CMS-1392-P-811 **Medicare**

Submitter : Teresa Paluso **09/12/2007**

Organization : IPC Surgical Center, LLC
Ambulatory Surgical Center

Category :

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

I recommend that Medicare reverse the proposed rule that assigns rechargeable (RC) neurostimulator and a non-rechargeable (NRC)neurostimulator to the same APC reimbursement. I further recommend that Medicare create a new APC for RC neurostimulators, separate from NRC neurostimulators.

I believe that should the proposed Medicare rule be finalized, it could limit Medicare patients' access to RC neurostimulators because of the high cost of RC neurostimulator as compared to Medicare's reimbursement. I also believe that the RC neurostimulator is a substantial clinical improvement over the NRC neurostimulator. Finally, I believe that it would cost Medicare and co-insurances more money over the long run to implant NRC neurostimulators and have to replace them when the battery wears out vs. implanting a RC neurostimulator.

Thank you for considering these comments.

CMS-1392-P-812 **Medicare**

Submitter : Mr. Steve Pitre **09/12/2007**

Organization : Mr. Steve Pitre
Health Care Professional or Association

Category :

Issue Areas/Comments

Impact

Impact

Contrast agents used in conjuction with Echocardiogram is already underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate for the patients care. This Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and more costly diagnostic tests on patients. Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures. IF it is decided to package echo contrast, it is required by statute to create separate payment groups for contrast-enhanced and un-enhanced procedures, which would require the creation of new HCPCS codes to identify contrast- enhanced procedures. Please reconsider this because it will cost medicare more money and will not be the best for patient care

CMS-1392-P-813 **Medicare**

Submitter : Nancy Krupin **09/12/2007**

Organization : Kadlec Medical Center
Dietitian/Nutritionist

Category :

Issue Areas/Comments

Quality Data

Quality Data

Re: Proposed Hospital Outpatient Measures
I am writing in opposition to the proposed rule that hospital outpatient diabetes education programs be required to report on the quality measure 'Hemoglobin A1c poor control in Type 1 or 2 diabetes mellitus' in order to receive full Medicare reimbursement.

We do consider A1c to be an important quality indicator and we do try to monitor each patient's A1c before and after they receive education at our center. However, we do not feel that achievement of a particular A1c value for an individual patient is a fair assessment of the quality of the education we provide for the following reasons: 1)We do not have control over how well patients implement what they learn from the education process. Patients are referred to us at different stages of readiness for making changes that result in improved blood glucose control. They may obtain important knowledge and skills but not be ready to take action. 2)We do not have control over whether the primary care provider implements our recommendations for changes in medication management. 3)A1c is a measure of blood glucose control over the past 2-3 months. Patients may complete their education in 4-6 weeks and the full effect of improvements to A1c may not be seen in that time period. It would be very time-consuming for us to try to obtain a follow-up A1c from their doctor at some later date. 4)The point of education is to teach the patient to self manage their disease by doing activities such as monitoring A1c themselves versus collecting the data for our records.

5)Patients do not always complete the education process. That does not mean that they didn't learn something important and useful in the session(s) they did attend, but we may not be able to obtain follow-up A1c data.

CMS-1392-P-814 **Medicare**

Submitter : Ms. Melissa Popailo-Napier **09/12/2007**

Organization : Baptist MC South
Other Technician

Category :

Issue Areas/Comments

OPPS Impact

OPPS Impact

I am a Cardiovascular U/S Tech and without definity I can honestly say that half of these Medicare pt's exams would not be easily diagnosed. Lots of Medicare pt's are obese or have lung trouble and these two things give us terrible pics and the definity works wonders. We need to remain being able to use this wonderful tool and be able to get reimbusement or else the hospitals will not be able to absorb this cost.

CMS-1392-P-815 **Medicare**

Submitter : Alexandria Hodes **09/12/2007**

Organization : Seton Medical Center
Health Care Professional or Association

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

September 14, 2007

RE: Calendar year 2008 Proposed Cut for Partial Hospitalization Programs (PHP) and Outpatient Services (OP).

Dear CMS,

I am writing to urge you to keep Medicare reimbursement to PHP and OP programs stable, at the 2007 rate. Over the past 19 years, a consistent decline of reimbursement rates offered to the nation□s mentally ill and elderly population has occurred. The proposed CMS per diem rate cut of 24% in CY 2008 would be devastating for those in need. It would result in a 44% cumulative cut in reimbursement over the past three years. Programs will be forced to shut down, forcing the mentally ill population into more expensive emergency room treatment.

