CMS-1392-P-697 **Medicare**

Submitter : Dr. C. William Murphy **09/12/2007**

Organization : Consultants in Pain Medicine
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1392-P-697-Attach-1.TXT

#697

C. WILLIAM MURPHY, M.D.

Consultants in Pain Medicine, P.A.
403 Treeline Park, Ste. 200
San Antonio, TX 78209
(210)-805-9800 fax (210)-497-8521

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:

I am a practicing pain specialist in San Antonio, Texas. I take care of all types of chronic pain and patients will all types of insurance products. It is very unfortunate to see that some of the proposed rules will limit my ability to offer some of my patients procedures and implantable products which might help with there pain. I hope that you will consider some of the comments that I am offering so that I can offer the best treatment to all of my patients, including my patients who are covered Medicare.

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,

C. William Murphy, MD

CMS-1392-P-698 **Medicare**

Submitter : Dr. Bryan Lee **09/12/2007**

Organization : Chaparral Medical Group
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-698-Attach-1.DOC

#F698

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
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***

Thank you for your consideration of my comments.

Sincerely,

Bryan Lee, MD
Pain Management Specialist
160 E. Artesia St, Ste 360
Pomona, CA 91767

CMS-1392-P-699 **Medicare**

Submitter : Dr. Gavin Chartier **09/12/2007**

Organization : Willow Creek Pain Center
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

see attached file

CMS-1392-P-699-Attach-1.DOC

#699

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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- Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,

Gavin D Chartier MD
Director
Willow Creek Pain Center
328 N. 2nd Street #308
Vincennes, Indiana 47591
812-886-1151
drsnooz@charter.net

CMS-1392-P-700 **Medicare**

Submitter : Mrs. Hannah Dolan **09/12/2007**

Organization : Mrs. Hannah Dolan
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs

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 (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,

Hannah Dolan

CMS-1392-P-701 **Medicare**

Submitter : Mrs. Hannah Dolan **09/12/2007**

Organization : Mrs. Hannah Dolan
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

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 spasmodic torticollis, (spasmodic torticollis 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,
Hannah Dolan

CMS-1392-P-702 **Medicare**

Submitter : Dr. Patricia Ollinger- Snyder **09/12/2007**

Organization : Dr. Patricia Ollinger- Snyder
Individual

Category :

Issue Areas/Comments

Packaged Services

Packaged Services

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.

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Thank you for allowing me to provide these comments.
Sincerely,

Dr. Patricia Ollinger-Snyder

CMS-1392-P-703 **Medicare**

Submitter : Mrs. Audrey Aldous **09/12/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding:y CMS-1392-P, Specified Covered Outpatient Drugs

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Sincerely,
Audrey Aldous

CMS-1392-P-704 **Medicare**

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

Organization : The B.A.C.K. Center
Physician

Category :

Issue Areas/Comments

ASC Impact

ASC Impact

attachment

CMS-1392-P-704-Attach-1.DOC

#704

September 12, 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
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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 M. Brooks, MD
Interventional Pain Specialist
The B.A.C.K. Center
650 S. Courtenay Pkwy, Suite 100
Merritt Island, FL 32952

CMS-1392-P-705 **Medicare**

Submitter : Mrs. Quirina Harman **09/12/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs

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,
Quirina Harman

CMS-1392-P-706 **Medicare**

Submitter : Mr. KENNIS BELLAMY **09/12/2007**

Organization : BAYSHORE COMM HOSPITAL
Health Care Professional or Association

Category :

