CMS-1392-P-757 **Medicare**

Submitter : Mrs. Regina Keyser **09/12/2007**

Organization : Woodcrest Healthcare, Inc
Nurse

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

2

I am writing in response to the proposed rule referenced above, specifically in regards to proposals that would adversely affect CMHC□S Partial Hospitalization Programs.

I am the administrator of the Woodcrest Healthcare, Inc. Partial Program in Natchitoches, Louisiana. We are a small, family owned business, which has been serving the mental patients of our area for ten years. During those ten years, we have seen successive cuts in funding exceeding 50% from our original reimbursement rates.

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). 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.

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.

CMS recognizes 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 has

actually 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 partial hospitalization program 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.

The proposed rule referenced above continues to place extreme hardship on providers of Partial Hospitalization Programs. The rate proposed for 2008 once again falls below the actual cost of providing such services. Cost analysis demonstrates that the proposed APC rate is insufficient to provide the cost of care to the mentally ill in these programs.

We simply cannot provide these valuable services at the rates proposed. The proposed cut of 23.7% will cripple our business and we will be forced to close. This program is too important to our patients to close, and for our services to no longer be available. Our closing would leave them with no support system and many will end up being hospitalized for extended periods of time, some for the duration of their life, which will significantly burden the healthcare system as a whole.

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 health care in my community and across the state of Louisiana.

Thank you for considering these comments. Please contact me if you have any questions.

Sincerely,

Regina Keyser - Administrator

CMS-1392-P-758 **Medicare**

Submitter : Mr. Kenneth Reid **09/12/2007**

Organization : Carlinville Area Hospital Hospital

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-758-Attach-1.DOC

#158

September 14, 2007

Herb Kuhn
Acting Deputy 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*

Subject: CMS-1392-P – Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to proposals made affecting the Critical Access Hospital (CAH) program. I am a Hospital Administrator at Carlinville Area Hospital in Carlinville, Illinois.

As proposed, the guidelines will limit Critical Access Hospitals (CAH) from establishing off-campus provider-based locations with another Hospital or when a CAH creates or acquires an off-campus location unless those entities are greater than 35 miles from the nearest Hospital.

Approximately 850 of the 1,300 CAH's nationally are necessary provider CAH's and are therefore within 35 miles of another Hospital. If the aspect of the proposed rule is finalized, these CAH's will be significantly limited, if not in many cases prohibited, from opening new off-campus provider-based sites, or converting existing sites that are not provider based after January 1, 2008. This is because in many areas, the necessary provider CAH's are located with 35 miles of several other Hospitals or CAH's. Carlinville Area Hospital is designated as a necessary provider; therefore, it may be geographically impossible to find a new qualifying off-campus location.

Carlinville Area Hospital is considering the possibility of establishing off-site clinics in smaller communities, which we serve. These communities currently have no provider or a limited number on a limited basis. Additionally, the Hospital is considering a new replacement facility at a new location and it may make economic sense for the current outpatient physical therapy service to remain at the existing location, which is located across the street from the current Hospital location. If the proposed rules are finalized, the off-campus arrangement would not be allowed.

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to off-site clinics owned by CAH's. As stated above, such provisions would have a devastating impact on the access to quality health care in my rural community. This is the opposite of the intention of the CAH program, which is to provide the financial stability for small, rural hospitals to serve their communities. Such provisions would eliminate our flexibility to provide the care needed to rural seniors.

Thank you for considering these comments. Please contact me if you have any questions.

Sincerely,

Kenneth G. Reid, FACHE
President/CEO

CMS-1392-P-759 **Medicare**

Submitter : Mr. Harvey Sowell **09/12/2007**

Organization : Woodcrest Healthcare, Inc
Other Health Care Professional

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

I am writing in response to the proposed rate cuts for Partial Hospitalization Programs. Our program will not survive another rate cut. Our facility will have to close and I will loose my job. The patients that we serve in our area will also be unable to receive treatment.
Due to these concerns, I respectfully ask that you withdraw the provisions in this rule pertaining to reduction in rates for Partial Hospitalization Programs.
Sincerely, Harvey Sowell

CMS-1392-P-760 **Medicare**

Submitter : Ms. Ponda Arterberry **09/12/2007**

Organization : Woodcrest Healthcare, Inc.
Individual

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

I am writing in response to the proposed rate cuts for Partial Hospitalization Programs. Our program will not survive another rate cut. Our facility will have to close and I will loose my job. I am a single mother and the sole provider for my family. I am also concerned about the patients that we serve in our area going untreated for their mental illnesses.
Due to these concerns, I respectfully ask that you withdraw the provisions in this rule pertaining to reduction in rates for Partial Hospitalization Programs.
Sincerely, Ponda Arterberry

