CMS-1392-P-785 **Medicare**

Submitter : Ms. Ruth Perry **09/12/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Impact

Impact

I have been a patient at area hospiatls in both Hickory and Asheville NC and believe that the use of echo contrast agents can improve the quality of care by providing better images in echocardiography. If separate payment for echo contrast agents is eliminated for hospital outpatients I believe it will reduce patient access to echo contrast agents.

CMS-1392-P-786 **Medicare**

Submitter : Amy Gullion **09/12/2007**

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 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 right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
Thank you for allowing me to provide these comments.

Sincerely,
Amy Gullion
HC 33 Box 25
Alliance, NE 69301

CMS-1392-P-787 **Medicare**

Submitter : Ms. David Meister **09/12/2007**

Organization : Ms. David Meister
Critical Access Hospital

Category :

Issue Areas/Comments

GENERAL

GENERAL

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 an Asst Adm/CFO at Memorial Hospital of Lafayette (MHLC) in Darlington, Wisconsin.

MHLC current situation is described below:

" MHLC received CAH status on April 1, 2001. We are in the one of the poorest and lower populated counties in Wisconsin. We are appr 30 miles from another CAH.
" MHLC is growing as a CAH and a strong provider in caring for patients that would otherwise

receive no healthcare services unless travel as far away as 50 miles from home.
" MHLC would be considering Rural Health Clinics geared to assisting the rural agricultural and lower income population for a rural area.
" MHLC and Patients in Lafayette County would be impaired if no rural health clinic was available in the surrounding communities. The Population character is strong □ however with the rising costs of transportation and close proximity of rural clinic is instrumental in providing for a small community.

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to off-site clinics owned by CAHs. 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,

David A. Meister
Asst Adm/CFO

CMS-1392-P-787-Attach-1.DOC

#787

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:

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- MHLC received CAH status on April 1, 2001. We are in the one of the poorest and lower populated counties in Wisconsin. We are appr 30 miles from another CAH.
- MHLC is growing as a CAH and a strong provider in caring for patients that would otherwise receive no healthcare services unless travel as far away as 50 miles from home.
- MHLC would be considering Rural Health Clinics geared to assisting the rural agricultural and lower income population for a rural area.
- MHLC and Patients in Lafayette County would be impaired if no rural health clinic was available in the surrounding communities. The Population character is strong – however with the rising costs of transportation and close proximity of rural clinic is instrumental in providing for a small community.

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

Sincerely,

David A. Meister
Asst Adm/CFO

CMS-1392-P-788 **Medicare**

Submitter : Mr. Harry Wolin **09/12/2007**

Organization : Mason District Hospital
Hospital

Category :

Issue Areas/Comments

Necessary Provider
CAHs

Necessary Provider CAHs

I am writing on behalf of Mason District Hospital, a 'necessary provider' designated Critical Access Hospital in Havana, Illinois, in reference to proposed changes that will impact the Critical Access Hospital (CAH) program and the availability of physician services in our nation's rural underserved areas. 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 Rural Health Clinic (RHC)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 communities. This rule 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.

#788

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 Mason District Hospital, a "necessary provider" designated Critical Access Hospital in Havana, Illinois, in reference to proposed changes that will impact the Critical Access Hospital (CAH) program and the availability of physician services in our nation's rural underserved areas. 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).

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As you well know, physician shortages are one of the most difficult challenges facing our rural communities. This rule 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,

Harry Wolin
Administrator, CEO
Mason District Hospital
615 N. Promenade Street
PO 530
Havana, IL 62644

Voice: 309.543.8575
Fax 309.543.8523
E-mail h-wolin@masondistricthospital.org

CMS-1392-P-789 **Medicare**

Submitter : Amy Gullion **09/12/2007**

Organization : none
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

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

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

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

Thank you for allowing me to provide these comments.
Sincerely,
Amy Gullion HC 33 Box 25 Alliance, NE 69301

CMS-1392-P-790 **Medicare**

Submitter : Dr. Dean Ornish **09/12/2007**

Organization : Preventative Medicine Research Institute Association

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-790-Attach-1.DOC

FF 190

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:

Dr. Dean Ornish and the Preventive Medicine Research Institute (PMRI) appreciate this 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] Recently, we submitted to CMS comments on its Proposed Rule regarding revisions to payment policies under the physician fee schedule and other Part B payment policies for calendar year 2008. The favorable implementation of both the proposed rule for physician payment and this Proposed Rule are critical to allowing patients to benefit from our program and other proven programs for reversing heart disease.

