to retain this rule, NACDS urges CMS to create an exception to allow pharmacies to dispense medication for a given period of time if a patient presents a prescription for such drug without the required information.

We thank you for the opportunity to comment on proposed rules related to reimbursement for Part B drugs and supplying and dispensing fees, the elimination of the exemption for computer generated facsimiles, and anemia quality indicators. If we can be of any assistance, please do not hesitate to contact me at 703-837-4136.

Sincerely,

Mary Ann Wagner, R.Ph.
Senior Vice President
Policy and Pharmacy Regulatory Affairs

Submitter : **Robert Emerson** **Date: 08/31/2007**

Organization : **Robert Emerson**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Robert Emerson

Submitter : **Date: 08/31/2007**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

I strongly urge CMS to remove rehabilitation services (physical, occupational and speech therapy) as designated health service (DHS) permissible under the in-office ancillary exception of the federal physician self-referral laws.The potential for fraud and abuse exists whenever physicians are able to refer Medicare beneficiaries to entities in which they have a financial interest. Physicians who own practices that provide rehabilitation services have an inherent financial incentive to refer their patients to the practices they have invested in and to overutilize those services for financial reasons. By eliminating rehabilitation services as a designated health service (DHS) furnished under the in-office ancillary services exception, CMS would reduce a significant amount of programmatic abuse, overutlization of rehabilitaiton services under the Medicare program, and enhance the quality of patient care.

Thank you for your consideration of this important matter.

CMS-1385-P-14453

Submitter : **Kevin Shinn** **Date: 08/31/2007**

Organization : **Kevin Shinn**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

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Kevin Shinn

14456

JASON D. HANSON
Executive Vice President and General Counsel

August 30, 2007

Mr. Herb Kuhn
Deputy Administrator (Acting)
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850.

ATTN: FILE CODE CMS-1385-P

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007; ASP ISSUES

Dear Mr. Kuhn:

Medicis submits this comment on the proposed revisions to the physician fee schedule (PFS) for calendar year (CY) 2008. This comment addresses the average sales price (ASP) reporting requirements with respect to bundled price concessions by a drug manufacturer.

Medicis is the leading independent specialty pharmaceutical company focusing primarily on the treatment of dermatological conditions. We appreciate CMS's decision to provide additional guidance with regard to the treatment of bundled sales. We hope that additional clarity with respect to the reporting obligations will ensure accurate payment for Part B drugs.

<u>ASP Reporting for Bundled Arrangements</u>

In the CY 2007 PFS final rule with comment period, CMS did not establish a specific methodology that manufacturers must use for the treatment of bundled price concessions for purposes of the ASP calculation. This has led to uncertainty among manufacturers regarding reporting discounts on bundled products, and has lead to inconsistent industry practices. In the 2008 Proposed Rule, CMS defines bundled arrangements to include all arrangements under which

> the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biologcial or other drugs or biologicals or some other performance requirement.

8125 North Hayden Road, Scottsdale, AZ 85258
Telephone: (602) 808-8800 Facsimile: (602) 808-0822
Web Site: http://www.medicis.com

CMS proposes that "the total value of all price concessions on all drugs sold under a bundled arrangement must be allocated proportionately according to the dollar value of the units of each drug sold under the bundled arrangement."

Medicis supports the approach CMS has taken to treating bundled price concessions. We believe that this methodology for allocating discounts associated with bundled arrangements will provide consistency between a manufacturer's reported ASP and the fair market value of its products.

We are submitting this comment to request that CMS provide further clarification with respect to the definition of bundled arrangements and the policy for reporting price concessions. Specifically, we suggest that CMS include the following clarifications in the Final Rule:

- bundled arrangements include arrangements where a price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals *(including both Part B and non-Part B drugs or biologicals)*;
- in reporting manufacturer average sales price, the total value of all price concessions on all drugs *or other products included in a bundled arrangement* must be allocated as proposed in § 414.804;
- a manufacturer is only required to allocate price concessions for bundled arrangements offered by that manufacturer, and is not responsible for any price concessions or bundled arrangements offered by other manufacturers with respect to the same drug or biological.

CMS Should Clarify That Bundled Arrangements Include both Part B and Non-Part B Drugs and Products

Based on industry practice some bundling arrangements will condition price concessions for a non-Part B drug, biological, or other product on the purchase of that manufacturer's Part B drug. It is our interpretation that the proposed rule would require a drug manufacturer to report sales data for the Part B-drug component of a bundled sale, along with any price concessions granted for that manufacturer's non-Part B products as part of the ASP calculation. If "bundled arrangements" are limited to only Part B products, it would enable drug manufacturers to insulate certain price concessions that are integral to the sale of their Part B drugs from the ASP reporting requirement. The effect would be to artificially inflate the reported ASP of the Part B drug, and, with it, the Medicare payment rate.

In order to address this concern, **drug manufacturers should be required to apportion price concessions granted for their non-Part B drugs, biologicals, and other products when those price concessions are conditioned on the purchase of that**

manufacturer's Part B drug. Such a clarification is necessary to ensure that drug manufacturers do not misrepresent the actual market price of Part B drugs.

In this context, CMS should further clarify what constitutes a price concession for non-Part B drugs that may not have an established price under Part B. For non-part B products, "price concessions" should be defined as the difference between the price offered as part of the bundled arrangement and the price that would be available to the purchaser if the drug was purchased separately (outside any bundled arrangement). CMS should also specifically address the treatment of free goods offered as part of a bundled arrangement. If free goods are offered contingent on the purchase of Part B drugs, the cost of the free goods should be treated as a 100% price concession for those goods, which should be appropriately allocated using the methodology established in § 414.804.

This conclusion is consistent with CMS's proposed definition of a "bundled arrangement," which does not distinguish on its face between products based on their coverage status under Part B. However, we believe that additional clarification in this area would be useful to provide guidance to manufacturers in identifying bundled arrangements, and correctly allocating discounts made therein.

Bundled Arrangements Should Include Sales of Non-Drug Products

It is our understanding that some manufacturers provide discounts or other price concessions as part of bundled arrangements that include sales of Part B drugs and other non-drug products. In order to appropriately capture the market price of Part B drugs, these arrangements should also be considered bundled arrangements.

This approach is consistent with the Medicaid final rule (CMS-2238-FC), which defines a Bundled Sale to include arrangements involving "the same drug, drugs of different types . . . or another product or some other performance requirement" (emphasis added). In the Physician Fee Schedule Proposed Rule, CMS stated its intent to establish a consistent approach to bundled arrangements between the Medicare and Medicaid programs, where appropriate. Including "other products" in the definition of bundled arrangements will both reinforce this consistency, thereby reducing manufacturer reporting burdens, as well as encouraging the most accurate price reporting for both programs.

In adopting this definition, CMS should clarify that "another product" includes all non-drug products and devices associated with a bundled arrangement as defined.

Manufacturers Are Only Responsible for Reporting Bundled Sales

Medicis further requests that CMS clarify that reporting requirements for bundled price concessions apply only to sales made and concessions granted by the reporting manufacturer. For the purpose of the ASP reporting requirements, the term "manufacturer" covers a broad range of entities, including not only parties engaged in

the literal production and processing of prescription drug products, but also their "packaging, repackaging, labeling, relabeling, distribution." However, a manufacturer submitting an ASP report to CMS would only have access to information about its own bundled arrangements, and would not be able to evaluate the sales arrangements of other "manufacturers" who sell the same product.

In order to avoid confusion among manufacturers with respect to the reporting of bundled price concessions, CMS should clarify that a manufacturer is not required to report price concessions granted by some other, independent entity for sales of the same product. We believe that this interpretation is consistent with the language and intent of the ASP statute and regulations, as well as the present standard practice of manufacturers.

Conclusion

Medicis appreciates CMS's efforts to ensure the accuracy of the ASP calculation. In order to support this goal and ensure uniformity in manufacturer reporting, we encourage CMS to clarify that the methodology for reporting discounts associated with bundled sales arrangements should apply to both Part B drugs and biologicals as well as drugs, biologicals, and other products that are not covered under Part B. In addition, CMS should make clear in the final rule that manufacturers are not required to report price concessions granted by third parties.

Thank you for your attention to this important matter.

Sincerely,

Jason D. Hanson
Executive Vice President, General Counsel
& Corporate Secretary

Submitter : **Edwin Moreano** **Date: 08/31/2007**

Organization : **Edwin Moreano**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

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In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Edwin Moreano

Submitter : **shawn mcneally crna** **Date: 08/31/2007**

Organization : **AANA**

Category : **Other Practitioner**

Issue Areas/Comments

Background

Background

August 20, 2007
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018 RE: CMS 1385 P (BACKGROUND, IMPACT)
Baltimore, MD 21244 8018 ANESTHESIA SERVICES
Dear Administrator:
As a member of the American Association of Nurse Anesthetists (AANA), I write to support the Centers for Medicare & Medicaid Services (CMS) proposal to boost the value of anesthesia work by 32%. Under CMS proposed rule Medicare would increase the anesthesia conversion factor (CF) by 15% in 2008 compared with current levels. (72 FR 38122, 7/12/2007) If adopted, CMS proposal would help to ensure that Certified Registered Nurse Anesthetists (CRNAs) as Medicare Part B providers can continue to provide Medicare beneficiaries with access to anesthesia services.
This increase in Medicare payment is important for several reasons.
ı First, as the AANA has previously stated to CMS, Medicare currently under-reimburses for anesthesia services, putting at risk the availability of anesthesia and other healthcare services for Medicare beneficiaries. Studies by the Medicare Payment Advisory Commission (MedPAC) and others have demonstrated that Medicare Part B reimburses for most services at approximately 80% of private market rates, but reimburses for anesthesia services at approximately 40% of private market rates.
ı Second, this proposed rule reviews and adjusts anesthesia services for 2008. Most Part B providers services had been reviewed and adjusted in previous years, effective January 2007. However, the value of anesthesia work was not adjusted by this process until this proposed rule.
ı Third, CMS proposed change in the relative value of anesthesia work would help to correct the value of anesthesia services which have long slipped behind inflationary adjustments.
Additionally, if CMS proposed change is not enacted and if Congress fails to reverse the 10% sustainable growth rate (SGR) cut to Medicare payment, an average 12-unit anesthesia service in 2008 will be reimbursed at a rate about 17% below 2006 payment levels, and more than a third below 1992 payment levels (adjusted for inflation).
America s 36,000 CRNAs provide some 27 million anesthetics in the U.S. annually, in every setting requiring anesthesia services, and are the predominant anesthesia providers to rural and medically underserved America. Medicare patients and healthcare delivery in the U.S. depend on our services. The availability of anesthesia services depends in part on fair Medicare payment for them. I support the agency s acknowledgement that anesthesia payments have been undervalued, and its proposal to increase the valuation of anesthesia work in a manner that boosts Medicare anesthesia payment.
Sincerely,
shawn mcneally crna____________________________
Name & Credential
merit care medical center 720 n 4th st.______________________________
Address
_Fargo, ND 58107____________________________
City, State ZIP

