CMS-1392-P-628 Medicare

Submitter : **Dr. Bradley Christianson** **09/11/2007**

Organization : **Dr. Bradley Christianson**
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1392-P-628-Attach-1.RTF

#628

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 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:

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.

Sincerely,

Bradley G. Christianson, D.O.
Anesthesiologist/Pain Management

CMS-1392-P-629 Medicare

Submitter : Mrs. Christiana Paul **09/11/2007**

Organization : Sharp HealthCare
Social Worker

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

I believe the direct impact of the 4th consecutive rate cut will jeopardize the very existence of the partial hospitalization benefit itself. I would recommend that CMS take the following course of action: 1. Allow the PHP per diem to remain $234.73, the same as CY2007. 2. Support a legislative amendment to: remove PHP from the APC codes and have independent status, establish the current rate of $234.73 as the base per diem rate for services, annually adjust the base rate by a conservative inflation factor such as the CPI, and establish quality criteria to judge performance and that influences future rate reimbursement.

CMS-1392-P-630 Medicare

Submitter : Dr. Shevin Pollydore **09/11/2007**

Organization : Peachtree Orthopaedic Clinic
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1392-P-630-Attach-1.TXT

#630

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,

Shevin D. Pollydore, M.D.
Peachtree Orthopaedic Clinic
1901 Phoenix Boulevard
Suite 200
College Park, GA 30349

CMS-1392-P-631 **Medicare**

Submitter : **Mrs. Roberta Stefanowicz** **09/11/2007**

Organization : **None**
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

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 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 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 correct muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.

Thanks you for allowing me to provide these comments.

Sincerely,

Roberta Stefanowicz
3232 Valley Forge Drive
Brunswick, Ohio 44212

CMS-1392-P-632 **Medicare**

Submitter : Mr. David Matteodo **09/11/2007**

Organization : Mass. Assoc. of Behavioral Health Systems
Health Care Provider/Association

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

See Attached Comments

CMS-1392-P-632-Attach-1.DOC

CMS-1392-P-632-Attach-2.DOC

Massachusetts Association of Behavioral Health Systems, Inc.

115 Mill Street
Belmont, MA 02478
Phone: 617-855-3520

Gary Gilberti
President

David Matteodo
Executive Director

Members:
AdCare Hospital
Arbour Hospital
Arbour-Fuller Hospital
Arbour-HRI Hospital
Bournewood Hospital
McLean Hospital
Pembroke Hospital
Westwood Lodge

***Associate Members*:**
Anna Jaques Hospital
Bayridge Hospital
Baystate Health System
Berkshire Health Systems
Beth Israel Deaconess
Brockton Hospital
Cambridge Health Alliance
Cape Cod Hospital
Caritas Carney Hospital
Caritas Good Samaritan
Caritas Holy Family Hospital
Caritas Norwood Health System
Caritas St. Elizabeth's
Children's Hospital
Cooley Dickinson Hospital
Emerson Hospital
Faulkner Hospital
Franciscan Hosp. for Children
Gosnold Treatment Center
Hallmark Health System
Harrington Memorial Hospital
Henry Heywood Hospital
Holyoke Medical Center
Marlboro Hospital
Mass General Hospital
Metro West Medical Center
Morton Hospital
Mount Auburn Hospital
New England Medical Center
Newton Wellesley Hospital
Noble Hospital
North Adams Regional Hospital
North Shore Medical Center
Quincy Medical Center
Providence Behavioral Health
St. Luke's Hospital
St. Vincent Hospital
U Mass Memorial Health Care

#632

September 10, 2007 — Submitted electronically and by US Mail

Mr. Herb Kuhn, Acting Administrator
Center 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 Changes to Hospital Outpatient PPS

Dear Mr. Kuhn,

On behalf of the Massachusetts Association of Behavioral Health Systems (MABHS), a statewide organization of 46 inpatient facilities, most of who maintain Partial Hospital Programs, I appreciate the opportunity to offer these comments regarding proposed Partial Hospital rates. We are extremely concerned that the proposed 24% payment reduction to Partial Hospitals may result in significant problems for our Partial Hospital programs and threatens their ongoing viability.