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, we 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. Specifically, these studies demonstrated the following benefits: (a) decreased size and severity of ischemic myocardial perfusion abnormalities (blood flow to the heart) using cardiac positron emission tomography (PET), exercise thallium scintigraphy, and exercise radionuclide ventriculography (1-6); (b) regression of coronary artery stenosis using quantitative coronary arteriography (5);

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

(c) safe avoidance of revascularization procedures such as coronary bypass surgery, angioplasty, and intracoronary stents in almost 80% of those who were eligible for these procedures, with comparable clinical outcomes (7); (d) significantly greater exercise capacity (1-2, 6, 8-11); (e) substantial cardiac risk factor improvements, such as reductions in LDL-cholesterol comparable to what can be achieved with statin drugs without the costs and potential side-effects as well as significant reductions in weight, BMI, blood pressure and fasting blood glucose (1-3, 6, 8-11); (f) marked, rapid, and often dramatic decreases in the frequency and severity of angina (1-3, 6, 8); (g) substantial improvements in quality of life by a variety of measures (including decreased emotional stress and depression and increased vitality, physical function, and well-being) (3, 6, 8-11); and (h) 2.5 times fewer cardiac events (6). In addition, significant improvements in other chronic diseases prevalent in the Medicare population, including obesity, diabetes, hypertension, hypercholesterolemia, depression, prostate cancer, and related illnesses have been recorded. (1-13)

These findings were published in the leading peer-reviewed medical journals, 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 United States. 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 (7). 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 (personal communication with Highmark Blue Cross Blue Shield, 13). The Ornish program achieved similar improvements in Medicare patients as in these earlier demonstration projects and randomized controlled trials.

We are writing to comment on the proposal regarding reporting of cardiac rehabilitation services under the Hospital Outpatient Prospective Payment System. We are 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, we 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.

PMRI appreciates the time and effort CMS has dedicated considering our recommendations for ensuring that Medicare beneficiaries can participate in proven cardiac rehabilitation programs under the national coverage determination (NCD) issued last year.[2]

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

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 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, we are 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. Therefore, we have worked closely with CMS since the NCD was issued in March 2006, and recommended that CMS take certain specific steps to ensure that beneficiaries have meaningful access to these programs, as intended by CMS in issuing the NCD.

We are pleased to see that in the Proposed Rule CMS proposes to implement one of our 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."

We 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. We support this proposal and we ask CMS to implement it in the final rule. We 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 42,773.

4 Id.

5 Id.

While we applaud CMS's proposal to create new G-codes, we believe that beneficiary access to proven cardiac rehabilitation programs will be limited unless CMS implements our other recommendations. First, we 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. We 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, we 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, 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. We 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.

Finally, we 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

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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).

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.

* * *

PMRI greatly appreciates 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 Dean Ornish, MD at 415-332-2525 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Dean Ornish

Dean Ornish, MD
President and Founder, Preventive Medicine Research Institute
Clinical Professor of Medicine
School of Medicine
University of California, San Francisco