CMS-1385-P-14459

Submitter : **Karen Shinn** **Date: 08/31/2007**

Organization : **Karen Shinn**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.
Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
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Karen Shinn

Submitter : **Dr. Nick Kaminsky** **Date: 08/31/2007**

Organization : **Dr. Nick Kaminsky**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Submitter : **Julie Miller** **Date: 08/31/2007**

Organization : **Julie Miller**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Julie Miller

Submitter : **Kevin Logue**

Organization : **Kevin Logue**

Date: 08/31/2007

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Centers for Medicare and Medicaid Services
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Kevin Logue

CMS-1385-P-14463

Submitter : **Dr. Anmol Mahal** **Date: 08/31/2007**

Organization : **California Medical Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Geographic Practice Cost Indices (GPCIs)

Geographic Practice Cost Indices (GPCIs)

correcte version 8/31/07

CMS-1385-P-14463-Attach-1.DOC

#14463

California Medical Association

Established 1856

August 31, 2007

Leslie Norwalk, Esq.
Acting Director
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P "GEOGRAPHIC PRACTICE COST INDICES (GPCIs)
P.O. Box 8018
Baltimore, MD 21244-8018

RE: CMS-1385-P Medicare Program;
Proposed Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2008
"GEOGRAPHIC PRACTICE COST INDICES (GPCIs)"

Dear Ms. Norwalk:

On behalf of the California Medical Association, I am writing to provide comment on the proposed rules regarding the Medicare physician payment localities (72FR38122) and Geographic Practice Cost Indices (GPCIs). We appreciate the opportunity to provide our views on the three proposed California options.

I. Statement of the Problem

A. California

The intent of current Medicare law is to reimburse physicians according to the cost of providing services and to make adjustments for geographic differences in those costs. Since 1999, CMA has contended that the geographic boundaries of some Medicare physician payment localities in California and across the nation do not accurately address variations in the cost of operating a medical practice and therefore, Medicare is not paying physicians accurately pursuant to federal law. Shifts in demographics and economic conditions have created serious underpayment problems for physicians in 447 counties across the country.

In California there are several counties whose individual county geographic adjustment factors exceed the locality factor by 5% or more and should qualify for an update. Physicians in Santa Cruz are paid 10% less than they should be paid (according to Medicare's own geographic cost calculations) and these physicians are paid 21% less than physicians across the border in Santa Clara County with similar practice costs. Each of these California counties have become more urban and costly to practice medicine and

despite Medicare's own data that shows their geographic practice costs rising, CMS has failed to update the locality groupings to more accurately pay these physicians.

The problem continues to compound because CMS has not updated the payment localities in nearly a decade and the last revision in 1997 was based on carrier-defined localities established more than 30 years ago in 1966. Further, the revisions were not uniformly applied in 1997. High cost counties are grouped with low cost counties resulting in a serious payment inaccuracies in these localities. These payment issues are addressed in detail in the CMA Medicare Geographic Payment Locality Report, January 2006.

B. Access To Care Problems in California's Underpaid GPCI Counties
Many seniors in these areas of California are experiencing problems accessing physicians. While physician shortages are a chronic problem across California, the underpaid GPCI counties have experienced substantial difficulty attracting and retaining physicians. As you are aware, California has one of the highest Medicare beneficiary populations in the country so these problems affect a greater number of seniors. The Medicare underpayment problem compounds for physicians because most of the private payers in California base their rates on Medicare.

o As mentioned above, no medical groups in Santa Cruz County are accepting new Medicare patients because of the low reimbursement.

o Sonoma County is experiencing a 30% primary care physician turn-over rate. Physicians are attracted to the quality of life in Sonoma County but after two years of practice are forced to leave because the reimbursements do not cover their high practice costs. Moreover, the largest number of physician group bankruptcies per capita have occurred in Sonoma County. The number of active physicians has declined by roughly 10% - 10.2% for specialist physicians and 9.2% for primary care specialties (not adjusted for population).

o Because of the low reimbursement rates and difficult practice environment, Sacramento County has experienced a nearly 20% decline in the number of physicians. More than a third of that loss occurred in the primary care specialties.

o 30% of physicians in San Diego County reported difficulty attracting new physicians to join their physician practices and medical groups. 33% reported to CMA that they planned to move out of state, retire early or change professions.

o A "slow water torture" is how a California board-certified internist recently described the practice of medicine in California when being interviewed by U.S. News and World Reports for its article, *Doctors Vanish from View*. This article details the phenomenon of California physicians limiting or leaving their practices altogether because of administrative hassles and declining reimbursements from insurers and the corresponding inability to devote themselves to the provision of continuous, quality patient care.

o The University of California Office of Health Affairs commissioned a report on California's physician workforce conducted by the University of Albany's Center for Health Workforce Studies. The report concludes that "growth in physician demand is likely to outpace growth in *(California)* physician supply by between 4.7% and 15.9%." The population of California is growing rapidly, which will place great strains on the health-care delivery system and the physician workforce.

o More than one quarter of the state's practicing physicians were over the age of 55 in 2000.

o Without appropriate access to physicians, patients seek care in California's emergency departments. California's ERs are already operating at critical capacity, and risk jeopardizing quality of care. Unfortunately, due to financial difficulties, more than 70 emergency departments have closed in the past decade.

o In a CMA Medicare survey more than 60% of California physician respondents said they cannot sustain future Medicare payment cuts and continue to accept new Medicare patients.

C. The Government Accountability Office (GAO) Report, June 2007

The Government Accountability Office (GAO) recently published a report entitled, "Medicare: Geographic Areas Used to Adjust Physician Payments for Variation in Practice Costs Should be Revised, June 2007" that substantiates the CMA concerns with the geographic payment problems around the country. The GAO was asked to examine how CMS has revised the localities; the extent to which they accurately reflect variations in physician's costs and alternative approaches to constructing the localities. The GAO reported the following:

> ***"...more than half of the current physician payment localities had at least one county within them with a large payment difference – that is, there was a payment difference of 5% or more between physicians' cost and Medicare's geographic adjustment for an area."***
>
> ***" Overall, there were 447 counties with large payment differences – representing 14% of all counties. These counties were located across the U.S., but a disproportionate number were located in five states. Specifically, 60% of counties with large payment differences were located in California, Georgia, Minnesota, Ohio and Virginia.***
>
> ***"...although substantial population growth has occurred in certain geographic areas, potentially leading to increased costs, CMS has not revised the payment localities to reflect these changes."***

These findings led the GAO to recommend that CMS "...(1) examine and revise the payment localities using an approach that is uniformly applied to all states and based on the most current data and (2) update the payment localities on a periodic basis..."

CMA strongly concurs with the GAO findings that the localities need to be revised using a uniform methodology and updated on a timely basis.

D. Past Petitions to Update Physician Payment Localities

As you know, CMA submitted a payment locality update proposal to CMS in 2004 during the public comment period on the CY 2005 Physician Fee Schedule rule. While the proposal was budget neutral on a statewide basis, CMS determined that it was not consistent with the law and did not adopt the plan. At CMS' suggestion, CMA re-submitted the budget neutral proposal to be implemented as a demonstration project. However, in 2005 CMS again responded that the approach was not feasible because it would not be subject to public comment through the normal rule-making process.

For the CY 2006 Physician Fee Schedule, CMS proposed to remove two counties, Santa Cruz and Sonoma, from the Rest of California, Locality 99. While the proposal would have provided payment accuracy for Santa Cruz and Sonoma and significantly helped physicians in those areas, it would have imposed a payment reduction on the counties remaining in Locality 99, including counties that also qualified for an increase. For this reason, CMA could not take a position on the proposal and provide the support that CMS required. Moreover, the proposal appeared to be a one-time only approach for helping only two counties. At the time, we believed there were 10 counties in California and nearly 200 across the country that qualified for an update. CMA asked CMS to adopt a long-term plan for updating the payment localities with a defined, uniform methodology that can be applied into the future on a periodic basis.

We appreciate CMS attempting to work with CMA over the years to address this problem but it remains unresolved and the payment discrepancies are getting much worse. It is time for CMS to act to keep payments current with geographically changing practice costs without imposing significant payment reductions on other physicians. We believe that any notable payment reductions that would be imposed on physicians are a direct result of CMS' unwillingness to update payment localities in over 10 years. Therefore, we believe it is paramount that CMS seek to minimize payment reductions to the fullest extent possible when considering locality revisions.

II. CMA Requests For GPCI Source Data Denied by CMS

CMA must express its great frustration that for the first time in eight years, CMS has refused to provide CMA the GPCI source data so that CMA could validate the CMS proposals and model alternatives to determine the impact on California physicians. This lack of data has completely crippled CMA's ability to comment appropriately on the three proposed California GPCI options in the 2008 physician payment rule. CMA would have preferred to model alternatives to the three proposed GPCI options to present

to CMS in the spirit of finding a mutually acceptable solution. However, without the information, CMA cannot develop alternatives and determine their true impact on California physicians. Without knowing the impact on payments, our physicians cannot vote on a proposal. The three proposed California options will have an enormous impact on physician payments in California. Therefore, we urge you to make the information available and transparent.

Information is Necessary to Verify CMS Calculations

There is a high probability that calculation errors are occurring that effect payments and may effect locality revisions. Errors are expected considering the nearly 20,000 figures (three GPCIs and three corresponding RVUs for each of the greater than 3000 counties) used to determine locality payments. Those errors could be minimized if the data used for the calculations were available to interested parties. Errors in GPCIs to the third decimal point can affect payment in millions of dollars to an area. For instance, in 2004, CMA found errors in the GAF calculations for Los Angeles County. The error would have imposed a half percent payment reduction on physicians in Los Angeles. The underpayment amount would have exceeded $50 million between 2005-2007. CMA contacted CMS and CMS immediately corrected the error. CMS working collaboratively with CMA, effectively and prospectively prevented that error from occurring.

Furthermore, there are many errors and typos in the current 2008 proposed options. In fact, in our efforts to replicate the methodology for Option #3, CMA discovered that CMS did not uniformly follow the methodology described in the rule. Therefore, proposed option #3 significantly misrepresents the true impact of the methodology on California physician payments in ten counties. Moreover, there would only be five payment localities instead of six.

Using HUD data provided to us by other entities, we believe that the proposed 9.2% reduction in payments to Santa Clara County are not the result of the most recent rent reductions but a correction of an error that CMS' contractor made in 2004. This kind of information should also be disclosed to all parties.

Because of the impact on physician payments, it is appropriate and essential that CMS make this information as transparent as possible. We urge CMS to make all data used to develop GPCIs and GAFs available to interested parties.

Information is Necessary to Model Potential Alternative Solutions

It is also important to establish the long-standing history of collaboration between CMA and CMS to share county GPCI and RVU data. Every year, CMS either performed the calculations or made the county GPCI, county RVU, and most recent HUD data available to CMA almost immediately upon CMA's request.