In Massachusetts, we have seen the situation where several years ago, there was a strong push from government and insurers to provide Partial Hospital services as a less expensive alternative to inpatient care. It also was perceived as beneficial to patients because it could provide them with extensive services, yet allow patients to remain in the community and avoid hospitalization. Many of our hospitals stepped forward and enthusiastically began providing Partial Hospital services. Patients seemed to like it, and clearly the programs had provided significant benefits.

Unfortunately, it seems that much of the initial interest in the service has waned significantly among government and insurers. We have seen programs close in Massachusetts because they could not maintain their fiscal viability. These closures are particularly unfortunate in certain parts of the State, where geographically it is not feasible for patients to travel far distances to another program. Once programs close, most if not all will probably not reopen. We have seen this occurrence with the Detoxification Programs in Massachusetts, many of which closed due to State Budget cuts, only to not reopen when conditions improved.

We fear the proposed 24% payment reduction for beginning in January, 2008 will be devastating for our programs. The proposed cut will result in 41% reduction in payments over the last three years. Notwithstanding these reductions, Partial Hospital Programs' costs continue to rise. When CMS announced the proposed cut, I conducted a survey of our memberships' Partial Hospital Programs (PHP) and the response was uniform as follows:

- The proposed reduction would be devastating to the Partial Hospital Programs, and may lead to program closures as hospital financial administrators are already questioning the financial viability of the PHPs even before the proposed reduction;

- Hospitals forecast that inpatient length of stay will increase if PHP were not available as a step-down option;

- Partial Hospitalization is an important link between inpatient and outpatient and without PHPs waiting lists for outpatient services would be more difficult to manage;

- PHP services may include psychiatric evaluation by a psychiatrist, nursing and social work admission assessments, case management, medication management, five groups per day (education, interactive and therapy), outpatient liaison, family meeting if indicated, and discharge planning and evaluation by the psychiatrist;

- Finally, and perhaps most importantly, Partial Hospitalization is viewed as a positive experience for the patients with tangible results, resulting in high patient satisfaction, whereas inpatient stays tend to focus more on crises stabilization and safety.

In Massachusetts, we already have problems with finding appropriate discharge options for our patients. PHP is a very important step-down alternative that is good for patients and families. It also saves CMS money by helping to reduce inpatient length of stay. **Our PHP programs are comprehensive and require resources in order to provide valuable services to patients. They can not be asked to absorb an additional 24% cut on top of what they experienced in CMS payments the past two years.**

We strongly urge CMS to keep the PHP rates at their current level at a minimum. Our costs are going up- even maintaining the current level will be difficult for our programs. Please reconsider the proposed cut so our Partial Hospital Programs can continue to provide this valuable service for our patients.

Thank you for the opportunity to offer these comments. Should you have any questions please do not hesitate to contact me.

Sincerely,

David Matteodo, Executive Director
Massachusetts Association of Behavioral Health Systems
DMatteodo@aol.com
(617) 855-3520

CMS-1392-P-633 Medicare

Submitter : Ms. Melinda Martin **09/11/2007**

Organization : ASIPP
Other Health Care Professional

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-633-Attach-1.DOC

#633

September 10, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
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Attention: CMS–1392–P, Mail Stop C4–26–05
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***

Thank you for your consideration of my comments.

Sincerely,

Melinda Martin
Paducah, KY

CMS-1392-P-634 Medicare

Submitter : Mr. Eric Hauth **09/11/2007**

Organization : Neuromodulation Therapy Access Coalition Device Association

Category :

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

I am writing on behalf of the Neuromodulation Therapy Access Coalition (NTAC) concerning reimbursement for rechargeable neurostimulators under its Proposed Changes to the Hospital Outpatient Prospective Payment System (CMS-1392-P).

NTAC is newly formed coalition of national medical specialty societies, device manufacturers and patient advocates dedicated to promoting appropriate access to neuromodulation therapies. Although you have certainly heard from members of our coalition, I wish to express the coalition□s concern with the proposed rules, as they relate to the implantation of spinal neurostimulators.