The impact of the proposed CMS rate cut affects more than the consumers currently receiving Medicare benefits. The private insurance industry is likely to follow the standard that Medicare sets, which could mean lower rates across the board. If PHP and OP programs were forced to close due to financial hardship, the nation would potentially be flooded with an unstable mentally ill population, capable of taxing the healthcare, social service, and criminal justice systems even further. The nation would also be losing out on the potential for citizens to recover and return to gainful employment.

PHP and OP programs help to keep mental health consumers out of the hospital and more expensive, higher levels of care. They are fiscally responsible programs that do not have a track record of fraud. These programs provide necessary care to consumers at a relatively low cost,

reducing the need for more costly, higher levels of care. By keeping the 2007 reimbursement rate stable and (avoiding the proposed 24% decrease), these programs can continue to provide valuable services that benefit mental health consumers, and society as a whole. I urge you to:

Suspend the current PHP and OP rate proposal and leave the current CY 2007 rate in place. Identify a reasonable inflation adjustment factor each year that is developed and legislated by Congress.
Develop a new PHP and OP rate Calculation Taskforce, which includes CMS staff and representatives the Association of Ambulatory Behavioral Health (AABH), National Alliance for the Mentally Ill (NAMI) and other Psychiatric Healthcare Organizations.
Protect the integrity of the PHP and OP benefits that will ensure availability for the nation□s Mentally Ill population.

Sincerely,

Alexandria B. Hodes, M.F.T.
Outpatient Mental Health
Seton Medical Center

CMS-1392-P-816 **Medicare**

Submitter : Dr. Reginald Rousseau **09/12/2007**

Organization : Dr. Reginald Rousseau
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

Attachment

 HF S16

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-1392-P-817 **Medicare**

Submitter : Dr. Joseph Turnipseed **09/12/2007**

Organization : Spine Diagnostic and Treatment Center
Ambulatory Surgical Center

Category :

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1392-P-817-Attach-1.DOC

CMS-1392-P-817-Attach-2.DOC

CMS-1392-P-817-Attach-3.DOC

#817

September 10, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient P rospective Payment System (HOPPS) and CY 2008 Payment Rates" (the Proposed Rule) published in the *Federal Register* on August 2, 2007. My comments cover two main issues related to the HOPPS and ambulatory surgery center (ASC) payment methodologies.

I. ASC Procedures

There are several specific procedure issues we ask CMS to review and address. I believe that two procedures that have not been included on the ASC payment list, but that are paid under the HOPPS and should also be included on the ASC list. These procedures are described by CPT codes 22526 (percutaneous intradiscal electrothermal annuloplasty, single level) and 22527 (percutaneous intradiscal electrothermal annuloplasty, one or more additional levels). There is no reason why ASCs should not be entitled to payment for these two procedures. The procedures are safely done in ASCs, and they are not procedures routinely performed in a physician's office. I ask CMS to include both procedures on the ASC list in the final rule.

ASIPP also is concerned that procedures 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography – lumbar - radiological supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. These services are payable separately in the HOPD in certain circumstances and I believe the same should be true for ASCs.

Lastly, I ask CMS recalculate the payment rate of CPT code 64517. The proposed payment rate for this procedure is $178 for CY 2008. While I do recognize that the payment for the procedure following the transition period will be $295, a payment of $178 seems too low.

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

I ask that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on

the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

Approximately 25 to 30 percent of all the neurostimulator implant procedures performed each year are required to replace a depleted, non-rechargeable battery. Thus, in the long term, the use of rechargeable devices likely would result in cost savings to the Medicare program and beneficiaries due to the decreased need for battery replacement procedures. The need for fewer surgeries also would reduce the chances that patients will experience operative complications such post-operative infection or other possible co-morbidities.

I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

While I recognize the difference in median costs does not create a two times rule violation, the difference in median cost is not insignificant. CMS has assigned pass-through devices to a new APC or to a different, existing APC in absence of a "two-times" rule violation and for median costs differences significantly less than $1,000. I urge CMS to take a similar approach here. The creation of two separate APCs would result in more appropriate payment for both types of procedures—rechargeable and non-rechargeable neurostimulator procedures—based on their relative costs. To implement our recommendation, we further recommend that CMS create a G-Code to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator.

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all

settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary my recommendations to CMS are:

- Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
- Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
- Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,

Joseph W. Turnipseed, M.D.

CMS-1392-P-818 **Medicare**

Submitter : Dr. Michael Chang **09/12/2007**

Organization : Muir Orthopaedics Specialists
Physician

Category :

Issue Areas/Comments

Hospital CoPs

Hospital CoPs

Please see attached

CMS-1392-P-818-Attach-1.DOC

#818

September 10, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

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the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

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I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

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Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all

settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary my recommendations to CMS are:

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- Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
- Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,

Michael Y. Chang DO
Muir Orthopaedic Specialists

CMS-1392-P-819 **Medicare**

Submitter : Tanis Lewis **09/12/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with spasmodic torticollis -cervical dystonia (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptons. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.