In 1999, (after the 1997 payment locality revision), CMA began contacting CMS to advocate for more appropriate payment locality groupings. From 1999 to 2003, CMA submitted requests to CMS staff to model different CMA-proposed solutions so that

CMA could determine the impact on California physicians. At CMA's request, CMS staff routinely performed geographic adjustment factor calculations. As CMA intensified its efforts to find a solution, this process became extremely burdensome and time-consuming for CMS staff. Therefore, in 2003 CMS began sharing all of the county GPCI and county RVU data with CMA so that CMA could make the necessary calculations to develop potential solutions. Using the CMS data in 2004, CMA developed a proposal that was budget neutral on a statewide basis. Because CMA had the appropriate data, physicians in California could determine the impact upon their practice. This proposal had the support of the vast majority of physicians within the CMA. CMA used the most recent data again in 2005 and 2006 to develop a major white paper that outlined several alternatives for updating the payment localities on a national basis.

The CMA is extremely frustrated that CMS refused to share the county GPCI data and the county RVU data for the first time in nearly a decade. After multiple requests, CMA was forced to file an expedited request for this data under the Freedom of Information Act. CMS never responded to any of our repeated requests. Therefore, we cannot provide alternative approaches to CMS that may have been more acceptable to our physician members.

III. Errors and Discrepancies

Before commenting on the three options, we would like to comment on discrepancies in the tables and text of Options 1-3.

In Column 3 of Table 7 Option 1 (72FR38140), the "New CY 2009 GAF, no locality change" for the Rest of California Locality and Counties is listed at 1.017. We calculate (from the 2009 GPCI's listed in Addendum E) the CY 2009 Rest of California Locality GAF is 1.012. Therefore, the "New CY 2009 GAF, with locality change" in column 4 of the same table for Rest of California is incorrectly listed as 1.012. This error is also present in Table 8, Option 2. We estimate that the correct Rest of California GAF for CY2009 with Option 1 or 2 Locality change is 1.006-1.007.

TABLE 7--OPTION 1--Apply 5 Percent Threshold To Remove Counties From Their Current Payment Localities, California Impact---(revised by CMA)

Locality Name	County Name	New CY 2009 GAF, no locality change	New CY 2009 GAF, with locality change	Percent change, due to locality change
Santa Cruz	Santa Cruz	**1.012**	1.100	**8.70%**
Monterey	Monterey	**1.012**	1.080	**6.72%**
Sonoma	Sonoma	**1.012**	1.076	**6.32%**
Marin	Marin	1.112	1.173	**5.49%**
Napa/Solano	Solano	1.112	1.066	**-4.14%**
Napa/Solano	Napa	1.112	1.066	**-4.14%**
Rest of California	Rest of California	**1.012**	**1.006-1.007**	-0.49%

CMA has the capability to calculate locality GAFs from GPCI data, assess the impact of locality revision, and calculate payment accuracy that is not provided in the proposal. However, without the new GPCI and RVU data for California Counties, we cannot perform the calculations necessary to accurately evaluate the impact of Option 1 and 2.

In addition, we observed that the NEW CY 2009 GAF with locality change for the single counties listed in Table 7 (column 4) and Table 8 (column 3) differ from the Current county GAF (column 3) in Table 9, Option 3 for the same counties.

County GAF differences Table 7, 8 & 9

Locality Name	County Name	Table 7 & 8 New CY 2009 GAF, with locality change	Table 9 County 2009 GAF
Santa Cruz	Santa Cruz	1.100	1.098
Monterey	Monterey	1.080	1.077
Napa	Napa	1.080	1.077
Solano	Solano	1.053	1.051
Sonoma	Sonoma	1.076	1.074
Marin	Marin	1.173	1.170

These discrepancies lead us to question the accuracy of the impact of the three options listed in Tables 7, 8, and 9 and the accuracy of the locality configurations.

A significant discrepancy is present in Option 3. The text describes methodology similar to the County-based GAF range option studied in the GAO report (GAO-07-466) applying a "top-down" approach. After counties are sorted by descending GAFs, all counties within a 5% range of the highest GAF County are combined in the same locality. The process is repeated with the next highest GAF County outside of the 5% range, until all counties are assigned a locality. In Table 9, Option 3 (72FR38141-2) San Mateo County (GAF 1.204) is listed as the highest GAF County. 5% of GAF 1.204 is .062. Therefore, applying the methodology according to the text, Santa Clara County (GAF 1.148 or .058 difference) should be included in Locality 1. However, the table lists Santa Clara County as the highest GAF County in Locality 2 rather than the lowest GAF County in Locality 1. The methodology used to create the new localities listed in Table 9 appears to use a 0.05 GAF difference rather than a 5% difference. The methodology described in the text is not the methodology that was applied in the calculations.

Option 3--.05 vs 5% difference

County	County 2009 GAF	.05 difference CMS Published	5% difference CMS Corrected
San Mateo	1.204		**1.1438**
San Francisco	1.201	**Locality 1**	**=5% floor**
Marin	1.17		
Santa Clara	1.148	**error**	
Contra Costa	1.134		**1.0773**
Alameda	1.129		**=5% floor**
Orange	1.128	**Locality 2**	
Ventura	1.121		
Los Angeles	1.112		
Santa Cruz	1.098	**error**	
Napa	1.077		**1.0232**
Monterey	1.077		**=5% floor**
Sonoma	1.074	**Locality 3**	
Santa Barbara	1.053		
San Diego	1.053		
Solano	1.051		
Sacramento	1.047		
El Dorado	1.033		
San Bernardino	1.023	[illegible]	[illegible]
Placer	1.021		=5% floor
Riverside	1.017		
San Luis Obispo	1.015		
San Joaquin	1.006	**error**	
Yolo	0.995	**error**	
Stanislaus	0.979	**error**	
Mono	0.977	**error**	
Nevada	0.975		**0.9263**
Kern	0.973		**=5% floor**
San Benito	0.971		
Sierra	0.967		
Amador	0.967		
Fresno	0.963		
Mendocino	0.960		
Madera	0.960	**Locality 5**	
Tuolumne	0.959		
Alpine	0.957		

Mariposa	0.956		
Tulare	0.950		
Butte	0.950		
Calaveras	0.949		
Merced	0.949		
Humboldt	0.947		
Lake	0.947		
Imperial	0.945		
Plumas	0.945	error	
Lassen	0.944	error	
Sutter	0.942	error	
Yuba	0.942	error	
Colusa	0.940	error	
Del Norte	0.940	error	
Modoc	0.938	error	
Shasta	0.937	error	
Kings	0.935	error	
Inyo	0.935	error	
Siskiyou	0.934	error	
Trinity	0.933	error	
Tehama	0.932	error	
Glenn	0.930	error	

Santa Cruz County (GAF 1.098 in Table 9, GAF 1.100 in Table 7 & 8) appears to be within both the 5% and 0.05 thresholds of Locality 2 (Santa Clara County GAF 1.148 used for comparison), but is listed, instead, as the highest GAF County in Locality 3. Imperial and Plumas Counties have Current County GAFs listed as 0.945, yet Imperial is listed in Proposed Medicare Locality 5 and Plumas County is listed in Locality 6. We do not believe this is due to rounding effects. Including County GAFs to four digits might elucidate these apparent discrepancies.

Please also see the more detailed discussion below (V. Specific Comments on the General GPCI Update (72FR38136)) related to San Benito County. Based on the work of the GAO, we believe that CMS used the wrong MSA data for San Benito County. San Benito County is in the San Jose MSA, not the California Non Metropoitan Area. Applying the correct MSA data to San Benito County would move San Benito to Locality 2 and increase payments by 9.8% -- an appropriate classification given the dramatically rising costs in that community.

We urge CMS to correct these errors and discrepancies and reissue the proposals for public comment so that physicians may comment on the correct application of the methodologies described in Options #1-3.

IV. Specific Comments on Options 1-3

To assist CMS in the evaluation of Options #1-3, CMA provides the following specific comments on each option.

Option 1 & 2

CMA has extensively studied payment localities and advocated that the 5% iterative methodology be applied (as described in GAO-07-466 County-based iterative option and Option 1 5%i (61FR34618)). Unlike the GAO and HCFA application, however, we advocate the methodology be applied to existing localities. The iterative methodology compares the highest GAF County to the weighted average (GAF) of the remaining counties of the locality. The 5% (non iterative) methodology proposed in Option 1 and 2 compares the highest GAF County to its Locality GAF. The highest GAF County is, therefore, included in the calculation of the Locality GAF to which it is being compared. As described by HCFA in 1996 (61FR34618) the 5% iterative methodology is preferred because mid sized areas in large states and large areas in small states with considerably higher input prices have difficulty meeting the threshold (see description p34618 Federal Register July 2, 1996).

For example, San Diego County in Rest of California Locality has considerably higher input prices than the Rest of California (72FR38141-2). San Diego County contributes about 20% to the calculation of the Rest of California's GAF. As San Diego County's GAF increases to the threshold, the Rest of California's GAF also increases disproportionately, raising the payment error for all counties. San Diego County is not included in Option 1 or 2, we believe, because the 5% iterative methodology was not applied. If the same methodology is applied more broadly in other states, areas exist where a county is so heavily weighted in the locality average that the threshold can never be met, unless they are compared separately (refer to CMS US County GPCI data).

CMA strongly prefers the 5% iterative methodology to the non-iterative methodology applied in Option 1 and Option 2 of the CMS Locality proposal. Our comparison of the three options shows greater payment accuracy with the 5% iterative option. Administration could be simplified by consolidating single county localities with similar GAF's or Metropolitan Statistical Areas (MSA's) into Localities. Furthermore, there is greater payment accuracy than the 5% iterative county-based option reported by the GAO because the methodology is applied to existing localities rather than states. Such an application creates less disruption among existing localities with high payment accuracy.

We are also troubled that the methodology consolidating counties in Option 2 (after the threshold is applied) is not clearly stated. Combining the Counties into one locality has less payment accuracy than Option 1. The three Counties are not geographically contiguous and reside in separate MSAs. It is not clear how such a consolidation would occur on a more broad application. CMS should clearly define the methodology (threshold) used to consolidate counties with similar cost structures into one new locality. We oppose an arbitrary consolidation of counties for administrative simplification at the expense of payment accuracy.

CMA cannot support Options 1 and 2 for the reasons listed above but most notably because the iterative methodology was not employed. An iterative methodology would recognize and corrects the underpayment problems in many additional counties. Moreover, an iterative methodology in Options 1 and 2 would impose the least disruption

on counties in California that are not experiencing problems and that have high payment accuracy. However, we are also concerned with the proposed payment reductions, particularly the 4.3% payment reductions in Napa and Solano Counties. In general, we refer you to the GAO report findings on the county-based iterative approaches. Most important, CMA is seeking a long term solution to the problem. Options 1 and 2 only update three counties on a one-time basis. The non-iterative methodology is flawed and is silent on future updates. We urge CMS to adopt a methodology that can uniformly be applied and updated every three years.

