CMS-1392-P-882 **Medicare**

Submitter : **Date & Time: 09/13/2007**

Organization :

Category : **Device Industry**

Issue Areas/Comments

OPPS: Packaged Services

See attached document

#882

iCAD

September 11, 2007

Herbert B. Kuhn, Acting Administrator
Centers for Medicare and Medicaid Administration
Department of Health and Human Services
CMS 1385-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1392-P; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Dear Mr. Kuhn:

On behalf of iCAD, Inc., I appreciate the opportunity to comment on the Proposed Notice of the Hospital Outpatient Prospective Payment System ("HOPPS") for CY 2008 set forth in the August 2, 2007 *Federal Register* (the "CY 2008 HOPPS Proposed Rule").

iCAD, Inc. is headquartered in Nashua, NH and manufactures mammography Computer-Aided Detection (CAD) systems used for the early identification of breast cancer. CAD systems incorporate advanced pattern recognition and image analysis capabilities to aid radiologists in the detection of abnormalities on mammography images. The use of CAD provides a targeted second review. The clinical efficacy of CAD in the early detection of breast cancer with mammography is well documented and based on strong peer-reviewed clinical evidence.

CMS is proposing a number of significant changes to expand packaging and create payment bundles for groups of services. Specifically, CMS is proposing to package payment for "image processing" HCPCS codes, including computer aid detection (CAD) procedures and three dimensional imaging.

We are concerned that expanded packaging and bundling, as described in the proposed rule, will produce artificial payment reductions that do not accurately reflect the complexity of services provided. When payments are bundled, accurate costs of the components are difficult to identify. This may lead to a reluctance on the part of providers to purchase important innovative technologies, which may ultimately result in reduced patient access to emerging and current products and services. Not only

could access to critical screening and diagnostic services be impeded, but delayed detection could result in later stage cancer diagnosis. This would be detrimental to the health of Medicare beneficiaries, as well as impose significant and unnecessary additional costs on the nation's healthcare system. According to the American Cancer Society, the average cancer patient receives 12.5 procedures per year, and total cost of cancer treatments is over $72B per year, as well.

We ask that CMS study the potential effects of packaging payments for "imaging processing" codes more thoroughly, and to consult with relevant stakeholders before implementing these proposals.

We appreciate the opportunity to comment on this proposal and would be pleased to work with you regarding these concerns.

Sincerely,

Ken Ferry

Ken Ferry
President and Chief Executive Officer

CMS-1392-P-883 **Medicare**

Submitter : **Ms. Marilyn Litka-Klein** **Date & Time: 09/13/2007**

Organization : **Michigan Health**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

See Attachment

#883

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

September 13, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS—1392—P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Medicare Program; Outpatient Prospective Payment System Rule for 2008; Proposed Rule. CMS-1392 – P

Dear Sir:

On behalf of Michigan's 145 nonprofit hospitals, the Michigan Health & Hospital Association (MHA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 2008 proposed rule to update the Medicare outpatient prospective payment system (OPPS). The MHA is concerned about policy changes that would reduce Medicare outpatient payments to Michigan hospitals since this would further threaten the financial viability of hospitals. This is particularly concerning since the latest data available indicates that statewide, Michigan hospitals have a negative margin of 7 percent for outpatient services and lose approximately $86 million annually on OPPS services provided to Medicare beneficiaries. In addition, for some Michigan hospitals, outpatient services comprise 60 percent or more of total revenue. **Hospitals cannot sustain these losses and remain financially viable as the commercial insurers and self-pay patients are unwilling to absorb the cost of government under-funding.**

REPORTING OF HOSPITAL OUTPATIENT QUALITY DATA (Federal Register Pages 42799-42806)

In order for hospitals to receive the full OPPS payment update for services furnished in 2009, the CMS proposes to require that hospitals submit data on ten measures, effective Jan. 1, 2008. Hospitals that do not participate in the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), withdraw from the program, or fail to meet its requirements will receive an update that is reduced by 2.0 percentage points for the affected payment year. To participate in the HOP QDRP for 2009 and subsequent years, hospitals must meet administrative, data collection/submission and data validation requirements. For the most part, these procedures and requirements mirror those currently in place under the IPPS RHQDAPU program.

SPENCER JOHNSON, PRESIDENT
CORPORATE HEADQUARTERS ◆ 6215 West St. Joseph Highway ◆ Lansing, Michigan 48917 ◆ (517) 323-3443 ◆ Fax (517) 323-0946

As required by law, the 10 proposed measures were developed in collaboration with professionals and providers, as well as the Hospital Quality Alliance. According to the proposed rule, the CMS expects to submit these measures for endorsement by the National Quality Forum (NQF). Once the HOP QDRP is established, the CMS anticipates expanding the set of measures on which hospital outpatient settings must report data. In the proposed rule, the CMS identified and is seeking comment on whether any of the 30 additional measures should be included effective for services provided on and after Jan. 1, 2008 for the 2009 rate update. Unlike the measures proposed for 2008, the 30 additional measures are either currently in use or were developed for use in setting other than hospital outpatient and have not received formal review by either the HQA or the NQF as measures of outpatient performance.

In addition to not allowing adequate time for hospitals to collect additional quality measure data, finalizing quality reporting requirements in the final OPPS rule, which is anticipated to be released by the CMS by Nov. 1, 2007, **does not** allow adequate time for vendors to develop, test and release changes necessary for data reporting effective sixty days later on Jan. 1, 2008. **To allow more time for both hospitals and vendor to adapt, the MHA urges the CMS to provide a minimum of six months notice in regard to quality measure data collection requirements.**

Prior to linking any set of measures to the payment for outpatient care, there should be clear evidence that the measures specifically have an impact on the quality and outcome of patients who are treated in hospital outpatient settings. Many measures that can provide insights into the quality in outpatient care settings are being reviewed by the Hospital Quality Alliance and the NQF. **The MHA urges the CMS to continue working with the HQA and the NQF to identify and implement measures that assess important aspects of outpatient care quality.** Once appropriate measures have been identified, the CMS should work with Congress to consider how the payment system should be modified to support the provision of high quality care in the outpatient setting. Since appropriate outpatient care measures have not been identified, **the CMS should remove any link between quality measures and outpatient payments in this rule.** In addition, the MHA believes it would be inappropriate for the CMS to require data for the 30 additional quality measures as more time is needed to allow hospitals and their quality measure software vendors to adapt to the change and collect the appropriate data. **As a result, the MHA opposes further expansion of the required measures effective January 1, 2008.**

OPPS PACKAGING PROPOSAL (Federal Register pages 42648 – 42690)

The OPPS currently utilizes moderate packaging of services and generally makes a separate payment for each individual service provided during a patient encounter. For 2008, the CMS proposes to broaden the OPPS payment groupings, APCs, by packing into the primary service provided seven categories of items and services that the CMS considers to be typically ancillary and supportive. Currently, these services are billed separately. The seven categories of items and services the CMS proposes to package into primary diagnostic and therapeutic procedures with which they are performed include:

- Guidance services,
- Image processing services,
- Intra-operative services,
- Imaging supervision and interpretation services,
- Diagnostic radiopharmaceuticals,
- Contrast media, and
- Observation services.

The American Hospital Association (AHA), MHA and others have generally supported the CMS' efforts to package more services into large payment bundles and broadly agree that appropriately-sized bundled can provide incentives to improve efficiency and manage resources. However, we have concerns about the CMS proposal and underlying analysis behind the proposal. While the CMS estimates that the proposal would redistribute approximately 1.2 percent of the 2007 expenditures under the OPPS, analyses prepared by The Moran Company indicate that the seven categories in the CMS' proposal represent 6 percent of outpatient costs. The resulting impact reveals significantly different impacts by type of hospitals than the CMS' impact tables and we are concerned that the full implications of this policy are not fully understood.

The MHA recommends that the CMS reevaluate its new packaging proposal in light of the methodological and data concerns. If the CMS decides to move forward with its proposal, at minimum, **we urge the CMS to exclude observation services from its final packaging strategy at this time.** The MHA supports continuation of separately payable status for observation services and the CMS' use of the Outpatient Claims Editor (OCE) logic to automatically determine whether observation services on a claim are separately payable began in 2002.

OPPS:PARTIAL HOSPITALIZATION (Federal Register pages 42690 – 42693)

Partial hospitalization (PHP) is an intensive outpatient psychiatric program provided to patients in place of inpatient psychiatric care and may be provided by a hospital outpatient department or a freestanding Community Mental Health Center (CMHC). Providers are paid on a per-diem basis for these services. In 2006 and 2007, the CMS implemented drastic reductions to the per diem rates for PHP. For 2007, the CMS is utilizing an alternate methodology for computing the per diem cost by computing a separate per diem cost for each day rather than for each bill. When there are multiple days of care entered on a claim, a unique cost is computed for each day of care. All of these costs are then arrayed from lowest to highest and the middle value of the array would be the median per diem cost. For 2008, the CMS proposes to adopt this alternate method for computing PHP median per diem costs, resulting in an APC payment of $179.88, which is a 23 percent reduction from the current PHP rate of $234.73. The MHA is extremely concerned that an additional reduction in the per diem payment rate for partial hospitalization services could jeopardize the financial viability of outpatient psychiatric programs in hospitals and health care systems, and endanger Medicare beneficiary access to these services. This will be the third consecutive year that the per diem rate was reduced by 15

percent or more and hospitals cannot sustain further reductions in the per diem rates. These services already are quite vulnerable, with many programs in recent years closing or limiting their patients. We understand the CMS's concern about volatility of the community mental health center data. However, it is inappropriate to penalize hospital providers for the performance of another.

The MHA recommends that for 2008, the CMS freeze payment rates for partial hospitalization services at the current rate of $234.73. This approach will provide payment stability for these services and protect beneficiary access to hospital-based services while allowing the CMS adequate time to address the instability in the CMHC data. **We further request that the CMS require CMHCs to improve their reporting or have that provider group face economic consequences.**

REPORTING OF PHARMACY OVERHEAD CHARGES (Federal Register Pages 42733 – 42736)

Currently, the payment methodology provides for a single, bundled pharmacy payment representing average hospital acquisition costs and associated pharmacy overhead costs. The CMS proposes to require that hospitals separately report pharmacy overhead charges from drug charges to provide data for possible future payment changes. For 2008, the CMS proposes to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological and report the pharmacy overhead charge on an uncoded revenue code line on the claim. The CMS proposes to apply this policy to the reporting of charges for all drugs and biologicals, including contrast agents, irrespective of the item's packaged or separately payable status for the 2008 OPPS. The CMS would not apply this policy to radiopharmaceuticals since it has previously instructed hospitals to include the overhead and handling charges in the charges for the radiopharmaceutical products. Once 2008 claims data is available for rate-setting, this proposal would lead to pharmacy overhead for separately payable drugs being packaged with payment for the associated procedure, likely a drug administration procedure, rather than the current policy where pharmacy overhead for these charges is packaged with the payment for the drug. Since actual claims data reflecting these changes will not be available until 2010, the CMS proposes to continue providing a combined payment rate for acquisition costs and pharmacy overhead for separately payable drugs and biologicals in 2008.

The Medicare payment for all APCs includes components for direct cost and overhead. To target pharmacy charges and require hospitals to change billing practices for only one payer is unnecessarily burdensome. Hospitals will incur significant programming expenses to modify their computer systems, or pay their vendors to accommodate this request. **The MHA believes the CMS should withdraw its proposal and re-evaluate the recommendations of the APC Panel and to consider more streamlined approaches that limit new requirements to specific drugs with significant pharmacy overhead and administration costs. Proceeding with this proposal will create significant complexity and burden in an area that is already one of the most difficult areas for hospital coding staff. In the end, it is unlikely that the CMS proposal will improve the OPPS rate setting process.**

REPLACED DEVICES (Federal Register Pages 42734-42727)

In 2007, the CMS adopted a policy that requires a reduced payment to a hospital or ambulatory surgical center when a device is provided to them at no cost. Under this policy, the CMS reduces the payment for selected device-dependent APCS when the hospital receives certain replacement devices with cost or receives a full credit for the device being replaced. The reduction policy does not apply to cases in which there is a partial credit toward the replacement of the device. The CMS now proposes to expand the policy to require hospitals to report occurrences of devices being replaced under warranty or otherwise with a partial credit granted to the hospital so that the agency can identify systematic failures of devices or other problems through claims analysis and so that it can make appropriate payment adjustments in those cases.

For 2008, the CMS proposes to create a HCPCS modifier that would be reported in all cases in which the hospital receives a partial credit toward the replacement of one of the 31 medical devices listed in Table 39 of the proposed rule. These devices are the same devices to which the policy governing payment when the device is furnished to the provider without cost or with full credit applies.

The CMS proposes to reduce the payment for the APC into which the device cost is packaged by one half of the amount of the offset amount that would apply if the device were being replaced without cost or with full credit when the amount of the device credit is at least 20 percent of the cost of the new replacement device being implanted. In addition, the CMS proposes to base the beneficiary's copayment on the reduced APC payment rate so that the beneficiary shares in the hospital's reduced costs.

The CMS applies three criteria when determining the APCs to which the existing and proposed policy should apply:

- All procedures assigned to the selected APCs must require implantable devices that would be reported if device replacement procedures were performed;
- The required device must be surgically inserted or be an implanted device that remains in the patient's body after the conclusion of the procedures (at least temporarily); and
- The device offset amount must be significant, defined as exceeding 40 percent of the APC cost.

Under the analogous policy adopted in the final inpatient regulation for FY 2008, the CMS only applies the reduced payment to cases in which the hospital receives a credit equal to 50 percent or more of the cost of the device. This ensures that the reduction in payment does not occur when the credit is nominal or relatively inconsequential in comparison to the overall payment for the case. **The MHA recommends that the CMS should raise the proposed threshold from 20 percent to 50 percent in the final OPPS rule, consistent with the FY 2008 IPPS final rule.**

NEW TECHNOLOGY APCS (Federal Register Pages 42703 – 42706)

The CMS proposes to assign seven procedures currently assigned to New Technology APCs to clinically appropriate APCs. The CMS generally retains a service within a New Technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, the CMS proposes to assign some services that have been paid under the New Technology APCs for less than two years to clinically appropriate APCs.