Thank you for allowing me to provide these comments.

CMS-1392-P-820 **Medicare**

Submitter : Tanis Lewis **09/12/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

I would like to commend CMS for seeking to improve patient access care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with spasmodic torticollis - cervical dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally. I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, the change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given. Thank you for allowing me to provide these comments.

CMS-1392-P-821 **Medicare**

Submitter : Ms. Nancy Atkinson **09/12/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

September 12, 2007

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with, both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers,

depending on where the injections are given.
Thank you for allowing me to provide these comments.
Sincerely,

CMS-1392-P-822 **Medicare**

Submitter : Dr. Adam Locketz **09/12/2007**

Organization : HealthPartners
Physician

Category :

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

Please See Attached Comments:

I ask that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS□s own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable

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" Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
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" Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
" Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,

Adam J. Locketz, MD
Interventional Pain Medicine
HealthPartners
401 Phalen Boulevard
St. Paul, MN 55130

CMS-1392-P-823 **Medicare**

Submitter : Dr. Michael Schuster **09/12/2007**

Organization : Manhattan Pain & Spine
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1392-P-823-Attach-1.DOC

CMS-1392-P-823-Attach-2.DOC

#823

September 13, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient P rospective Payment System (HOPPS) and CY 2008 Payment Rates" (the Proposed Rule) published in the *Federal Register* on August 2, 2007. My comments cover two main issues related to the HOPPS and ambulatory surgery center (ASC) payment methodologies.

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I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on

the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

Approximately 25 to 30 percent of all the neurostimulator implant procedures performed each year are required to replace a depleted, non-rechargeable battery. Thus, in the long term, the use of rechargeable devices likely would result in cost savings to the Medicare program and beneficiaries due to the decreased need for battery replacement procedures. The need for fewer surgeries also would reduce the chances that patients will experience operative complications such post-operative infection or other possible co-morbidities.

I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

While I recognize the difference in median costs does not create a two times rule violation, the difference in median cost is not insignificant. CMS has assigned pass-through devices to a new APC or to a different, existing APC in absence of a "two-times" rule violation and for median costs differences significantly less than $1,000. I urge CMS to take a similar approach here. The creation of two separate APCs would result in more appropriate payment for both types of procedures—rechargeable and non-rechargeable neurostimulator procedures—based on their relative costs. To implement our recommendation, we further recommend that CMS create a G-Code to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator.

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all

settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary my recommendations to CMS are:

- Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
- Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimulator procedures to a new APC.
- Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,

Michael Schuster, MD
1135 Westport Drive
Manhattan, KS 66502
(785) 537 7299

#824

CMS-1392-P

Because the referenced comment number does not pertain to the subject matter for CMS-1392-P, it is not included in the electronic public comments for this regulatory document.

CMS-1392-P-825 **Medicare**

Submitter : Mr. Robert Cathey **09/13/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
I commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Benign Essential Blepharospasm (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic systems. These injections are critically important to my ability to funciton normally.

I respectfully request tht CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursment will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payment made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

CMS-1392-P-826 **Medicare**

Submitter : Mrs. Beverly Fisher **09/13/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
I would like to commend CMS for seeking to improve paient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with both Benign Essential Blepharospasm and Meige Syndrome (movement disorders resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin every 70 days to alleviate the debilitating dystonic symptoms; these injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. The proposed change in policy would destroy the uniformity of payments made across settings that ensures that there are no economic rewards or penalties to providers, depending on where the injections are given. It is critical to maintain as many capable physician injectors as possible.

Thank you for allowing me to provide these comments.

Sincerely,

Beverly Fisher

CMS-1392-P-827 **Medicare**

Submitter : **Miss. Ann Lyond** **Date & Time: 09/13/2007**

Organization : **none**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (list the form dystonia you have), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
Thank you for allowing me to provide these comments.
Sincerely,
Ann Lyons

CMS-1392-P-828 **Medicare**

Submitter : **Mr. David Snyder** **Date & Time: 09/13/2007**

Organization : **Mr. David Snyder**

Category : **Individual**

Issue Areas/Comments

GENERAL

Dear Mr. Weems: 9/12/07
Regarding: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a spouse of a patient with (list the form dystonia you have), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. My wife receives injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections she receives are critically important for her ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
Thank you for allowing me to provide these comments.
Sincerely,

CMS-1392-P-829 **Medicare**

Submitter : **Rebecca Smith** **Date & Time:** **09/13/2007**

Organization : **Flight Attendant**

Category : **Drug Industry**

Issue Areas/Comments

Payment for Diagnostic Radiopharmaceuticals

Please do not deny Bexxar and Zevalin to cancer patients ... my friend Carol Johnson is cancer-free thanks to this treatment !!! The cost of these drugs are much cheaper then Chemo. And it is a single treatment ... jacking up these prices individually is insane when they both (Bexxar and Zevlin) are used together for great results.