Option 3

Option 3 provides the greatest payment accuracy overall. In California, it creates fewer payment areas which is less burdensome for CMS. However, it creates payment error in localities that have high payment accuracy. Six of the nine payment areas in California have 100% payment accuracy (costs, as measured by county GAF, are the same as locality payment). Option 3 creates payment errors in these six localities. Option 3 creates localities with counties that are not geographically contiguous. The locality border difference is higher in Option 3 than the 5% iterative county-based methodology as reported by GAO. However, improving payment accuracy overall could reduce problematic boundary differences.

In addition, counties of the same MSA (and similar cost indices) are assigned different localities. Methodology used to create Option 3 would be difficult to apply for future revision without potentially disrupting all payment localities. While an MSA approach is attractive because the source cost indices are similar, CMA is also compelled by the GAO findings that it creates unacceptable ranges and higher overpayments within localities in other states.

Our greatest concern with Option 3 is the negative impact to low cost rural "Rest of California" – Locality 99 counties. These counties would receive 4.9% to 7.3% payment reductions in an environment of rising costs, no payment updates for five years and a 9.9% conversion factor reduction. Moreover, these rural counties have historically suffered from physician shortages and access problems. In our opinion, such a payment reduction would unquestionably affect access to care for Medicare beneficiaries in these areas.

V. Specific Comments on the General GPCI Update (72FR38136)

In past years, budget neutrality adjusting factors were described in the proposed update (69FR47504). Changes observed in the physician work GPCI update for 2009 were due to minor changes in utilization and budget neutrality factors (72FR38138). However, these factors were not specified in the proposed 2008 rule. In the interest of transparency, we recommend that this adjustment factor be published. We also recommend that all data used to calculate GPCIs be available to interested parties.

San Benito County
It is reported that "the geographic adjustment factors (GAF's) for more than 90 percent of counties are developed using proxies based on larger geographic areas" (72FR38139). Using the same census data as CMS, the GAO was able to calculate individual work and practice expense GPCIs for 1091 counties that were part of a metropolitan statistical area (MSA)(GAO-07-466 p46). This represents a third of all counties. We noted a significant discrepancy in the GAF for San Benito County, California between the GAF reported by GAO and GAF published by CMS (GAO San Benito GAF-1.081 on p.54, CMS San Benito GAF-.971 p.38142) that could not be explained by differences in rent indices and Malpractice GPCIs. We believe this might be explained by an error in MSA derived census data by CMS. We believe the wrong MSA data was applied to San Benito County by CMS. San Benito County resides in the San Jose MSA not the California Non Metropolitan Area as suggested by the CMS GAF.

If the correct San Jose MSA data is applied, we believe San Benito would more appropriately be placed in Locality 2 under CMS proposed Option #3 and receive a 9.8% payment increase instead of the proposed -4.9% reduction. This MSA application is of major importance to San Benito County which is experiencing an exodus of physicians from the County. We request that this be reviewed along with the accuracy of the Census data used to develop the Work and PE GPCIs for all California Counties, like San Benito, where the County data is derived from MSA data.

Santa Clara County
We are extremely troubled by the 2009 Practice Expense (PE) GPCI for Santa Clara County. Since the PE GPCI is derived from wage census data and rent indices, and the wage census data has not changed since the last revision, the difference between the 2007 and 2009 PE GPCI can only be accounted for by changes in the rent indices. Santa Clara County had a 29% reduction in HUD FMR rent indices between 2004 and 2007 (the years used to determine 2006 and 2009 PE GPCIs). San Francisco County and San Mateo County had a 27% reduction in HUD rent indices between 2004 and 2007. Yet Santa Clara County's 2009 PE GPCI fell 16% while San Francisco and San Mateo County's 2009 PE GPCI only fell by 7%. We have been told that the Santa Clara County 2009 PE GPCI has been recalculated and is accurate (personal communication with CMS). We can only conclude, therefore, that an error was made in the calculation of the 2007 PE GPCI for Santa Clara County that has been corrected with the 2009 revision.

We urge CMS to investigate the Santa Clara calculation because Santa Clara physicians are facing a disproportionate payment reduction of 9.2% versus a 4.3% reduction for the neighboring bay area counties. Moreover, if the 2009 Santa Clara GAF represents a correction of an earlier mistake, it should be fully disclosed to the public. A 30% reduction in rent should not equate to a nearly 10% payment decrease.

CMA believes that the CMS contractor has made errors over the past several years that CMS has not been made aware. CMA suggests that CMS provide closer oversight of the contractor making the GPCI calculations. Moreover, if the contractor is making

adjustments in the 2008-2009 proposed rule to account for errors made in previous years, those errors should be disclosed to the public.

San Diego County
We observed that San Diego County's GAF listed in Table 9 (1.053) is .02 less than what we calculated their GAF to be from previous 2006 GPCIs (1.072). San Diego County's 2007 HUD FMR is higher than their 2004 HUD FMR (used to determine the rent indices for PE GPCI). Therefore, the 2009 PE GPCI for San Diego County should be no lower than the 2006 PE GPCI. The 2009 Work GPCI should not be significantly different than the 2006 Work GPCI. The Malpractice GPCI contributes less than 4% of the GAF calculation. The .02 drop in San Diego GAF cannot be explained by the Malpractice GPCI alone. Since the San Diego County GAF is important in determining locality configurations for all three proposed options and contributes to 20% of Rest of California GPCIs if none of the options are finalized, we request that San Diego County's cost indices be reviewed.

VI. HUD Data Problems

There is considerable volatility in the HUD FMR data (used to generate rent indices for the PE GPCI) which makes us question its validity as a proxy for office rents. We do not believe that Santa Clara physicians experienced a 29% reduction in office rent relative to the national average. The GAO recommended in its 2005 report on GPCIs that CMS "consider the feasibility of replacing the practice expense GPCIs current rent index with a commercial rent index; if using a commercial rent index is not feasible, consider a residential rent index directly based on ACS data"(GAO-05-119). If the HUD FMR data is still considered the best proxy for office rents, we recommend that it be modified to adjust for the volatility in rental units that physicians are not seeing in their practice overhead.

VII. CMA Position

The California Medical Association cannot support any of the three GPCI options as proposed by CMS at this time for the reasons stated above. Of most concern are the significant reductions on physicians practicing in rural areas of California. Unfortunately, because CMS refused to provide the source data to CMA, we were unable to craft amendments to these three options that would have made them more consistent with our policy.

Therefore, the CMA urges CMS to adopt a payment locality update option that is consistent with the following policy that was unanimously adopted by the CMA House of Delegates in the Fall of 2006.

Resolution 102-06: MEDICARE LOCALITY REVISION

RESOLVED: **That CMA apply the following principles in supporting revised Medicare Geographic Payment Localities:**
(1) methodology for revision is applied consistently;
(2) payment accuracy within the locality is improved;
(3) there is a mechanism for future revision of localities that is formula driven;
(4) implementation of the revision minimizes payment reduction in each payment locality; and
(5) evaluation of any revision is based on accurate data gathered by CMA which shows that the revision minimizes any negative effect on access to care in California.

We also want to emphasize that we agree with the GAO recommendations that CMS needs to adopt a methodology and update payment localities on a timely basis rather than only considering locality issues when concerns are raised by interested parties. Medicare should pay as accurately as possible and appropriately account for geographic variation in practice costs.

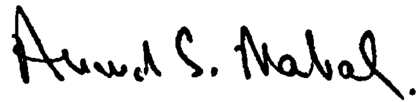
CMS also requested specific comments related to administrative burden. We do not believe that any of the proposed options impose an undue administrative burden on CMS or physicians. The goal of paying physicians accurately outweighs any one-time administrative cost concerns.

Finally, we would like to summarize our specific recommendations related to the discrepancies in the three California options and the General GPCI update:

1. The data used to develop the GPCIs and the GAFs should be transparent and made available to all interested parties.
2. CMS should correct the GAF errors listed in Options 1-3.
3. CMS should correct the GPCIs of San Benito, San Diego and all California Counties with indices derived from the wrong multi-county MSAs.
4. CMS should investigate the Santa Clara HUD indices discrepancies and provide an explanation for the disproportionate 9.2% payment reduction.
5. CMS should correctly apply the methodology described in Option #3.
6. CMS should consider alternative methods to develop indices for office rent.
7. CMA urges CMS to resubmit options for locality revision for public comment once the errors and discrepancies have been fixed.

The CMA appreciates the opportunity to comment. We appreciate CMS' attempt to resolve the payment locality problem in California. We hope CMS will continue to work to equitably improve payment accuracy in California without imposing unreasonable payment reductions on physicians practicing in California's already underserved rural areas.

Sincerely,



Anmol S. Mahal, MD
President

Submitter : **Greg Cruse** **Date: 08/31/2007**

Organization : **Greg Cruse**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Greg Cruse

Submitter : **Leta Cruse** **Date: 08/31/2007**

Organization : **Leta Cruse**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Leta Cruse

Submitter : **Scott Hadden** **Date: 08/31/2007**

Organization : **Scott Hadden**

Category : **Health Care Professional or Association**

Issue Areas/Comments

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Scott Hadden

Submitter : **Kerry Knight** **Date: 08/31/2007**

Organization : **Kerry Knight**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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Centers for Medicare and Medicaid Services
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Baltimore, MD 21244-8018

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Thank you for your consideration of this serious matter.

Kerry Knight

Submitter : **Amy Knight** **Date: 08/31/2007**

Organization : **Amy Knight**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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Centers for Medicare and Medicaid Services
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Thank you for your consideration of this serious matter.

Amy Knight

CMS-1385-P-14469

Submitter : Dr. Mark Workman **Date:** 08/31/2007

Organization : The Pain Rehabilitation Group of Wichita Falls, PA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1385-P-14469-Attach-1.DOC

14169

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%

64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

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The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

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Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Mark A. Workman, M. D.
4301 Maplewood Ave Ste A
Wichita Falls, Texas 76308

Submitter : Mrs. C M **Date:** 08/31/2007

Organization : Private Office

Category : Physical Therapist

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

My patients have been so happy for having the physician so closely involved in their care and how easy is for them to come for therapy. Otherwise many of them could not complete their treatment or would be at great risk of injury since big clinic can't afford to provide care with the necessary one-on-one care.
In addition, I have had two situations that requiere emergency care with one pt having a heart attack in the clinic and another one having a dangerously high blood preassure that needed immediate attention from the doctor. Thanks to having them next door bot patients recieved the care that they needed in a timely and caring manner. Additionally, I can honestly say that I can be a much better PT and provide better use of the resources because of the expediate way to provide services.