References

1 Ornish D, Gotto AM, Miller RR, et al. Effects of a vegetarian diet and selected yoga techniques in the treatment of coronary heart disease. Clin Res, 1979; 27: 720 A.
2 Ornish D, Scherwitz LW, Doody RS, Kesten D, McLanahan SM, Brown SE, DePuey E, Sonnemaker R, Haynes C, Lester J, McAllister GK, Hall RJ, Burdine JA, Gotto AM. Effects of stress management training and dietary changes in treating ischemic heart disease. JAMA, 1983; 249: 54-59.
3 Ornish D, Brown SE, Scherwitz LW, Billings JH, Armstrong WT, Ports TA, McLanahan SM, Kirkeeide RL, Brand RJ, Gould KL. Can lifestyle changes reverse coronary heart disease? Lancet, 1990; 336(8708): 129-133.
4 Gould KL, Ornish D, Kirkeeide RL, Brown SE, Stuart Y, Buchi M, Billings J, Armstrong W, Ports T, Scherwitz L. Improved stenosis geometry by quantitative coronary arteriography after vigorous risk factor modification. AJC, 1992; 69: 845-853.
5 Gould KL, Ornish D, Scherwitz L, Brown S, Edens RP, Hess MJ, Mullani N, Bolomey L, Dobbs F, Armstrong WT, et al. Changes in myocardial perfusion abnormalities by positron emission tomography after long-term, intense risk factor modification. JAMA, 1995; 274: 894-901.
6 Ornish D, Scherwitz LW, Billings JH, Gould KL, Merritt TA, Sparler S, Armstrong WT, Ports TA, Kirkeeide RL, Hogeboom C, Brand RJ. Intensive lifestyle changes for reversal of coronary heart disease. JAMA, 1998; 280(23): 2001-2007.
7 Ornish D. Avoiding revascularization with lifestyle changes: The Multicenter Lifestyle Demonstration Project. *AJC,* 1998; 82: 72T-76T.
8 Koertge J, Weidner G, Elliott-Eller M, Scherwitz L, Merritt-Worden TA, Marlin R, Lipsenthal L, Guarneri M, Finkel R, Saunders DE, McCormac P, Scheer JM, Collins RE, Ornish D. Improvement in medical risk factors and quality of life in women and men with coronary artery disease in the Multicenter Lifestyle Demonstration Project. AJC, 2003; 91: 1316-22.
9 Pischke CR, Weidner G, Elliott-Eller M, Scherwitz L, Merritt-Worden TA, Marlin R, Lipsenthal L, Finkel R, Saunders D, McCormac P, Scheer JM, Collins RE, Guarneri EM, Ornish D. Comparison of coronary risk factors and quality of life in coronary artery disease patients with versus without diabetes mellitus. AJC, 2006; 97(9): 1267-73.
10 Pischke CR, Weidner W, Elliott-Eller E, Ornish D. Lifestyle changes and clinical profile in coronary heart disease patients with an ejection fraction of ≤40% or >40% in the Multicenter Lifestyle Demonstration Project. European Journal of Heart Failure, in press.
11 Daubenmier JJ, Weidner G, Sumner MD, Mendell M, Merritt-Worden T, Studley J, Ornish D. The contribution of changes in diet, exercise, and stress management to changes in coronary risk in women and men in the Multisite Cardiac Lifestyle Intervention Program. Ann Behav Med, 2007; 33(1): 57-68.
12 Ornish D, Weidner G, Fair WR, Marlin R, Pettengill EB, Raisin CJ, Dunn-Emke S, Crutchfield L, Jacobs FN, Barnard RJ, Aronson WJ, McCormac P, McKnight DJ, Fein JD, Dnistrian AM, Weinstein J, Ngo TH, Mendell NR, Carroll PR. Intensive lifestyle changes may affect the progression of prostate cancer. Journal of Urology, 2005 Sep;174(3):1065-9; discussion 1069-70
13 Perelson G, Day B, DeVries A, Jiang, Y, Sumner, MD, Weidner, G, Merritt-Worden, T, Lipsenthal, L, Studley, J, Ornish, D. Reduced healthcare costs among cardiac patients making changes in diet and lifestyle: Results from three years of claims utilization of patients and matched controls. Circulation 2005 111(20): e311.

CMS-1392-P-791 **Medicare**

Submitter : Mrs. Ann Erwin **09/12/2007**

Organization : None
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

September 7, 2007

Dear Mr. Weems:

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services.

However, as a patient with Blepharospasm, (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic 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,

Ann Erwin

CMS-1392-P-792 **Medicare**

Submitter : Cathy Sharp **09/12/2007**

Organization : Cathy Sharp
Individual

Category :

Issue Areas/Comments

GENERAL

GENERAL

attachment

#752

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

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

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

CMS-1392-P-793 **Medicare**

Submitter : Dr. Ricardo Buenaventura **09/12/2007**

Organization : DaytonPainMed
Physician

Category :

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1392-P-793-Attach-1.DOC

#793

From: Ricardo M. Buenaventura, M.D.
DaytonPainMed
3490 Far Hills Ave, Ste 202
Kettering, OH. 45429

To: 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: September, 12, 2007

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,

Ricardo M. Buenaventura, M.D.
Medical Director
Dayton Pain Med
Kettering, Ohio

CMS-1392-P-794 **Medicare**

Submitter : Mr. Howard Thiel **09/12/2007**

Organization : none
Individual

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

Do not package the payment of these services together but continue to pay for them separately.