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

PLEASE CONSIDER CREATING A SEPARATE APC FOR RECHARGEABLE NEUROSTIMULATORS. THE RECHARGABLE OPTION TRANSLATES INTO FEWER STIMULATOR REPLACEMANES, AN ADVANTAGE TO THE PATIENT AND THE HEALTHCARE SYSTEM IN THE LONG RUN. SINCE THE RECHARGEABLE STIMULATOR HAS A HIGHER PRICE TAG, CREATING A SERPARTATE APC WILL HELP FACILITIES CONTINUE TO OFFER THE ADVANTAGE OF CLINICAL IMPROVEMENT WITHOUT SUFFERING A HARDSHIP BY SUPPLYING THE MORE EXPENSIVE, BUT PREFERABLE NEUROSTIMULATOR. USING AN INDIVIDUAL HCPCS CODE FOR EACH TYPE OF STIMULATOR IS NO DIFFERENT THAN CHOOSING BETWEEN HOT BIOPSY FORCEP AND SNARE TECHNIQUE FOR COLONOSCOPY, AND WILL HAVE LITTLE TO NO ADVERSE EFFECT ON HOSPITAL PROCEDURES, NOR CAUSE ADMINISTRATIVE BURDEN.

CMS-1392-P-707 **Medicare**

Submitter : Vicker DiGravio III **09/12/2007**

Organization : Mental Health
Other Association

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

Mr. Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Re: CMS-1392-P: Proposed Change to the Hospital Outpatient PPS, Partial Hospitalization Programs

Dear Mr. Kuhn:

Mental Health and Substance Abuse Corporations of Massachusetts, Inc. (MHSACM) is a statewide association representing eighty-eight community-based mental health and substance abuse provider organizations across the state. Our members are the primary providers of publicly-funded behavioral healthcare services in the Commonwealth, serving approximately 117,000 residents on any given day. On behalf of the membership of MHSACM, I thank you

for the opportunity to submit comments in opposition to the proposed changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates.

Psychiatric partial hospitalization is a distinct and organized intensive outpatient treatment of less than 24 hours of daily care designed to provide patients with serious mental health conditions with an individualized, coordinated, intensive, comprehensive, and multidisciplinary treatment program not provided in a regular outpatient setting. Partial hospitalization services are furnished by a hospital or community mental health center to patients who exhibit disabling psychological

#707

MHSACM, Inc.

251 West Central Street, Suite 21, Natick, MA 01760 (508) 647-8385 / Fax (508) 647-8311 www.mhsacm.org

Vicker V. DiGravio III, *President / CEO*

Ellen Attaliades, MA, *Chairman*

September 14, 2007

Mr. Herb Kuhn, Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Re: CMS-1392-P: Proposed Change to the Hospital Outpatient PPS, Partial Hospitalization Programs

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The Centers for Medicare and Medicaid Services (CMS) has proposed a 24% reduction in reimbursement rates for partial hospitalization services. The proposed rule would cut per diem payment rate from $233.27 to $178 in calendar year 2008. This, coupled with rate cuts of 5% in calendar year 2006 and 12% in calendar year 2005, will be extremely devastating to partial hospital programs and severely limit access to needed services. The cut to this Medicare benefit disregards congressional intent and may prevent programs from providing this essential intensive clinical treatment to clients who would otherwise not be able to function in the community. **MHSACM recommends keeping the current reimbursement rate at $233.27.**

Additionally, MHSACM is concerned that the current methodology used to calculate the daily rate does not capture all relevant data nor does it reflect the actual cost to providers to deliver these services. Although CMS analyzed the mapping of revenue codes for hospital-based programs, the same was not performed for community-based partial hospitalization programs. As a result, the cost of providing partial hospital services in a community setting is underestimated, and MHSACM recommends that CMS perform a similar analysis of revenue codes for community-based programs.

Community–based partial hospitalization programs are a critical component of the continuum of mental health care in Massachusetts. These services are a proven, cost-effective model of care for clients who are at high risk for admission to more costly inpatient services. We need to maintain existing services and increase access through expansion of services, rather than further decimate access via rate reductions.

Thank you for your consideration.

Sincerely,

Vicker V DiG III

Vicker V. DiGravio III
President & CEO

symptoms, who experience an acute exacerbation of a severe or persistent mental disorder, or who have been discharged from inpatient psychiatric care. These services are designed to prevent hospitalization and provide a cost- effective alternative to admission to a psychiatric hospital.

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maintain existing services and increase access through expansion of services, rather than further decimate access via rate reductions.

Thank you for your consideration.