CMS-1392-P-830 **Medicare**

Submitter : **Mr. Karl Schwartz** **Date & Time: 09/13/2007**

Organization : **Patients Against Lymphoma and undersigned**

Category : **Consumer Group**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

Patients Against Lymphoma is a non-profit organization, independent of health industry funding.

In the attached letter we are representing the concerns of many lymphoma survivors and their loved ones regarding proposed CMS payment policies for radioimmunotherapy (RIT) agents (Bexxar and Zevalin), administration, and supply.

These are our main concerns about proposed reimbursement rates for RIT for patients with life-threatening lymphomas:

o It will limit patient access to highly effective radioimmunotherapy by creating a strong disincentive to prescribe it.

o It will exacerbated the □disuse□1 of RIT, contributing to lost opportunities for patients to live longer and better with lymphomas.

o It will contribute to the termination of radioimmunotherapy in the near future.

o It will be a strong disincentive for companies to develop novel therapies for lymphomas and other cancers in future.

The public outcry against the proposed cuts is further evidenced by the fact that this letter was endorsed by more than 1,500 citizens representing every region of the United States in the very short time period of approximately 14 days since we learned about this issue.

Among the names are physicians who specialize in treating lymphoma patients, which validates and reinforces our concerns.

The confidential list has been mailed separately because of the privacy concerns of some patients.

Respectfully,

Karl Schwartz (caregiver)

President, Patients Against Lymphoma
Patient Consultant to the FDA/Oncologic Drug Advisory Committee (ODAC)
Participant: NCI Progress Review Group for Blood Cancers (LMPRG)
Participant: Biospecimen Access and Ethical, Legal, and Policy Issues Workshop (ELP)

CMS-1392-P-831 **Medicare**

Submitter : **Mrs. Charlotte Brooks** **Date & Time:** **09/13/2007**

Organization : **Carilion Health System**

Category : **Hospital**

Issue Areas/Comments

GENERAL

See attachment.

#831

CARILION
Health System

September 13, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
PO Box 8010
Baltimore, MD 21244-1850

Dear CMS:

To follow are comments related to the 2008 OPPS Proposed Rule.

OPPS: PACKAGED SERVICES
The Carilion Clinic does not oppose **all** packaging proposed.

1. Guidance Services
In this rule, CMS proposes to change the status indicators for 31 guidance procedures from separately paid to unconditionally packaged (status indicator N). In CY 2007, there were 5 guidance procedures with the status indicator of N, unconditionally packaged. Page 42655 of the proposal states, "*Resource cost was not a factor we considered when proposing to package guidance procedures. Notably, most of the guidance procedures are relatively low cost in comparison to the independent services they frequently accompany*". We believe resource cost should be considered when determining whether or not to package payment for guidance services. If all guidance procedures are packaged into the needle placement, biopsies, or various procedural codes where guidance is usually associated, our hospital will be doing highly specialized procedures for far less reimbursement. With the rising cost of supplies for these procedures, the reimbursement will not be enough to recoup the cost of the supplies that are needed to perform the procedures. To ensure quality care, hospitals must stay current in equipment and also maintain adequate staffing to provide patient care. We adamantly oppose this proposal particularly in the areas of CT, MRI and Radiation Oncology, due to the increased resource consumption on hospitals, and respectfully request CMS to delay the number of codes to be changed and move forward in a more realistic approach.

2. Image Processing Services
For CY 2008, CMS is proposing to package 3-D post processing (CPT codes 76376 and 76377) into whichever service it is provided with their use. We ask CMS to

continue to pay for these two codes separately due to the staff hours and additional computer software needed to provide this service. We believe resource cost should be considered prior to any decision of packaging payment as the resources used for this service are significant.

3. Intraoperative Services

For CY 2008, CMS is proposing to change the status indicator for 34 intraoperative services from separately paid to unconditionally packaged (status indicator N). CMS stated in the 2008 Federal Register Proposed Rule, *"resource cost was not a factor we considered when determining which supportive intraoperative procedures to package"*. The staff and equipment used to support these procedures is not inexpensive. To package the 34 supportive services would create a large financial burden for hospitals. We strongly disagree with CMS' proposal to change the status indicators for these supportive services due to the large swing in payment and request CMS to delay their proposal and if necessary, implement in small increments.