CMS-1392-P-795 **Medicare**

Submitter : Mrs. Joy Strand **09/12/2007**

Organization : Schoolcraft Memorial Hospital
Critical Access Hospital

Category :

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

Please see attached letter.

CMS-1392-P-795-Attach-1.DOC

#795

September 12, 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 the Chief Operating Officer at Schoolcraft Memorial Hospital in Manistique, Michigan.

Schoolcraft Memorial Hospital is a Critical Access Hospital located in the Upper Peninsula of Michigan, a large geographic area with many HPSA's. We are the sole healthcare provider for Schoolcraft County, operating a Rural Health Clinic on campus and two outreach clinics in remote communities. Because access to healthcare is limited throughout the county we are considering offering satellite clinics for Primary Care, Rehabilitation, and Home Health, further expanding the current clinics and adding additional access points throughout the service area.

The proposed changes will limit our ability to offer expanded access to healthcare to these smaller, more remote communities that are 'in between' CAH's or other healthcare providers and serves only to further limit quality healthcare to a population already challenged and disadvantaged in this realm. If CAH's are unable to expand into more remote communities within their service areas, these limitations will force seniors in remote areas to drive up to sixty miles to access primary care.

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to off-site clinics owned by CAHs. 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 at 906.341.3212.

Sincerely,

Joy A. Strand
Chief Operating Officer
Schoolcraft Memorial Hospital

CMS-1392-P-796 **Medicare**

Submitter : Mr. Howard Thiel **09/12/2007**

Organization : Mr. Howard Thiel
Individual

Category :

Issue Areas/Comments

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

I respectfully request that CMS not change the payment formula for physician-injectable drugs for 2008 and instead maintain the current payment formula.

CMS-1392-P-797 **Medicare**

Submitter : **09/12/2007**

Organization : Fremont Hospital
Hospital

Category :

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

Fremont Hospital is a 96-bed acute psychiatric hospital providing inpatient services to adolescents and adults, and outpatient services (including partial hospitalization) to adults. The hospital is located in the San Francisco Bay Area, in Alameda County which has a wage index of 1.5299, the highest in the country.

We strive to provide excellent care, and to hire experienced nurses, therapists and other mental health professionals to provide that care. We do face staffing challenges, due to the shortage of nurses and other professionals,and the competition from other hospitals in recruiting and retaining qualified staff.

We are writing to express our major concern regarding the proposed change in partial hospitalization reimbursement for Medicare beneficiaries. Over the past year, with our increases in salary and benefits costs, utility costs, workers' comp costs,food costs, etc. we have seen our overall cost of providing care increase by 10.8%. We have been able to re- negotiate all of our managed care contracts to increase our inpatient and outpatient rates to off- set a significant portion of our cost increase.

And now, in contrast to our increasing cost of providing care, CMS is proposing a 24% decrease in our partial reimbursement. If this is implemented, it will make it very difficult for

Fremont Hospital to cover the costs of nursing staff, group and individual therapy professional staff, support staff, facility operating costs, transportation costs,psychiatrists' fees and food costs for the six-hour partial program.

We recognize that CMS has encountered a lot of inconsistent and conflicting cost data in your evaluation of partial reimbursement, but this is a service that we have been providing for almost twenty
years, and we have a clear picture of what it costs to provide an effective, high quality partial

program that will offer significant benefits to participants. And we know that these costs are increasing.

Mental health has very thin margins, compared to other hospital services, and we need compare payment-to-cost on an on-going basis.
If we reach a point at which our reimbursement from CMS for partial hospitalization does not meet our fixed and variable costs of providing that service, then we would no longer be able to provide the partial program to Medicare beneficiaries in our service area.
That would be most unfortunate, and would be detrimental to the mental health and well-being of Medicare partial patients.

As a significant provider of mental health services in the Bay Area, (with 4,000 psychiatric inpatient admissions and several thousand outpatient visits annually), we are asking CMS to re-consider the proposed cuts in partial reimbursement. Thank you.