Sincerely,
Vicker V. DiGravio III
President & CEO

CMS-1392-P-707-Attach-1.WPD

CMS-1392-P-708 **Medicare**

Submitter : Dr. Louis Pau **09/12/2007**

Organization : The Pain Center of Kansas
Other Practitioner

Category :

Issue Areas/Comments

GENERAL

GENERAL

See attachment

#108

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-709 **Medicare**

Submitter : Dr. John Swicegood **09/12/2007**

Organization : Advanced Interventional Pain Physician

Category :

Issue Areas/Comments

Physician Paymen Services Provided in ASCs

Physician Paymen Services Provided in ASCs

See Attachment

CMS-1392-P-709-Attach-1.DOC

#F709

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 t hey are not p rocedures routinely p erformed 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:

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

***

Thank you for your consideration of my comments. **I realize you are receiving many "standardized letters", however, this is my real life as I know it as an interventional pain physician. These are important issues that impact access for Medicare beneficiaries, please consider these policy revisions.**

Sincerely,

John Swicegood, M.D., F.I.P.P.

CMS-1392-P-710 **Medicare**

Submitter : Mrs. Lydia Muller **09/12/2007**

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 patient access to care while also kepping related costs down and eliminating abuse of services. However, as a patient with severe eye and facial spasms, a mobement disorder resultiong from sustained involuntary muscle spasms, I have concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin toalleviate the debiliating symptoms. These injections are critically important to my ability to finction ormally.
I respectfully rquest CMS not change the payment formula for physician-injectable drugs for 2008, and instead maintain the current payment forula. Any reduction in payments will lead to fewer knowledgeableinjectors where we already have too few. Not just anyone can inject Botulinium toxin successfully to relieve the spasms. The change in policy would also destroy the unifoemity of payments made across settings that assures 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.
Lydia A. Muller 1718 Magsalene Manoe Drive, Tampa, Fl. 33613

CMS-1392-P-711 **Medicare**

Submitter : Ms. Shelly Carling **09/12/2007**

Organization : Cook Medical
Device Industry

Category :

Issue Areas/Comments

GENERAL

GENERAL

Identification of Covered Surgical Procedures-ASC, See attachment

CMS-1392-P-711-Attach-1.DOC

#711

Cook Medical
750 Daniels Way, P.O. Box 1608
Bloomington, IN 47402-1608
Phone: 812-339-2235
Fax: 812-332-0281

September 11, 2007

Via Electronic Submission

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: [CMS-1392-P], Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Identification of Covered Surgical Procedures

Dear Mr. Weems:

The Cook Group, Inc. ("Cook") is pleased to have the opportunity to comment on the proposed changes to the CY 2008 Ambulatory Surgical Center payment system. CMS has solicited recommendations regarding additional surgical procedures that should not be excluded from ASC payment beginning in CY 2008.[1] Cook would like to recommend that CMS not exclude surgical procedure *0170T, Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])* because it meets the general standards for inclusion under 42 CFR 416.166(b) and is not excluded under 42 CFR 416.166(c).

For background purposes, Cook is a holding company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gynecology, gastroenterology, wound care, emergency medicine and surgery. We pioneered the development of products used in the Seldinger technique of angiography and in techniques for interventional radiology and cardiology. Cook products benefit patients by providing doctors with a means of diagnosis and intervention using minimally invasive techniques, as well as by providing innovative products for surgical applications. The company sells over 15,000 different products worldwide.

Surgical procedure *0170T, Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS])* is a minimally invasive procedure that repairs the fistula tract

[1] 72 Fed. Reg. 42785 (August 2, 2007)

Cook Medical
750 Daniels Way, P.O. Box 1608
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Fax: 812-332-0281

without cutting the sphincter muscle, thus minimizing the risk of post-operative incontinence. A conically shaped bioengineered plug is sutured into the fistula tract, maintaining structural support while allowing in-growth of the patient's body tissue and, over time, being completely resorbed by the body. This procedure is typically performed under general anesthesia on an outpatient basis and patients are able to return to normal activity almost immediately. Over 10,000 procedures have been performed in the United States. Published results indicate fistula tract healing rates of almost 80% in complex anal fistulae. (Further description of medical procedure provided in Attachment A).