In the proposed rule, CMS proposes to pay hospitals the same rate ($12,314) for rechargeable and non-rechargeable neurostimulators when implanted in hospital outpatient departments in 2008. The cost differential (according to CMS□s claims data) between the two therapies is approximately $6,500 □ a substantial difference that warrants separate reimbursement.

Although the existing pass-through payment for rechargeable neurostimulators is set to expire December 31,2007, we believe the conditions that led to the pass-through payment still hold true. First, CMS already recognizes that rechargeable neurostimulators represent a substantial

clinical improvement, due to advancements in battery power for rechargeable neurostimulators. Second, the cost of the device and the differential between non- rechargeable and rechargeable neurostimulators are not □ as noted in the proposed rule □ □insignificant.□ Finally, the distortions in payment resulting from inclusion of both rechargeable and non-rechargeable stimulators in the same APC make it clear that the proposed APC 0222 is not appropriate for rechargeable technology.

As discussed in the proposed rule, the cost differential between rechargeable and non- rechargeable technology does not violate the □2 times□ rule. We agree with this finding, but maintain that a

$6,500 differential is meaningful and should be addressed. We believe that the 2 times rule is a sufficient, but not necessary condition for splitting APCs. We are unaware of other APCs where the cost differential between packaged services is as large as that proposed for neurostimulators.

Based on these and other factors, we urge CMS to create a new APC to provide adequate payment for rechargeable technologies to ensure appropriate access to rechargeable neurostimulators.

We recognize that the creation of a new APC will require unique coding. We believe that CMS can make this work within the existing coding structures and would not impose an undue burden on facilities. Feedback provided by implanting centers to our coalition partners indicates that these coding approaches would not create an undue burden on facilities if such changes provide adequate reimbursement for the technolgoy.

Without a separate APC for rechargeable neurostimulators, we are deeply concerned that the proposed rules would substantially and negatively impact patient access to this vital therapy. Again, we urge CMS to recognize this shortcoming in the proposed rule by establishing an APC that reflects the true device and facility overhead costs of procedures that use rechargeable neurostimulators and allows facilities to continue offering this important therapy option to their patients.

Thank you for your consideration on this important issue.

Sincerely,

Eric Hauth, Executive Director
NTAC

CMS-1392-P-635 Medicare

Submitter : Dr. Clinton Dille **09/11/2007**

Organization : Southern Idaho Pain Institute
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1392-P-635-Attach-1.DOC

#635

Southern Idaho Pain Institute
236 Martin Street
Twin Falls, ID 83301
208-733-3181 Ph
208-733-3168 Fax

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 these comments. The greatest concern is for the patients treated in our facility and isolating these procedures as proposed will cause an access to care issue for many Medicare beneficiaries and potentially cost the Medicare system more. Any questions or comments you have on this letter are welcome and thank you for your service to Health and Human Services and specifically the Centers for Medicare and Medicaid.

Sincerely,

Clinton Dillé , M.D. , President

Christy Davies, Administrator

Southern Idaho Pain Institute

CMS-1392-P-636 Medicare

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

Organization : John Manter
Nurse

Category :

Issue Areas/Comments

Implantation of Spinal Neurostimulators

Implantation of Spinal Neurostimulators

Table 35, page 42716 indicates that the difference in cost between a rechargeable vs. non-rechargeable neurostimulator is over $6000. To pay both rechargeable on non-rechargeable procedures the same, as you propose, does not violate the times two rule, but it violates logical thought and fair payment principles. I suggest that for devices/implants with costs over $5000 that you continue with level II HCPCS coding and APC payment for such devices, possibly using a new status indicator. By proposing the same payment for devices which differ in cost by thousands of dollars, you create incentive for the lower cost item, whether or not this benefits Medicare patients better. Also, if you were genuinely concerned about the administrative burden that HCPCS device codes cause hospitals, as you state on p 42715 why not discontinue the CMS mandated HCPCS level II device edits ??