Sincerely, Management Staff, Fremont Hospital, September 12, 2007

CMS-1392-P-798 **Medicare**

Submitter : Dr. Peter Rahko **09/12/2007**

Organization : University of Wisconsin-Madison Physician

Category :

Issue Areas/Comments

Pass-Through Drugs

Pass-Through Drugs

The use of effective echocardiographic contrast agents has had an important beneficial impact on image quality. We have used contrast agents since they were first introduced. We have found that these agents markedly enhance the ability of a study to produce reliable information about left ventricular function, left ventricular regional wall motion, and in selected cases Doppler information about aortic stenosis and tricuspid valve regurgitation.

The utilization of contrast agents in my institution has never been constrained by hospital administration. They have allowed me to direct my sonographers to utilize these agents whenever necessary. This has not been the case in many other institutions. I have helped other laboratories in the state of Wisconsin establish contrast programs, and many times have met with ill-conceived resistance, particularly from administrators. This resistance was always to maintain the bottom line and to try to perform the service as cheaply as possible. It is very difficult to convince administrators about quality of images.

When one can use contrast agents without having to worry about incurring extra cost, the overall quality of laboratory performance improves. In the past (and my experience extends back to the early 1980s), many studies would have to be read out as inconclusive with regard to left ventricular function or regional left ventricular function. In these situations, alternate imaging procedures were performed, particularly studies utilizing nuclear agents or invasive

studies such as a transesophageal echo or cardiac cath. In other situations, erroneous conclusions were reached and patients were treated differently because of a perceived abnormality that may not have been securely diagnosed because of poor image quality.

The number of inconclusive studies in our laboratory since the availability use of imaging agents has dramatically dropped. With contrast agents, technically limited studies are frequently still adequate to draw secure clinical conclusions and the number of technically limited studies is well below 5%. Indeed, we hardly ever do TEE exams anymore for the reason of poor transthoracic

image quality.

Similar conclusions can be reached about stress echocardiograms. In the past we cancelled 3- 5% of our stress echocardiograms because of poor images. In the current era we cancel virtually none of our stress echocardiograms (now under 1%) because of image quality.

My fear is for the way administrators will handle this change in payment for contrast. A laboratory performs best when it□s not under fiscal constraints to conserve the agent. Indeed, contrast agents are probably still underutilized in most laboratories, with people putting up with □marginal□ studies. The proposed change in reimbursement will stifle any expansion of the use of contrast agents to appropriate cases and will in turn most likely reduce the number of studies in which contrast is utilized. This will increase the number of inconclusive or nondiagnostic results.

In conclusion, I strongly disagree with this proposed rule. I think it would be detrimental to overall quality of performance of echocardiograms. The current cost-neutral system works well and it promotes quality. A change would be a disincentive. Furthermore, bundling of the procedures would probably result in some arbitrary assumption being made by CMS about how much utilization of contrast is occurring at this time. For quality laboratories that are appropriately using contrast agents, this would probably serve as another financial disincentive because □above average□ laboratories would be penalized for heavier use of contrast agents whereas □below average□ laboratories that are currently not fully utilizing the benefit of these agents and thus underperforming would be financially incentivized. Thus, rather than regress everybody to the mean,I urge you to leave the current system intact.

CMS-1392-P-799 **Medicare**

Submitter : Daniel Goddard **09/12/2007**

Organization : Scripps Mercy Hospital San Diego Hospital

Category :

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

Dear Sir/Madam,
Regarding the proposed decrease in payment rates for Partial Hospitalization Programs, this would have a detrimential effect on the quality of care for our patients. I have worked with adults with chronic and severe mental illnes for the past 8 years, and have witnessed the positive impact PHP's have on our patients. Treatment services outside of inpatient hospitalization for this population are scarce, which brings me to the next point.
Our rate of decreasing inpatient hospitalizations and using PHP as an alternative to inpatient, and then as a transition to intensive outpatient programs and then into the community, is substantial, resulting in PHP as a cost-effective treatment solution.
The proposed 24% rate cut would severely impact our ability to serve this population, resulting in higher utilization of inpatient hospitalization in the absence of availability of PHP opportunities.
Thank you,
Daniel Goddard, MFT

CMS-1392-P-800 **Medicare**

Submitter : Mr. Howard Thiel **09/12/2007**

Organization : ST/Dystonia, Inc.
Other Association

Category :