4. Supervision & Interpretation Services

For CY 2008, CMS is proposing to change the status indicator for 33 imaging supervision and interpretation services from separately paid to unconditionally packaged (status indicator N). CMS states on page 42663, *"we believe that these services are always integral to and dependent upon the independent services that they support and, therefore, their payment would be appropriately packaged because they would generally be performed on the same date and in the same hospital as the independent services"*.

CMS is also proposing to change the status indicator for 93 imaging supervision and interpretations services from separately paid to conditionally packaged (status indicator Q) as "special" packaged codes. Therefore, hospitals would not receive separate reimbursement for the 93 codes listed on page 42665-42667 if they are billed with a code that has a SI of S, T, V, or X. This could potentially have a significant financial impact for hospitals We understand the direction CMS is going, however we do not agree with the large number of changes surrounding the supervision and interpretation codes. We recognize the need for packaging but at the same time we request a staged implementation process

5. Diagnostic Radiopharmaceuticals

With drug costs continuing to rise, we continue to work with our contracted pharmacies and vendors to keep costs down, while at the same time provide the highest quality of care to our patients. We are a not-for-profit hospital, and we never turn anyone away, regardless of their financial means. As a provider of a Chest Pain Center after hours and on weekends, and being the only Level 1 Trauma Center in Southwest Virginia, we fear if reimbursement continues to decline it will impact our ability to provide for those services in which we provide a safety net in our geographical region. Therefore, we disagree with the packaging of diagnostic radiopharmaceuticals due to the increased expense hospitals will be forced to absorb and request that CMS withdraw this proposal.

OPPS: SPECIFIED COVERED OUTPATIENT DRUGS

The Carilion Clinic recognizes the need for cost containment as relates to acquisition, handling, and dispensing of drugs. Our system expends considerable resources to manage contracts with vendors, monitor drug cost changes and accurately capture charges. We therefore, strongly oppose the proposed requirement for hospitals to separately report charges for pharmacy overhead and handling.

The current coding and charging systems in our hospitals fail to capture this type of information. Valuable resources would have to be diverted from the current work load and collect this information manually, until a system could be developed to automate this policy's mandates.

Our recommendation is that this proposed regulation not be implemented at this time and that CMS work with stakeholders to identify better ways to accomplish this goal. Our organization would find these changes tremendously burdensome, and impossible to implement before 01/01/08. We would be surprised if any hospital has the resources to implement this sweeping policy in such a short time frame.

OPPS: OBSERVATION SERVICES

The Carilion Clinic requests that CMS **not** implement observation packaging at this time but rather look for other possible solutions that have less negative impact on the patients.

Based on our own experience we understand that observation services and billing are very complex. No two payers have the same guidelines and while we have worked to educate and work with our medical staff there are still opportunities to improve the reporting for such medically necessary services.

Comparative reviews of observation utilization between outpatient services and inpatient DRG stays should be completed to determine what impact the separate observation allowances for CHF, Asthma and Chest Pain short stays have had for CMS as well as providers on cost containment. The increased volume of patients treated in the outpatient setting should reflect a direct impact on the inpatient volume relative to the applicable inpatient DRG's.

Observation regulatory guidelines allow for up to 48 hours, (in rare instances 72 hours). Implementation of packaged observation services, without adequate reimbursement adjustments, could become a financial hardship to provide quality patient care for all providers of outpatient services. CMS' proposed packaging of observation services into an ER level has the potential to misrepresent patient volume requiring that level of care, thus creating unreliable data for future decisions.

Since the implementation of APC's in August 2000, observation services have been difficult to manage for the provider. Because of this difficulty, one can understand the complexity that CMS has had with observation services. While CMS has defined

observation services in the rules and regulations, to bill for these services has proved difficult. The regulations clearly specify that observation status is not to be utilized for routine postoperative care. The QIO for the State of Virginia has frequently denied inpatient statuses of 1-2 day stays and instructed the provider to utilize observation status in these cases as well as other medical 1-2 day stays. The QIO has also denied inpatient surgical stays stating that the procedure is on the CMS outpatient list and can be performed on an outpatient basis. Yet, CMS has repeatedly specified in the regulations that the APC list is not to be used as the determining factor of how a procedure is to be performed, but determined by the attending physician. Also of note, the QIO's scope of work includes appropriateness of site of service. Subsequently, providers acquiesce to the QIO's instructions for billing purposes but inadvertently supply CMS with questionable data to determine future observation utilization. CMS needs to review 1-2 day inpatient QIO denials for accuracy of observation status utilization and denial appropriateness.