In addition, due to the availability of data, for 2008, the CMS is proposing to assign Positron Emission Tomography (PET)/Computed Tomography (CT) Scans, and IVIG Pre-Administration-Related Services, currently assigned to new Technology APCs to clinically appropriate APCs. Consistent with our past comments, **the MHA recommends that when the CMS assigns a new service to a new technology APC, the service should remain there for at least 2 years until sufficient claims data are collected.**

While new technology may increase outpatient cost, it frequently eliminates more invasive inpatient procedures that are most costly for Medicare. While this means that Medicare may be paying more for new technologies in hospital outpatient settings, in the end these costs are likely to be less than the cost of caring for such patient in an inpatient setting or using more invasive, but traditional, outpatient procedures.

EVALUATION & MANAGEMENT (E/M) CODES (Federal Register Pages 42751 – 42765)

Currently the CMS instructs hospitals to use the 2007 CPT codes, as well as six HCPCS codes that became effective Jan. 1, 2007, to report clinic visits, emergency department visits and critical care services on claims paid under the OPPS. However, the CMS believes that CPT Evaluation and Management (E/M) codes were defined to reflect the activities of physicians and fail to appropriately describe the range and mix of services provided by hospitals during clinic and ED visits and critical care encounters. There are three types of visit codes to describe three levels of service for each of these visits. However, there is no uniform policy to determine the assignment of E/M codes as the CMS continues its efforts to develop uniform guidelines. Hospitals are required to report facility resources for clinic and ED visits using CPT E/M codes and to develop internal hospital guidelines to determine what level of visit to report for each patient. While national guidelines are under development, the CMS has advised that each hospital's internal guidelines should follow the intent of the CPT code descriptors, in that the guidelines should be designed to reasonably relate the intensity of hospital resources to different levels of effort represented by the codes.

For clinic visits in 2008, the CMS will continue to recognize the CPT codes for new and established patients under the OPPS. For ED visits, the CMS will continue to distinguish between Type A and B ED visits, with Type a visits continuing to be paid based on the five ED visit APCs, while type B ED visits would continue to be paid based on the five Clinic Visits

APCs. (Hospitals that maintain an ED and have obligations to the EMTALA but do not operate a 24-hour ED are referred to as Type B EDs).

The MHA continues to believe that the CMS finalize national coding definitions and guidelines, with input by hospitals and other stakeholders. This approach would provide for stability for hospitals in terms of coding and payment policy and would allow the CMS and stakeholders to focus on the development and fine-tuning of a set of national hospital visit guidelines that could be applied to a new set of E/M codes in the future.

OPPS: OBSERVATION SERVICES (Federal Register Pages 42768 -42770)

Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment and reassessment, before a decision can be made regarding whether a patient requires further inpatient treatment or if he/she should be discharged from the hospital. Prior to 2002, payment for all observation care under the OPPS was packaged into other APCs. Since 2002, separate payment for a single unit of an observation APC for an episode of observation care has been provided in limited circumstances.

For 2008, the CMS proposes to expand their general packaging approach to move the OPPS toward more encounter-based and episode-based payments in the future. Based on this approach, the CMS has proposed to package payment for observation services except in the case of direct admissions for observations.

The MHA opposes this change and urges the CMS to continue making separate payments for observation services as provided in 2007. Observation services are often vital for determining the more appropriate treatment and whether to admit a patient. As a result, rather than discontinuing separate payment for observation services, we believe coverage should be expanded to all cases where the physician deems observation to be the appropriate level of care. The CMS payment for observation is significantly less than an inpatient DRG payment.

OPPS: OUTLIER PAYMENTS (Federal Register Pages 42698 0 42699)

Outlier payments are additional payments to the APC amount to mitigate hospital losses when treating high-cost cases. For 2008, the CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, the CMS proposes to increase the fixed-dollar threshold by approximately 9.5 percent from the current $1,825 threshold to $2,000 – to ensure that outlier spending does not exceed the outlier target. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least $2,000 more than the APC rate.

The CMS has indicated that the fixed dollar increase is largely due to the CMS' revised methodology used in calculating the overall cost-to-charge ratio (CCR), the APC recalibration and the proposed changes to packaging. The MHA is concerned that Medicare may not actually spend the outlier target set-aside. We believe the CMS should publish the annual outlier

payments as a percent of total expenditures for previous years. **The MHA believes the outlier threshold increase should be limited to the increase in APC rates each year unless clear evidence exists that proves the outlier payments exceed the allocated pool.**

NECESSARY PROVIDER CAHs (Federal Register Pages 42806-42807)

In the proposed rule, the CMS states that "the intent of the Critical Access Hospital (CAH) program is to maintain hospital-level services in rural communities while ensuring access to care." The CMS is proposing to **terminate a hospital's CAH status** if any new facility location, including a replacement facility or an outpatient clinic, does not satisfy the CAH distance requirements.

Despite Medicare's payment policy for CAH that reimburses hospitals 101 percent of Medicare allowable cost, the reimbursement does not cover GAAP cost. In addition, most CAHs have perilous financial status despite Medicare providing 101 percent Medicare allowable cost reimbursement. The CMS has proposed to rescind a hospital's CAH status if an off-campus location opened or acquired after Jan. 1, 2008 does not satisfy the CAH distance requirement. Given the normal time requirement for building a facility, a CAH that began construction of an outpatient facility earlier this year, with an anticipated opening in March 2008, would lose CAH reimbursement for the entire CAH as a result of this proposed policy. **We believe this would result in a significant number of hospital closures nationally as CAHs would be unable to sustain their operations under the IPPS and OPPS payment rates.**

CAHs develop off-site facilities to meet the needs of their communities, providing care close to home without an undue burden on the Medicare enrollees to travel considerable distances. Proper outpatient care generally prevents more costly inpatient admissions with better outcomes for the patient, saving money for the Medicare program. The CMS indicates that 453 CAHs have health clinics, or 35 percent of CAHs nationally. While one might question whether the costs of these additional facilities are necessary, the MHA urges the CMS to conduct a more in-depth study on the rationale for the development of these clinics. Many CAHs are outdated, inpatient focused facilities that have been modified to accommodate the shift in care delivery to the outpatient setting. In some instances, the original building just does not have the space to accommodate all services necessary in the community. To void the CAH reimbursement level as a result of a hospital building an outpatient clinic to provide better service to the community seems ludicrous. In addition, finalizing this policy by January 2008, does not give providers enough time to adapt particularly as many hospitals are in the middle of planning or actively constructing new facilities that are needed to meet community needs. Officially modifying this requirement around November 1 for implementation sixty days later is very unreasonable. **The MHA urges the CMS to rescind the proposal altogether. It is contrary to the CMS' original intention "to ensure access to essential health care services for rural residents". As proposed, this policy would make physician recruitment and retention in rural areas even harder, thus jeopardizing access to services in rural areas.**

OPPS: INPATIENT ONLY PROCEDURES (Federal Register Pages 42779 – 42781)

The CMS proposes to remove 13 procedures from the inpatient list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and assign them to clinically appropriate APCs.

The MHA remains concerned about the inconsistency between Medicare payment policy for physicians and hospitals in regard to procedures that are on the inpatient only list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient list are performed in outpatient settings, that physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient list changes annually, physicians may not always be aware of that a procedure they have scheduled for performance in an outpatient department is on the inpatient list. There may be valid clinical circumstances that support the patient having the procedure as an outpatient.

The MHA again recommends that the CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would provide the hospital an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without a more costly inpatient admission.

Again, the MHA appreciates this opportunity to provide input to the CMS and urge you to modify the OPPS proposed rule based on our comments above. If you have questions or require additional information, please contact me at (517) 703-8608 or mklein@mha.org.

Sincerely,

Marilyn Litka-Klein

Marilyn Litka-Klein
Senior Director, Health Policy

CMS-1392-P-884 **Medicare**

Submitter : **Caroline Thomas** **Date & Time:** **09/13/2007**

Organization : **Allegheny General Hospital**

Category : **Nurse**

Issue Areas/Comments

GENERAL

See Attachment

#884

September 13, 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 Case Manager for the Dr. Dean Ornish Program for Reversing Heart Disease at Allegheny General Hospital in Pittsburgh, PA. The Ornish Program 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, 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*

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

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/our] 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 four years of experience, I have worked with a large number of patients who are 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 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

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

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 implement 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."

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.

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3 72 Fed. Reg. at 38,419.

4 Id.

5 Id.

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.

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

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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).

Ornish Program. Please feel free to me, or our Program Director, David Seigneur, MS (phone: 412-359-3276, e-mail: dseigneu@wpahs.org) if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Caroline Thomas, RN, MS
Case Manager
Dr. Dean Ornish Program for Reversing Heart Disease
Allegheny General Hospital
Pittsburgh, PA
Phone: 412-359-3698
E-mail: cthomas1@wpahs.org

CMS-1392-P-885 **Medicare**

Submitter : **Mr. Robert Jetland** **Date & Time:** **09/13/2007**

Organization : **Pacific Imaging and Treatment Center**

Category : **Health Care Industry**

Issue Areas/Comments

PET/CT Scans

See Attachment

#885

Pacific Imaging and Treatment Center, LLC

5395 Ruffin Road, Suite 202

San Diego, CA 92123

(858) 569-7800

Centers for Medicare and Medicaid Services

U.S. Department of Health and Human Services

Attention: Docket ID CMS – 1392 – P

7500 Security Boulevard

Baltimore, MD 21244-1850

September 12, 2007

Gentlemen,

Currently, I own and operate a state-of-the-art freestanding 16-slice combination PET/CT Center. CMS is one of our most important payers.

Your proposed plan to bundle all of the radiopharmaceutical costs into a base reimbursement charge threatens the survival of my small enterprise. If these changes occur, CMS will have gone from paying $2,400 in global fees in December 2006, to about $1,200 in January 2008. Reducing reimbursement rates through two back-to-back changes by 50% in 13 months is a unique and draconian proposal in my 30+ years of dealing with CMS. I and many of my friends are struggling to survive the DRA cuts which took effect on January 2007. Some PET and PET/CT centers have already failed. Many more will fail if you follow through with this proposal.

- I would urge you to consider bundling radiopharmaceuticals which cost $175 or less or have the reimbursements decrease in a period of at least four (4) years or so. That would allow other outpatient PET/CT providers (and us) adequate time to prepare for the ultimate reimbursement decreases. This idea is similar to what the Advisory Panel has proposed.
- My colleagues and I do not take issue with your cost control objectives. We realize that you obtain your data from reporting hospitals. Their employees are usually overwhelmed with work. Therefore, we believe that their data is often flawed. However, we realize that you really cannot readily validate their reported information.

To get a different perspective, the Society of Nuclear Medicine (SNM) asked their members to report on their individual practice costs for radiopharmaceutical (RP) supplies. Often, their own reported costs varied by up to 500%. Part of the price differences were related to how far away the user was from the producing lab. Your new single price seems to ignore these materially different prices, different shipping costs, etc.

Your reporting hospitals' costs for the same RP vary hugely. Most healthcare providers agree that reporting hospitals traditionally do not spend much time compiling the information which you receive. However, you accept their data as presented even though your staff acknowledges the hospitals' very flawed data. Perhaps you should consider going to an ASP+ basis for RP reimbursement. This approach seems to work with the complex medical oncology infusion products.

As you know, RP supplies often have a measurable and short half-life. This requires our PET/CT Center has to use it or lose it. Your current proposal doesn't recognize this obsolescence element of our operations. The long shelf-life of most contrast agents differ sharply from our two hour half-life of FDG or the 8 second half-life of Rubidium.

Three years ago, our PET/CT Center borrowed $3.5 Million to provide this valuable imaging service to San Diego. At that point, none of our local hospitals were willing to risk their money to create a PET/ CT Center with these diagnostic capabilities. If you complete these reimbursement reductions without any changes, all of my colleagues agree that they should have been far more cautious before entering this business.

PET/CT providers have some materially different situations from other nuclear medicine providers. We are very few in number compared to CTs, MRs, nuclear cameras, we have far higher entry costs, and we now face proposed CMS reimbursement cuts which are bigger than every other modality.

Getting 50 cents on our prior collection of $1 over a 13-month period far exceeds the largest reimbursement cuts of any other imaging modality.

Please seriously consider giving us some relief, even if it is temporary.

Sincerely yours,

Robert T. Jetland

President and Owner

CMS-1392-P-886 **Medicare**

Submitter : **Mr. Don Sipes** **Date & Time: 09/13/2007**

Organization : **Saint Luke's Health System**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

See Attachment

#886

Saint Luke's Health System
saintlukeshealthsystem.org

September 13, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: 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 (Vol. 72, No. 148), August 2, 2007.

Dear Mr. Weems:

Thank you for the opportunity to comment on the proposed rule cited above (CMS-1392-P). I submit these comments on behalf of Saint Luke's Health System (SLHS) in the Kansas City Metropolitan Region. SLHS consists of eleven hospitals, several physician groups, and other medical services organizations in both Missouri and Kansas. Of the eleven hospitals, three are Critical Access Hospitals (CAHs): Anderson County Hospital in Garnett, Kansas; Hedrick Medical Center in Chillicothe, Missouri; and Wright Memorial Hospital in Trenton, Missouri. On behalf of these three hospitals, I write to specifically address the "Proposed Changes Affecting CAHs."

Necessary Provider CAHs

CMS proposes to clarify that if a CAH operates a provider-based facility or a psychiatric or rehabilitation distinct part unit that was created after January 1, 2008, it must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital, or 15 miles in the case of mountainous terrain or secondary roads. CMS is of the opinion that the necessary provider CAH designation cannot be considered to extend to any facilities not in existence when the CAH originally received its necessary provider designation from the state. If a necessary provider CAH violates the requirement in this proposed rule, CMS would terminate its provider agreement, unless the CAH corrected the violation or converted to a hospital paid under the prospective payment system (PPS).