CMS-1392-P-761 **Medicare**

Submitter : Ms. Kim Sterk **09/12/2007**

Organization : Lehigh Valley Hospital
Nurse

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-761-Attach-1.RTF

#761

September 12, 2007

BY ELECTRONIC DELIVERY

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

Re: Cardiac Rehabilitation Services under CMS-1392-P(Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates Medicare and Medicaid Programs: Proposed Changes to Hospital Conditions of Participation; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals)

Dear Acting Deputy Administrator Kuhn:

I appreciate the opportunity to comment on a proposal related to the reporting of Cardiac Rehabilitation Services contained in the Centers for Medicare & Medicaid Services (CMS) Proposed Rule regarding revisions to payment policies under the Hospital Outpatient Prospective Payment System for calendar year 2008 (the "Proposed Rule").[1]

I am the Program Director for the Dr. Dean Ornish Program for Reversing Heart Disease at Lehigh Valley Hospital in Allentown, PA. The Dr. Dean Ornish Program for Reversing Heart Disease is a comprehensive lifestyle modification program based on a low-fat, whole foods eating plan, moderate exercise, stress management and group support. During the past 30 years of conducting randomized controlled trials and demonstration projects, Dr. Ornish and his colleagues have consistently shown that they can motivate people throughout the U.S. to make and maintain bigger changes in diet and lifestyle, achieve better clinical outcomes and larger cost savings than have ever before been reported. They were able to prove, for the first time, that the progression of even severe coronary heart disease can be reversed in most patients by making comprehensive lifestyle changes. They also have shown that there were 2½ times fewer cardiac events such as heart attacks, operations, and hospital admissions for patients participating in the Ornish program. These findings were published in the leading peer-reviewed medical journals,

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1 72 Fed. Reg. 148 (August 2, 2007).

including Journal of the American Medical Association, The Lancet, American Journal of Cardiology, The New England Journal of Medicine, Circulation, Journal of Cardiopulmonary Rehabilitation, Yearbook of Medicine, Yearbook of Cardiology, Homeostasis, Journal of the American Dietetic Association, Hospital Practice, Cardiovascular Risk Factors, World Review of Nutrition and Dietetics, Journal of Cardiovascular Risk, Obesity Research, Journal of the American College of Cardiology, and others.

In addition to these randomized controlled trials, Dr. Ornish has conducted three demonstration projects that confirmed these findings in over 2,000 patients throughout the U.S. The results from my institution and our patients are among those in these data sets. Our clinical and cost outcomes parallel those in the clinical trials. In the first demonstration project, Mutual of Omaha found that almost 80% of patients who were eligible for bypass surgery or angioplasty were able to safely avoid it for at least three years, saving almost $30,000 per patient in the first year. In the second demonstration project, Highmark Blue Cross Blue Shield found that their overall health care costs were reduced by 50% in the first year and by an additional 20-30% in subsequent years. We have also found that the Ornish Program achieved similar improvements in Medicare patients as in these earlier demonstration projects and randomized controlled trials.

In 30 years of experience, I have worked with a large number of patients who are in need of cardiac services, and I have seen first-hand the benefits of the Ornish Program. Our patients have successfully used the Ornish Program to help prevent and reverse heart disease and other health concerns significantly improving cardiovascular risk factors through the comprehensive lifestyle change program

I am writing to comment on the proposal regarding reporting of cardiac rehabilitation services under the Hospital Outpatient Prospective Payment System. I am pleased that CMS in its proposed rule recognized the need to clarify coding and payment for these services that can dramatically improve the health and quality of life for the growing numbers of Medicare beneficiaries with heart disease. However, I believe that CMS must do more to support the expanded use of cardiac rehabilitation programs – especially those with published, peer-reviewed research showing that they achieve quantifiable results.

I appreciate the time and effort CMS has dedicated to ensure that Medicare beneficiaries can participate in proven cardiac rehabilitation programs under the national coverage determination (NCD) issued last year.[2] Under that revised NCD, Medicare requires cardiac rehabilitation programs to provide a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education, and counseling. This contrasts markedly with the prior NCD for cardiac rehabilitation, under which only exercise was reimbursed by Medicare. In addition, the revised NCD contemplates contractors extending coverage, on a case-by-case basis, to

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[2] NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10.