We fear that these proposed changes may not only be detrimental to patients but also increase costs. We fully understand that with a budget neutral system with volumes rising that CMS must control costs and therefore, if observation must be addressed, we ask that CMS seek ways to come up with a composite APC that could be used with those visits that drive these numbers. Specifically look at the "visit" or "ED visits" that also result in billing for observation. Not totally implementing the current regulations would also give CMS the opportunity to look at additional data which might explain the increase in both volumes and costs in these areas.

QUALITY DATA

Without the specifications for the outpatient quality measures, it is difficult to comment on the measure themselves.

The Carilion Clinic is working hard across our organization to meet the ever increasing unfunded mandates to collect data. Our organization has been seen as one of the "most wired" and one of the "most wireless" and yet much of the current data requires chart reviews and collection of data on a manual basis.

We believe that CMS and others should do two things to help improve quality and efficiency for our patients. First, work with organizations like JCAHO, NQF, and the QIOs to select a standard set of measures which are seen as the most important for patient care. Secondly, have those measures required with common data reporting requirements and formats. The constant increase in the number of indicators that various organizations have has placed a burden on large and small hospitals alike.

We are supportive of quality measures and other outcome indicators, but at the same time the man hours necessary to collect the data have continued to divert resources away from patient care and there appears to be no end to the numbers of indicators that are being proposed.

We suggest a smaller number until such time as most of us have met the intent of the national push for an electronic medical record. We are currently installing such a system and know that collecting data will be easier in the future, but we would prefer to utilize our current resources to care for patients and find better ways to be more efficient and effective in the delivery of our care. The burden is especially noticed in light of the ever increasing shortages of health care professionals in various areas like Nursing, RT, PT, and Pharmacy. We are also concerned about the availability of clinical coders who are an integral part of this process and yet they are quickly moving towards ICD-10, MS-DRGs, POA requirements and other mandated or required activities.

OPPS IMPACT

The Carilion Clinic recommends that CMS maintain APC 0421 for continuous glucose monitoring. Packaging this service would potentially result in limiting patient access to this helpful monitoring for those patients who struggle to keep their glucose levels in check and such monitoring may help explain the hourly changes. This is especially true for the nighttime reading necessary to adjust insulin and work with brittle/out of control diabetics.

We thank CMS for the opportunity to respond to the 2008 OPPS Proposed Rule.

Sincerely,

APC Task Force
Carilion Health System
Roanoke, VA 24033

CMS-1392-P-832 **Medicare**

Submitter : **Mrs. Billie Humphrey** **Date & Time: 09/13/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Dear Mr. Weems:
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (or the form dystonia you have), both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment formula. Any reduction in reimbursement will lead to fewer injectors in an area where we have too few knowledgeable injectors in the first place. Anyone can inject botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.
Thank you for allowing me to provide these comments.
Sincerely, Billie Humphrey

CMS-1392-P-833 **Medicare**

Submitter : **Ms. Ann Kaplan** **Date & Time: 09/13/2007**

Organization : **Pharmaceutical Research and Manufacturers of Ameri**

Category : **Association**

Issue Areas/Comments

GENERAL

Please see attachement.

#833

PhRMA

September 12, 2007

BY HAND DELIVERY AND EMAIL
http://www.cms.hhs.gov/eRulemaking

Acting Administrator Kerry Weems
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, D.C. 20201

Re: **CMS 1392-P; Comments Regarding the Proposed Hospital Outpatient Prospective Payment System Rule for Calendar Year 2008**

Dear Mr. Weems:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the proposed rule published by the Centers for Medicare and Medicaid Services (CMS) concerning revisions to the hospital outpatient prospective payment system (OPPS) for 2008.[1] PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA has a long-standing interest in ensuring that Medicare beneficiaries have access to the most appropriate therapies, both under the OPPS and in other settings. As a consequence, we are particularly concerned with two proposals in the CY 2008 Proposed Rule:

) CMS' proposal to reimburse specified covered outpatient drugs (SCODs) at a payment rate of Average Sales Price (ASP) + 5 percent:

PhRMA is concerned that this payment may not cover hospital handling and acquisition costs and could therefore jeopardize beneficiaries' access to needed drugs. The Proposed Rule presents no new information suggesting that there is greater understanding of or confidence in the accounting of pharmacy overhead costs than in past years, or that an ASP + 5 percent

[1] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates, 72 Fed. Reg. 42628 (August 2, 2007) (the Proposed Rule).

payment rate would cover hospitals' acquisition costs for SCODs which was rejected in past years. CMS should therefore maintain the current ASP + 6 percent payment rate.