CMS-1385-P-14471

Submitter : Dr. MELISSA CARTER **Date:** 08/31/2007

Organization : UNIVERSITY HOSPITALS OF CLEVELAND ANESTHESIOLOGY

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Submitter : Ms. Wilma Bouska
Organization : Ms. Wilma Bouska
Category : Individual

Date: 08/31/2007

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

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To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Wilma Bouska

CMS-1385-P-14473

Submitter : Mr. D S

Date: 08/31/2007

Organization : Mr. D S

Category : Individual

Issue Areas/Comments

Physician Self-Referral Provisions

Physician Self-Referral Provisions

It's more convenient for me to have services in the doctor's office because all your records are together and can spend more one-on-one time with therapist and less wait to get in to see the therapist. More flexibility of the schedule that accomodates my schedule and I can get more intense therapy and more detail.

CMS-1385-P-14474

Submitter : Dr. Miguel Dominguez

Date: 08/31/2007

Organization : Miguel A. Dominguez MD Inc

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14474-Attach-1.DOC

14474

Miguel A. Dominguez, M.D.

Board Certified in Pain Medicine & Anesthesiology
Qualified Medical Examiner, State of California

18102 Irvine Blvd Suite 208 Tustin CA 92780
Phone 714 371-9000 Fax 714730-2711 www.easethepain.net Email Miguel@americanpain.us

Friday, August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, "Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" (the "Proposed Rule") published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the "all physicians" crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians' ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries' access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that

CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as "interventional pain physicians" for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to "all physicians" for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect

compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%
64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system—physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to "all physicians" for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey ("Physician Practice Survey") will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a

customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

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Respectfully Yours,

Miguel A Dominguez M.D.
Medical Director
American Pain Institute-California

Submitter : **Thomas Ashby** **Date: 08/31/2007**

Organization : **Magic Valley Anesthesiology Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just about $16 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation. This will serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Thomas Ashby

Submitter : Mr. WILLIAM CARTER
Date: 08/31/2007
Organization : Mr. WILLIAM CARTER
Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
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#11477

Miguel A. Dominguez, M.D.

Board Certified in Pain Medicine & Anesthesiology

Qualified Medical Examiner, State of California

18102 Irvine Blvd Suite 208 Tustin CA 92780

Phone 714 371-9000 Fax 714730-2711 www.easethepain.net Email Miguel@americanpain.us

Friday, August 31, 2007

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

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customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the "MMA") mandated CMS to pay providers 106% of the manufacturer's Average Sales Price ("ASP") for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate ("SGR") formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Respectfully Yours,

Miguel A Dominguez M.D.
Medical Director
American Pain Institute-California

Submitter : Dr. Richard Lindstrom

Date: 08/31/2007

Organization : ASCRS and OOSS

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1385-P-14478-Attach-1.PDF

#14478

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

August 31, 2007

Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ATTN: CMS-1385-P
200 Independence Avenue
Room 445-G
Washington, DC 20201

Re: Medicare Programs; Revision to Payment Policies to the Medicare Physician Fee Schedule (MPFS) for Calendar Year 2008; Proposed Rule

Dear Mr. Kuhn:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing more than 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures done annually in the United States.

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association of more than 1,100 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical procedures performed in cost-effective outpatient environments, including ambulatory surgical centers (ASCs).

ASCRS and OOSS appreciate the opportunity to submit comments on the proposed rule for the 2008 Medicare physician fee schedule.

Sustainable Growth Rate (SGR)

Due to the flawed Sustainable Growth Rate (SGR) formula, physicians are faced with a 9.9% reduction in their Medicare payments beginning January 1, 2008. The flawed formula is also slated to produce steep negative updates of 40% through 2017. CMS has agreed with the medical community, Congress, and policy experts that the SGR formula is unsustainable. However, the agency has done nothing to address some of the problem areas over which it has control. Some problems have been discussed by ASCRS and OOSS in previous comments, and we again outline them below.

Removal of Physician-Administered Medicare-Covered Drugs Retroactively

We again ask CMS to use its administrative authority to remove drugs from the physician payment pool retroactive to 1996, filling the gap between actual spending and target spending, thereby making it more likely Congress will permanently repeal the SGR.

Here are the facts:

- Physicians do not have control over the cost of drugs and biologics.
- Part B drugs are not procedures, diagnostic tests, or services.
- Part B drugs are only used in conjunction with certain procedures, diagnostic tests, and/or services.

For the past several years, ASCRS and OOSS as well many other medical and specialty societies, members of the Medicare Payment Advisory Commission (MedPAC) and the Practicing Physicians Advisory Committee (PPAC), the Government Accountability Office (GAO), congressional committees with jurisdiction over the Medicare program, and the majority of Congress have identified the cost of physician-administered drugs as a primary factor that drives physician spending above the expenditure target. Collectively and independently, these groups have consistently recommended that CMS use its administrative authority to remove drugs from the definition of physician services back to the base year, 1996.

We continue to believe the agency has the authority to follow through with our requests. CMS is aware that making these adjustments would drastically reduce the cost of replacing the flawed SGR formula with a stable payment system, and there is overwhelming support in favor of making this necessary change. At the very least, we urge CMS to use its authority to remove drugs from the SGR pool, prospectively.

ASCRS and OOSS respectfully ask that CMS use its administrative authority to remove drugs from the physician payment pool retroactive to 1996, filling the gap between actual spending and target spending, thereby making it more likely Congress can permanently repeal the SGR.

Accurately Accounting for Changes in Law and Regulation

ASCRS and OOSS, again, urge CMS to accurately account for changes in law and regulation when calculating the physician payment update. Specifically, we urge the agency to ensure that national and local coverage decisions and screening benefits (including the services they generate) that have been added to the Medicare program be included in the expenditure target.

We continue to believe that new coverage decisions—national and local—have an impact on utilization. Most notable are coverage decisions that require certain diagnostic tests be performed in conjunction with the procedure(s) being addressed by the coverage decision. Furthermore, we

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understand that only coverage decisions added to the program by legislation—not by regulation—have been accounted for in the expenditure target. However, we continue to believe that CMS should include all coverage decisions—whether added to the program by statute or by the agency—when calculating the expenditure target.

In previous comments, ASCRS and OOSS used as an example the national coverage determination (NCD) on ocular photodynamic therapy (OPT) with verteporfin (Visudyne) for age-related macular degeneration (ARMD). This NCD, which was implemented in April 2004, expanded coverage for this type of therapy to beneficiaries with certain diagnoses; however, the coverage decision states that the newly expanded coverage is only allowed "provided certain criteria are met." As a result of the coverage policy created, physicians are required to perform certain diagnostic tests to perform OPT with verteporfin.

Therefore, CMS is directly responsible for volume increases related to certain services and procedures and must adjust the SGR target accordingly.

TRHCA – Section 101(d): PAQI

ASCRS and OOSS urge CMS to use the $1.35 billion available in the Physician Assistance and Quality Improvement (PAQI) Fund to reduce the cost of preventing the proposed 9.9% payment cut, rather than for a 2008 Physician Quality Reporting Initiative (PQRI). We were extremely disappointed to see CMS' proposal to use the PAQI fund to finance a 2008 PQRI program, particularly at a time when physicians are faced with a 9.9% cut in 2008 and without any evidence that the 2007 PQRI program proved successful. Certainly, the agency is aware that using the PAQI to improve the significant reduction to the fee schedule will have a more positive impact on all physicians than a reporting program whose value is unknown.

TRHCA – Section 101(b): PQRI

ASCRS and OOSS are extremely concerned about CMS' proposal on the 2008 PQRI. Our major concerns are outlined below:

- Lack of transparency associated with the measure development process
- Numerous proposals to include quality measures that were not created through a "consensus-based development process"
- No clarification on the reporting requirements for the 2008 PQRI and lack of transparency associated with the method for determining successful reporting (validation method)
- No plan to identify gaps in care and prioritize the development of measures.

Lack of transparency associated with the measure development process

In the proposed rule, CMS describes the provisions in the Tax Relief and Health Care Act of 2006 (TRHCA) relating to its requirement to implement a system for the reporting of data on quality measures by eligible professionals. CMS further discusses how the agency interprets

those provisions.

With regard to CMS' interpretation of "consensus organizations" and "consensus-based process for measure development," CMS provides only confusion. In fact, CMS makes a number of contradictory statements and offers different interpretations of what a consensus organization and consensus-based development process are. We maintain that "consensus organizations," such as the AQA Alliance and National Quality Forum (NQF), and a "consensus-based development process" are separate and distinct and that the two terms should not be used synonymously. Therefore, CMS must make this clarification as it moves forward.

In addition, as required by statute, quality measures included in the 2008 PQRI "...shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include measures that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures..." We believe that Congress' intent was to make certain that physician-level quality measures were developed by physicians (through medical specialty societies) and using a consensus-based process. As you know, for a reporting system to be meaningful, quality measures must be evidence-based and developed with the medical specialty societies that have expertise in the area of care in question. In addition, measures should conform to clinical guidelines developed by the various physician specialties.

We are pleased the CMS proposed to include measures developed through the American Medical Association's (AMA) Physician Consortium for Performance Improvement (PCPI) and urge the agency to formally recognize the AMA PCPI as the *sole entity* for the development of physician-level quality measures. As CMS is aware, the Consortium uses a well-thought-out consensus-based process involving numerous medical specialties (national and state-level), quality improvement organizations, medical specialty boards, government agencies, and public and private payers. This ensures that all health professionals have an opportunity to participate and have a voice at the table when quality measures are being developed. No other entity offers this level of rigor for measure development and, again, this ensures everyone has a voice and is participating in the development of the measures from the ground up.

Therefore, we again urge CMS to recognize the AMA PCPI as the sole entity for the development of physician-level quality measures.

Numerous proposals to include quality measures that were not developed through a "consensus-based development process"

Not only does CMS propose to include several measures that were not developed through a consensus-based process, it also "leaves the door open" for anyone and everyone to develop and put forward measures for inclusion in CMS' quality programs. There is no guarantee that any measure developed by a group other than the AMA PCPI will include every health professional who is, or who could potentially be, involved in the development of physician-level quality measures. For example, we cannot be assured that quality measures developed by Quality Insights of Pennsylvania and American Podiatric Medical Association allowed the input of

representatives from every medical specialty who could potentially be involved in the care of the patient population for which the measures were developed.

To avoid confusion and prevent the need for reconciliation of measures at the end of the process, CMS should name one entity as the sole developer of quality measures for physicians. We again ask that CMS recognize the AMA PCPI as the sole entity for the development of physician-level quality measures.

In addition, we are not sure whether the measures developed by Quality Insights of Pennsylvania are intended for physicians and non-physicians or are for non-physicians only, given the way the measures are specified by this group. We ask CMS to clarify this in the final rule.

No clarification on the reporting requirements for the 2008 PQRI and lack of transparency associated with the method for determining successful reporting (validation method)

We ask CMS to clarify how the reporting requirements indicated in the 2008 PQRI program apply across the seven categories of proposed measures—including clinical, process, and structural measures—and how successful reporting can be achieved. As you know, this was not provided for in the 2007 PQRI; therefore, it is difficult to determine what CMS' plan for 2008 will be.

