CMS-1392-P-644 **Medicare**

Submitter : John Manter **09/11/2007**

Organization : John Manter
Nurse

Category :

Issue Areas/Comments

Blood Transfusions

Blood Transfusions

I request that you base blood administration charges according to instructions established when Medicare was created. In the paper based carrier manual section on Medicare□s blood deductible billing, Section 2455 □ It is very clear that the deductible three units does not include administration costs. The Manual cites an example on one encounter where each unit received separate charges for administration. The below example shows that blood administration was charged and paid per unit. Please re-consider the APC Advisory Committee□s suggestion, or state that hospitals may choose to bill their costs per unit, regardless of payment.

Nowhere in the original billing guidelines for blood administration did Medicare state administration was per encounter and not per unit.

2455 COVERAGE AND LIMITATIONS 04-91

2455. MEDICAL INSURANCE BLOOD DEDUCTIBLE

. Accordingly, although payment may not be made for the first three pints of blood and/or

units of packed red cells furnished to a beneficiary in a calendar year, payment may be made (subject to the cash deductible) for the administration charges for all covered pints or units including the first three furnished in a calendar year.

D. Distinction Between Blood Charges and Blood Administration Charges.--Since the blood deductible applies only to charges for blood and does not apply to charges for blood administration, these two charges must be considered separately.

F. Example of Application of the Part B Blood Deductible.--In 1991, a beneficiary received three pints of blood from a physician for which the total charge is $100 per pint. (The physician does not specify how much of the charge is for blood, and how much is for blood administration.) The physician accepted assignment and submitted a claim for Part B payment.

Determine that the beneficiary has not met any part of the Part B blood deductible and has met only $40 of the cash deductible. You determine that the physician's customary charge for blood administration is $50 per unit and that it is reasonable. Consequently, charges for blood administration are $50 per unit or a total of $150 for the three units furnished and charges for blood are $50 per unit or a total of $150 for the three units furnished. The beneficiary replaces one pint of blood. Since the beneficiary had not met any of the Part B blood deductible, none of the $150 in blood charges are payable nor may any of such charges be applied to satisfy the annual cash deductible ($100). Of the $150 in blood administration charges, $60 is applied to satisfy the beneficiary's unmet cash deductible and a payment of $72 is made on the remaining $90 in charges ($90 x 80%). Since the physician accepted assignment and since the beneficiary replaced one pint of blood, the physician may charge the beneficiary the reasonable charge only for the two remaining deductible pints.

CMS-1392-P-645 **Medicare**

Submitter : Dr. Aaron K Calodney **09/11/2007**

Organization : Texas Pain Society
Physician

Category :

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

September 10, 2007

Department of Health and Human Services
Attn: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Implantation of Spinal Neurostimulators

To whom it may concern:

I am writing to you as President of the Texas Pain Society representing nearly 250 physicians. The Texas Pain Society□s membership includes physicians in the fields of anesthesiology, neurology, physical medicine, neurosurgery, psychiatry, and orthopedics. The society is committed to providing physicians with the latest information in our field as well as educating Texans about pain management.

In 2005, providers brought to the attention of CMS the importance of the rechargeable spinal cord stimulator system. Then on January 1, 2006, CMS granted a new technology pass- through for the rechargeable system. That pass-through expires December 31, 2007. However, in the proposed rules for OPPS 2008, CMS has not made any reimbursement differences in the non-rechargeable and rechargeable spinal cord stimulation systems. These two modalities have significant differences in costs for the actual equipment. When there are no differences in reimbursement, and there are significant differences in costs, it effects the decisions providers make. A hospital cannot afford to lose significant amounts on one implant, and we believe this will impact the Spinal Cord Stimulation system that is allowed to be implanted. The difference in costs of a non-rechargeable

and rechargeable has been found to be great. Even though the rechargeable system has vast clinical benefit, a hospital administrator may be slow to adopt a new technology when the reimbursement does not come close to covering the cost of the device/implant.

Over time, the rechargeable system will provide cost savings to the Medicare system. With the increase in battery life, there will be fewer replacements for the Medicare beneficiary. Additionally, the system should benefit from fewer office visits related to the depletion of the battery and reduced complications from device-related hospitalizations.

On behalf of the Texas Pain Society, we are asking CMS to reconsider the reimbursement methodology in the proposed rule and create a separate APC for rechargeable neurostimulators. Along with that a separate coding structure for the rechargeable system would need to be established. Our belief is the rechargeable systems are almost always the best choice of neurostimulators for the Medicare beneficiary. A separate payment category with more appropriate reimbursement would allow the physician the ability to do what is best for the patient.

Thank you for your consideration. Please don□t hesitate to contact me if you have any questions or need additional information.

Best regards,

Aaron K. Calodney, MD

CMS-1392-P-646 **Medicare**

Submitter : Charlet Homick **09/11/2007**

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 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,

Charlet Homick

CMS-1392-P-647 **Medicare**

Submitter : Dr. Mitchell Anscher **09/11/2007**

Organization : Virginia Commonwealth University Medical Center
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See attachment

#617

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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Please direct your questions or comments to 1 800 743-3951.

CMS-1392-P-648 **Medicare**

Submitter : William Marston **09/11/2007**

Organization : University of North Carolina School of Medicine
Physician

Category :

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

I commend CMS for its work to establish a comprehensive process for APC and ASC payment.

I have reviewed RVUs as well as the facility cost to provide services for CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser, first vein treated).