CMS-1392-P-637 Medicare

Submitter : Dr. Richard Chudacoff **09/11/2007**

Organization : Las Vegas Int'l Center for Adv Gyn Care
Physician

Category :

Issue Areas/Comments

APC Relative Weights

APC Relative Weights

September 11, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P (Hospital Outpatient Prospective Payment System)

Comment Reference: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Deputy Kuhn:

As a practicing gynecologist I am pleased that the CMS has offered the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

MR guided Focused Ultrasound (MRgFUS) has the potential to revolutionize surgery as we know it today and I am proud to be among the leading physicians offering this technology to patients. We believe that this technology has tremendous potential to improve health outcomes and the uterine fibroid application is only the first of many to come.

I welcome CMS□ proposal to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43 and the recognition that it belongs with other image guided therapies. It shares many similarities with these procedures both clinically and in terms of resources required:

1) Treatment objective is non-invasive tumor destruction
2) The surgery is conducted using an external source of energy which penetrates into the body to reach the tumor
3) Imaging technology is required
4) Extensive treatment planning is involved with continuous monitoring during treatment
5) Expensive capital equipment in dedicated specialized treatment rooms
6) Lengthy procedure time ranging from 2-5 hours

However the payment rate for this procedure continues to be far below the costs incurred to provide this service and does not reflect the treatment planning component that is required to perform the MRgFUS procedure.

I recommend that CMS consider assignment of 0071T and 0072T to APC 0127, Level IV

Stereotactic Radiosurgery, which would permit appropriate payment for the extensive treatment planning. Level IV Stereotactic Radiosurgery assignment would permit MRgFUS to be classified into an APC with similar clinical and resource homogeneity.

The MRgFUS procedure provides excellent clinical results in a cost effective manner and should be assigned to an appropriate APC that permits hospitals and outpatient centers to offer this less invasive procedure option to patients with uterine fibroids. We urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127 which more accurately reflects the clinical and economic resources utilized.

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

Richard Chudacoff, MD, FACOG
Las Vegas International Center for Advanced Gynecologic Care
(Specializing in minimally and non-invasive surgery)
7170 Smoke Ranch Rd. #110

Las Vegas, NV 89128
TEL: 702-485-8893
FAX: 702-974-0945

Other Services in New Technology APCs

Other Services in New Technology APCs

September 11, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

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Respectfully,

Richard Chudacoff, MD, FACOG
Las Vegas International Center for Advanced Gynecologic Care

(Specializing in minimally and non-invasive surgery)
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Las Vegas, NV 89128
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Physician Paymen Services Provided in ASCs

Physician Paymen Services Provided in ASCs

September 11, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P (Hospital Outpatient Prospective Payment System)

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Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

Richard Chudacoff, MD, FACOG
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Las Vegas, NV 89128
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FAX: 702-974-0945

CMS-1392-P-638 Medicare

Submitter : Ms. Anna Van Fleet **09/11/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

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 CMSs 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,
Name and address (not needed if submission is electronic)
Instructions for Using CMS eRulemaking web site:

Type the following in your browsers search field: http://www.cms.hhs.gov/eRulemaking and press Go or search button.
At the Centers for Medicare & Medicaid Services eRulemaking web site, click on Submit

electronic comments on CMS Regulations with an open comment period.
On the Dockets Open for Comment page, find the Docket ID CMS-1392-P. You may have to look through other pages at the bottom of the screen to find this docket number.
Click on docket ID CMS-1392-P. The Docket Information page will appear showing the comment period end date. Click on Submit Comment.
On the Document Management Comment Form, enter your Postal Code, Country, Category (should be Individual), your First and Last Names and in the Organization Name field, type None. Click on Continue.
A list of Issue Areas will appear. Choose Specified Covered Outpatient Drugs. Choosing this option will paste it above the comment box. Enter your message into the comment box. Click on Continue.

On the Review Comment Submissions screen, read your comment and check for spelling and grammar errors. If you need to make changes, click on Modify and make the changes. At the bottom of the page, click on Save Comments.
Your submitted comment will appear on the screen with a Temporary Comment Number. Use the printer icon on your browser to print your comment. Click on Exit. Close your browser (clicking on the back arrow will delete your comment).
If you want to copy information from an Action Alert and paste it into the comment box, you must first save what you copy from the Action Alert into Word with an .rtf file extension (instead of a .doc extension). Then you can copy it from the .rtf document and paste it into the comment box.