It is our opinion that this rule will impede the ability of a CAH to provide quality and accessible health care services to rural citizens now and in the future. Limiting a CAH from operating a provider-based entity or a psychiatric or rehabilitation distinct part unit created after January 1, 2008 by imposing the CAH distance requirement would directly impact the care received for rural America. It is unclear why CMS would propose such broad and excessive language. SLHS concurs with the Kansas Hospital Association, the

Missouri Hospital Association, and the American Hospital Association when they state they do not believe the proposed language is necessary or beneficial to the rural residents of America. Furthermore, while CAHs are reimbursed differently than their PPS counterparts for inpatient and outpatient services, there are no differences in payment between CAH and PPS psychiatric and/or rehabilitation units. In addition, the ability of a CAH to create or acquire an off-campus location does not pose an unfair market advantage compared to its neighboring hospitals. This proposed rule could potentially put CAHs at a distinct disadvantage compared to their PPS counterparts.

If CMS moves forward and implements this policy, it may have broader affects on community access to care than CMS anticipates. CAH provider-based entities are located in different places for various reasons often unrelated to where the next hospital is located. Hospitals consider such factors as available land, natural boundaries, increased need, preference of physicians and other practitioners. While community members may be willing to travel a distance to a hospital for urgent/emergent care or services not available elsewhere, beneficiaries want something closer to home for more routine visits, therapy, lab work, and other essential services. By forcing CAHs to have all services on-campus, CMS will be creating geographical bare patches that leave some community members without access to services.

Clinics and distinct part units are often a way for CAHs to recruit physicians to rural areas. By hiring a physician at one of the CAHs' provider-based entities, the CAH guarantees that there is a physician in the area to serve on the medical staff. There are small communities throughout Kansas and Missouri within 35 miles of a CAH that would have no physician without these provider-based entities. As older physicians retire or younger physicians relocate, the ability to set up a rural health clinic would be critical to the continuation of basic medical care in rural areas. The hospitals that would be impacted by this rule are small and rural by their nature and are most likely already experience difficulties recruiting and retaining physicians. CMS should not make more difficult for CAHs to recruit and retain needed personnel.

It is also unclear whether the "grandfather" provision would allow provider-based entities to relocate to nearby areas in the future or be forced to remain in antiquated facilities. Some CAHs are operating provider-based entities in very old buildings that need to be replaced, which often means relocation. CAHs should not be discouraged from replacing these entities in order to improve patient safety and quality of care, and make upgrades in technology. Forcing physicians to continue to practice in outdated units and clinics could drive these vital health care professionals to other locations.

Many CAHs are in the middle of planning or actively constructing new facilities. The financial viability of these projects revolves around provider-based status. Officially changing this requirement and setting a January 1 implementation date is neither reasonable nor feasible.

We respectfully ask CMS to rescind this proposal. It is contrary to the stated intention of the rule "to ensure access to essential health care services for rural residents."

Additionally, this policy would make physician recruitment and retention in rural areas even more difficult, thus jeopardizing access to healthcare services in rural locations.

Thank you for your consideration. If you should have questions regarding these comments, please do not hesitate to contact me or Jodi Faustlin, Director, Public Affairs, at 816-932-8160.

Sincerely,

Don Sipes
Vice President, Regional Services
Saint Luke's Health System
(816) 532-7765

CMS-1392-P-887 **Medicare**

Submitter : **Mr. John Rivers** **Date & Time: 09/13/2007**

Organization : **Arizona Hospital and Healthcare Association**

Category : **Hospital**

Issue Areas/Comments

ASC Impact

See attached letter

Cardiac Rehabilitation Services

See attached letter

Necessary Provider CAHs

See attached Letter

New HCPCS and CPT Codes

See Attached letter

OPPS Impact

See attached letter

Observation Services

See attached letter

Packaged Services

See attached letter

Packaging Drugs and Biologicals

See attached letter

#887

September 11, 2007

Mr. Herb B. Kuhn
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital OPPS and CY 2008 Payment Rates

Dear Mr. Kuhn,

Thank you for the opportunity to comment on the proposed outpatient prospective payment system (OPPS) rule for CY 2008. I submit these comments on behalf of the Arizona Hospital and Healthcare Association (AzHHA). AzHHA and its members are concerned about the negative several of the proposed provisions will have on the ability of hospitals to care for Medicare beneficiaries. These provisions include: (1) changes to the Critical Access Hospital Conditions of Participation; (2) changes to cardiac rehabilitation billing; (3) payment for medical devices; (4) observation services; and (5) payment for drugs and biologicals.

Critical Access Hospital Medicare Conditions of Participation

One and half million Arizonans who reside in rural areas of the state receive healthcare services from approximately twenty-five sole community and critical access hospitals (CAHs), exclusive of tribal and Indian Health Service facilities. These services are spread over nearly 100,000 square miles. Because of the large distances between Arizona's rural healthcare providers, this population is particularly vulnerable to reductions in services. For this reason, it is imperative that the Centers for Medicare and Medicaid Services (CMS) continue to support the services provided by CAHs and not place these hospitals in jeopardy. To our dismay, this is exactly what the proposed CY 2008 OPPS changes would do.

Under the proposed regulation, a CAH-operated provider-based facility or a psychiatric or rehabilitation distinct part unit that was created after January 1, 2008 must comply with the CAH distance requirement of a 35-mile drive to the nearest hospital (or 15 miles in the case of mountainous terrain or secondary roads). If a necessary provider CAH violates this requirement, CMS would terminate its provider agreement. This could be avoided if the CAH corrected the violation or converted to a hospital paid under the PPS.

Because access to primary care is particularly limited in rural Arizona, 55 areas have been designated as primary care health services shortage areas, 33 of which have a score of greater than 14. Arizona CAHs have responded to the needs of their communities by providing -- in many cases -- the only primary care available. Under Arizona law, these primary care clinics are licensed as outpatient treatment centers (OTCs) and operate federally as rural health clinics (RHCs). Without the provision of these primary care and other OTC services, Medicare beneficiaries in rural Arizona would be required to travel many miles to receive treatment, placing their health at risk.

The changes proposed by the CY 2008 OPPS regulation will negatively impact Medicare beneficiaries by disincentivizing CAHs from building or replacing necessary satellite facilities. While it appears the intent of CMS is to address market saturation and infringement with respect to necessary provider CAHs, the regulations may have unintended consequences. At this point it is not clear whether the regulation applies to RHCs, whether it applies to on-campus clinics of a necessary provider CAH, and whether all CAHs are subject to the regulation, if they open up a clinic within 35/15 miles of another hospital.

We strongly urge CMS to eliminate the CAH provider-based facility restrictions of the proposed regulation or alternatively clarify that these do not apply to RHC, on-site facilities or non-necessary provider CAHs.

Cardiac Rehabilitation

CMS proposes billing cardiac rehabilitation services in hourly increments, as opposed to the current per session increments utilized since the mid-1980s. The current CPT codes will be replaced by G codes representing one hour of service. We are specifically concerned that the descriptor used for the new G codes, "Physician service, cardiac rehab with (and without) ECG monitoring," could be

misinterpreted by Medicare contractors as requiring a physician to directly deliver the care or be in attendance during each service episode. Medicare administrative contractors and fiscal intermediaries could use this interpretation to develop restrictive policies requiring the physical attendance of a physician during the delivery of care, similar to requirements imposed by Medicare in the past, and which have been recently revised.

AzHHA is also concerned with the implementation costs that providers could incur. Many hospitals' billing software only facilitates the creation of one set of billing parameters for each procedure. Because many managed care payers will not accept Medicare's G codes or hourly billing, but will continue to require providers to report per session with CPT codes, hospitals will need to bill Medicare differently than other payers. This could result in the need to manually change claims before billing and increase the likelihood of billing errors, potentially causing problems with denials from secondary payers who do not model CMS billing practices.

We urge CMS to clarify that the proposed regulations does not require the physical attendance of a physician during the delivery of care. In addition, we urge CMS to consider an alternative to changing billing regulations solely for the purpose of gathering informational data when the current method has been in place for such a long time and has remained stable and reliable.

Payment for Medical Devices

CMS proposes a reduction in APC payment and beneficiary co-payment when hospitals receive a partial credit toward the replacement of a medical device listed in Table 39 of the proposed rule. Payments for these APCs would be reduced by half of the amount of the offset that would apply if the device were replaced at no cost or with full credit. This policy would apply only if the amount of the device credit is at least 20 percent of the cost of the new replacement device.

In its summary statement of the rule, CMS argues that "this policy is necessary to pay equitably for these services when the hospital receives a partial credit for the cost of the device being implanted." AzHHA strongly disagrees with the statement that this rule would "pay equitably" for services. Although this change would positively impact Medicare and possibly some providers, it would be detrimental to providers who typically receive a large number of cases with credits ranging near 20 percent.

Moreover, there is virtually no data available to providers regarding the number of devices this rule could affect annually. Providers are unable to compare their own data with national averages to identify areas with higher frequencies of device failure or other discernable negative patterns, which could potentially help providers choose a device that would be beneficial for the patient and cost effective on a long term basis.

We are also concerned about the different reporting requirements for outpatient and inpatient device credits. The rule proposes partial credits of 50 percent or greater for inpatient devices and partial credits of 20 percent or greater for outpatient devices. Creating a system to identify credits correctly according to patient type will be operationally difficult. Among our concerns is the risk for reporting errors due to differences in the minimum percentage of credit required to be reported based on patient type. There is little time to evaluate and modify current systems used for implementation of the full device/no cost rule instituted for the CY 2007 OPPS.

We urge CMS to publish any data specific to the number of cases reported nationally since the 2007 rule became final, to consider increasing the OPPS final rule to equal the inpatient rule of reporting reduced costs of 50 percent or greater with the FB modifier for CY2008, and to evaluate the effects of this change before instituting the 20 percent requirement.

Observation Services

CMS proposes packaging payment for all observation care, reported under HCPCS code G0378 (Hospital observation services, per hour), into the separately payable services with which they are billed. CMS believes packaging observation services would help address its concerns about increased OPPS spending. CMS has also expressed concern that the current criteria for separate payment for observation services, which requires that observation services must last a minimum of 8 hours, provides disincentives to hospitals to make timely decisions with regard to patients' placement after observation care ends. CMS believes that packaging would contribute to more efficient use of observation services and improve the flow of patients through emergency departments.

While AzHHA understands CMS' concern with billing under observation code G0378 and the desire for more efficiency, we disagree with the decision to package all observation services provided under HCPCS code G0378. There are many patients who meet the guidelines for continuous observation monitoring, and for whom hospitals will receive reduced payments for their care and treatment.

AzHHA urges CMS to reconsider its decision to institute packaging of observation in cases of care extended beyond 24 hours for patients who do not meet Interqual criteria for inpatient admission, but who continue to exhibit symptoms which could be associated with a life threatening condition that would prevent the hospital from safely discharging the patient.

Payment for Drugs and Biologicals

CMS proposes that hospitals report pharmacy overhead charges to provide data for possible future payment changes. Hospitals would be required to remove the overhead cost from the price charged for drugs and biologicals and report it on a separate revenue code line. The policy would apply to all drugs, biologicals, and contrast agents irrespective of the item's packaged or separately payable status for CY 2008.

AzHHA is concerned about the requirement to report overhead as an uncoded revenue code line. We request CMS to clarify the meaning of "un-coded revenue code line." Does CMS intend providers to bill with two separate lines on the UB04 for "each medication", "total overhead" per claim, or "total overhead per day" for claims with multiple dates of service? Billing multiple lines could create claims with several pages just for pharmacy for Medicare outpatients who receive multiple medications that span several dates of service. This also presents the issue that most billing software is limited in the number of billable lines per claim. Additionally, hospital's Charge Description Masters (CDM) would need to reflect these changes in reporting overhead costs, requiring that each charge in the CDM with associated overhead would have to be modified to comply with the two line requirement. Considering the size of these areas, this would also be a large undertaking for completion before the 2008 implementation.

AzHHA urges CMS to eliminate the proposed reporting requirements for pharmacy overhead charges or alternatively delay implementation so that hospitals have time to put appropriate systems in place.

Conclusion

In summary, AzHHA commends CMS for their efforts to provide accurate claims payments to providers and supports CMS in reducing Medicare spending identified as incorrect or wasteful. But we urge CMS to further consider the implications of making the proposed changes. The number of changes in this rulemaking, including the recalculated wage index, restructured APC payments, packaged services, additional bundled procedures, and quality reporting requirements would result in a 2 percent market basket reduction for CY2009 for those providers who fail to comply. Additionally, we are concerned with the limited amount of time providers will have to implement and evaluate the needed modifications prior to the January 1 effective date. Several Arizona hospitals have conferred with vendors and operational system directors and determined that completing modifications to meet CMS' requirements would be very difficult and would leave little time for testing prior to implementation. They also project significant additional labor costs related to the changes.

We urge CMS to consider the complicated modifications and the financial cost the proposed rule could cause providers and their ability to continue to provide patient care in compliance with CMS standards. We further ask CMS to reconsider proposing all of the proposed changes for CY2008 with effective dates of January 1st, and to allow providers more time to complete modifications, upgrade systems, and implement and evaluate processes that will ensure their ability to comply with Federal Standards.

We appreciate the opportunity to comment on the proposed rule. If you have any questions or would like further information regarding our comments, please call me.

Sincerely,

John R. Rivers, FACHE
President and Chief Executive Officer

CMS-1392-P-888 **Medicare**

Submitter : **Ms. Karla Ashenhurst** **Date & Time: 09/13/2007**

Organization : **Ministry Health Care**

Category : **Critical Access Hospital**

Issue Areas/Comments

Necessary Provider CAHs

September 13, 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:

Ministry Health Care, located in the states of Wisconsin and Minnesota, officially submits comments on the above CMS proposed rule. Specifically, the proposed rule could have a negative impact on Critical Assess Hospitals located throughout our rural health system. The mission of Ministry Health Care is provide access and care to the poor and underserved.

In our rural areas, significant patient populations are those who are elderly covered under Medicare. Limiting Critical Access Hospital off-site clinic locations would inhibit our mission to provide access and care to the poor and underserved.

Specifically, we are seeking withdrawal of the provision of the draft rule pertaining to off-site clinics operated by the Critical Access Hospitals. As part of our integrated delivery of care, our Critical Access Hospitals may also include off-site clinics and other services. We consider this off-site patient access necessary for the continuum of care to serve our elderly patients.