2) CMS' proposal to package all "diagnostic" radiopharmaceuticals and contrast agents.

This proposal is inconsistent with the rationale supporting CMS' packaging threshold approach for separately payable drugs in the OPPS and could result in underpayment for important radiopharmaceuticals and contrast agents.

Our detailed comments on the proposed rule are set out below.

* * *

A. Proposed Payment for Specified Covered Outpatient Drugs (SCODs)

A SCOD is a drug for which a separate APC has been established and that is either a radiopharmaceutical agent or is a drug or biological for which pass-through payment was made on or before December 31, 2002 (subject to certain exceptions).[2] By statute, payment for SCODs in CY 2006 and subsequent years must equal the "average acquisition cost for the drug for that year . . . as determined by the Secretary," subject to any adjustment for overhead costs and taking into account the GAO hospital acquisition cost surveys for CYs 2004 and 2005.[3]

Although CMS currently pays for SCODs at ASP + 6 percent, CMS proposes a CY 2008 payment rate of ASP + 5 percent. CMS arrived at this figure using the same data analysis methodology that it employed in last year's proposed rule (and then rejected in the final rule). This method compares two sources of data: ASP data from the fourth quarter of CY 2006 and mean costs derived from the CY 2006 hospital claims data.[4] CMS states that its data analysis indicates that using mean cost to set SCOD payment rates for drugs would be "equivalent to basing their payment rates, on average, at ASP+5 percent."[5]

CMS did not finalize the ASP + 5 percent rate in CY 2007. Instead, CMS decided "after carefully considering all comments and the recommendations of the APC [Ambulatory Payment Classification] panel, [to accept] the Panel's recommendation to continue to pay for separately payable drugs, biologicals, and their associated pharmacy handling in the hospital outpatient department for CY 2007 at a combined rate of ASP + 6 percent . . ."[6] The reasons that CMS

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2 Social Security Act (SSA) § 1833(t)(14)(B)(i). SCODs do not include drugs that first received pass-through payments on or after January 1, 2003, and drugs that have not been assigned a temporary HCPCS code.

3 SSA § 1833(t)(14)(A)(iii).

4 72 Fed. Reg. at 42736.

5 Id.

6 71 Fed. Reg. 67960, 68091 (November 24, 2006).

maintained the ASP + 6 percent rate for CY 2007 are as follows (as stated in the CY 2007 OPPS final rule):

- Although CMS' "final rule analysis indicated an average ASP-based payment of ASP + 4 percent [for separately payable drugs and biologicals]," CMS noted that this was "the same relative ASP-based amount that was comparable to the GAO purchase price data for a subset of drugs reviewed in our CY 2006 final rule with comment period, which did not include pharmacy overhead costs."[7] This finding suggests doubt on the part of CMS as to whether the CY 2007 final rule analysis properly accounted for pharmacy overhead costs.

- CMS "further believe[d] [that] maintaining stability in the payment levels for drug and biologicals should be considered in light of the inherent complexity in determining how best to account for pharmacy overhead costs."[8]

- CMS "believe[s] a better understanding of the full nature and magnitude of hospitals' costs related to these important [overhead and handling] activities is needed."[9]

- CMS "believe[s] that [the ASP + 6 percent rate] will ensure suitable payment for the hospital pharmacy overhead costs associated with drugs and biologicals, while [CMS] continue[s] to work with the hospital industry to understand the complex issues related to capturing and evaluating these overhead costs."[10]

In the CY 2008 Proposed Rule, CMS has adopted the same data analysis method for setting the separately-payable SCOD payment rate as in the CY 2007 Proposed Rule. Unlike the 2007 Proposed Rule, CMS did not even provide a theory as to why this method might account for pharmacy overhead costs incurred by hospital outpatient departments as well as drug acquisition costs.[11] CMS has also proposed a method to collect data on pharmacy overhead costs in the future, by having hospitals include pharmacy overhead costs on an uncoded revenue code line on the claim. However, the 2008 Proposed Rule does not provide any new information indicating that the circumstances that led to CMS maintaining the ASP + 6 percent payment rate for CY 2007 have changed for 2008. The proposal to collect overhead costs through revenue center coding will not produce OPPS data until the CY 2010 Proposed Rule. Until such time as

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7 Id. (emphasis added).

8 Id. (emphasis added).

9 Id.

10 Id.

11 In the CY 2007 proposed rule, CMS had theorized that mean costs from claims data (i.e., data on charges reduced to costs via cost to charge ratios(CCRs)) would capture pharmacy overhead costs because a MEDPAC Report had suggested that hospital charges (not charges reduced to cost via CCRs) reflected hospitals' pharmacy overhead costs. However, even if hospital charges did capture pharmacy overhead costs, this does not mean that charges reduced to costs via CCRs would capture pharmacy overhead costs as well as drug acquisition costs.