According to the proposed rule, for purposes of the 2008 PQRI, CMS proposes that physicians continue to participate in the same manner in which they participated in the 2007 PQRI. We find this language very troublesome because some proposals include many new measures; this could affect the number of measures a provider would have available and be required to report to qualify for the bonus.

No plan to identify gaps in care and prioritize the development of measures

In the proposed rule, CMS does not discuss how it plans to identify gaps in care and prioritize the development of measures. This is a major concern for our specialty, in particular our members who provide high-quality cataract surgical care to Medicare beneficiaries.

According to the agency, the goal of the PQRI is to improve the quality of care provided to beneficiaries. If this is indeed the case, we maintain that CMS should focus its efforts on clinical areas that require improvement. That is, CMS should work with the medical community to identify where there are gaps in care and focus on improving those areas first.

As you know, ophthalmology struggled to obtain AQA approval and NQF endorsement for measures related to cataract surgery. Our efforts were unsuccessful because according to NQF, the measures developed for cataract surgery through the Consortium did not address a significant enough gap in care.

The fact that cataract surgery is one of the most successful surgical services provided to Medicare beneficiaries should be considered a positive. However, as a consequence, we continue

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to have difficulty developing measures for this service that can meet the approval of AQA and achieve NQF endorsement. As you can see, our subspecialty represents one example of an area in medicine in which no significant gap in care exists, yet we are put in a position in which we must develop measures to assist our members in being able to participate in CMS' quality programs for the mere sake of reporting.

We maintain that for any reporting system to improve quality, the measures must be meaningful to clinical care and relevant to physicians and other health professionals providing the care. Measures should not be developed for the sake of developing measures. Reporting should not be done just for the sake of reporting. **Instead, CMS should work with the medical community to identify gaps in care and prioritize the development of measures so the agency can achieve its goal of improving the quality of care provided to beneficiaries.**

Other items

We would also like to point out that, since July 1, 2007, there have been a host of problems with the 2007 PQRI. These include carriers processing claims improperly or not at all, carriers providing misinformation about the PQRI to its providers, and problems associated with implementing the National Provider Identifier (NPI), which is a key component to participating in the PQRI as it is based on individual physician reporting. We are concerned that the process for developing the 2008 PQRI is moving forward without these issues being addressed and without 2007 PQRI data being analyzed. We believe a thorough evaluation of data from the 2007 PQRI is necessary before CMS can reasonably move ahead. Some areas CMS should consider are as follows: the impact of the 2007 PQRI program on patient care because according to the agency, this is its number one priority; data related to physician participation rates to determine whether the program, as established, draws enough participation to outweigh the administrative costs associated with its operation; and finally, the costs physicians have and will continue to incur should they participate in the PQRI.

For all the above-stated reasons, we strongly urge CMS to support provisions included in S. 1519/ H.R. 2749, the Voluntary Medicare Quality Reporting Act. Specifically, we ask CMS to:

- **Name the AMA PCPI as the sole entity for the development of physician-level quality measures**
- **Work with the medical specialty community to identify gaps in care for which quality measures are genuinely needed**
- **Ensure that any Medicare quality program for physicians remains voluntary and non-punitive**
- **Provide positive incentives for those who participate in the PQRI and ensure those incentives are compensated with new funding.**

Finally, Table 16 in the proposed rule contains the quality measures that were included in the 2007 PQRI. We note, however, that one ophthalmology measure "dilated macular exam for patients with age-related macular degeneration," which was developed by the Consortium,

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endorsed by the NQF, and included in the 2007 PQRI program, is missing from the table. **We ask CMS to correct this oversight by adding the aforementioned measure.**

Budget Neutrality

ASCRS and OOSS again urge CMS to reconsider its proposal to make budget-neutrality adjustments to the work RVUs and encourage the agency to apply the budget-neutrality adjustments to the 2007 conversion factor.

Last year, CMS finalized a proposal from its 5-year review of work relative value units (RVUs) and 2007 MPFS proposed rules to meet its budget-neutrality requirement by reducing all work RVUs by an estimated 10%. This was against the recommendation of the majority of medical specialty societies, including the AMA. This year, CMS proposes to make a similar adjustment by reducing work RVUs by an additional 2%. As we explained before, the application of a budget-neutrality work adjustor to the work RVUs is counterintuitive and halts the progress made by specialty societies, the AMA Relative Value System Update Committee (RUC), and CMS, which spent countless hours developing accurate changes to work RVUs. In addition, the application of a budget-neutrality adjuster to the work RVUs goes against CMS' longstanding policy that adjustments to RVUs to maintain budget neutrality are ineffective and cause confusion. It is for this reason CMS has been applying budget-neutrality adjustments, due to changes in the work RVUs, to the physician fee schedule conversion factor since 1998.

In addition, the vast majority of private payers use the Medicare fee schedule in their contracts with physicians, and physicians could be negatively affected if private payers used budget-neutrality-adjusted work RVUs. To maintain two separate work RVU lists, one adjusted for budget neutrality and one not adjusted for budget neutrality, has already generated needless confusion and administrative hassle for most physicians. Let's not create a similar situation this year.

Finally, CMS explained last year that it would implement the work adjuster instead of applying budget-neutrality adjustments to the conversion factor because it believed it would be more equitable to make the reduction to the portion of the physician payment formula that was directly involved in the 5-year review. This rationale was not plausible because it assumed all work RVUs were involved in the 5-year review. As you know, only about 6% of the more than 7,500 physician codes were involved in third 5-year review of work RVUs. Under CMS' plan, many codes will be penalized simply because they have work RVUs. Again, it only makes sense to apply budget-neutrality adjustments to the conversion factor because it is the only monetary factor in the formula.

For the above stated reasons, we again urge CMS to reconsider its proposal and apply its budget-neutrality adjustment to the conversion factor rather than the work RVUs.

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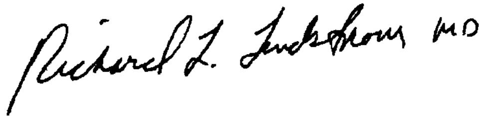
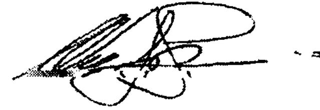
Associate Director of Regulatory Affairs, at 703-591-2220 or egraham@ascrs.org, or Michael A. Romansky, OOSS Legal Counsel, at MRomansky@OOSS.org.

Sincerely,





Richard L. Lindstrom, MD
President, ASCRS

William Fishkind, MD
President, OOSS

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Submitter : Ms. Lori Sasser **Date:** 08/31/2007
Organization : Ms. Lori Sasser
Category : Individual

Issue Areas/Comments

Payment For Procedures And Services Provided In ASCs

Payment For Procedures And Services Provided In ASCs

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: CMS-1385-P
Anesthesia Coding (Part of 5-Year Review)

Dear Ms. Norwalk:

I am writing to express my strongest support for the proposal to increase anesthesia payments under the 2008 Physician Fee Schedule. I am grateful that CMS has recognized the gross undervaluation of anesthesia services, and that the Agency is taking steps to address this complicated issue.

When the RBRVS was instituted, it created a huge payment disparity for anesthesia care, mostly due to significant undervaluation of anesthesia work compared to other physician services. Today, more than a decade since the RBRVS took effect, Medicare payment for anesthesia services stands at just $16.19 per unit. This amount does not cover the cost of caring for our nation s seniors, and is creating an unsustainable system in which anesthesiologists are being forced away from areas with disproportionately high Medicare populations.

In an effort to rectify this untenable situation, the RUC recommended that CMS increase the anesthesia conversion factor to offset a calculated 32 percent work undervaluation a move that would result in an increase of nearly $4.00 per anesthesia unit and serve as a major step forward in correcting the long-standing undervaluation of anesthesia services. I am pleased that the Agency accepted this recommendation in its proposed rule, and I support full implementation of the RUC s recommendation.

To ensure that our patients have access to expert anesthesiology medical care, it is imperative that CMS follow through with the proposal in the Federal Register by fully and immediately implementing the anesthesia conversion factor increase as recommended by the RUC.

Thank you for your consideration of this serious matter.

Sincerely,

Lori Sasser

Submitter : Dr. Marcom Herren **Date:** 08/31/2007

Organization : The Pain Rehabilitation Group of Wichita Falls, PA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1385-P-14480-Attach-1.DOC

14430

Kerry Weems
Administrator Nominee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1385-P

Dear Mr. Weems:

I would like to thank you for the opportunity to comment on the Proposed Rule CMS-1385-P, ?Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008? (the ?Proposed Rule?) published in the *Federal Register* on July 12, 2007 As requested, I have limited my comments to the issue identifiers in the Proposed Rule.

There are approximately 7,000 physicians practicing interventional pain management in the United States I am included in this statistic. As you may know physician offices, along with hospital outpatient departments and ambulatory surgery centers are important sites of service for the delivery of interventional pain services.

I appreciated that effective January 1, 2007, CMS assigned interventional pain and pain management specialties to the ?all physicians? crosswalk. This, however, did not relieve the continued underpayment of interventional pain services and the payment shortfall continues to escalate. After having experienced a severe cut in payment for our services in 2007, interventional pain physicians are facing additional proposed cuts in payment; cuts as much as 7.8% to 19.8% in 2008 alone. This will have a devastating affect on my and all physicians? ability to provide interventional pain services to Medicare beneficiaries. I am deeply concerned that the continued underpayment of interventional pain services will discourage physicians from treating Medicare beneficiaries unless they are adequately paid for their practice expenses. I urge CMS to take action to address this continued underpayment to preserve Medicare beneficiaries? access.

The current practice expense methodology does not accurately take into account the practice expenses associated with providing interventional pain services. I recommend that CMS modify its practice expense methodology to appropriately recognize the practice expenses of all physicians who provide interventional pain services. Specifically, CMS should treat anesthesiologists who list interventional pain or pain management as their secondary Medicare specialty designation, along with the physicians that list interventional pain or pain management as their primary Medicare specialty designation, as ?interventional pain physicians? for purposes of Medicare rate-setting. This modification is essential to ensure that interventional pain physicians are appropriately reimbursed for the practice expenses they incur.

RESOURCE-BASED PE RVUs

I. CMS should treat anesthesiologists who have listed interventional pain or pain management as their secondary specialty designation on their Medicare enrollment forms as interventional pain physicians for purposes of Medicare rate-setting.

Effective January 1, 2007, interventional pain physicians (09) and pain management physicians (72) are cross-walked to ?all physicians? for practice expenses. This cross-walk more appropriately reflects the indirect practice expenses incurred by interventional physicians who are office-based physicians. The positive affect of this cross-walk was not realized because many interventional pain physicians report anesthesiology as their Medicare primary specialty and low utilization rates attributable to the interventional pain and pain management physician specialties.