Comments may also be submitted by mail to:

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS1392P
P.O. Box 8011
Baltimore, MD 212441850

Or by express/overnight mail service to:
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention:CMS1392P
Mail Stop C42605
7500 Security Boulevard
Baltimore, MD 212441850

CMS-1392-P-639 Medicare

Submitter : Dr. Howard Sandler **09/11/2007**

Organization : University of Michigan
Physician

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

See attached pdf

Howard Sandler

CMS-1392-P-639-Attach-1.PDF

#639

University of Michigan Medical School

Department of Radiation Oncology
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(734) 936-4300
(734) 763-7371 fax
www.med.umich.edu/radonc

Alpena General Hospital
1501 West Chisholm
Alpena, MI 49707
(888) 356-7151
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Central Michigan Community Hospital
Norval K Morey Cancer Center
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(989) 772-6811
(989) 772-6813 fax

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(517) 367-5070
(517) 372-6464 fax

Providence Hospital
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(248) 849-3321
(248) 849-8448 fax

Assarian Cancer Center Providence Park
47601 Grand River Avenue
Novi, MI 48376-1233
(248) 465-4300
(248) 465-5471 fax

Veterans Administration Medical Center
2215 Fuller Road, 114B
Ann Arbor, MI 48105
(734) 769-7426
(734) 213-3826 fax

September 11, 2007 Submitted electronically via attachment to

http://www.cms.hhs.gov/eRulemaking

Kerry N. Weems
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1385-P
P.O. Box 8018
Baltimore, MD 21244-8018

Re: Comments to Proposed Rule
File Code: CMS-1385-P

Dear CMS Staff:

I am writing this letter with respect to the Hospital Outpatient Prospective Payment System Proposed Rule for CY 2008.

I am currently the Newman Family Professor and Senior Associate Chair of the Department of Radiation Oncology and Professor of Urology at the University of Michigan Medical School. My MD and MS (in physics) were obtained at the University of Connecticut and I was trained in radiation oncology at the University of Pennsylvania. I am the principal investigator of a national Radiation Therapy Oncology Group (RTOG) protocol studying radiotherapy and chemotherapy for prostate cancer and am the principal investigator of an NIH-funded clinical trial grant investigating novel technological aspects of prostate cancer irradiation. I'm an active clinical trial scientist and have used an extensive prostate cancer database to study to role of radiation therapy in the treatment of prostate cancer. The University of Michigan is center of excellence for prostate cancer treatment and, as such, we are at the forefront of modern radiation technological implementation.

Tumor targeting is essential in optimizing the delivery of radiation to the tumor while minimizing exposure of uninvolved normal tissues. Radiation is give, usually, with a series of outpatient treatments – for example for prostate cancer treatment we use approximately 42 treatment sessions, given Monday through Friday. Each session requires accurate daily setup and monitoring of the tumor to ensure that the radiation is delivered on-target. In prostate cancer

management, this requires daily prostate localization.

As I understand it, the Proposed Rule would financially reward hospital outpatient departments to provide services using existing guidance methods – known to be inferior to newer methods -- in conjunction with radiation therapy treatment. We've begun to use a new FDA-510k-cleared system from Calypso Medical that tracks the prostate continuously during a radiation session and allows us to use a more focused beam to treat the prostate. Every cubic inch of the body that is unnecessarily irradiated may result in side effects. The continuous tracking method allows for a more compact treatment volume, which is a significant breakthrough.

Please accept the recommendation of the APC Panel that occurred on September 6, 2007 to exclude radiation oncology guidance procedures from packaging in the Final Rule. Further assessment of costs related to specific procedures needs to be undertaken before implementing such a significant change to the radiation oncology practice.

Please feel free to contact me with any questions on radiation oncology and prostate cancer management treatment.