CMS has collected accurate data on pharmacy overhead costs, it should maintain the ASP + 6 percent payment rate for separately payable SCODs for all of the reasons outlined in the CY 2007 final rule -- i.e., uncertainty about whether pharmacy overhead costs are fully reflected in the drug claims data, the need for greater understanding of the "full nature and magnitude" of pharmacy overhead costs, and the need for suitable payment until better data is available with which to evaluate the effects of any payment reductions.

During the March 2007 APC meeting, the APC Panel recommended that "the overhead payments be made in addition to the current ASP + 6 percent payment rates for separately payable drugs."[12] If CMS is not prepared to accept the Panel's recommendation, for purposes of payment stability it should at least maintain the ASP + 6 percent payment rate until accurate claims data becomes available on pharmacy overhead costs.

If payment for SCODs were reduced to ASP + 5 percent for CY 2008, PhRMA is concerned based on the APC Panel recommendation and even CMS' concerns in the past, that this lower rate may not cover drug acquisition and handling costs, which could impede beneficiary access to important drug therapies and compromise the quality of care furnished to Medicare beneficiaries in the hospital outpatient setting. We urge CMS to maintain the current ASP + 6 percent rate for CY 2008 as it works to collect and evaluate accurate data on pharmacy overhead costs.

B. OPPS: Packaged Services -- "Diagnostic Radiopharmaceuticals" and Contrast Agents

CMS proposes to pay separately for most drugs, biologicals, and radiopharmaceuticals with per-day costs that exceed a threshold amount of $60, and to package those products with per day costs less than or equal to the $60 threshold. CMS has used this approach in the past to determine whether products are separately payable or packaged, but for CY 2008 CMS has increased the threshold from $55 to $60.

In addition to the cost-based approach to packaging that CMS proposes to continue for CY 2008, it is also proposing to package all "diagnostic" radiopharmaceuticals and contrast agents, regardless of the cost of the particular radiopharmaceutical or contrast agent. This proposed policy ignores the underlying rationale for the cost-based packaging threshold and would automatically package any agent that CMS describes as either a "diagnostic radiopharmaceutical" or a contrast agent. This is especially problematic because in establishing the proposed packaged payment rate for the combined radiopharmaceutical and procedure, CMS is using all claims for the procedures although a fairly significant number of claims may not include the necessary radiopharmaceuticals or contrast agent.

Separate payment for relatively costly drugs, biologicals, and radiopharmaceuticals traditionally has been designed to ensure that adequate payment for such agents is both available

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[12] 72 Fed. Reg. at 42735.

and predictable in the OPPS. Packaging under a prospective payment system such as the OPPS is appropriate for relatively inexpensive products and supplies that function to support the primary resources that are employed in an intervention, whether classified as either diagnostic or therapeutic. However, the proposed policy for 2008 would package "diagnostic" radiopharmaceuticals and contrast agents that have per day costs above the otherwise applicable packaging threshold -- and would risk inadequate payment for these products even if their costs are not properly reflected in the procedure code payment (into which the "diagnostic" radiopharmaceutical or contrast agent is packaged). Separate payment for SCODs above the current $55 packaging threshold is designed to guard against such problems.

To avoid access restrictions due to inadequate payment for advanced radiopharmaceuticals and contrast agents, CMS should continue a cost-based approach to packaging SCODs and should not rely on classifications such as "diagnostic" or "therapeutic" that could create access problems for relatively costly products in the OPPS. CMS has traditionally used a packaging threshold for high-cost drugs, biologicals, or radiopharmaceuticals because separate payment is needed to ensure that higher cost agents are accessible to Medicare beneficiaries. Nothing in the Proposed Rule undermines or supports a departure from this logic, which is fundamental to ensuring that Medicare beneficiaries receive the highest-quality, most appropriate care. PhRMA therefore urges CMS to apply its cost-based packaging approach consistently, instead of arbitrarily carving out "diagnostic" radiopharmaceuticals and contrast agents from the otherwise applicable packaging threshold.

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PhRMA hopes that these comments will be useful to CMS in developing the final OPPS rule for 2008. We look forward to further dialogue on enhancing beneficiaries' access to care in the hospital outpatient setting. Please do not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,

Richard I. Smith
Senior Vice President for
Policy, Research, and Strategic Planning

Diane E. Bieri
Senior Vice President and General Counsel

Ann Leopold Kaplan
Assistant General Counsel

Maya J. Bermingham
Assistant General Counsel