72 sessions. Under the former NCD, coverage of more than 36 sessions was highly exceptional, with contractors required to have significant documentation of the need for sessions beyond 36. By explicitly citing the Ornish program, in fact, the NCD made clear that it was the intention of CMS to provide coverage under Medicare for this program.

Without several further clarifications and modifications, however, I am concerned that Medicare's current reimbursement for cardiac rehabilitation services may make it difficult for providers to offer effective programs, such as the Ornish Program, to Medicare beneficiaries in a sustainable manner. As a provider of the Ornish Program, there are still certain specific steps that need to occur to ensure that beneficiaries have meaningful access to these programs, as intended by CMS in issues the NCD. I understand that Dr. Dean Ornish and the Preventive Medicine Research Institute (PMRI) has made several recommendations to CMS in regards to these steps.

I am pleased to see that in the Proposed Rule CMS proposes to irnplement one of PMRI's recommended steps by creating two new Level II Healthcare Common Procedure Coding System (HCPCS) G-Codes for cardiac rehabilitation services.[3] These codes are Gxxx1, Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour), and Gxxx2, Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour), and would replace the Current Procedural Terminology (CPT) codes, 93797 and 93798, respectively, for these services when billed under the Medicare physician fee schedule.[4] The G-codes would have the same descriptions as 93797 and 93798, except that they would apply to an hour of cardiac rehabilitation services instead of a "session."

I agree that this change will help to "clarify the coding and payment for these services"[5] by more accurately describing the services provided. Those furnishing cardiac rehabilitation will be able to use these codes to bill for one hour of a modality of cardiac rehabilitation identified in the NCD, such as prescribed exercise or education, rather than an undefined "session" of services. I support this proposal and we ask CMS to implement it in the final rule. I do however, respectfully request that the description in the payment tables included in the proposed rule be modified to ensure the Medicare fiscal intermediaries and carriers/Medicare Administrative Contractors (MACs) do not misinterpret the codes as requiring physician presence. To avoid any confusion or any unwarranted reading by MACs that physician presence is required for the provision of these services, the term "cardiac rehabilitation services", as has been used in previous payment tables in relation to the CPT codes 93797 and 93798, should be used in those tables in lieu of the term "physician services."

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3 72 Fed. Reg. at 38,419.

4 Id.

5 Id.

While I applaud CMS's proposal to create new G-codes, I believe that beneficiary access to proven cardiac rehabilitation programs will be limited unless CMS implements PMRI's other recommendations. First, I strongly urge CMS to state clearly and explicitly in the final rule that multiple sessions of cardiac rehabilitation can be covered on the same day. I believe that this was in fact CMS' intent in proposing the two new G-codes in the proposed rule. But a more explicit statement to this effect would go a long way toward avoiding any confusion in the future on the part of MACs, providers and beneficiaries. In the Ornish program, patients participate in several modalities of cardiac rehabilitation, such as a medical evaluation, prescribed exercise, education, and counseling, in a single day. Providers of the program should be reimbursed for each hour of each modality a beneficiary receives. Fortunately, Medicare already has a mechanism to recognize when a code is billed multiple times in a single day for distinct services. Modifier 59 indicates that "a procedure or service was distinct and independent for other services performed on the same day."[6] CMS should facilitate payment for these services by clearly stating in the final rule that payment may be made for each session when modifier 59 is used and documentation in the patient's record explains that each use of the code represents an hour of a component of the cardiac rehabilitation program.

Second, I ask CMS to explain in the final rule that it is likely to be reasonable and necessary to cover 72 cardiac rehabilitation sessions when multiple sessions are provided in one day. The NCD gives contractors the discretion to cover up to 72 sessions of cardiac rehabilitation.[7] Unlike many cardiac rehabilitation programs in which "patients generally receive 2 to 3 sessions per week,"[8] in our program, patients typically receive multiple sessions per day, not just limited to exercise. When a beneficiary participates in a program of several one-hour sessions of various modalities in a single day, coverage of 72 sessions is necessary to provide enough hours of each modality for the patient to receive the full benefit of the program. By advising contractors that 72 sessions are likely to be reasonable and necessary for programs providing multiple sessions per day, CMS will ensure that the goals behind the revised, expanded NCD can be met. In view of the fact that 36 sessions – only of exercise – were covered under the prior NCD, it makes little sense to limit coverage to 36 sessions for programs such as Ornish. I ask CMS, in the final rule or other guidance, to remind contractors of their discretion to cover up to 72 sessions and to explain that 72 sessions are likely to be reasonable and necessary where beneficiaries receive cardiac rehabilitation from programs that provide several one-hour sessions per day of the various modalities that are included in the cardiac rehabilitation NCD.