Payment for CPT code 36478, in the hospital outpatient department is in APC 0092 with an unadjusted national average payment of $1,684.02. Other procedures in that category include:
a. 37650: Ligation femoral vein
b. 37760: Ligation of perforator veins
c. 37765: Stab phlebectomy of varicose veins

These codes bear little relation to the procedure performed under CPT code 36478, which involves the endovenous ablation of the saphenous veins in almost all cases. This procedure more closely resembles the following procedures under APC 0091. Other procedures in this category include:
d. 37700: Ligation and division of long Saphenous vein at SFJ or distal interruptions
e. 37718: Ligation, division and stripping, short Saphenous vein
f. 37722: Ligation, division and stripping GSV from SFJ to knee or below

g. 37735: Ligation, division and complete stripping of GSV or LSV with radical excision of ulcer and skin graft and/or interruption of communicating veins of lower leg, with excision of deep fascia

h. 36478: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency, first vein treated

We believe CPT code 36478 is more clinically related to procedures in APC 0091 than to APC 0092.

In previous years, low cost laser fibers (not matched to the laser for compatibility) were available from various companies. March 28, 2007, a successfully litigated patent infringement suit resulted in these fibers being removed from the market. Although there has been no increase in fiber cost, the potential to reduce cost through the use unmatched fibers has been removed. Ensured compatibility between laser and fiber enhances patient safety. We believe resource consumption for CPT code 36478 is more closely related to APC 0091.

We are requesting that you move CPT code 36478 from APC 0092 to APC 0091.

Thank you for your consideration of this matter. Please do not hesitate to contact me if further information is required.

Sincerely,
William Marston MD
Associate Professor of Surgery

CMS-1392-P-649 **Medicare**

Submitter : Dr. Thomas Masten **09/11/2007**

Organization : Dr. Thomas Masten
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1392-P-649-Attach-1.DOC

#649

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.
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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,

Thomas Masten M.D.

CMS-1392-P-650 **Medicare**

Submitter : Ms. Janet Brown **09/11/2007**

Organization : Moundview Memorial Hospital and Clinics Hospital

Category :

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

See Attachments.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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CMS-1392-P-651 **Medicare**

Submitter : Dr. Rafal Wyszkowski **09/11/2007**

Organization : Lansdale Pain Management Center
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1392-P-651-Attach-1.DOC

#651

Rafal Wyszkowski, MD
Lansdale Pain Management Center
262 Bethleham Pike
Colmar, PA 19002

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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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.

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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.

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- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
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***

Thank you for your consideration of my comments.

Sincerely,

Rafal J. Wyszkowski, MD

CMS-1392-P-652 **Medicare**

Submitter : Dr. michael peattie **09/11/2007**

Organization : ASIPP
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

These proposed cuts need to be fixed now. This is absurd, if this continues there will not be enough physicians in this country willing to care for an aging population. I do not think people really understand the magnitude of this reimbursement issue!

CMS-1392-P-653 **Medicare**

Submitter : Dr. Ronald Jones **09/11/2007**

Organization : Royse City Medical/Tri-County Pain Management Cent
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-653-Attach-1.DOC

#653

ROYSE CITY MEDICAL CLINIC
TRI-COUNTY PAIN MANAGEMENT CENTRE

Dr. Ron Jones, DACOFP; FAAFP; ASIPP
Fully Credentialed Interventional Pain Management
200 Arch St. Royse City, Tx. 75189
4101 Wesley St. Suite B Greenville, Tx. 75403
Tele: 972.636.9577 Fax: 972.636.7048

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

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- Maintain non-rechargeable neurostimulator procedures in APC 0222.

Thank you for your consideration of my comments.

Sincerely,

Dr. Ron Jones

CMS-1392-P-654 **Medicare**

Submitter : Mr. Jonathan Shinefeld **09/11/2007**

Organization : Mr. Jonathan Shinefeld
Nurse

Category :

Issue Areas/Comments

Outlier Payments

Outlier Payments

re Hospital Acquired Condition: I strongly suggest that CMS incorporate physician payment sanctions along with the hospital sanctions that have been described. Physicians are intimately involved with patient assessment and care and are legally, ethically and professionally responsible for patient outcomes. Creating physician payment sanctions will save CMS additional money and even more importantly, will begin to create alignment in this critical national performance improvement project.

CMS-1392-P-655 **Medicare**

Submitter : Dr. Mark Workman **09/11/2007**

Organization : The Pain Rehabilitation Group of Wichita Falls, PA
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

#655

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-656 **Medicare**

Submitter : Dr. Marcom Herren **09/11/2007**

Organization : The Pain Rehabilitation Group of Wichita Falls, PA
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED LETTER

CMS-1392-P-656-Attach-1.DOC

#656

September 11, 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 Prospective 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,

Mark A. Workman, M. D.
The Pain Rehabilitation Group of Wichita Falls, P.A.
4301 Maplewood Ave Ste A
Wichita Falls, Texas 76308
940-696-8500

CMS-1392-P-657 **Medicare**

Submitter : Dr. Mark Workman **09/11/2007**

Organization : The Pain Rehabilitation Group of Wichita Falls, PA
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED LETTER

CMS-1392-P-657-Attach-1.DOC

#657

September 11, 2007

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Acting Deputy Administrator
Centers for Medicare & Medicaid Services
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Mark A. Workman, M. D.
The Pain Rehabilitation Group of Wichita Falls, P.A.
4301 Maplewood Ave Ste A
Wichita Falls, Texas 76308
940-696-8500

CMS-1392-P-658 **Medicare**

Submitter : Dr. Standiford Helm **09/11/2007**

Organization : American Society of Interventional Pain Physicians
Physician

Category :

Issue Areas/Comments

ASC Impact

ASC Impact

IMPLANTATION OF SPINAL NEUROSTIMULATORS

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