The following Ministry Health Care facilities are designated as Critical Access Hospitals:

Wisconsin:
Door County Memorial Hospital (Sturgeon Bay)
Our Lady of Victory (Stanley)
Good Samaritan Health Center (Merrill)
Eagle River Memorial Hospital (Eagle River)
Sacred Heart Hospital (Tomahawk)
Calumet Medical Center (Chilton; co-sponsored by Wheaton Franciscan Healthcare, under the Affinity Health System)

Flambeau Hospital (Park Falls; co-sponsored by Marshfield Clinic)

Minnesota:
Saint Elizabeth□s Medical Center (Wabasha)

Respectfully submitted,

Karla Ashenhurst
Director of Government Affairs
Ministry Health Care
11925 West Lake Park Drive
Milwaukee, WI 53224
ashenhuk@ministryhealth.org

CMS-1392-P-889 **Medicare**

Submitter : **Mr. Jerry Stringham** **Date & Time: 09/13/2007**

Organization : **Medical Technology Partners, Inc.**

Category : **Device Industry**

Issue Areas/Comments

Device-Dependent APCs

Please see attachment.

MEDICAL TECHNOLOGY PARTNERS

#4489

September 15, 2007

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

Ref: 2008 OPPS Proposed Rule (CMS–1392–P)

Dear Administrator Weems:

This letter is in response to the Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule for CY 2008. This comment focuses on HCPCS codes 36566 (Insertion of tunneled centrally inserted central venous access device, requiring two catheters via two separate venous access sites; with subcutaneous port(s)) and device code C1881 (Dialysis access system (implantable)).

CMS proposes to keep HCPCS 36566 as a device-dependent APC with C1881. The device-dependent methodology has been a critical addition to CMS' payment setting process. Medical Technology Partners supports requiring facilities to bill C1881 in conjunction with 36566.

However, Medical Technology Partners is concerned that the short procedure description for 36566 and the description of C1881 are vague and could lead to hospitals miscoding claims. For example, the long and short descriptions for 36566 are as follows:

HCPCS	Long Description	Short Description
36566	Insertion of tunneled centrally inserted central venous access device, requiring two catheters via two separate venous access sites; with subcutaneous port(s)	Insert tunneled cv cath

This short description is identical to six other procedures (36557, 36558, 36560, 36561, 36563, 36565). We request that CMS consider changing the short description for 36566 to read "Ins tunneled cath w/subq port."

In addition, the description for C1881 is "Dialysis access system." Since the only indication that is accepted for device-dependent status for C1881 is for a system with a subcutaneous port or valve, we believe that more accurate coding and payment will be achieved if CMS changes the description for C1881 to read "Dialysis access system with subcutaneous port or valve."

Medical Technology Partners strongly believes that such changes will not only lead to more accurate rate setting, but also better ensure proper payment by CMS. We would encourage the HAPG to support the creation of clearer short procedure and device descriptions.

9700 Great Seneca Highway, Rockville, Maryland 20850 • 240-453-0550 • (f) 443-583-2476

Medical Technology Partners applauds the use of correctly coded claims for rate setting purposes. This policy has corrected many of the inequities in the rate setting process. We also believe that using externally supplied information as a benchmark for reasonable payment is a valuable exercise when payment is significantly out of the range of realistic. If the benchmark analysis is considerably off, rather than revising the level, CMS could consider whether there is a methodological fix, such as removing claims where the RCC is clearly incorrect. Medical Technology Partners noted an RCC of approximately 10 percent in several claims containing both 36566 and C1881.

Medical Technology Partners agrees with CMS that year-to-year variation will be greater in lower volume device-dependent APCs than in higher volume procedures. Medical Technology Partners believes that the 2007 payment for 36566 was adequate for this procedure, considering the known $3,500 price from the only FDA-cleared technology in 2006.

Medical Technology Partners agrees that there are important advantages to using internal data; however we encourage CMS to consider placing dampers on changes to low volume APCs, provided there is a reason to believe that substantial over- or under-payment is proposed without these dampers. We would support a reduction in proposed 2008 payment based upon such a methodology. We believe that such dampers would be limited to a small number of low volume APCs but provide important protection for the Medicare trust fund and beneficiary access to critical medical procedures.

Partial Credit Offset

In the proposed rule, CMS proposes to reduce payment for replacement devices when the manufacturer provides credit for the device. Medical Technology Partners supports this recommendation.

Payment for Device-Dependent APCs in Ambulatory Surgery Centers

MTP supports a methodology that recognizes that ASCs pay the same price for devices as hospitals. While inadequate, the proposed transitional payment of $4,204 for HCPCS 36566 is a step forward in realistically offering this procedure to beneficiaries in the ASC setting.

Please feel free to contact me if you have any questions or if you require additional information.

Sincerely,

Jerry Stringham

Jerry Stringham
President

CMS-1392-P-890 **Medicare**

Submitter : **Dr. Peter Kasprzak** **Date & Time: 09/13/2007**

Organization : **Quail Surgery Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

See Attachment

#890

Peter J.Kasprzak, M.D.
Quail Surgical and Pain Management Center
6630-C South McCarran Boulevard
Reno, Nevada 89509
September 12, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: **Comments on CMS-1392-P; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (High – Energy Extracorporeal Shock Wave Therapy)**

Dear Sirs:

I believe that I am uniquely qualified to comment on the use of extracorporeal shock wave technology (ESWT) for the treatment of Lateral Epicondylitis and Plantar Fasciitis. I am an anesthesiologist, the medical director of a surgery center, and have personally undergone ESWT treatment for Plantar Fasciitis of my right foot.

Studies show that the efficacy rates of high energy ESWT are greater and better patient outcomes are achieved, when patients are treated with the appropriate high energy level. Treating with the proper high energy level, typically results in the patient requiring only a single treatment. However, it is difficult if not impossible, for patients to tolerate sufficient energy levels to achieve maximum clinical efficacy without general anesthesia, which can only be safely administered in a facility such as a hospital or ambulatory surgical center (ASC).

It is not safe for a patient to receive general anesthesia in an office setting, especially for Medicare aged patients who often have multiple co-morbidities. Patient safety is better assured in an operating room setting with the appropriate monitoring, personnel and equipment. Performing high energy ESWT in a physician office allows for too many different treatment protocols (inappropriate low energy levels) with varying clinical outcomes. Since patients are unable to tolerate the recommended higher energy levels of ESWT without general anesthesia, this ultimately increases costs to the Medicare program due to ineffective and multiple repeat procedures.

I urge the Centers for Medicare and Medical Services not to adopt the proposed Payment

Indicator for High-Energy ESWT for plantar fasciitis. Although the final rule on ASC payments recognizes the appropriate site of service as a facility setting, the proposed 2008 payment schedule suggests that the procedure is performed mostly in the physician office setting, which I believe to be incorrect. Further, unless the appropriate payment indicator is recognized, Medicare beneficiaries will be denied access to highly effective treatment. Therefore, I request the agency to retain the Payment Indicator (G2) for CPT code 28890, as published in the final 2008 ASC rule.

Sincerely,

Peter J. Kasprzak, M.D.

CMS-1392-P-891 **Medicare**

Submitter : **Dr. Vijay Singh** **Date & Time: 09/13/2007**

Organization : **Pain Diagnostics Associates**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

See Attachment

#891

September 13, 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, 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.

I am also 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 to 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 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 would result in 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 payment 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,

Vijay Singh, MD
1601 Roosevelt Rd
Niagara, WI 54151

CMS-1392-P-892 **Medicare**

Submitter : **Dr. J. Gregory Cox** **Date & Time: 09/13/2007**

Organization : **Dr. J. Gregory Cox**

Category : **Physician**

Issue Areas/Comments

GENERAL

See Attachment regarding CMS-1392-P

#892

J. Gregory Cox, M.D., Inc

4140 W. Memorial Rd, Ste 408, Oklahoma City, OK 73120

September 16, 2007

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

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

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

Dear Deputy Kuhn:

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

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

I welcome CMS' proposal to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43 and the recognition that it belongs with other image guided therapies. It shares many similarities with these procedures both clinically and in terms of resources required:

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

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

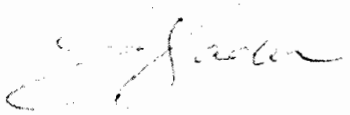
I recommend that CMS consider assignment of 0071T and 0072T to APC 0127, Level IV Stereotactic Radiosurgery, which would permit appropriate payment for the extensive treatment planning. Level IV Stereotactic Radiosurgery assignment would permit MRgFUS to be classified into an APC with similar clinical and resource homogeneity.

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

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

Respectfully,

J. Gregory Cox, M.D.



Signed by Erin Vaden for J. Gregory Cox, M.D.

CMS-1392-P-893 **Medicare**

Submitter : **Dr. Chandur Piryani** **Date & Time: 09/13/2007**

Organization : **Pain Diagnostics Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

See Attachment

#893

September 13, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

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Lastly, I ask CMS to 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.

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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 will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize

program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

Approximately 25 to 30 percent of all the neurostimulator implant procedures performed each year are required to replace a depleted, non-rechargeable battery. Thus, in the long term, the use of rechargeable devices likely would result in cost savings to the Medicare program and beneficiaries due to the decreased need for battery replacement procedures. The need for fewer surgeries also would reduce the chances that patients will experience operative complications such post-operative infection or other possible co-morbidities.

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Thank you for your consideration of my comments.

Sincerely,

Chandur Piryani, MD
1601 Roosevelt Rd
Niagara, WI 54151

CMS-1392-P-894 **Medicare**

Submitter : **Dr. Katherine Liao** **Date & Time: 09/13/2007**

Organization : **Pain Diagnostics Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

See attachment

#894

September 13, 2007

Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1392-P

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- Maintain non-rechargeable neurostimulator procedures in APC 0222.

Thank you for your consideration of my comments.

Sincerely,

Katherine Liao, MD
1601 Roosevelt Rd
Niagara, WI 54151

CMS-1392-P-895 **Medicare**

Submitter : **Ms. Barbara Marone** **Date & Time: 09/13/2007**

Organization : **American College of Emergency Physicians**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

See Attachment

#895

American College of
Emergency Physicians
ADVANCING EMERGENCY CARE

September 13, 2007 **Attention: CMS-1392P**

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

RE: CMS-1392-P: Medicare Program: Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates

Dear Mr. Weems:

On behalf of the American College of Emergency Physicians (ACEP), I am pleased to submit comments on the proposed rule for the Hospital Outpatient Prospective Payment System for Calendar Year 2008, published in the Federal Register on August 2, 2007. ACEP is a national medical specialty society with more than 25,000 members, dedicated to improving the quality of emergency care through continuing education, research, and public education. We appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our comments on outpatient hospital payment policy and its effects on the delivery of emergency medicine services.

WASHINGTON D.C. OFFICE
2121 K Street, NW
Suite 325
Washington, D.C. 20037-1801

202-728-0610
800-320-0610
202-728-0617 (FAX)
www.acep.org

Observation Services

ACEP strongly opposes CMS' proposal to bundle observation services for all diagnoses and conditions and asks that the observation APC 0039 be maintained until more data has been collected and analyzed. We understand that the program is under pressure to reduce the rate of cost growth, but growth of this code may represent best practice use of medically necessary services that improve patient quality and safety and avoid inpatient admissions. We do not believe that bundling observation meets the definition of "value" and will not "encourage(s) hospital efficiency." To the contrary.

First, the fundamental requirement for packaging is not present in observation. Packaging a service can only be reasonable when certain requirements are met:

- Consistency within the APC in which it is packaged. There is no evidence that the use of observation services is consistent across emergency department APCs. For example, for an ED visit associated with APC 616/HCPCS 99285, departments across the country vary in terms of what percent of visits in that APC are observed. CMS' data shows that 12 percent of 99285 ED visits included observation. If these services are bundled, some hospitals will be overpaid and those with designated observation units will be underpaid.

- Consistency across all hospitals. The use of observation services is not consistent across U.S. hospitals. For example, the percentage of ED patients observed following an ED visit may vary from 1% to 10% based on the case mix and acuity.

- A service for which use is compulsory and without alternatives. Packaging observation care is inadvisable because there are less cost effective alternatives to the

use of observation. CMS previously used the example of packaging anesthesia payment with an outpatient surgical procedure. This makes sense since anesthesia must always occur with a surgical procedure. Observation is fundamentally different because a substantial portion of observation patients could alternatively be admitted as inpatients.

The 2006 Institute of Medicine (IOM) Report *Hospital-Based Emergency Care: At the Breaking Point* made a clearly worded recommendation to CMS to expand the use of observation units and make separate payment for all conditions where observation is clinically indicated. CMS' own APC Advisory Panel has repeatedly recommended expanded use of diagnoses and conditions for separately paid observation over the past three years, including at its most recent meeting September 5-6, 2007. CMS acknowledges that separate observation payment (APC 0339) is currently made only for three diagnoses/conditions, but inexplicably rejects recommendations made by both the IOM and CMS'APC Advisory Panel experts. The only form of separately paid observation proposed is for direct admits which seems to encourage the type of passive observation that CMS seeks to avoid.

CMS' rationale that 70 percent of observation services are already bundled warrants bundling the rest begs the question of the type of patients that clearly benefit from active monitoring before discharge or inpatient admission. According to the CDC's Emergency Department Survey Report released in June, 2007, over 115.3 million visits were made to the nation's EDs in 2005 and 14.5 percent of visits were by persons age 65 years and older. Put another way, 51 out of every 100 Medicare beneficiaries had at least one visit to the ED and the leading diagnosis for ED patients age 65 and over was heart disease and/or chest pain. These statistics alone should provide ample support for the benefits of a paid observation unit from a patient safety, quality, and overall system efficiency standpoint.

When CMS points out "we recognize that use of observation may play an important role in the treatment of many Medicare beneficiaries,... decreasing the need for short inpatient admissions and ensuring safe discharges..." one would expect the logical extension of this statement would be to increase opportunities to closely monitor patients in a dedicated unit. Model observation units could serve as testing grounds for best practices to avoid unnecessary short stay admissions, another issue of great interest to the government in its pursuit of value-based purchasing. Instead, packaging observation is likely to provide incentives for hospitals to admit patients rather than incur the revenue losses likely to arise as a result of such packaging.

At the same time, CMS proposes to require hospitals to continue to document observation data. After many years of analyzing Medicare claims, CMS knows all too well that when a service is unfunded, claims data are unreliable. It seems as if this proposal was based solely on the significant growth in use of observation without any analysis as to whether growth of this service is appropriate, good for patients, and encouraging of hospitals to maintain well-staffed observation units where patients can be actively managed. Further, with staff in constant attendance, patients are much more likely to be discharged in a more timely fashion.