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6 American Medical Association, CPT 2007, at 438.

7 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(D).

8 NCD for Cardiac Rehabilitation Programs, National Coverage Determinations Manual (CMS Pub. 100-3), § 20.10(B)(1)(a).

Finally, I ask CMS to encourage contractors to factor the proven results of a program into their coverage decisions. For example, 72 sessions should be presumptively covered when they are provided by a program, such as the Ornish program, with extensive peer-reviewed and published research showing that it achieves quantifiable results on important metrics, such as reductions in LDL-cholesterol, triglycerides, blood pressure, blood glucose, and weight, or that it affects the progression of coronary heart disease and/or reduces the need for bypass surgery, angioplasty, or stents and/or the need for medication. This consideration of a program's proven results would help to prevent over-utilization of programs that have not demonstrated positive results and is consistent with CMS's goals of furthering evidence-based medicine and improving actual health outcomes.

* * *

I greatly appreciate the opportunity to comment on the proposed changes to coding for cardiac rehabilitation services and to recommend additional changes that will help Medicare beneficiaries to receive the benefits of successful cardiac rehabilitation programs, such as the Ornish Program. Please feel free to contact me at 610.969.2562 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Kim M. Sterk MSN, RN, CDE
Dr. Dean Ornish Program Director
Lehigh Valley Hospital
17th & Chew Streets, Suite 403
P.O. Box 7017
Allentown, PA 18105-7017

CMS-1392-P-762 **Medicare**

Submitter : Mr. Steven Tenhouse **09/12/2007**

Organization : The John and Mary E. Kirby Hospital
Critical Access Hospital

Category :

Issue Areas/Comments

OPPS Impact

OPPS Impact

See Attachment

CMS-1392-P-762-Attach-1.PDF

#762

September 14, 2007

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

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

Subject: CMS-1392-P Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates: Proposed Changes Affecting Necessary Provider Designation of Critical Access Hospitals

Dear Deputy Administrator Kuhn:

I am writing on behalf of The John and Mary E. Kirby Hospital, Monticello, Illinois in reference to proposed changes that will impact the Critical Access Hospital (CAH) program. I respectfully urge you to withdraw the provisions in this rule relating to provider based off-site facilities owned by "necessary provider" Critical Access Hospitals (CAHs).

Of major concern is the provision that would restrict CAHs from operating any offsite facilities after January 1, 2008 unless they meet the 35 mile criteria. All of our Illinois CAHs are "necessary providers." For my hospital, it will be geographically impossible to find a new off-campus location that would meet the 35 mile requirement.

As you well know, physician shortages are one of the most difficult challenges facing our rural hospitals. This will have a serious negative impact on the provision of physician services, especially in our rural designated shortage areas in Illinois.

The CAH program was enacted to help struggling small rural hospitals maintain the financial strength to enable them to care for their communities. The proposed rule changes run counter to this goal and would jeopardize the ability of hospitals like mine to provide essential health care for our seniors.

With these issues in mind, I again, respectfully urge you to withdraw the provisions in this rule relating to off-site clinics owned by CAHs. .

Thank you for your consideration. Please contact me with any questions you may have.

Sincerely,

Steven D. Tenhouse
Chief Executive Officer
(217) 762-2115

CMS-1392-P-763 **Medicare**

Submitter : Ms. Mina Spadaro **09/12/2007**

Organization : Prime Health Services
Psychiatric Hospital

Category :

Issue Areas/Comments

OPPS: Partial Hospitalization

OPPS: Partial Hospitalization

3033 West Orange Avenue,
Anaheim, CA-92804
Phone:(714) 827-3000

September 10, 2007

Dear Sirs:

Re: Response to Proposed Changes to the CY2008 Hospital Outpatient PPS-CMS-1392-P Partial Hospitalization (APC 0033)

On behalf of Prime Health Services, West Anahiem Medial Center and Huntington Beach Hospital we appreciate the opportunity to submit comments regarding CMS□s proposed OPPS rates concerning APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 □ Outpatient Psychiatric Services.