Procedure *0170T* meets the criteria for inclusion in the CY 2008 ASC payment system as a covered surgical procedure, because:

1) It is a surgical procedure as defined in the Federal Register.[2] It is clinically similar to other anorectal fistulae procedures, including:

46706	Repair of anal fistula with fibrin glue
46020	Placement of seton
46060	I&D of ischiorectal or intramural abscess, with fistulectomy or fistulotomy, submuscular, with or without placement of seton
46270	Surgical treatment of anal fistula, subcutaneous
46275	Surgical treatment of anal fistula, submuscular
46280	Surgical treatment of anal fistula, complex or multiple, with or without placement of seton
46288	Closure of anal fistula with rectal advancement

2) The procedure is separately paid under the OPPS.[3] The CY 2008 reimbursement for *0170T* will be $1946.10. There is no separate reimbursement for the cost of the plug which is $850.

3) It does not pose a significant risk to beneficiaries when performed in an ASC.[4] Based on historical Medicare "Place of Service" data from claims submitted for

[2] 72 Fed. Reg. 42478 (August 2, 2007)
[3] Id.

Cook Medical
750 Daniels Way, P.O. Box 1608
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other types of anal fistula repair, it is estimated that 83% of the repairs were performed as non-inpatient procedures.

4) It is not expected to require active medical monitoring and care at midnight as standard medical practice.[5]

In addition to meeting the criteria for inclusion as a covered surgical procedure, *0170T* is not subject to any of the general exclusions because:

1) It does not generally result in extensive blood loss-the procedure is performed without cutting the patients' tissue;

2) It does not require major or prolonged invasion of body cavities-it is a minimally invasive procedure;

3) It does not directly involve major blood vessels;

4) It is not generally emergent or life-threatening;

5) It does not commonly require systemic thrombolytic therapy;

6) It is not designated as requiring inpatient care under §419.22. (n) of this sub-chapter;

7) It is not reported with an unlisted surgical procedure code;

8) It is not an excluded service under §411.15.[6]

Based upon the review of criteria for inclusion and exclusion, *0170T, Repair of anorectal fistula with plug (eg, porcine small intestine submucosa [SIS]),* should be a covered surgical procedure under the CY 2008 ASC payment system.

Cook appreciates the opportunity to comment on the proposed changes to the CY 2008 ASC payment system and hopes that CMS will take our recommendation under advisement.

---

[4] Id.
[5] Id.
[6] 72 Fed. Reg. 42546 (August 2, 2007)

Cook Medical
750 Daniels Way, P.O. Box 1608
Bloomington, IN 47402-1608
Phone: 812-339-2235
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Respectfully submitted,

Shelly Carling, JD
Manager of Reimbursement

shelly.carling@cookmedical.com

cc: Jim Gardner

Attachment

Cook Medical
750 Daniels Way, P.O. Box 1608
Bloomington, IN 47402-1608
Phone: 812-339-2235
Fax: 812-332-0281

ATTACHMENT A

A typical anal fistula repair utilizing the AFP plug is described as follows:

Under general anesthesia, the patient is placed into the prone jackknife position. The perineum is prepped and draped in a sterile fashion. The secondary (external) fistula opening is identified and, using a combination of probes, hemostats, and anoscopic visualization, the tract is cannulated and the internal opening is identified. The fistula tract is thoroughly cleaned, irrigated, and debrided with hydrogen peroxide. A hemostat is then passed through the secondary opening and advanced through the tract until it extends through the internal opening. This is used to grasp a suture attached to the "tail" of the anal fistula plug, which is then used to pull the plug into the fistula tract. The plug is pulled through the tract until its other, wider end is tightly aligned with and plugs the internal opening, with the "tail" extending distally through the external opening. The internal end of the plug is sutured into place, being careful to also suture closed the internal opening of the fistula tract. Excess "tail" protruding from the external opening is trimmed off and the distal end of the plug sutured to the skin at the external opening, being careful to leave this open for drainage. External opening is covered with a loose gauze dressing and the patient is transported to outpatient recovery.