Issue Areas/Comments

OPPS: Packaged Services

OPPS: Packaged Services

See attachment

Specified Covered Outpatient Drugs

Specified Covered Outpatient Drugs

See attachment

CMS-1392-P-800-Attach-1.DOC

CMS-1392-P-800-Attach-2.DOC

CMS-1392-P-800-Attach-3.DOC

CMS-1392-P-800-Attach-1.DOC

CMS-1392-P-800-Attach-2.DOC

CMS-1392-P-800-Attach-3.DOC

 #8800

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

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

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

CMS-1392-P-801 **Medicare**

Submitter : Craig Cudworth **09/12/2007**

Organization : Hendry Regional Medical Center Hospital

Category :

Issue Areas/Comments

Necessary Provider CAHs

Necessary Provider CAHs

See Attached

CMS-1392-P-801-Attach-1.DOC

#801

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 Hendry Regional Medical Center in Clewiston, FL.

Our Hospital received Critical Access Status under the exception granted from mileage restrictions which has now expired. We are the only hospital in Hendry County Fl which is one of the poorest counties in the state with a significant number of health issues facing its Medicare beneficiaries. We operate a rural health clinic currently on campus. We recently purchased a clinic in another town in the county for the purposes of extending access to Medicare beneficiaries there. This clinic, 30 miles away, is planned to be operated as a rural health clinic or provider based clinic in a physician underserved community. If this rule passes it will seriously affect our abilities to provide primary care clinic services in other than the area currently adjacent to our campus. I am concerned that we would be unable to sustain services to this side of the county under the proposed regulations.

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to off-site clinics owned by CAHs. 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 ,

Craig R Cudworth, FACHE
CEO

CMS-1392-P-802 **Medicare**

Submitter : **09/12/2007**

Organization :
Hospital

Category :

Issue Areas/Comments

Observation Services

Observation Services

see attached document regarding Observation Services

CMS-1392-P-802-Attach-1.DOC

#802

Asante Health System, OR
Avera Health, SD
Carolinas Healthcare System, NC
Community Hospital Anderson, IN
Erlanger Medical Center, TN
Forrest General Hospital, MS
Health First, Inc., FL
Lovelace Health System, NM
Mercy Medical Center, IA
Our Lady of the Lake Regional Medical Center, LA
Palomar Pomerado Health, CA
Saint Joseph's Hospital, WI
St. Joseph's/Candler Health System, GA
Saint Mary's Hospital, MN
Sheltering Arms Rehabilitation Hospitals, VA
Sisters of Mercy Health System, MO
Twin Lakes Regional Medical Center, KY
University Health System, TX
Vanguard Health System, TN

The Provider Roundtable (PRT) is a group of providers representing 19 different health systems from around the country. The PRT was formed in order to help providers submit substantive comments that have an operational focus and can be used by CMS staff in preparing future OPPS rules. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

OBSERVATION SERVICES

The Provider Roundtable (PRT) believes that based on CMS' own definition, observation is not a dependent service. CMS has defined observation care as "*a well defined set of specific, clinically appropriate services which include ongoing, short-term treatment, assessment and reassessment, that are furnished while a decision is being made regarding whether a patient will require further treatment as a hospital inpatient or if the individual is able to be discharged from the hospital.*" The ongoing assessment and monitoring is an active process that occurs during the observation stay. The medical monitoring itself becomes the primary independent service, and the other ancillary services become dependent to this active ongoing assessment.

The PRT realizes that CMS is alarmed by the rapid increase of separately payable observation service claims. However, we believe that this is directly related to the positive changes CMS made to the reporting system in response to work done by the APC Panel and other provider groups over the past several years. CMS listened to the operational burdens facing hospitals and responded with a simplified reporting and payment system. The PRT and the APC Panel reported to CMS that hospitals were likely under-reporting observation care in the past due to the complexity of billing

rules prior to the changes made in 2006. We believe that the claims data generated under the simplified reporting and payment system support this information and is the primary reason CMS has seen an increase in the frequency of the separately payable observation APC. The PRT believes that claims data will stabilize and the upward trend will vanish with 2007 and later claims data.