The practice expense methodology calculates an allocable portion of indirect practice expenses for interventional pain procedures based on the weighted averages of the specialties that furnish these services. This methodology, however, undervalues interventional pain services because the Medicare specialty designation for many of the physicians providing interventional pain services is anesthesiology. Interventional pain is an inter-disciplinary practice that draws on various medical specialties of anesthesiology, neurology, medicine & rehabilitation, and psychiatry to diagnose and manage acute and chronic pain. Many interventional pain physicians received their medical training as anesthesiologists and, accordingly, clinically view themselves as anesthesiologists. While this may be appropriate from a clinically training perspective, their Medicare designation does not accurately reflect their actual physician practice and associated costs and expenses of providing interventional pain services.

This disconnect between the Medicare specialty and their practice expenses is made worse by the fact that anesthesiologists have the lowest practice expense of any specialty. Most anesthesiologists are hospital based and do not generally maintain an office for the purposes of rendering patient care. Interventional pain physicians are office based physicians who not only furnish evaluation and management (E/M) services but also perform a wide variety of interventional procedures such as nerve blocks, epidurals, intradiscal therapies, implant stimulators and infusion pumps, and therefore have practice expenses that are similar to other physicians who perform both E/M services and surgical procedures in their offices.

Furthermore, the utilization rates for interventional pain and pain management specialties are so low that they are excluded from Medicare rate-setting or have very minimal affect compared to the high utilization rates of anesthesiologists. CMS utilization files for calendar year 2007 overwhelming report anesthesiologists compared to interventional pain physicians and pain management physicians as being the primary specialty performing interventional pain procedures. The following table illustrates that anesthesiologists are reported as the primary specialty providing interventional pain services compared to interventional pain physicians

CPT Code	Anesthesiologists - 05 (Non-Facility)	Interventional Pain Management Physicians - 09 (Non-Facility)
64483 (Inj foramen epidural l/s)	59%	18%
64520 (N block, lumbar/thoracic)	68%	15%

64479 (Inj foramen epidural c/t)	58%	21%
62311 (Inject spine l/s (cd))	78%	8%

The high utilization rates of anesthesiologists (and their extremely low practice expenses) drive the payment rate for the interventional pain procedures, which does not accurately reflect the resource utilization associated with these services. This results in payment rates that are contrary to the intent of the Medicare system?physician payment reflects resources used in furnishing items and services to Medicare beneficiaries.

I urge CMS to make a modification to its practice expense methodology as it pertains to interventional pain services such that its methodology treats physicians who list anesthesiology as their primary specialty and list interventional pain as their secondary specialty designation as interventional pain physicians for rate-setting. This pool of physicians should be cross-walked to ?all physicians? for practice expenses. This will result in a payment for interventional pain services that is more aligned with the resources and costs expended to provide these services to a complex patient population.

I urge CMS not to delay implementing our proposed recommendation to see if the updated practice expenses information from the Physician Practice Information Survey (?Physician Practice Survey?) will alleviate the payment disparity. While I believe the Physician Practice Survey is critical to ensuring that physician services are appropriately paid, I do not believe that updated practice expense data will completely resolve the current underpayment for interventional pain services. The accurate practice expense information for interventional pain physicians will continue to be diluted by the high utilization rates and associated low practice expenses of anesthesiologists.

II. CMS Should Develop a National Policy on Compounded Medications Used in Spinal Drug Delivery Systems

We urge CMS to take immediate steps to develop a national policy as we fear that many physicians who are facing financial hardship will stop accepting new Medicare beneficiaries who need complex, compounded medications to alleviate their acute and chronic pain. Compounded drugs used by interventional pain physicians are substantially different from compounded inhalation drugs. Interventional pain physicians frequently use compounded medications to manage acute and chronic pain when a prescription for a customized compounded medication is required for a particular patient or when the prescription requires a medication in a form that is not commercially available. Physicians who use compounded medications order the medication from a compounding pharmacy. These medications typically require one or more drugs to be mixed or reconstituted by a compounding pharmacist outside of the physician office in concentrations that are not commercially available (*e.g.*, concentrations that are higher than what is commercially available or multi-drug therapy that is not commercially available).

The compounding pharmacy bills the physician a charge for the compounded fee and the physician is responsible for paying the pharmacy. The pharmacy charge includes the acquisition cost for the drug ingredients, compounding fees, and shipping and handling costs for delivery to the physician office. A significant cost to the physician is the compounding fees, not the cost of drug ingredient. The pharmacy compounding fees cover re-packaging costs, overhead costs associated with compliance with stringent statutes and regulations, and wages and salaries for specially trained and licensed compounding pharmacists bourn by the compounding pharmacies. The physician administers the compounded medication to the patient during an office visit and seeks payment for the compounded medication from his/her carrier. In many instances, the payment does not even cover the total out of pocket expenses incurred by the physician (*e.g.*, the pharmacy fee charged to the physician).

There is no uniform national payment policy for compounded drugs. Rather, carriers have discretion on how to pay for compounded drugs. This has lead to a variety of payment methodologies and inconsistent payment for the same combination of medications administered in different states. A physician located in Texas who provides a compounded medication consisting of 20 mg of Morphine, 6 of mg Bupivicaine and 4 of mg Baclofen may receive a payment of $200 while a physician located in Washington may be paid a fraction of that amount for the exact same compounded medication. In many instances, the payment to the physician fails to adequately cover the cost of the drug, such as the pharmacy compounded fees and shipping and handling. Furthermore, the claim submission and coding requirements vary significantly across the country and many physician experience long delays in payment.

We urge CMS to adopt a national compounded drug policy for drugs used in spinal delivery systems by interventional pain physicians. Medicare has the authority to develop a separate payment methodology for compounded drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the ?MMA?) mandated CMS to pay providers 106% of the manufacturer?s Average Sales Price (?ASP?) for those drugs that are separately payable under Part B. The language makes clear that this pricing methodology applies only to the sale prices of manufacturers. Pharmacies that compound drugs are not manufacturers, and Congress never contemplated the application of ASP to specific drug compounds created by pharmacies. Accordingly, CMS has the discretion to develop a national payment policy.

We believe that an appropriate national payment policy must take into account all the pharmacy costs for which the physicians are charged: the cost of the drug ingredient, the compounding fee costs, and the shipping and handling costs. We stand ready to meet with CMS and its staff to discuss implementing a national payment policy.

III. CMS Should Incorporate the Updated Practice Expenses Data from Physician Practice Survey in Future Rule-Making

I commend CMS for working with the AMA, specialty societies, and other health care professional organizations on the development of the Physician Practice Survey. I believe that the survey data will be essential to ensuring that CMS has the most accurate and complete information upon which to base payment for interventional pain services. I urge CMS to take the appropriate steps and measures necessary to incorporate the updated practice expense data into its payment methodology as soon as it becomes available.

IV CMS Should Work Collaboratively with Congress to Fix the SGR Formula so that Patient Access will be preserved.

The sustainable growth rate (?SGR?) formula is expected to cause a five percent cut in reimbursement for physician services effective January 1, 2008. Providers simply cannot continue to bear these reductions when the cost of providing healthcare services continues to escalate well beyond current reimbursement rates. Continuing reimbursement cuts are projected to total 40% by 2015 even though practice expenses are likely to increase by more than 20% over the same period. The reimbursement rates have not kept up with the rising cost of healthcare because the SRG formula is tied to the gross domestic product that bears no relationship to the cost of providing healthcare services or patient health needs.

Because of the flawed formula, physicians and other practitioners disproportionately bear the cost of providing health care to Medicare beneficiaries. Accordingly, many physicians face clear financial hardship and will have to make painful choices as to whether they should continue to practice medicine and/or care for Medicare beneficiaries.

CMS should work collaboratively with Congress to create a formula that bases updates on the true cost of providing healthcare services to Medicare beneficiaries.

***

Thank you for the opportunity to comment on the Proposed Rule. My fear is that unless CMS addresses the underpayment for interventional pain services today there is a risk that Medicare beneficiaries will be unfairly lose access to interventional pain physicians who have received the specialized training necessary to safely and effectively treat and manage their complex acute and chronic pain. We strongly recommend that CMS make an adjustment in its payment methodology so that physicians providing interventional pain services are appropriately and fairly paid for providing these services and in doing so preserve patient access.

Sincerely,

Marcom E. Herren, D. O.
4301 Maplewood Ave Ste A
Wichita Falls, Texas 76308

Submitter : Dr. Ronald Polinsky **Date:** 08/31/2007

Organization : Berks Cardiologists

Category : Physician

Issue Areas/Comments

Coding--Reduction In TC For Imaging Services

Coding--Reduction In TC For Imaging Services

Bundling color Doppler codes into every echo will have a detrimental impact on the ability for my practice to offer echos in a timely fashion. Color doppler is not used in every study, and requires extra timc for the technician to obtain these images. If thcy are not proportionately re-imburscd for the cxtra acquisition, we may not be able to offcr this service.

GENERAL

GENERAL

The proposed changes is imaging reimbursement will have an adverse impact in the way that my practice offers timely and efficient care. I know the quality of studies will go down, and access to the correct imaging modality for my medicare patients may be limited.

Submitter : Mrs. Debra Lansey

Date: 08/31/2007

Organization : AAO-HNS

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#11482

American Academy of Otolaryngology—Head and Neck Surgery

Working for the Best Ear, Nose, and Throat Care

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August 28, 2007

Herb B. Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008

Dear Mr. Kuhn:

On behalf of the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS), I am pleased to submit the following comments on the "Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008" published in the *Federal Register* as a proposed notice on July 12, 2007. Our comments will address: (1) the proposed conversion factor update for 2008 and the Sustainable Growth Rate (SGR); (2) the budget neutrality/five-year review work adjustor; (3) the Physician Quality Reporting Initiative (PQRI); and (4) the Resource-Based PE RVUs Equipment Utilization Rate.

IMPACT: Proposed Conversion Factor Update for 2008 and the Sustainable Growth Rate (SGR)

CMS proposes a -9.9 percent update of the conversion factor for 2008. This would cause the conversion factor to fall from $37.8975 in 2007 to $34.1456 in 2008. If these cuts begin on January 1, 2008, the average payments will be less in 2008 than they were in 1995. To make matters worse, these reductions are not cuts in the rate of increase, but are actual cuts in the amount paid for each service because they do not account for substantial practice cost inflation. The American Medical Association estimates that physician practice costs have increased 18% since 2001 and are predicted to increase another 22% by 2016, while Medicare payments over the same period (2001-2016) will have decreased 40%. Many of our members practice in solo or small group practices, and, as small businesses, are unable to absorb these payment cuts. Unless Congress acts to legislatively stop this decrease in payment, our members may be forced to reevaluate their relationship with

are subjected to these substantial decrease in reimbursements. The combined CY2008 impact on the total allowed otolaryngology charges is -10% for the specialty, when one considers the remaining 5-Year Review of work RVUs, the PE changes, the HOPPS imaging services payment caps, and the CY2008 update. (Impact table, Table 25, Federal Register 72 (12 July 2007): 38214).