Observation services have been studied by clinical researchers. Seven random clinical trials have shown observation-eligible patients managed as inpatients have twice the cost and length of stay of those actively managed in an observation unit, and a study conducted by Cook County Hospital and Rush Medical School in Chicago found that among the 7500

patients admitted to the dedicated observation unit over a three-year period, 85 percent were discharged within 23 hours. Total inpatient admission fell by a similar number. [1]

When queried publicly, CMS acknowledges that it lacks the ability to look across its payment systems to analyze the overall impact in policy changes in delivery of services. What results is a constant migration of services and expenditures across payment silos without much evidence of overall Medicare savings or system efficiencies.

It is also clear that this policy could well lead to an increase in inpatient admissions at the same time that other groups within CMS - Quality Improvement Organizations (QIOs), Recovery Audit Contractor demonstrations, and the OIG are targeting one-day and short stay admissions and encouraging physicians and hospitals to use more observation. For example, the Texas QIO published a set of frequently asked questions about observation that defines appropriate use of observation as: (services) "for any patient who doesn't require more than 24 hours of in patient service:
Q: Under what circumstances is use of outpatient observation appropriate?
A: Use of outpatient observation is appropriate when:

1. The physician is unsure about the patient's need for inpatient admission and requires additional time to evaluate the patient;
2. The physician anticipates that the patient's condition can be evaluated/treated within 24 hours and/or rapid improvement of the patient's condition can be anticipated within 24 hours."
   (February 2006)

Finally, a policy change that will cause hospitals to reevaluate their business decisions to maintain observation units with higher nurse staffing ratios will inevitably result in more patients remaining in the ED. CMS' tacit requirement that ED physicians and staff add observation patients to overflowing EDs in addition to boarders waiting for inpatient beds, while trying to keep up with sheer numbers of patients who fill the exam and waiting rooms is an extremely misguided policy with potentially serious quality and patient safety implications.

In sum, ACEP urges CMS to rescind its proposal to bundle all observation services. We believe that CMS should continue to provide separate payment for observation services provided to patients with congestive heart failure, asthma and chest pain and add both syncope and dehydration to the list of conditions for which observation care would be separately payable, as recommended by the APC Advisory Panel.

Proposed Hospital Coding and Payments:
Emergency Department Visits

For CY 2008, CMS proposes to maintain the current distinctions between Type A and Type B emergency department visits in order to collect sufficient data on costs "in order to determine in the future whether a proposal of an alternative payment policy might be warranted" (possibly for 2009). Effective for 2007, CMS imposed a coding and payment distinction between Type B emergency departments that meet the EMTALA definition of emergency department but not the more restrictive CPT definition, which requires, among

[1] Martinez, Reilly, et al. The Observation Unit: A New Interface between Inpatient and Outpatient Care. The American Journal of Medicine. March 2001.

other things, 24-hour per day service. Services provided in Type B facilities would be paid at the five clinic APC rates, while Type As will be paid via five ED APCs.

We continue to believe that hospital-based EDs are more costly to operate than clinics and urge CMS to make a timely proposal in 2009 with respect to payment for Type B facilities. While the Type A and Type B distinction is tenuous, CMS' interpretation of EDs that operate fast tracks stretches credulity. In response to a question raised by a commenter last year about EDs that operate fast track areas, CMS opined that if a "hospital maintains a separately identifiable area or part of a facility which does not operate on the same schedule (that is, 24 hours per day, 7 days a week) as its emergency department, that area or facility would not be considered an integral part of the emergency department... and that facility or area would be evaluated separately to determine whether it is a Type A emergency department, Type B emergency department, or clinic."

ACEP objects to both the concept and the reporting burden this requirement imposes. With regard to fast tracks, we propose that if the service is provided in the hospital ED that has a common triage area, it should be paid at Type A visit rates regardless of the hours that the fast track is open. Discussions with numerous emergency physicians who work in hospitals with fast tracks say that many patients originally triaged to fast tracks actually require high intensity care, not infrequent inpatient admissions, and significant amounts of hospital resources. The cases do not fall neatly into lower level or non-emergent services and CMS is making what could be an erroneous presumption that they do. Further, the fast track beds are almost always available 24/7 based on patient demand. Taken together with this year's observation bundling proposal, it appears that CMS is attempting to thwart all attempts on the part of hospitals and emergency physicians to improve patient through-put, timeliness, safety, and quality.

Proposed Hospital Coding and Payments:
Visit Reporting Guidelines

After six years of study, CMS has not yet finalized its ED visit facility reporting guidelines. While continuing to cite concerns with the accuracy of guidelines developed by ACEP or the American Hospital Association/American Health Information Management Association, CMS is now considering maintaining the status quo. Results of claims analysis from 2002 through 2006 have shown a normal distribution of visit levels that has been stable for the entire period. Therefore, the current system that allows hospitals to develop their own guidelines appears to be working, so the urgency to select and implement new guidelines has waned.

As ACEP has stated each year, we are prepared to work with CMS and the AHA/AHIMA, and any other group working with CMS in the development of guidelines that will lead to accurate and reliable coding for ED visits. We believe that last year's addition of two more ED payment categories was a positive move that will continue to support a stable distribution of visit levels.

Proposed Hospital Outpatient Measures

ACEP generally supports CMS' draft measures, but we believe that some of the reporting requirements with transfer measures may redundant in light of long-standing EMTALA requirements. We offer specific recommendations on the following measures.

ED–AMI 4: Median Time to ECG. ACEP supports this measure with the recommendation that it be modified to be focused on time to interpretation, i.e.: "Median time to ECG Interpretation." Reporting median time is problematic when combined with public reporting as there is no evidence that a specific time to an ECG is better than another amount of time. For example, although faster treatment is better for STEMI (ST-Elevation Myocardial Infarction), it is questionable as to whether an 8 minute median time is truly better than a 10 minute median time. As written, the measure could lead to overuse. Additionally, by having a large denominator (chest pain) it is possible that an institution could have a good result overall but be slow for STEMI, which is essential.

ED–AMI 5: Median Time to Transfer for Primary Percutaneous Coronary Intervention (PCI). ACEP supports this measure with the recommendation that it be modified to focus only on STEMIs. This measure has most direct impact on these patients and has great potential for quality improvement. While the measure raises system wide logistical issues that are out of the control of the hospital, the measure could be made more manageable if modified to focus only on STEMIs, where faster time to transfer is critical to improving outcomes.

EC-01: ECG for Patients with Non-Traumatic Chest Pain. ACEP supports this measure with the recommendation that the terms "atypical chest pain" and "chest pain" be removed. The chest pain inclusions are too broad—often emergency physicians use these diagnoses for low risk groups where the true diagnosis is not yet known, and because of their risk profiles an immediate ECG or aspirin are not indicated.

We appreciate the opportunity to offer these comments and we look forward to continuing to work cooperatively with CMS in order to address these important issues. If you have any questions about our comments and recommendations, please contact Barbara Marone, ACEP's Federal Affairs Director at (202) 728-0610, ext. 3017.

Best wishes,

Brian F Keaton MD

Brian F. Keaton, MD, FACEP
President

CMS-1392-P-896 **Medicare**

Submitter : **Ms. Ruth Tesar** **Date & Time: 09/13/2007**

Organization : **Nothern California PET Imaging Center**

Category : **Individual**

Issue Areas/Comments

PET/CT Scans

see attachment

#896

To: Centers for Medicare and Medicaid Services
Attention: Docket ID CMS – 1392 – P

From: Ruth Tesar, CEO, Northern California PET Imaging Centers

Re: Comment on Proposed Changes to the Hospital Outpatient Prospective Payment System CY2008

Date: September 10, 2007

The following comments are from Northern California PET Imaging Center, a 501(c)(3) Not-for-profit community benefit organization designated by Medicare as an IDTF. Due to the Deficit Reduction Act, this imaging center is paid via Part B under the HOPPS rate for PET and PET/CT procedures. This center has existed since 1993 by specializing in clinical PET, but also performs clinical research and charity care for patients who are underinsured or uninsured. This center experienced a 40% reduction in payment rates from Medicare. Another decrease would adversely affect a well established center that has been providing a leading edge community benefit PET service since 1992.

The payment rate cut-backs due to the Deficit Reduction Act severely impacted single modality imaging centers, with PET procedures now being paid under the HOPPS rate. Single modality imaging centers do not have the ability to average costs which was one of the foundations of the HOPPS payment system. CMS cannot change the DRA, but it can look critically at a "broad bush" approach to bundling radiopharmaceuticals, or reducing the payment for PET procedure no matter which method CMS wishes to employ.

Over several years, the professional Societies associated with the PET community have communicated with CMS regarding the accuracy of the HOPPS rate for PET. The discussions have not been satisfactory from the PET provider's standpoint as the rates for PET continue to be erroneously low. Unfortunately, when asked by CMS during the proposed rulemaking process, the PET community has not had sufficient hospital based participation to address the sources of error for these rates. Hospitals do not uniformly report costs for PET radiopharmaceuticals as radiopharmaceuticals, sometimes they are bundled into pharmacy, or sometimes reported in various other areas. The errors do not seem to affect the hospitals in the same way this low rate affects non-hospital imaging centers/small businesses.

As I recall from being part of several of the efforts to look at the cost data from CMS and other sources, the data on PET costs had a tremendous variance in the range of costs which would lead me to believe the data is not being collected and/or reported in a consistent, accurate manner.

Unfortunately, the small PET community has fewer resources than CMS and cannot undergo they type of critical data review that is needed to specifically identify the true cost of PET procedures. Much of the cost data from hospitals was obtained by using mobile services where the PET radiopharmaceuticals may or may not have

been included in the service, therefore there could potentially be only a single radiopharmaceutical cost reported for a procedure, perhaps reported in a completely different cost area. At the time of CMS's data collection a large percentage of hospitals still use mobile services for PET and PET/CT procedures. This could be another source for error.

In specifically addressing the bundling of radiopharmaceuticals into the technical portion of the PET/CT scan the short half life of the PET radiotracer makes it unique from other radiopharmaceuticals that can be made on site using a kit, or that can be shipped in an efficient manner due to the longer half-life of the radiopharmaceutical.

Due to the short half life of PET radiopharmaceuticals, availability and cost vary depending on proximity to the cyclotron production facility. The radiopharmaceutical is made in locations central to many PET imaging centers, however the cost of that radiopharmaceutical may vary depending on the proximity of the source of the radiopharmaceutical to the PET provider. Not all providers are close to the source, therefore the price will vary accordingly. It would be extremely difficult to assume that the cost for PET radiopharmaceuticals is uniform across geographic areas, as the bundling of the payment rate would suggest.

Some sites, like ours, own the cyclotron to produce the PET radiopharmaceuticals. The costs are unique, vary with volume and will not be fairly represented if the radiopharmaceutical is bundled with the PET technical portion.

Since the proposed rate/bundling of the cost of the PET radiopharmaceutical decreases the payment for PET procedures so severely, quality centers will not be able to provide the level of service that they strive to provide to Medicare beneficiaries, if at all. The rate proposed does not accurately reflect the cost in non-hospital outpatient imaging centers. If an imaging center can provide PET/CT procedures at that payment level, I would question whether the equipment employed is up to date, or that perhaps corners are being cut to provide a service at that rate.

I would like to recommend that CMS exempt cyclotron produced radiopharmaceuticals that are made "per patient dose" from the bundling proposal.

CMS-1392-P-897 **Medicare**

Submitter : **Dr. C. David Finch** **Date & Time:** **09/13/2007**

Organization : **ProviFlo**

Category : **Physician**

Issue Areas/Comments

GENERAL

See Attachment

#897

ProviFlo
Dr. David Finch, Jr.
PO Box 1325
Clinton, MS 39060
(601) 925-0540

September 14, 2007

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

Ref: 2008 OPPS Proposed Rule (CMS–1392–P)

Dear Administrator Weems:

This letter is in response to the Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule for CY 2008. This comment focuses on HCPCS code 36566 (Insertion of tunneled centrally inserted central venous access device, requiring two catheters via two separate venous access sites; with subcutaneous port(s)) and device code C1881 (Dialysis access system (implantable)).

The technology and procedure described by these codes represent significant improvement over traditional access technologies. The technology is most typically used as a vascular access option for end-stage renal disease (ESRD) patients when there are no suitable access points. In randomized studies, the technology has been shown to provide higher flow rates, to have lower infection rates, and to lead to fewer complications compared to other options for these patients. In many cases, this technology has been life-saving.

For 2007, CMS assigned HCPCS 36566 to APC 0625 with an associated national payment of $5,130. The proposed 2008 rule continues to assign 36566 to APC 0625; however, the payment rate is proposed to increase to $5,562. Device code C1881 is not paid but is currently required to be on claims for future identification and rate setting purposes. Historically, there has been difficulty in ensuring that both 36566 and C1881 are reported together on claims. Attaching payment to proper coding, as has been enacted by CMS, should help improve reporting in the future. We applaud CMS' use of correctly coded claims in establishing payment rates for device-dependent APCs.

Rate-setting methodology continues to be a concern for the technology described by HCPCS 36566. Significant annual variance is likely to occur due to the low number of correctly coded claims and reliance on hospital reported cost data. For example, in the

2006 OPPS data, one hospital billed $8,047 for the implant with cost imputed as $883, or about 11% of cost. While CMS' use of medians helps to counter problems such as this, when the number of claims is small, the error could be quite significant. As CMS points out, this methodology facilitates CMS setting a payment rate based on data that is over- or underrepresented in any given year, meaning that the associated payment will be higher or less than the actual appropriate amount. According to our estimates of the cost of the procedure, which includes $3,500 of implant technology, the proposed payment of $5,562 would be generous. We believe that payment at the 2007 level ($5,130) is adequate.

While CMS has not been comfortable with the use of external data to set payment rates, we would like to request that CMS consider input on the true cost of a device as a benchmark in evaluating the reasonableness of the payment. If the value is substantially off, CMS could consider whether certain claims should be included or excluded to determine fair payment. Potentially, when device costs are clearly inaccurate, CMS could adjust the payment.