CMS-1392-P-764 **Medicare**

Submitter : Mrs. CYNTHIA MCMILLON **09/12/2007**

Organization : FRYE REGIONAL MEDICAL CENTER
Other Technician

Category :

Issue Areas/Comments

Impact

Impact

I am a sonographer at Frye Regional Medical Center and I use echo contrast agents.
If seperate payment for echo contrast agents is eliminated for hospital outpatients I believe it will reduce patient access to echo contrast agents

CMS-1392-P-765 **Medicare**

Submitter : Mrs. Geralde Theard **09/12/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dear Mr. Weems:
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with blepharospasm and meige syndrome (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 physian-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 injecy 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 that ensures there are no economic rewards or penalties to providers, depending on where the injections are given.
Thank you for allowing me to provide these comments,

Sincerely,

CMS-1392-P-766 **Medicare**

Submitter : Mrs. Cynthia Trantham **09/12/2007**

Organization : Frye Regional Medical Center
Other Technician

Category :

Issue Areas/Comments

Impact

Impact

I am a practicing sonographer at Frye Regional Medical Center and I use echo contrast agents. If seperate payment for echo contrast agents is eliminated for hospital outpatients I believe it will reduce patient access to echo contrast agents.

CMS-1392-P-767 **Medicare**

Submitter : Mr. George Roman **09/12/2007**

Organization : American Medical Group Association
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1392-P-767-Attach-1.DOC

#767

AMGA
American Medical Group Association

September 14, 2007

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

Re: ***Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates;***
Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Mr. Weems:

The American Medical Group Association (AMGA) is an association that represents medical groups, including some of the nation's largest, most prestigious multi-specialty practices, independent practice associations, and integrated health care delivery systems. AMGA members' 85,000 physicians deliver health care to more than 50 million patients in 40 states, including 15 million capitated lives. Thank you for the opportunity to comment on the proposed rule regarding revisions to the payment policies under Medicare for the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center (ASC) payments and related changes.

Overview
In the final rule issued in August, CMS applied its statutory authority to design a new ASC payment system. Although tying ASC payment to the payment system already established for OPPS transfers inherent imperfections to the ASC setting, AMGA believes that the OPPS represents a reasonable basis for the relative cost of procedures performed in the ASC.

For many of the procedures newly eligible for payment in the ASC, the reimbursement that will be available under the fully implemented payment system will provide generally speaking, an economically adequate alternative to allow beneficiaries to receive services outside the hospital. However, the system will not be adequate universally and certain individual and classes of surgical services will not, or will no longer be, reimbursed adequately to allow performance in the ASC setting. Comments below address procedures disadvantaged by provisions in the final ASC or proposed hospital outpatient department (HOPD) rule that could safely and efficiently be performed in the ASC.

Guiding principles that should pertain to policies for the ASC payment system:

- Configuration of the ASC with the HOPD payment systems to eliminate distortions between them that could unsuitably influence site of service selection

- Changes should facilitate maximal conveyance of the benefits of surgery done at ASCs to Medicare patients for services that can be safely and efficiently performed in the ASC

- Establish fair and reasonable payment rates to allow beneficiaries and the Medicare program to save money on procedures that can be safely performed at a lower cost in the ASC than in the HOPD

Ensuring Beneficiaries' Access to Services
Medicare beneficiaries have diverse needs for surgical services offered in outpatient settings. Ensuring that beneficiaries receive surgical care in the setting best suited for their medical needs, as determined by their physicians, in consultation with the patient and family, should be the primary objective of ambulatory surgery payment policies.

This goal will not be achieved by this rule for several reasons, but primarily because the proposal would limit a physician's ability to determine the appropriate site of service for a procedure by not allowing payment for many surgical procedures that are clinically appropriate in an ASC. We support the proposal to expand access to new procedures in the ASC setting to further choice, convenience and access by Medicare beneficiaries.

Establishing Reasonable Reimbursement Rates
Medicare payment rates for ASC services have remained stagnant for nearly a decade while inflation has driven double-digit increases in the price of many services and supplies used by ASCs. The payment system for ASCs should achieve the following policy goals:

- Achieve savings to the Medicare program and its beneficiaries;
- Promote payment neutrality across sites of service delivery and competition among surgical service providers; and
- Encourage increased transparency of information on Medicare providers.