Sincerely,

Howard Sandler, MD
Professor of Radiation Oncology

CMS-1392-P-640 Medicare

Submitter : Mr. George Griffin **09/11/2007**

Organization : Palmyra R-I Schools
Academic

Category :

Issue Areas/Comments

GENERAL

GENERAL

I am opposed to the discontinuance of this program. I work in a small rural NE school district serving about 190 special education students, several of which have Autism, or are physically handicapped. While the funds from school district administrative claiming does not nearly cover the cost for additional/supplemental therapies for these students, it does help defray some of the cost. Without such funding support, I am confident districts will not be able to maintain the needed funding to provide PT, OT, & Speech for these students. Their needs will go unaddressed and their development will be delayed even further. Eventually, these folks will exit school and be much less, (if at all), competitive in the job market and become a social services issue if SDAC is halted.

CMS-1392-P-641 Medicare

Submitter : Mr. E Paul Broussard **09/11/2007**

Organization : SOUTHWEST AMBULATORY BEHAVIORAL SVCS.
Other Health Care Provider

Category :

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1392-P-641-Attach-1.PDF

#641

September 11, 2007

Mr. Herb Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Delivered Via On-Line Form: http://www.cms.hhs.gov/eRulemaking

Ref: File Code CMS-1392-P

Dear Acting Administrator Kuhn:

I am an owner and manger of Southwest Ambulatory Behavioral Services, Inc., a community mental health clinic in rural Louisiana. I've operated my facility continuously since its inception in December 1996. I'm writing in response to the proposed rule referenced above, specifically in regards to proposals made affecting the daily rate for Partial Hospitalization Programs (APC 0033)

Our provision of service has been streamline since inception and the cuts that have been imposed by CMS over the past three years has caused undue stress on clinicians and administration staff in continuing to provide the quality of service we pride ourselves on and the community we serve deserve. As a community mental health center, we are paid for one of our required four core services, Partial Hospitalization Program. The other core services are not reimbursable by Medicare, although we are still required to provide those services to maintain certification by CMS. All of our employees are full time to the community mental health center and cannot be allocated to another department like a hospital based PHP. The affects of both Hurricanes Katrina and Rita have been felt dramatically by this facility in our unique location between both devastated areas in Southeast and Southwest Louisiana. An influx of Medicare Beneficiaries suffering from mental health problems relocated to our catchment area during and after the hurricanes creating more of a need for the services we offer. This increase in Medicare Beneficiaries and the scarcity of qualified clinicians has been trying to our facility. The cost of all related expenses in providing PHP services has also grown exponentially, i.e. labor costs, related employment taxes, property insurance, professional liability insurance, utilities, and cost of parts and labor for any repairs, as well as office equipment and supplies. In short, all costs to operate this facility and any business have increased tremendously over the past two years, which gives no credence to any proposed cuts for PHP. The economic impact of our facility to

318 E. Park Street
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Crowley, LA 70527-0370
Tel # 337.788.3600
Fax # 337.785.1188

The rural community and the surrounding area equates to $6,000,000. Our community recognizes the importance of our services as well as the medical industry we serve with.

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to reduction in rates for Partial Hospitalization Programs. As stated above, such provisions would have a devastating impact on the access to quality mental healthcare in my community.

Specifically, the proposed rule referenced above continues to place extreme hardship on providers of Partial Hospitalization Programs, especially free standing community mental health centers. The rate proposed for 2008 once again falls below the actual cost of providing such services. CMS has proposed a gross rate for APC-0033 of $179.88 for a day of services in a partial hospitalization program, which results in a net payment of $123.10 for my rural Louisiana facility after wage indexing and co-pay deductions.

At the current time the co-pay is reimbursable as a qualified bad debt when the patient is determined to be indigent and all collection activities over a minimum time of 120 days fails to reap any means of repayment. We have to borrow against our line of credit to make ends meet until filing our annual cost report to recoup those eligible bad debts, thus causing more costs in the form of interest expense to the facility. This is the fourth consecutive year of cuts for APC 0033, which have totaled over 42% over the last 4 years (2008-23.37% proposed; 2007-4.55%, 2006-12.59%, 2005-1.91%). These severe cuts, when most outpatient services received increases over the same four years, indicates that there are obvious issues with the proper setting of the APC-0033. These rates are insufficient to cover the cost of caring for an acutely ill person with mental illness. In the proposed rule, CMS recognized that this program represents "the most resource intensive of all outpatient mental health treatment". This program is just one step down from an inpatient psychiatric stay and actually has higher requirements than an inpatient stay. The current standard of Practice for Partial Hospitalization Programs is an average of 4 professional services per day. Services provided in a PHP are provided both on a group and individual basis. Partial Hospitalization Programs require extensive amounts of professional services, inclusive of nursing, social work, therapy, ancillary services and psychiatry.