In the past, CMS has indicated that the public only comments when payment is too low and that there is no comment forthcoming when payment is generous. We accept that generous payment would be beneficial to certain parties. However, should future claims analysis indicate significantly reduced payment, then those same parties will be disadvantaged. We are requesting CMS:

- To consider establishing a payment for 36566 that is more stable and appropriate from year-to-year.
- To continue to require the reporting of C1881 in conjunction with 36566 and to use only correctly coded claims (i.e., 36566 and the device code C1881) in its analyses.
- To use external data to establish an appropriate cost benchmark for C1881.

The proposed changes in the ASC setting bring 36566 procedures performed in an ASC more in line with the cost of the procedure and technology. While the 2007 ASC payment of $510 was grossly inadequate, the proposed transitional payment of $4,204 is a step forward in realistically offering this procedure to beneficiaries in the ASC setting. We support a methodology that recognizes that ASCs and hospital outpatient departments incur the same costs when purchasing devices.

Please feel free to contact me if you have any questions or if you require additional information.

Sincerely,

David Finch, MD
President

CMS-1392-P-898 **Medicare**

Submitter : **William Caster** **Date & Time: 09/13/2007**

Organization : **William Caster**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Dear Mr. Weems:
Regarding: CMS-1392-P, Specified Covered Outpatient Drugs
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (or the form dystonia you have), both types of dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS□s proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.
1. 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.
2. Thank you for allowing me to provide these comments

CMS-1392-P-899 **Medicare**

Submitter : **Dave Harshbarger** **Date & Time: 09/13/2007**

Organization : **West Virginia University Hospitals**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

See Attachment

#899

September 13, 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 West Virginia University Hospitals in Morgantown, WV. As I am sure you have read in other letters, The Dr. Dean Ornish Program for Reversing Heart Disease is the only program scientifically shown to reverse heart disease. When it was a covered benefit for Medicare recipients as a demonstration project, it was wonderful for this population to have as an option for managing their heart disease. The Ornish Program is an inexpensive option for managing this disease compared to interventions, medicines and repeat interventions. Here in WV we have the oldest mean age in the country. I do not like to tell our seniors they do not have coverage. I hope CMS considers full coverage of this often "only option left" for our Medicare population."

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

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

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 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 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. 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/We]*** 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 implement 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,

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

3 72 Fed. Reg. at 38,419.

4 Id.

5 Id.

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."

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

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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).

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, 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 304-598-4000 x73079 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Dave Harshbarger, MS
Wellness Manager
Ornish Program Director
West Virginia University Hospitals

CMS-1392-P-900 **Medicare**

Submitter : **Dr. Melissa Flint** **Date & Time:** **09/13/2007**

Organization : **Senior Horizons Outpatient**

Category : **Health Care Professional or Association**

Issue Areas/Comments

OPPS: Partial Hospitalization

Please see attached.

#900

Paradise Valley Hospital
An Affiliate of Abrazo Health Care

September 13, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Dear Sirs:

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

On behalf of Senior Horizons Outpatient, A Behavioral Health Service of Paradise Valley Hospital, I 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

Senior Horizons Outpatient is deeply concerned about the direct impact a fourth consecutive rate reduction will have on partial hospitalization and hospital outpatient services. I believe this rate cut will jeopardize the very existence of the partial hospitalization benefit itself. It is estimated that by the year 2020, one in four Arizonans will be over the age of 65. We CANNOT allow services to be further jeopardized when they are already lacking to begin with. With drastic, dramatic and irrational financial cuts such as these, programs such as the one we have will be forced to alter services, if not stop them completely. We cannot be asked to provide these needed services with a reimbursement rate lower than what it costs to provide the service.

As a representative of Senior Horizons, I am a member of The Association of Ambulatory Behavioral Healthcare (AABH) and we support their response to this situation which is as follows:

1. **CMS data does not support a PHP per diem rate of $179.88 by its' own methodology of calculation.**

CMS-1392-p, on pp. 255-256, describes the CMS methodology utilized to calculate the current proposed rates. Page 255 states "We use CCRs from the most recently available hospital and CMHC cost reports". Unfortunately, this data is aggressively **stale**. The costs utilized are at least **1 to 3 years old and are used to project rates 2 years forward.** A review of the data utilized for the CY 2008 rates would indicate that as much as 50% of the cost data could be 3 years old from 2004. Page 255 of the report goes on to say that "All of these costs are then arranged from lowest to highest and the middle value of the array would be the median per diem cost". This process guarantees that 50% of the providers will be providing services and be receiving reimbursement below their daily costs. Combining cost

data several years old with recent units of service does not accurately reflect the costs the providers endure.

2. CMS does not support a PHP per diem rate of $179.88.

CMS has identified the true Median Cost of APC 325 for group therapy at $66.17. With a minimum of 4 services per day (many programs offer more), CMS would recognize the minimum cost at $264.68 per day. These data are inconsistent with a rate of $179.88 and indicate that a higher payment rate is necessary to prevent providers from running substantial deficits that will risk financial viability.

3. The current methodology is not conducive to this APC code.

Unlike the other 1100+ APC codes which generally represent individual medical procedures, Partial Hospitalization is a complete service industry, that encompasses a complete business setting rather than one simple process such as a Corneal Transplant (0244) or a Transfusion (0110). There is precedent in other CMS OPPS service industries to exclude the services from the APC code listing and treat them independently. Two examples are Home Health and Hospice Care. Home health was just finalized for CY2008 with a set rate and a 3 percent increase if certain quality data standards are met or a 1 percent increase if the standards are not met. Positive performance results in reimbursement rewards. PHP could be treated the same. This would stabilize the rates and generate future rate predictability for these services.

4. The preliminary rate of $179.88 is excessively severe.

The CMS table on p. 257 of CMS-1392-p reflects 4 median per diem costs as determined by CMS. The projected rate of $179.88 is the lowest of the four samples. This would penalize all CMHCs providing four or more units of service per day and all hospitals in either category. All current PHP LCD's of the Fiscal Intermediaries state the CMS requirements that "Partial Hospitalization Programs must **offer** a minimum of 20 hours a week of structured program provided over at least a five-day period." The minimum patient participation is three hours per day of care with a minimum of 12 hours per week." AABH would offer 2 suggestions. First, enforce the minimum service requirement to assure PHPs are **offering** at least 20 hours of structured programming per week. Second, days of service with less than 4 services are being paid within the rules of CMS and Medicare. Programs should not be penalized for following the rules.

In further regard to the Hospital-based PHPs, CMS data indicated that over 66% of paid claims were for 4 or more units of service. The median cost of $218 for hospitals is $40 below the projected reimbursement rates. A decision of this nature would end these services in Hospital-based locations.

5. CMS's calculations for the CY 2008 PHP per diem payment are diluted.

CMS states that per diem costs were computed by summarizing the line item costs on each bill and dividing by the number of days on the bills. This calculation can severely dilute the rate and penalize providers. All programs are strongly encouraged by the fiscal intermediaries to submit all PHP service days on claims, even when the patient receives less than 3 services. Programs must report these days to be able to meet the 57% attendance threshold and avoid potential delays in the claim payment. Yet, programs are only paid their per diem when 3 or more qualified services are presented for a day of service. If only 1 or 2

services are assigned a cost and the day is divided into the aggregate data, the cost per day is significantly compromised and diluted. Even days that are paid but only have 3 services dilute the cost factors on the calculations. With difficult challenges of treating the severe and persistently mentally ill adults, these circumstances occur frequently.

6. **The proposed PHP per diem rate also severely compromises Hospital Outpatient Services.**

CMS pays hospital facilities for Outpatient Services on a per unit basis **up to** the per diem PHP payment. As previously shown, CMS has identified Group Therapy APC 0325 with a true Median Cost of $66.17. Most patients involved in the Outpatient Services are participating 1-3 days and generally receive 4 or more services on those days. While programs provide 4 services the per diem limit will only allow them to be "paid their cost" for about 2.75 services (3 x $66.17 = $198.51). The program is $18.63 short for the 3rd service and the 4th service is provided for no reimbursement.

7. **Cost Report Data frequently does not reflect Bad Debt expense for the entire year.**

As the cost report data is proposed surrounding Bad Debt, many "recent" bad debt copays of the last 4-5 months of the fiscal year have not completed the facility's full collection efforts and therefore are not eligible for consideration of bad debt on the cost report. Those that are, can only be recovered up to 55%. These costs are not being considered in the CMS data and severely short change the rate calculations.

8. **Data for settled Cost Reports fail to include costs reversed on appeal.**

CMS historically has reduced certain providers' cost for purposes of deriving the APC rate based on its observation that "costs for settled cost reports were considerably lower than costs from "as submitted cost reports". (68 Federal Register 48012) While CMS's observation is true, it fails to include in the provider's costs, those costs denied/removed from "as submitted" cost reports, and subsequently reversed on appeal to the Provider Reimbursement Review Board ("PRRB"), subsequently settled pursuant to the PRRB's mediation program, or otherwise settled among the provider and intermediary. During the relevant years at issue, providers of PHP incurred particularly significant cost report denials, but also experienced favorable outcomes on appeal. Because the CMS analysis did not take into consideration what were ultimately the allowable costs, its data are skewed artificially low. The cost data used to derive the APC rate should be revised to account for these costs subsequently allowed.

Based on the above issues, AABH would recommend that CMS take the following course of action:

1. Allow the PHP per diem to remain the same as the CY2007 per diem rate of $234.73.

2. **Senior Horizons Outpatient** encourages CMS to go with AABH to the legislature and support a legislative amendment to:

    - Remove PHP from the APC codes and have independent status using Home Health as an example
    - Establish the current rate of $234.73 as the base per diem rate for services
    - Annually adjust the base rate by a conservative inflation factor such as the CPI

- Establish quality criteria to judge performance and that influences future rate reimbursement

Thank you, for the opportunity to respond to this critical issue.

Respectfully,

Melissa Delgado Flint, Psy.D.
Outpatient Services Manager
Senior Horizons Outpatient, A Behavioral Health Service of Paradise Valley Hospital

CMS-1392-P-901 **Medicare**

Submitter : **Ms. Amy Barkholz** **Date & Time: 09/13/2007**

Organization : **Michigan Health**

Category : **Critical Access Hospital**

Issue Areas/Comments

Necessary Provider CAHs

Position: Oppose

Submitted by: Michigan Health & Hospital Association, Lansing Michigan. This organization represents 147 nonprofit community hospitals. 34 are Critical Access Hospitals. 28 are necessary provider CAHs.

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

#901

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

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:

The Michigan Health & Hospital Association (MHA) urges the Centers for Medicare and Medicaid Services to reconsider and withdraw the provisions of the proposed rule referenced above that pertain to off-site services owned by Critical Access Hospitals. The MHA represents 147 nonprofit community hospitals in Michigan. 34 of these are Critical Access Hospitals, 28 of which are necessary provider facilities.

Specifically, the proposed rule would prohibit Critical Access Hospitals that achieved their designation by meeting appropriate necessary provider criteria from initiating a new provider-based service or psychiatric or rehabilitation distinct part unit after January 1, 2008 unless the new service was located more than 35 miles from the nearest hospital. Penalties for violation of the proposed requirement are termination of CAH status.

The MHA opposes this policy for the following reasons:

1. The policy is not supported by law or Congressional intent.

There is nothing in the law to suggest that such an action is necessary and we have not seen any recent direction from Congress to apply the mileage requirements, intended for the CAH itself, to its other lines of business. This proposed rule simply creates a burden for CAHs and restricts access to care in the vulnerable communities they serve.

SPENCER JOHNSON, PRESIDENT
CORPORATE HEADQUARTERS ◆ 6215 West St. Joseph Highway ◆ Lansing, Michigan 48917 ◆ (517) 323-3443 ◆ Fax (517) 323-0946
CAPITOL ADVOCACY CENTER ◆ 110 West Michigan Avenue, Suite 1200 ◆ Lansing, Michigan 48933 ◆ (517) 323-3443 ◆ Fax (517) 703-8620
www.mha.org

2. The policy harms patient access to care.

Implementation of this policy will have broad affects on community access to care. The hospitals that are impacted by this rule are rural and/or small by their nature and they were granted necessary provider status because they treat underserved populations. In many instances it may be appropriate for the CAH to locate a provider-based service off campus to meet the needs of the population. Available land, natural boundaries, increased community need, and other factors are relevant considerations that may explain a CAH's decision to locate off campus.

3. This policy hinders recruitment of physicians to underserved areas and places Critical Access Hospitals at a disadvantage relative to for-profit corporations and larger hospitals.

In addition, offsite provider services such as clinics and distinct part units are often a way for CAHs to recruit physicians to practice in their underserved communities. By hiring a physician at one of the CAH's provider-based entities, the CAH can help ensure that there is a physician in the area to serve on the medical staff and provide care to the community. The hospitals that are impacted by this rule already have trouble recruiting and retaining physicians. CMS should not make it even more difficult for CAHs to recruit and retain needed personnel. This is a serious consideration in light of the fact that non-critical access hospitals and for-profit corporations are able to locate their provider-based entities wherever they choose as long as they continue to meet the provider-based criteria. Thus, this policy would put CAHs at a distinct disadvantage compared to regional PPS counterparts.

4. This policy negatively impacts all Critical Access Hospitals, not just necessary provider facilities.

Although this section was presumably meant to only affect necessary provider CAHs, this will have a detrimental effect on all CAHs. Two CAHs could be more than 35 miles apart but their provider-based entities may be within 35 miles of the other hospital; for instance at a town mid-way between the two facilities. This rule would prevent either hospital from serving such a community.

5. Adding services to the existing campus may be unfeasible whereas procuring offsite locations may be more economical.

The January 1, 2008 "grandfather" provision that extends to provider-based entities that maintain the same location is unreasonable and will merely serve to lock existing services

into outdated facilities. Many CAHs are operating provider-based entities in very old buildings that need to be replaced. Leasing underutilized off-campus space is often much more economical than locating services within the existing campus. CAHs should not be discouraged from replacing these entities in order to improve patient safety and upgrade technology. Forcing physicians to continue to practice in outdated units and clinics merely encourages them to practice elsewhere and could hinder improved patient care.