Alignment of ASC and HOPD Payment Policies
Aligning the payment systems for ASCs and HOPDs will allow Medicare beneficiaries to make better, broader and more informed choices regarding their surgical care alternatives. While the proposal moves towards consistency between the two systems, there are several instances in which alignment of the ASC and HOPD payment systems is incomplete or inconsistent. The following inconsistencies between how the payment system is applied to HOPDs and is proposed for ASCs should be addressed in the final rule:

Procedures Covered

We commend CMS for adopting the recommendations of MedPAC's March 2004 Report to the Congress. We fully support MedPAC's recommendation and CMS's decision that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from payment of an ASC facility fee. This use of an exclusionary, rather than inclusionary, list allows Medicare beneficiaries' access to the broader range of the ASC services currently offered safely to non-Medicare patients. Under this change, as new procedures are developed, Medicare beneficiaries are more likely to be assured timely access to technological advances in ambulatory surgical care. However, we are disappointed in the implementation of these criteria.

Definition of Surgical Procedure

One criterion that needs to be addressed is the definition of a surgical procedure. In the proposed rule revising ASC payment methodology, CMS solicited public comments on this matter, but as finalized, CMS maintains its narrow definition of surgical procedures as any procedure described within the Surgery s ection of CPT, which corresponds to Category I codes 10000-69999. We are disappointed that CMS did not expand the definition of surgical procedures to be:

(1) Any procedure described within the range of CPT Category I codes that the AMA defines as "surgery" (CPT codes 10000-69999);

(2) Any procedure described within the range of CPT Category I codes that the AMA defines as "medicine" that are invasive, that are performed under general anesthesia or that are specifically designated as intraoperative services;

(3) Any X-ray, fluoroscopy, or ultrasound procedures described within the range of CPT Category I codes that the AMA defines as "radiology" that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(4) Any radiology procedure that is integral to the performance of a non-radiological procedure described in paragraphs (1) or (2) above and performed

(i) During the non-radiological procedure, or

(ii) Immediately following the non-radiological procedure when necessary to confirm placement of an item placed during the non-radiological procedure; and

(5) Any procedure described by HCPCS Level II codes or by CPT Category III codes which are clinically similar to the procedures and services described in paragraphs (1)-(4) above.

We are pleased that CMS has finalized a methodology to provide payments to ASCs for these additional procedures and resources associated with performing those services that are surgical procedures as defined by the CPT Editorial Panel. We support CMS'

decision to allow payment for a number of covered ancillary services when they are furnished on the same day as a covered surgical procedure and are integral to the performance of that procedure in the ASC setting including certain radiology and other ancillary services.

Excluded Procedures

Safety Criteria –When CMS implemented the OPPS, it used three criteria to determine which procedures required inpatient care: 1) the invasive nature of the procedure, 2) the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or 3) the underlying physical condition of the patient. These standards remain today and are used to distinguish non-covered inpatient services from covered outpatient services. The OPPS standards have proven sufficient to safeguard patients in the hospital outpatient setting and can be reasonably applied to the ASC setting. Physicians should, in consultation with their patients, retain the ability to determine the site of service for a given procedure.

Overnight Stay – We support CMS's elimination of the four hour recovery time limit when determining what procedures should be payable in ASC setting. Included in the July 2007 proposed final rule was the issue of using midnight as a "defining measure" of overnight stay. In the past, CMS has recognized that midnight is not the only definition of an overnight stay. Given CMS's historic statements on overnight stays in the ASC, state regulations that allow stays of up to 24 hours and the more extensive length of stay permitted in the HOPD, it is reasonable to allow ASCs to offer either an episode of care or a postoperative recovery period of less than 24 hours. CMS should abide by its previously stated position and continue to define an overnight stay in an ASC as a stay that is less than 24 hours in duration.

Unlisted Codes – The final rule excludes unlisted surgical procedure codes from ASC payment under the revised ASC payment system. CMS has indicated that, due to a lack of specific procedural descriptions, it is not possible to determine whether such procedures would pose safety risks to Medicare beneficiaries. This policy is incongruent with the approach CMS takes to reimbursement of unlisted codes under OPPS and is unnecessarily restrictive. CMS should be consistent and evaluate unlisted codes for potential safety risks in both the ASC setting and the HOPD setting.

Payment Bundles. Allowing ASCs to bill separately for ancillary services integral to the primary procedure and separately payable under the OPPS is a significant improvement to the alignment of the payment systems. However, discounting the payment to ASCs for many of these ancillary services does not recognize that cost differences vary only slightly between the ASC and HOPD. In principle, we agree that services that are "packaged" under OPPS and therefore not separately payable to HOPDs should not be eligible for payment of a separate ASC facility fee. However, the proposed changes to the OPPS packaging policies will exacerbate problems that arise directly from limiting payment for surgical procedures performed in ASCs to those that fall in the range of CPT codes 10000-69999.