Another contributing factor to the increased volume of claims is related to CMS' policies aimed at reducing the occurrence of one-day stays in the inpatient setting. Therefore, the PRT recommends that CMS compare the increase in the number of claims containing HCPCS code G0378 (observation per hour) with the decrease in one-day inpatient stays. The PRT further recommends that CMS continue the current policy for reporting observation cases and strongly advocates that CMS delay any changes until the 2007 claims data is available for review.

CMS states in the proposed rule: "*We are also concerned that the current criteria for separate payment for observation services may provide disincentives for efficiency. In order for observation services to be separately payable, they must last at least 8 hours. While this criterion was put in place to ensure that separate payment is made only for observation services of a substantial duration, it may create a financial disincentive for an HOPD to make a timely determination regarding a patient's safe disposition after observation care ends. By packaging payment for all observation services, regardless of their duration, we would provide incentives for more efficient delivery of services and timely decision making.....To the extent that hospitals could change their behavior and cease providing observation services, refer patients elsewhere for that care, or increase the frequency of observation services, the data would show such a change in practice in future years and that change would be reflected in future budget neutrality adjustment.....We believe it is unlikely that hospitals would cease providing medically necessary observation care or refer patients elsewhere for that care if they were unable to reach a decision that the patient could be safely discharged from the outpatient department.*"

The PRT would like to remind CMS that it is incumbent upon the physician, not the hospital, to make the determination regarding the order for observation, the length of the observation stay, and the patient's safe discharge once the observation period ends. We do not see how increased packaging provides an incentive for hospitals to make a resource decision related to either selection of observation status or time spent in observation as both are determined by the physician.

The PRT also questions whether observation dollars are truly being packaged into other separately payable services. We believe that most observation charges, currently packaged or separately payable through APC 0339 are only claims that also contain other separately payable supportive services such as an outpatient visit, various lab and ancillary diagnostic studies, and/or other procedures or tests. By definition, claims that contain such services along with observation hours will be multiple-procedure claims that cannot be used in the APC rate-setting process. Hospitals need proof that the majority of observation charges are in fact being packaged under CMS' proposed packaging proposal. In addition, CMS should more fully disclose where the observation packaged charges reside.

The PRT concurs with the Observation subcommittee and full APC Advisory Panel's recommendation for a delay in the implementation of observation packaging and the need for further data analysis. We agree with and expand upon the APC Panel's recommendations:

1. To continue separate payment for the current conditions until future claims data beyond 2006 are analyzed for trends of either stabilization or continued exceptional growth.
2. Request that CMS provide a detailed analysis of the distribution of separately payable observation charges for APC 0339 present on single vs. multiple procedure claims so that the APC Advisory Panel and providers can analyze and understand what amount of observation dollars would be used for packaging and into which services these dollars would be packaged.
3. That observation services would be ideal for CMS to study for Composite APC payment. At the September 2007 meeting, the APC Advisory Panel recommended investigation of a composite APC regarding ED/Clinic services and observation status with separate payment made when a visit code and observation are reported together, regardless of the medical condition. The PRT further recommends inclusion of HCPCS code G0379 (direct admit to observation) in addition to the Emergency Department and Clinic E/M visit codes recommended by the APC Advisory Panel. While it was suggested that the volume of these claims was low, the PRT offers that a direct admit situation requires the same significant resource utilization since there is no difference in the services. Even if the patient was seen in the physician's office, the admission assessment and care provided is no different than the patient who was seen in the ED or in an outpatient clinic. This code should be included in the group of services included in a composite APC.

While CMS has made many positive strides to decrease the reporting burden for observation services, some FIs and MACs have increased the operational burden on hospitals by adding other requirements. Within the PRT membership, there are several providers who have FIs and MACs requiring the time related to diagnostic procedures to be carved out and disallowing the reporting of observation stays that are less than 8 hours. The PRT believes that these additional restrictions are contrary to the guidelines published by CMS and are resulting in inaccurate and incomplete data reported to CMS. The PRT requests that CMS issue further directives requiring its FIs and MACs to adhere to and not deviate from the explicit guidance issued by CMS as found in the IOM.

If CMS staff has questions about the information presented in this document, please contact the PRT spokesperson listed below:

Sincerely yours,

Denise Williams, RN, CPC-H
Vanguard Health System
Nashville TN
(615) 665-6052