6. **The wording of the policy is unclear and the January 1, 2008 timeframe is not reasonable or feasible given that this rule, if enacted, would take effect November 1, 2007.**

There is concern that wording of the proposed policy may also prohibit CAH operation of provider-based services within the hospital's current location. There is insufficient time before implementation of this proposed policy to adequately review the language and assess its full implications.

Michigan's 34 Critical Access Hospitals provide a broad array of vital health services to their underserved small and rural communities. They are almost universally the largest employer in their area and are drivers for economic stability in their region. Our small towns have suffered great economic hardships recently, especially in Michigan, and residents tend to be older, poorer, and have more chronic health needs than urban and suburban populations. Research shows that employers seek reliable health resources when deciding whether to locate in a community. The ability of Critical Access Hospitals to remain viable and offer needed health care services is therefore crucial to the economic stability of our small and rural communities.

CMS should rescind this proposed rule. It is contrary to CMS's stated intention in the rule "to ensure access to essential health care services for rural residents." Such a policy hinders recruitment and retention and jeopardizes access to services in small and rural communities.

Sincerely,

Spencer Johnson
President

CMS-1392-P-902 **Medicare**

Submitter : **Mrs. Michelle McEwen** **Date & Time: 09/13/2007**

Organization : **Speare Memorial Hospital**

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

See Attachment

#902

SPEARE
Memorial Hospital
A Critical Access Hospital

September 13, 2007

Mr. 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 CEO at Speare Memorial Hospital in Plymouth, New Hampshire.

Speare Memorial Hospital became a Critical Access Hospital in May of 2005 as a necessary provider. We pursued this designation for the purpose of preserving the future financial viability of our hospital. Despite many cost containment initiatives, declining Medicare reimbursements and increasing challenges in meeting the healthcare needs of our community left us no option but to seek this designation and its improved reimbursement for our largest payor group. Since that time, Speare has had to come to the rescue of financially struggling and failing primary care practices for the sake of maintaining access to care for our community. We are in the process of seeking Provider-Based Rural Health Clinic (RHC) status for these practices, again to achieve improved reimbursement that is necessary to ensure access and availability of primary care services in our service area. Due to the delays in obtaining an inspection, it does not appear feasible to get our designation prior to December 31, 2007. This will result in our Board of Directors facing a difficult decision. Do we pursue RHC designation to preserve access to primary care services, knowing that means the hospital will once again become vulnerable to the inadequacies of Medicare reimbursement for small safety net providers or do we drop our pursuit of RHC status for these practices to ensure the financial future of our hospital knowing that this will make the long-term sustainability of primary care unlikely? No matter which decision is

made, it is clear that this proposed provision will have a detrimental affect on access to services in our small rural community.

At the same time, we will be facing the situation of replacing our Rehabilitation Services department. It is currently located in a separate building from the hospital. This building is in the process of being sold. The hospital is currently securing a new home for this department, but construction will be required. In essence, this outpatient department will relocate after December 31, 2007 jeopardizing Speare's Critical Access Hospital designation under the proposed provisions.

Due to these concerns, I respectfully ask that you withdraw the provisions in this rule pertaining to provider-based facilities of Critical Access Hospitals. These provisions are counter to the original intent of CAH legislation, which was to preserve access to healthcare services in small rural communities. Such provisions as these would eliminate our flexibility to provide the care needed by our rural seniors.

Thank you for your consideration of these comments. Please contact me if you have any questions.

Sincerely,

Michelle L. McEwen

Michelle L. McEwen
President/CEO

CMS-1392-P-903 **Medicare**

Submitter : **Ms. LuAnne Ness** **Date & Time: 09/13/2007**

Organization : **Senior Horizons Outpatient**

Category : **Health Care Professional or Association**

Issue Areas/Comments

OPPS: Partial Hospitalization

Please see attached.

#903

Paradise Valley Hospital
An Affiliate of Abrazo Health Care

September 13, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Dear Sirs:

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

On behalf of Senior Horizons Outpatient, A Behavioral Health Service of Paradise Valley Hospital, I 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

Senior Horizons Outpatient is deeply concerned about the direct impact a fourth consecutive rate reduction will have on partial hospitalization and hospital outpatient services. I believe this rate cut will jeopardize the very existence of the partial hospitalization benefit itself. It is estimated that by the year 2020, one in four Arizonans will be over the age of 65. We CANNOT allow services to be further jeopardized when they are already lacking to begin with. With drastic, dramatic and irrational financial cuts such as these, programs such as the one we have will be forced to alter services, if not stop them completely. We cannot be asked to provide these needed services with a reimbursement rate lower than what it costs to provide the service.

As a representative of Senior Horizons, I am a member of The Association of Ambulatory Behavioral Healthcare (AABH) and we support their response to this situation which is as follows:

1. **CMS data does not support a PHP per diem rate of $179.88 by its' own methodology of calculation.**

CMS-1392-p, on pp. 255-256, describes the CMS methodology utilized to calculate the current proposed rates. Page 255 states "We use CCRs from the most recently available hospital and CMHC cost reports". Unfortunately, this data is aggressively **stale**. The costs utilized are at least **1 to 3 years old and are used to project rates 2 years forward.** A review of the data utilized for the CY 2008 rates would indicate that as much as 50% of the cost data could be 3 years old from 2004. Page 255 of the report goes on to say that "All of these costs are then arranged from lowest to highest and the middle value of the array would be the median per diem cost". This process guarantees that 50% of the providers will be providing services and be receiving reimbursement below their daily costs. Combining cost

data several years old with recent units of service does not accurately reflect the costs the providers endure.

2. CMS does not support a PHP per diem rate of $179.88.

CMS has identified the true Median Cost of APC 325 for group therapy at $66.17. With a minimum of 4 services per day (many programs offer more), CMS would recognize the minimum cost at $264.68 per day. These data are inconsistent with a rate of $179.88 and indicate that a higher payment rate is necessary to prevent providers from running substantial deficits that will risk financial viability.

3. The current methodology is not conducive to this APC code.

Unlike the other 1100+ APC codes which generally represent individual medical procedures, Partial Hospitalization is a complete service industry, that encompasses a complete business setting rather than one simple process such as a Corneal Transplant (0244) or a Transfusion (0110). There is precedent in other CMS OPPS service industries to exclude the services from the APC code listing and treat them independently. Two examples are Home Health and Hospice Care. Home health was just finalized for CY2008 with a set rate and a 3 percent increase if certain quality data standards are met or a 1 percent increase if the standards are not met. Positive performance results in reimbursement rewards. PHP could be treated the same. This would stabilize the rates and generate future rate predictability for these services.

4. The preliminary rate of $179.88 is excessively severe.

The CMS table on p. 257 of CMS-1392-p reflects 4 median per diem costs as determined by CMS. The projected rate of $179.88 is the lowest of the four samples. This would penalize all CMHCs providing four or more units of service per day and all hospitals in either category. All current PHP LCD's of the Fiscal Intermediaries state the CMS requirements that "Partial Hospitalization Programs must **offer** a minimum of 20 hours a week of structured program provided over at least a five-day period." The minimum patient participation is three hours per day of care with a minimum of 12 hours per week." AABH would offer 2 suggestions. First, enforce the minimum service requirement to assure PHPs are **offering** at least 20 hours of structured programming per week. Second, days of service with less than 4 services are being paid within the rules of CMS and Medicare. Programs should not be penalized for following the rules.

In further regard to the Hospital-based PHPs, CMS data indicated that over 66% of paid claims were for 4 or more units of service. The median cost of $218 for hospitals is $40 below the projected reimbursement rates. A decision of this nature would end these services in Hospital-based locations.

5. CMS's calculations for the CY 2008 PHP per diem payment are diluted.

CMS states that per diem costs were computed by summarizing the line item costs on each bill and dividing by the number of days on the bills. This calculation can severely dilute the rate and penalize providers. All programs are strongly encouraged by the fiscal intermediaries to submit all PHP service days on claims, even when the patient receives less than 3 services. Programs must report these days to be able to meet the 57% attendance threshold and avoid potential delays in the claim payment. Yet, programs are only paid their per diem when 3 or more qualified services are presented for a day of service. If only 1 or 2

services are assigned a cost and the day is divided into the aggregate data, the cost per day is significantly compromised and diluted. Even days that are paid but only have 3 services dilute the cost factors on the calculations. With difficult challenges of treating the severe and persistently mentally ill adults, these circumstances occur frequently.

6. **The proposed PHP per diem rate also severely compromises Hospital Outpatient Services.**

CMS pays hospital facilities for Outpatient Services on a per unit basis **up to** the per diem PHP payment. As previously shown, CMS has identified Group Therapy APC 0325 with a true Median Cost of $66.17. Most patients involved in the Outpatient Services are participating 1-3 days and generally receive 4 or more services on those days. While programs provide 4 services the per diem limit will only allow them to be "paid their cost" for about 2.75 services (3 x $66.17 = $198.51). The program is $18.63 short for the 3rd service and the 4th service is provided for no reimbursement.

7. **Cost Report Data frequently does not reflect Bad Debt expense for the entire year.**

As the cost report data is proposed surrounding Bad Debt, many "recent" bad debt copays of the last 4-5 months of the fiscal year have not completed the facility's full collection efforts and therefore are not eligible for consideration of bad debt on the cost report. Those that are, can only be recovered up to 55%. These costs are not being considered in the CMS data and severely short change the rate calculations.

8. **Data for settled Cost Reports fail to include costs reversed on appeal.**

CMS historically has reduced certain providers' cost for purposes of deriving the APC rate based on its observation that "costs for settled cost reports were considerably lower than costs from "as submitted cost reports". (68 Federal Register 48012) While CMS's observation is true, it fails to include in the provider's costs, those costs denied/removed from "as submitted" cost reports, and subsequently reversed on appeal to the Provider Reimbursement Review Board ("PRRB"), subsequently settled pursuant to the PRRB's mediation program, or otherwise settled among the provider and intermediary. During the relevant years at issue, providers of PHP incurred particularly significant cost report denials, but also experienced favorable outcomes on appeal. Because the CMS analysis did not take into consideration what were ultimately the allowable costs, its data are skewed artificially low. The cost data used to derive the APC rate should be revised to account for these costs subsequently allowed.

Based on the above issues, AABH would recommend that CMS take the following course of action:

1. Allow the PHP per diem to remain the same as the CY2007 per diem rate of $234.73.

2. **Senior Horizons Outpatient** encourages CMS to go with AABH to the legislature and support a legislative amendment to:

    - Remove PHP from the APC codes and have independent status using Home Health as an example
    - Establish the current rate of $234.73 as the base per diem rate for services
    - Annually adjust the base rate by a conservative inflation factor such as the CPI

- Establish quality criteria to judge performance and that influences future rate reimbursement

Thank you, for the opportunity to respond to this critical issue.

Respectfully,

LuAnne Ness, RN
Senior Horizons Outpatient, A Behavioral Health Service of Paradise Valley Hospital

CMS-1392-P-904 **Medicare**

Submitter : **Ms. Gladys Cooper** **Date & Time: 09/13/2007**

Organization : **Quantum Management**

Category : **Nurse**

Issue Areas/Comments

OPPS: Partial Hospitalization

Please see attached

#904

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-905 **Medicare**

Submitter : **Mr. Lyle Johnson** **Date & Time: 09/13/2007**

Organization : **Front Range Mobile Imaging,Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

See attachment

#905

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

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CMS-1392-P-906 **Medicare**

Submitter : **Ms. Cheryl Moore** **Date & Time: 09/13/2007**

Organization : **Vanguard Heath Management**

Category : **Health Care Professional or Association**

Issue Areas/Comments

OPPS: Partial Hospitalization

Please see attached.

#906

VANGUARD
HEALTH SYSTEMS

September 13, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Dear Sirs:

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

On behalf of Vanguard Health Systems, Behavioral Health Services, I 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

I am deeply concerned about the direct impact a fourth consecutive rate reduction will have on partial hospitalization and hospital outpatient services. I beelieve this rate cut will jeopardize the very existence of the partial hospitalization benefit itself.

As a member of The Association of Ambulatory Behavioral Healthcare (AABH) I support their response to this situation which is as follows:

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Based on the above issues, AABH would recommend that CMS take the following course of action:

1. Allow the PHP per diem to remain the same as the CY2007 per diem rate of $234.73.

2. I encourage CMS to go with AABH to the legislature and support a legislative amendment to:

    - Remove PHP from the APC codes and have independent status using Home Health as an example
    - Establish the current rate of $234.73 as the base per diem rate for services
    - Annually adjust the base rate by a conservative inflation factor such as the CPI
    - Establish quality criteria to judge performance and that influences future rate reimbursement

Thank you, for the opportunity to respond to this critical issue.

Respectfully,

Cheryl L Moore, ACSW, LCSW
Manager, Clinical Operations
Clinical Specialty Services
Vanguard Health Systems
832-326-6569

CMS-1392-P-907 **Medicare**

Submitter : **Ms. Sharmila Sandhu** **Date & Time: 09/13/2007**

Organization : **American Occupational Therapy Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

See Attached Letter.

AOTA The American Occupational Therapy Association, Inc.

#907

Occupational Therapy: Skills for the Job of Livin

Via email to http://www.cms.hhs.gov/erulemaking

September 13, 2007

Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-P
7500 Security Boulevard
Baltimore, Maryland 21244-7850

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Rule

Dear Acting Administrator Weems:

The American Occupational Therapy Association (AOTA) represents more than 35,000 occupational therapy professionals, many of whom provide services to Medicare beneficiaries in hospital outpatient departments. We appreciate the opportunity to comment on the regulations refining hospital outpatient prospective payment system (OPPS), particularly with regard to the proposed Hospital Outpatient Quality Data Reporting Program (HOP QDRP). This proposed rule was published in the *Federal Register* on August 2, 2007 (72 Fed. Reg. 42628).

Occupational therapy is a health, wellness, and rehabilitation profession working with people experiencing stroke, spinal cord injuries, brain injury, congenital conditions, joint replacements and surgeries, mental illness, and other conditions. It helps people regain, develop, and build skills that are essential for independent functioning, health, and well-being in the home and community. Occupational therapy services provided through the outpatient benefit are integral to help beneficiaries regain functional independence in order to ultimately manage their own health and successfully age in place.