AMGA Recommendation: Services should not be newly excluded from the ASC because of changes to the OPPS packaging policies. This policy unnecessarily forces procedures back into the hospital that could be safely performed in less expensive settings. At a minimum, procedures described by CPT Category III codes and Level II HCPCS codes should be exempt from being excluded from the ASC list since CMS will cover these services under the revised ASC payment system. Likewise, if future changes to the OPPS packaging policies result in unbundling, the unbundled services should continue to be included on the ASC list. We agree that the packaging rules applied for services under OPPS should be applied in the same manner to ASCs. However, CMS should alter its current definition of surgical services in order to avoid inconsistencies in its payment policies for the same procedures when provided in different sites of service.

Device Related Services

AMGA Recommendation: If CMS does not fix payments for implants to allow for adequate payments during the transition, beneficiaries will be forced back to the higher cost hospital setting. This situation could also result in access issues for beneficiaries. Absent relief from the transition period, it is likely to be several years before the device costs are compensated at a level at which the procedure can be economically viable in the ASC. As a result, these services will continue to be provided primarily in the more expensive hospital setting. During the first period of the transition as the rates are phased in over four years, the payment for the procedure may not adequately cover the costs for the procedure and the cost of the implants. There are a number of these procedures, which for certain procedures, will greatly impact beneficiary access to care if not adequately paid for in the ASC.

Payment Limits

CMS finalized its rule to limit payment for ASC services frequently performed in the physician office. However, the policy was not extended to the OPPS from which the resource requirements necessary to provide procedures of low complexity for patients, varies little. The process used by the agency to identify services for permanent placement on the list of "capped" procedures should also be refined to address the emergence of new technology, the complexity of patient needs, and the annual fluctuations in the volume and location of procedures performed.

The payment limit will force patients who are not appropriately treated in the physician office to go to an HOPD, bypassing the ASC where the service could be done safely and cost-effectively. Physician offices generally treat a less complex and severely ill patient case mix. As such, the office is less likely to have the staff and equipment resources to provide on a regular basis many of the services that a more medically complex patient might require. Capping payment at the physician office rate undermines the stepped reimbursement policies that underlie the level of resources available to the physician and beneficiary at the three sites for outpatient surgical services: the HOPD, ASC, and physician office.

AMGA Recommendation: We recommend that CMS drop its policy of designating procedures as "office-based" services. Site of service volume characteristics are arbitrary and without clinical basis and should not be used to determine ASC eligibility. In any case, services should not be designated "office-based services" indefinitely but should be evaluated based solely on whether or not done more than 50% of time in the physician office (using the most recent volume data). CMS should not use clinical information or comparable data for related procedures to determine what should be office-based. I f CMS continues to use other data, it should provide that data and rationale that it employed in making that determination.

Inflation Update

CMS continues using the CPI-U inflation update for ASCs despite any evidence that the rate of inflation between the ASC and HOPD varies. The Secretary should implement the new payment system with application of the hospital market basket to the ASC payment system. Absent that adjustment, annual updates will increase the payment gap between ASCs and HOPDs and create incentives for procedures to migrate from the ASC to the hospital when inflation updates fail to keep pace with providers' costs.

Secondary Rescaling of APC Relative Weights

CMS applies a budget neutrality adjustment to the OPPS relative weight values after they are recalibrated with new cost data each year and decided to apply a secondary rescaling of the ASC weights. The relative costliness of surgical services continues to outpace the cost growth of non-surgical services in the OPPS. Applying a secondary recalibration to the ASC, absent evidence that ASC services became relatively less expensive than the HOPD, will create unjustifiable variance in the payment rates between the ASC and HOPD.

Physician Payment for Procedures and Services Provided in ASCs

AMGA Recommends that CMS should continue to provide payment under the physician fee schedule for non-covered services that would otherwise be paid if they were p erformed in a p hysician office. Beneficiaries should be liable only for the c o-payment and deductible associated with the physician fee schedule. We urge CMS to alter its current policy under OPPS and apply this modified policy to the ASC setting. Acknowledging that the course of a planned procedure cannot always be determined in advance and allowing for contractor-based adjudication allows for more equitable treatment of beneficiaries under these circumstances.