CMS noted in the final rule that they would accumulate appropriate data and determine if refinements to the per diem methodology were warranted. The current proposed rule once again acknowledges that cost data from CMHC's and hospitals has fluctuated greatly. The median costs varied by large amounts. Due to CMS's acknowledgement that the base data varies so greatly, it is not appropriate to propose such a cut for this service. The proposed cut of approximately 23% is not reflective of the cost pattern for the freestanding CMHC partial programs in our state. In the two prior years, CMS acknowledges that appropriate cost finding data was not available; therefore recommending 15% cuts for both years. **However, CMS did appropriately cost find and set the rate for the components of the psychiatric services rendered in a partial program. It is unclear why CMS continues to say that a full partial day should not equal the cost of the separate services in an outpatient hospital setting.**

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COMMENT I - DECREASE IN PARTIAL HOSPITAL PAYMENT BY 23.37% WHILE LOUISIANA PARTIAL COSTS INCREASED SUBSTANTIALLY

Louisiana has seen an unprecedented increase over the past two years in costs for staffing, repairs and maintenance, supplies and insurance.

In the aftermath of Hurricanes Rita and Katrina in 2005, the cost of doing business in Louisiana has risen substantially. Insurance rates across the State have risen from 50-200% (Insurance Journal 10/24/2006), Nursing Salaries have increased by 10-15% (Louisiana Nurses Association, 2005), use of high cost staffing agencies have increased by 25% and cost for labor has increased by 7.4% Statewide and 28.7% in New Orleans (US Bureau of Labor and Statistics 4th Quarter 2005). Louisiana has lost 2046 RN's by application for change of address to another State since the storms (Louisiana State Board of Nursing, 2005). This added to an already strained nursing supply has substantially increased labor costs.

The proposed wage index in Louisiana has been lowered post hurricane instead of adjusted upward. This results in a much lower payment rate for Louisiana. Mississippi had a very slight wage index increase that is not nearly reflective of the true labor cost increase. The time lag on the wage indexing is a huge factor for Hurricane Zone providers. The wage index decrease makes the assumption that the cost of labor has actually decreased since the hurricanes. That would mean that despite the biggest shortage in staffing for hospitals in the past 20 years as well as the loss of professional and paraprofessional staff, salaries have gone down. Any employer in the Gulf Coast states can verify that this is not correct. Wages have increased substantially.

COMMENT II - PAYMENT FOR PARTIAL HOSPITALIZATION VERSUS OUTPATIENT

The Payment for Partial Hospitalization Services includes a full program, inclusive of Nursing Staff, Psychiatrists, Medical Doctors, Psychologists, Masters Prepared Therapists, Chemical Dependency Counselors, Activity Therapists, Occupational Therapists and Medical Technicians. All therapies provided are included in the one daily rate for APC 033.

In contrast, Outpatient Hospital Psychiatric Services do not require a multidisciplinary team, there are no requirements for nursing staff, and services may consist of one Psychiatrist and one Therapist. In addition, the criteria for admission for patients treated at this level are much less than for PHP, resulting in a much lower patient acuity.

It is clear the rates for PHP should be adequately set to reimburse providers appropriate for the setting and level of care. Partial Hospitalization Programs should be reimbursed at a minimum, the average payment rates set for Psychiatric Outpatient Services. CMS acknowledges that they do have appropriate cost finding for these individual outpatient codes. (HCPCS 90801-90862 or APC 322-325)

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CMS has clearly defined what a partial day of service must include and local medical review policy takes that a step further. Detailed below are two tables reflective of a typical day of services offered in a partial day program utilizing the outpatient psychiatric service rates proposed by CMS.