Updates to Medicare physician payments are made each year based on a statutory formula established in section 1848(d) of the Social Security Act. The calculation of the Medicare physician fee schedule update utilizes a comparison between target spending for Medicare physicians' services and actual spending. The update is based on both cumulative comparisons of target and actual spending from 1996 to the current year, known as the Sustainable Growth Rate (SGR), as well as year-to-year changes in target and actual spending. The use of SGR targets is intended to control the growth in aggregate Medicare expenditures for physicians' services.

In many previous comments, we have joined the AMA and other physician specialty societies in describing the flaws in the SGR formula. In 2002, physicians received a 5.4% payment cut. Additional cuts in 2003 through 2007 were avoided only after Congress intervened. Consistent with the position of the American Medical Association (AMA), we identified several steps that CMS could take that would significantly reduce the costs associated with a permanent legislative fix to the Sustainable Growth Rate (SGR) formula. Specifically, CMS must:

- Remove Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996;
- Ensure that government-induced increases in spending on physicians' services are accurately reflected in the SGR target. The SGR should accurately reflect the changing demographics of the beneficiary population (e.g., increases in the number of eligible recipients, the increased costs due to medical technology changes which result in increased patient demands and expectations) and,
- Ensure that the SGR fully reflects the impact on physician spending due to national coverage decisions. Providers cannot continue to absorb the costs of unfunded mandates.

We recommend that that CMS act on the recommendations it already has received, especially the removal of the Medicare-covered, physician-administered drugs and biologics from the physician payment formula, retroactive to 1996.

"BACKGROUND": Budget Neutrality/Five-Year Review Work Adjustor

The Medicare statute requires that increases or decreases in relative value units (RVUs) for a year may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. In 2007, CMS created a new "work adjustor" to ensure budget neutrality following the implementation of the improved work RVUs from the 2005 Five-Year Review of the RBRVS, despite the vigorous opposition of virtually every specialty society including AAO-HNS. For 2008, CMS again proposes to apply a work adjustor (0.8816 or -11.8 percent) to all work RVUs to maintain budget neutrality. As in the past, we

strongly oppose this proposal. We assert that budget neutrality adjustments should be applied only to the conversion factor.

We are opposed to the use of a work adjustor for the following reasons:

- It adds an extra element to the physician fee schedule payment calculation that creates confusion and questions among the public who have difficulty using the RVUs to determine a payment amount that matches the amount actually paid by Medicare
- Adjusting the work RVUs affects the relativity of services. For example, if the work RVUs are adjusted as proposed, it will disproportionately affect codes with physician work, such as E/M services and surgical procedures. Codes without work RVUs, such as the technical component of imaging services, will be unaffected. Ironically, the impact of increased work RVUs for E/M services that occurred with the most recent 5-year review -- and that CMS supported in the interest of improving payments for primary care services -- will be dampened by the use of a work adjustor.
- Adjusting the work RVUs has an adverse impact on payments to physicians by other payers who use the Medicare RVUs and their own conversion factors. Typically, an adjustment in the Medicare conversion factor does not necessarily affect the payment rates of other payers who use the Medicare RVUs and their own conversion factors. However, any adjustment in the RVUs will impact the payment rates of such payers. Physicians will be paid less for their non-Medicare patients as a result of CMS' use of a work adjustor. This represents a significant impact to the overall market, and we urge CMS to carefully consider the impact of its regulations on the broader health policy arena, and the cascading effects on physicians and their patients.

If a budget neutrality adjustment is necessary, we strongly recommend elimination of the work adjustor and instead utilize an adjustment of the conversion factor to maintain budget neutrality.

TRHCA – Section 101(b): PQRI (Physician Quality Reporting Initiative)

The proposed rule discusses in detail plans for implementing the second year (2008) of the Physician Quality Reporting Initiative (PQRI) for physicians and other practitioners billing under the physician fee schedule. CMS is proposing a significantly expanded list of clinical and structural measures from the following sources:

- The 66 2007 PQRI measures, plus 8 additional measures, adopted by the Ambulatory Quality Alliance (AQA) in January 2007 for a total of 74;
- 58 AMA-Physician Consortium for Performance Improvement measures;
- 11 measures currently under development by Quality Insights of Pennsylvania (the Pennsylvania quality improvement organization);
- 2 structural measures related to the use of e-prescribing and electronic health records under development by Quality Insights;
- 6 measures from the AQA starter-set not used in 2007;
- 7 measures endorsed by the National Quality Forum (NQF) but not used in 2007; and
- 3 podiatric measures related to foot care for diabetics under development by the American Podiatric Medical Association (APMA).

Not considered in this list are structural measures, which have been developed by the NCQA. These measures are currently being considered in the AQA consensus process. The NCQA structural measures may very well overlap or conflict with the Quality Insights measures. Reconciliation of these measures needs to be addressed before adopting any structural measures developed by Quality Insights.

CMS notes that it plans to evaluate and test mechanisms for collecting quality measures from medical registries as an alternative to submitting data through the claims processing system. CMS describes five options for data submission from medical registries to CMS:

- Option 1: Registries could provide measurement codes and beneficiary/service identifiers that could be linked with Medicare claims data;
- Option 2: Registries could provide quality measure codes and diagnosis codes that could be linked to beneficiary claims data;
- Option 3: Registries could calculate and submit directly to CMS measures and performance rates for Medicare beneficiaries in aggregate by NPI and tax identifiers;
- Option 4: Registries could provide all of the claims data elements using the Part B claims process; or
- Option 5: Registries could provide their Medicare data ("data dump") to CMS.

At the present time the PQRI is based on administrative claims data. Unfortunately, claims data do not always adequately or accurately reflect the complexities of individual patients and the quality of the clinical care they receive. Therefore the added value of a patient data registry would allow the evaluation of actual clinical data to more accurately assess quality of care, beyond the evaluation of claims data. The Academy advocates Option 3 as being the most amenable to our members since no individual beneficiary level information would be shared. In addition, the Academy supports the addition of clinical data elements needed to compute the measures.

The Academy would oppose any attempt at simply aggregating claims data, since this would not add to the richness of the data beyond what is already reported on the claim form.

The Academy has concerns about the elimination of measures that were accepted by AQA, but not endorsed by NQF. This means that physicians who have structured their billing systems to report on some measures will have to re-tool their practice billing and reporting systems to report on alternative measures if they want to continue to participate in 2008. This is likely to discourage continued participation by those physicians who must modify their systems.

The AAO-HNS encourages the utilization of performance measures that are consistent with evaluating and improving patient care. It is our opinion that after a measure has been developed and approved/endorsed by AQA or NQF, the reporting measure should remain in the PQRI for at least two to three years. This would allow the collection of data for a full reporting period (twelve months for the majority of measures). This would also allow physicians to receive feedback reports for a full reporting period on the measures they worked so diligently to implement.

In concurrence with the American College of Surgeons, we strongly encourage CMS to maintain any measures that have been included in the PQRI program for two or three years before rotating them off the list of accepted measures. This will lead to greater stability of measurement, some possibility of examining trends, and a better ability to evaluate the reliability and validity of measures when many of

them have had little pilot testing prior to adoption. In addition, maintaining stability in measures for multiple reporting periods will encourage more physicians to stay with the program over time.

Although the Academy applauds the progress that the NQF has recently made in streamlining and revamping many of their processes to be more transparent, consistent and fair, NQF does not currently possess a consistent record in evaluating and endorsing physician measures. Those physician-level measure sets that have been through NQF review have often received highly variable assessments from different workgroups. At the same time, AQA (while recognized as a consensus organization in TRHCA) does not have a sufficiently rigorous scientific process for evaluating measure sets or a formalized adoption process. AQA's initial mission was to standardize performance measure implementation across payers and markets–not to create or endorse measures. Therefore the Academy looks forward to continued developments in the areas of formalization, institutionalization, transparency and consistency in both the NQF endorsement process and the AQA adoption process.

In the press release that accompanied the release of the proposed rule, CMS stated "This proposed rule is a further step in Medicare's efforts to ensure that payment policies provide incentives to improve the quality of care." The Acting CMS Administrator at that time, Leslie V. Norwalk, Esq. said "CMS will continue working with Congress as well as physician groups to identify payment methods that help improve the quality and efficiency of care in a way that is cognizant of the costs to taxpayers and to Medicare and its beneficiaries. The Medicare program needs to compensate physicians appropriately for the services they provide to people with Medicare. But how the program pays also matters. We think the early work on the PQRI program is one of those reforms that could help lead us to a point where we can promote better quality care and more efficient care."

We are supportive of initiatives that are directed toward the improvement of patient care. However, we believe it is important to recognize that the PQRI program has a long way to go before it can be said that it has improved the quality of care provided to Medicare beneficiaries. At the present time, it is a pay-for-reporting program and the evidence that compliance with the reporting of some of the indicators will increase quality is minimal or non-existent. It is our position that the development of high-quality, evidence-based, patient-centered performance measures that focus on clinical outcomes is critical. Such performance measures should form the foundation upon which valid and relevant pay-for-reporting or pay-for-performance programs will be built.

We ask CMS to recognize and minimize the burden that compliance with the PQRI will impose on many physician practices and to take all necessary steps to ensure that only valid measures be adopted. In addition, we recommend that CMS build an evaluation component into the PQRI program so that several years from know we will be able to know whether the program has made a difference in the care of Medicare beneficiaries.

Resource-Based PE RVUs: Equipment Utilization Rate

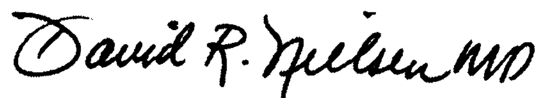
As part of the calculation of the practice expense (PE) equipment costs, the Centers for Medicare & Medicaid Services (CMS) assumes equipment is in use 50 percent of the time a physician's office is open. In the proposed rule, CMS acknowledges that it does not have sufficient empirical evidence to justify an alternative assumption and proposes no change at this time.

Like others, we suspect strongly that a uniform 50 percent utilization rate may not be accurate. However, we agree with CMS that insufficient information currently exists to adopt an alternative utilization assumption with respect to equipment. We suggest that CMS present its current data, showing the PE allocations for equipment usage – and the potential impacts on each code (or grouping of codes) if the assumed utilization rate were increased or decreased. As an alternative, we suggest that CMS consider a survey of physicians to determine the most accurate rate(s) of utilization. We further urge CMS not to assume that data relating to the utilization of one type of equipment could be fairly applied to other types of equipment. Implementing a system of classifications, or bands of utilization rates, is an option to consider. In sum, we recommend that CMS continue to proceed in a careful and thorough manner in its evaluation of equipment utilization.

Conclusion

The American Academy of Otolaryngology - Head and Neck Surgery appreciates the opportunity to provide these comments and recommendations on behalf of behalf of our members. If you require further information, please Debi Lansey, MPA, Senior Manager for Socioeconomic Affairs at (703) 519-1560 or DLansey@entnet.org.

Sincerely,



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