When a planned covered procedure is altered by intra-operative findings and becomes a non-covered procedure, the beneficiary should not incur additional financial liability. Under such circumstances, standard cost-sharing formulas should remain in effect. A modifier should be created that allows communication of these circumstances on both ASC and HOPD claims. In these cases, payment would be priced by the contractor based on a review of the operative report. The conversion of a planned covered procedure to an unplanned non-covered procedure occurs infrequently. Allowing contractor review would not impose a significant burden on the adjudication process. Claims of this type could be easily monitored through tracking of the specific modifier created for reporting.

Any concerns regarding billing practices could be readily audited, since scheduling a procedure creates a record of the planned intervention.

Reporting Quality Data for Annual ASC Payment Rate Updates

We concur with CMS's decision not to implement ASC reporting of quality measures prior to January 1, 2009. We request CMS work with outside parties, including AMGA, with interest and expertise in ASCs to develop quality measures. For reporting data, those with advanced capabilities should be able to participate in direct reporting from electronic medical records and data registries rather than using claims-based information. This approach preferable and should be encouraged since it will yield more accurate, clinically meaningful, and overall more reliable data.

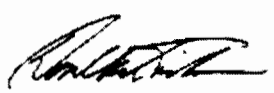
AMGA urges CMS to consider the following in future rulemaking regarding publication of quality data collected: Consumers should be able to access quality and cost information on websites organized to allow easy comparisons of information that is correct, current and clearly presented. Information should be presented on all available sites of service so consumers can compare a hospital outpatient department and an ASC for a procedure that could be performed in both locations; there should be a speedy mechanism for corrections or resolving disagreements about any information posted for public presentation; there should be a provider narrative section for each provider-specific item presented to the consumer, that would allow the provider to advise the consumer of any concerns the provider has regarding the reliability or accuracy of the information presented; and in addition to quality measures, other useful information such as accreditation status, state licensure and Medicare certification should be made available.

Conclusion

Inadequate payment will force providers to respond in a variety of ways, some of which may limit patients' ability to have surgical services performed in a safe, convenient and low cost environment. The implementation of the revised ASC payment system will result in significant redistribution of dollars within the ASC payment system with system-wide consequences. Therefore we strongly urge CMS to use its considerable discretionary authority to ensure a smooth transition to the new payment system.

We appreciate the opportunity to opine on these proposed changes and would be happy to work with CMS to assure best access and information on surgical surgery choices for Medicare patients. Feel free to contact George H. Roman, Senior Director, Health Policy, of my staff at groman@amga.org or (703) 838-0033 ext. 342, if you have questions or need additional information.

Sincerely,



Donald W. Fisher, Ph.D.
President and CEO

CMS-1392-P-768 **Medicare**

Submitter : Dr. sukdeb datta **09/12/2007**

Organization : Vanderbilt University Interventional Pain Program
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1392-P-768-Attach-1.PDF

#768

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) ha ve been p ackaged in a ll c ircumstances under t he AS C p roposed r ule. T hese 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,

Sukdeb Datta, MD, DABPM, FIPP
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CMS-1392-P-769 **Medicare**

Submitter : Ms. Diane Killian **09/12/2007**

Organization : Frye Regional Medical Center
Other Technician

Category :

Issue Areas/Comments

Impact

Impact

I am a practicing technician at Frye Regional Medical Center and my department uses echo contrast agents. If seperate payment for echo contrast agents is eliminated for hospital patients, I believe it will greatly reduce patient access to echo contrast agents.I feel that no changes should be made in this matter.

CMS-1392-P-770 **Medicare**

Submitter : Pamela Breeckner **09/12/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

Dr. 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 Blepharospasm (Benign Essential Blepharospasm) a type of dystonia/movement disorder, I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injuctions of botulinum toxin to alleviate the debilitating dystonic symptoms. The 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 injust botulinum toxin. Not just anyone can inject it successfully to relieve the spasms. I went to two specialists before the doctor I have been treated by for the last 4 years. My current doctor is a neurologist at the Univ. of TN, who specializes in movement disorders. The treatments by the previous doctors, who were neuropthalomologists, were not at all successful. Dr. LeDoux, my current doctor, is an expert in administering the injections in the correct locations.

Also, this change in policy would destroy the uniformity of payments made across settings that ensures there are no economic rewards or penalities to providers, depending on where the injections are given.

Thank you for allowing me to provide these comments.

Sincerely,

Pamela Breeckner
5118 Greenway Cove
Memphis, TN 38117