TYPICAL DAY 1

HCPCS	APC	DESCRIPTION	RATE
90853	325	GROUP PSYCHOTHERAPY SESSION	$ 64.45
90818	323	INDIVIDUAL PSYCHOTHERAPY SESSION	$106.49
90853	325	GROUP PSYCHOTHERAPY SESSION	$ 64.45
90853	325	GROUP PSYCHOTHERAPY SESSION	$ 64.45
TOTAL		**TOTALS FOR PARTIAL DAY SERVICES**	**$299.84**

TYPICAL DAY 2

HCPCS	APC	DESCRIPTION	RATE
90853	325	GROUP PSYCHOTHERAPY SESSION	$ 64.45
90818	323	INDIVIDUAL PSYCHOTHERAPY SESSION	$106.49
90847	324	FAMILY THERAPY SESSION	$141.61
TOTAL		**TOTALS FOR PARTIAL DAY SERVICES**	**$312.55**

This argument has been dismissed for 4 years now by CMS. If you are truly finding the cost of these separate services, it only makes logical sense to combine them to get the total cost in a partial program.

In addition to PHP, these core services are provided by "free standing" community mental health centers: on call services to clients 24 hours a day 7 days per week, traditional outpatient services and screening for admission to in-patient psychiatric state facilities. The typical partial services program day tables above yield an average componentized rate of $306. These component costs are not reduced when given in a partial setting. If anything, they can run higher due to the inability to share costs like hospital programs can. How can CMS propose a daily rate of $179.88 for the intense services offered? Does CMS wants to simply close this program altogether when there is a severe need for the services for the chronic mentally ill?

QUESTIONS FOR CMS

1. ARE THE 2008 PROPOSED APC RATES FOR PSYCHIATRIC OUTPATIENT SERVICES CODES APC 322-325 (HCPCS 90801-90862) PROPERLY SET AND BASED UPON SUBSTANTIATED DATA?

2. DO YOU RECOGNIZE THAT A PARTIAL DAY PROGRAM IS MORE INTENSE THAN AN OUTPATIENT PSYCHIATRIC SERVICE AND ACTUALLY IS COMPRISED OF A MINIMUM OF 3-4 INTENSE SERVICES?

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3. IF A PARTIAL DAY PROGRAM IS OFFERING 3-4 SERVICES THAT YOU DO HAVE ADEQUATE COST DATA ON WITH APPROPRIATE RATES COMPUTED, WHY CAN'T YOU SIMPLY CALCULATE A PARTIAL DAY COST BASED UPON YOUR ADEQUATE COST DATA FOR THE PSYCHIATRIC SERVICES OFFERED?

4. **WHY WERE NO FREESTANDING CMHC PHP CONSIDERED IN YOUR IMPACT STATEMENT**? ISN'T THAT REQUIRED BY REGULATION?

5. COULD CMS TAKE A 23.37% CUT IN THEIR 2008 BUDGET, **WITHOUT REDUCING SERVICES?**

Once again, we are asking for your minimal consideration to leave the APC rate for code 033 at the 2007 rate or set it as a total of 4 of your calculated outpatient psychiatric component costs. In either case, this would not equate to a 23.37% cut. An alternative request would be to freeze at the 2005 rates to assist the Hurricane Zones until a proper impact study could be commissioned.

Your favorable consideration of my comments and concerns is appreciated.

Sincerely,

E. Paul Broussard, CFO
Southwest Ambulatory Behavioral Services, Inc. (SABS)

Cc: Honorable Senator Mary Landrieu
Honorable Senator David Vitter
Honorable Representative Charles Boustany

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CMS-1392-P-642 Medicare

Submitter : Ms. Anna Van Fleet **09/11/2007**

Organization : None
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 (list the form dystonia you have), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMSs 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.
1. 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.
2. Thank you for allowing me to provide these comments.
3. Sincerely,

CMS-1392-P-643 **Medicare**

Submitter : **Dr. Demetrios Kaiafas** **09/11/2007**

Organization : **Clearwater Pain Management Associates**
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1392-P-643-Attach-1.DOC

#643

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 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,

Demetrios N. Kaiafas, M.D,
Clearwater Pain Management Associates
430 Morton Plant Street, Suite 210
Clearwater, FL 33756