The reimbursement system for occupational therapy services furnished through hospital outpatient departments is not under the OPPS for the most part. While hospital outpatient occupational therapy services furnished through partial hospitalization programs are reimbursed under OPPS, the remainder of hospital outpatient occupational therapy services is reimbursed under the Medicare Physician Fee Schedule (MPFS) billed by individual code. Occupational therapists furnishing services in hospital outpatient departments do not submit claims to the Medicare Contractor under an occupational therapist in private practice provider number; rather the hospital outpatient department submits all the claims for the outpatient services of occupational therapists to the Medicare Contractor. Therefore, except in partial hospitalization, occupational therapists would not be part of the HOP QDRP.

The American Occupational Therapy Association, Inc. 4720 Montgomery Lane Bethesda, MD 20814-3425 301-652-2682 301-652-7711 Fax 800-377-8555 TDD www.aota.org

Hospital Outpatient Quality Data Reporting Program: Quality Measures

Section 109(a) of TRHCA (Pub. L. 109-432) requires CMS to establish a program under which hospitals will report data on the quality of outpatient hospital care using standardized measures of care to receive the full annual update to the OPPS payment rate. The Proposed Rule identifies a number of quality measures that it plans to use in the HOP QDRP that were endorsed by the National Quality Forum. Furthermore, CMS proposes 30 measures that could be reported to measure hospital outpatient quality of care, some of which are being used in the 2007 Physician Quality Reporting Initiative (PQRI) and are expected to be used in the 2008 version of PQRI.

AOTA supports CMS for identifying quality measures endorsed by the National Quality Forum. AOTA also supports CMS's consideration of other valid national endorsement bodies for purposes of reviewing and adopting HOP QDRP. AOTA strongly agrees with CMS that it is vital to harmonize outpatient hospital quality measures with those reported in both inpatient and ambulatory settings. For that reason, AOTA urges CMS to adopt a number of quality measures that are in use in or proposed for the PQRI program for use in hospitals. AOTA encourages CMS to adopt the following 2007 PQRI measure for the HOP QDRP:

- PQRI #4 Screening for Future Fall Risk

AOTA believes that screening for fall risk for Medicare beneficiaries as part of the HOP QDRP in the same manner proposed for the PQRI program would improve quality of care by identifying, when patients receive other care such as diagnostic procedures, whether they have fallen in the past months and whether that has caused injury, thus a potential risk for a future fall.

Also, AOTA recommends that CMS adopt the additional quality measures that its contractor Quality Insights of Pennsylvania have recommended as Physical Therapist and Occupational Therapist Measures in their Draft Technical Manual dated July 2007:

- Patient Co-Development of Plan of Care
- Pain Assessment Prior to Initiation of Patient Treatment
- Universal Documentation and Verification of Current Medications in the Medical Record

These items too would be appropriate to ask of many patients and would improve quality of care. AOTA particularly recommends the use of these by therapists and others in the partial hospitalization program. AOTA has worked closely with CMS and the American Medical Association to facilitate occupational therapists' participation in the 2007 PQRI, and have been granted explicit approval for occupational therapists in independent practice to report PQRI # 4 Screening for Future Fall Risk. AOTA is also asserting with CMS that occupational therapists should be deemed eligible to report on the additional measures noted above developed by Quality Insights of Pennsylvania as well as continue to be able to report PQRI #4 in 2008.

Therapists in Hospital Outpatient Departments Should Have a Mechanism to Report Quality Data

Because the majority of occupational therapy services provided in hospital outpatient departments is exempt from OPPS and instead is paid under the MPFS, occupational therapists cannot participate in the HOP program except in partial hospitalization. Neither can hospital therapists in general outpatient departments participate in the PQRI when the bill using the MPFS. CMS previously indicated that only practitioners who directly submit claims to CMS under a provider number are eligible to participate in PQRI. AOTA believes that occupational therapists in hospital outpatient departments should be able to report quality measures under the quality data reporting system that corresponds to the payment method, which for the MPFS is the PQRI. However, since hospital outpatient departments submit occupational therapy claims to CMS under the hospital provider number, the hospitals cannot participate in PQRI at this time. Given CMS' desire to harmonize the reporting of quality measures across all settings, AOTA strongly urges CMS to explicitly permit occupational therapists in hospital outpatient departments to report quality data through PQRI and be eligible for bonus payments under that program.

AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on this proposed rule. We look forward to a continuing dialogue with CMS on these issues as they apply to occupational therapy.

Sincerely,

Leslie Stein Lloyd, Esq.
Senior Regulatory Counsel

CMS-1392-P-908 **Medicare**

Submitter : **Dr. Jeff Michalski** **Date & Time: 09/13/2007**

Organization : **Siteman Cancer Center**

Category : **Physician**

Issue Areas/Comments

OPPS: Packaged Services

#908

Washington University in St. Louis
SCHOOL OF MEDICINE

Department of Radiation Oncology

September 13, 2007

Submitted electronically via attachment to
http://www.cms.hhs.gov/eRulemaking

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

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

Dear Administrator Weems:

I am writing this letter with respect to the Hospital Outpatient Prospective Payment System Proposed Rule for CY 2008. I am concerned about the packing proposal for guidance procedures with the use of external beam radiation therapy. I am concerned that the proposed rule will discourage hospital outpatient services from using important technologies as part of my radiation oncology practice.

I am currently the Clinical Director of Radiation Oncology at the Siteman Cancer Center in St. Louis, Missouri. The Siteman Cancer Center is affiliated with the Barnes-Jewish Hospital and Washington University School of Medicine. Our cancer center is an NCI designated comprehensive cancer center and we treat more than 2500 patients per year with radiation therapy.

Targeting tumors for radiation therapy is an absolutely essential component in the management of patients with a variety of cancers, including cancer of the prostate, lung and GI tract. We have been successful in implementing intensity modulated radiation therapy (IMRT) in prostate cancer, which requires accurate daily set-up to minimize radiation dose from hitting adjacent critical structures, such as the bladder and rectum. Failure to use daily image guidance for patients receiving IMRT for prostate cancer or cancers of the lung and GI tract necessitates treating a larger margin of adjacent normal tissues, thereby increasing the normal tissue toxicity rates.

The Proposed Rule, if implemented, would encourage hospital outpatient departments to use inferior methods for guiding radiation therapy. Existing technologies, such as skin marks and surface lasers do not provide precise real time monitoring that comprehensive guidance solutions can provide. This packaging proposal recommended in the Proposed Rule would create a disincentive in the adoption of emerging technologies, such as the Calypso 4D Localization System, a system that we have put into use this year. This decision will only serve to slow clinical advancements in radiation therapy delivery options. Most hospitals would have difficulty justifying the use of guidance technologies without separate coding and payments. Entities like the Siteman Cancer Center are in the process of determining actual cost and utilization patterns associated with the guidance technologies used in conjunction with external beam radiation therapy.

MIR Mallinckrodt Institute of Radiology

Washington University School of Medicine at Washington University Medical Center, Campus Box 8224,
4921 Parkview Place, St. Louis, Missouri 63110, (314) 362-8502, Fax: (314) 362-8521, *www.wustl.edu*

Further, the Proposed Rule inappropriately assumes uniformity in treatment approaches for services such as external beam radiation therapy. Individual patient characteristics, stage of the disease, and associated treatment approaches vary dramatically and require customized treatment delivery and guidance. CMS's Proposed Rule assumes uniform treatment for life-threatening diseases, such as prostate cancer. As each patient's treatment is unique, we require the option to use various types of guidance technologies available to us based on the patient's individual case. Having specific codes and payments for a range of guidance technologies is important in the practice of radiation oncology so we may analyze the utilization with specific codes to better understand use and the cost to deliver these new procedures.

Packaging guidance technologies with therapeutic delivery in radiation oncology will serve to diminish the quality of care Medicare beneficiaries receive from our institution. This broad sweeping Proposed Rule, in its current format, eliminates distinct and separate payment which will make it difficult for hospitals to justify adoption of new, and clinically more effective, technologies, like the Calypso 4D Localization System. Furthermore, the overall utilization data for guidance procedures needs to be studied before CMS makes such significant changes in radiation oncology packaging and payments.

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

Please feel free to contact me with any clinical questions on radiation oncology and treatment.

Sincerely,

Jeff Michalski, M.D.
Clinical Director
Department of Radiation Oncology
Washington University School of Medicine
Siteman Cancer Center

JMM/sls

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CMS-1392-P-909 **Medicare**

Submitter : **Gail Daubert** **Date & Time: 09/13/2007**

Organization : **Alliance for Orthopedic Solutions**

Category : **Device Association**

Issue Areas/Comments

Packaged Services

See attached.

#909

September 13, 2007

Filed Electronically

Mr. Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1392-P / Proposed Changes to Medicare Hospital Outpatient PPS for CY 2008
Request that Imaging & Computer-Assisted Navigation Not Be Packaged into APC Payment

Dear Administrator Weems:

On behalf of the Alliance for Orthopedic Solutions (the "Alliance"), we welcome the opportunity to submit comments on the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital outpatient prospective payment system ("HOPPS") proposed rule for calendar year 2008 (the "Proposed Rule").[1] Alliance members include leading developers and manufacturers of orthopedic devices and their clinical expert teams who are dedicated to high quality clinical care, education, and research in Orthopedics.

Although the Alliance generally supports the 2008 proposed changes for HOPPS, we wish to comment on the proposal to eliminate separate payment for certain imaging and computer-assisted navigation procedures (CPT codes 72291, 72292, 0054T, 0055T and 0056T) and, instead, bundle those procedures into the APC payment for the related surgical procedure. Our comments on this issue are discussed in detail below.

Request that Imaging & Computer-Assisted Navigation Not Be Packaged into APC Payment

CMS is proposing to package payment for seven additional categories of supportive and ancillary services that are integral to the performance of primary diagnostic and treatment procedures into the payment for the associated APCs including certain radiologic supervision and interpretation services (i.e., CPT codes 72291, 72292) and of certain computer-assisted navigation and imaging guidance services (i.e., CPT codes 0054T, 0055T, 0055T). Although we understand the logic behind this packing proposal, we have the following concerns and comments regarding this approach to payment, particularly with respect to guidance services.

- Packaging computer-assisted navigation and imaging guidance services into the APCs for the related surgical procedures will likely undermine the clinical cohesiveness of the orthopedic APCs since, although use of guidance services is increasing, the majority of orthopedic procedures performed in the U.S. do not use or involve guidance systems or services.

- Packaging payment for computer-assisted navigation and imaging guidance services into the APCs for the related surgical procedures undermines payment parity between these procedures when performed in the hospital outpatient setting and when performed in the physician office

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1 Proposed Changes to the Hospital Outpatient Prospective Payment System Calendar Year (CY) 2008 Payment Rates, 72 Fed. Reg. 42628 (August 2, 2007).

setting since these guidance services may be separately reimbursed under the Medicare Physician Fee Schedule in the physician office setting.

- Hospital claims data has been historically unreliable and, due at least in part to charge compression, may not represent an accurate picture of hospital costs. The issue of charge compression is particularly relevant with respect to procedures that involve the use of higher-cost new technology since hospitals tend to apply smaller markup rates to these medical devices and technology than they do to lower-cost supplies used in a procedure. The result of charge compression under the HOPPS payment system is that when CMS calculates the weight for APCs based on these differentially marked-up hospital charges, the higher-cost technology and medical devices are undervalued and the APC payment level inappropriately suppressed. Further, it is unclear from the Proposed Rule whether the hospital outpatient costs for guidance and computer-assisted navigation services have, in fact, been appropriately accounted for, cross-walked, and factored into the 2008 APC payment rates for all procedures which may involve use of such imaging guidance and navigation.

- Our recommendations are as follows:

  1. CMS should not package computer-assisted navigation for orthopedics. These codes are just graduating to Category I CPT codes and the data is incomplete/inadequate at the present time.

  2. Computer-assisted navigation for orthopedics is used for a limited number of cases by a limited number of hospital outpatient departments. The costs of low volume procedures should not be packaged because they will not be appropriately reflected in the APC payment rates when packaged.

  3. The Alliance supports CMS's proposal to develop quality measures that are appropriate for measuring the quality of care in hospital outpatient and ambulatory surgery center settings. We believe that computer-assisted navigation has the potential to improve clinical outcomes and, thus, the quality of care rendered in outpatient settings. However, in order to facilitate outcome-related research for computer-assisted navigation, the Alliance recommends that separate payment be maintained for these services.

  4. If CMS does seek to move forward with its proposal to package image guidance/computer-assisted navigation, we request that CMS delay implementation for at least one year. This would allow time for CMS to fully disclose its methodology for packaging and provide a cross-walk identifying the primary procedure/APC for each of the procedures it is proposing to package and give interested parties an opportunity to study the impact on hospital outpatient departments and the impact on patient access.

  5. CMS should continue to evaluate and update the ASC list and include all procedures done in the outpatient setting in the ASC list.

In closing, the Alliance appreciates the attention that CMS staff has given to making HOPPS reimbursement for orthopedic procedures more equitable and appropriate. We request that CMS continue to provide appropriate reimbursement for orthopedic procedures by not adopting the proposal to package payment for computer-assisted navigation and other guidance services and certain radiologic supervision and interpretation services into the APC payment for the related orthopedic procedures.

The Alliance appreciates the opportunity to submit these comments and encourages CMS staff to contact me at 202.414.9241, if we can provide further information.

Sincerely,

Gail Daubert

Gail L. Daubert, Esq.
Counsel for the Alliance

cc: Carol Bazell, M.D., Acting Director, Division of Outpatient Care (email)
Edith Hambrick, M.D., J.D. CMS Medical Officer (email)
Alliance Members (email)

CMS-1392-P-910 **Medicare**

Submitter : **Dr. Jeff Michalski** **Date & Time: 09/13/2007**

Organization : **Siteman Cancer Center**

Category : **Physician**

Issue Areas/Comments

OPPS: Packaged Services

See attached pdf

#910

Washington University in St. Louis
SCHOOL OF MEDICINE

Department of Radiation Oncology

September 13, 2007

Submitted electronically via attachment to
http://www.cms.hhs.gov/eRulemaking

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

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

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CMS-1392-P-911 **Medicare**

Submitter : **Mr. Mark Taylor** **Date & Time: 09/13/2007**

Organization : **Spectrum Health Hospitals**

Category : **Hospital**

Issue Areas/Comments

GENERAL

See Attachment

#911

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.