CMS-1392-P-844 **Medicare**

Submitter : **Dr. Sarjoo Bhagia** **Date & Time:** **09/13/2007**

Organization : **OrthoCarolina**

Category : **Physician**

Issue Areas/Comments

GENERAL

Attachment

#844

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 P rospective Payment System (HOPPS) and CY 2008 Payment Rates" (the Proposed Rule) published in the *Federal Register* on August 2, 2007. My comments cover two main issues related to the HOPPS and ambulatory surgery center (ASC) payment methodologies.

I. ASC Procedures

There are several specific procedure issues we ask CMS to review and address. I believe that two procedures that have not been included on the ASC payment list, but that are paid under the HOPPS and should also be included on the ASC list. These procedures are described by CPT codes 22526 (percutaneous intradiscal electrothermal annuloplasty, single level) and 22527 (percutaneous intradiscal electrothermal annuloplasty, one or more additional levels). There is no reason why ASCs should not be entitled to payment for these two procedures. The procedures are safely done in ASCs, and they are not procedures routinely performed in a physician's office. I ask CMS to include both procedures on the ASC list in the final rule.

ASIPP also is concerned that procedures 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography – lumbar - radiological supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. These services are payable separately in the HOPD in certain circumstances and I believe the same should be true for ASCs.

Lastly, I ask CMS recalculate the payment rate of CPT code 64517. The proposed payment rate for this procedure is $178 for CY 2008. While I do recognize that the payment for the procedure following the transition period will be $295, a payment of $178 seems too low.

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

I ask that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on

the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

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

I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

While I recognize the difference in median costs does not create a two times rule violation, the difference in median cost is not insignificant. CMS has assigned pass-through devices to a new APC or to a different, existing APC in absence of a "two-times" rule violation and for median costs differences significantly less than $1,000. I urge CMS to take a similar approach here. The creation of two separate APCs would result in more appropriate payment for both types of procedures—rechargeable and non-rechargeable neurostimulator procedures—based on their relative costs. To implement our recommendation, we further recommend that CMS create a G-Code to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator.

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all

settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary my recommendations to CMS are:

- Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
- Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
- Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,

Sarjoo "Sam" Bhagia, MD
OrthoCarolina
1025 Morehead Medical Dr,
Charlotte, NC 28204
Tel: (704) 323-3525

CMS-1392-P-845 **Medicare**

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

Organization : **Scripps Outpatient Behavioral Health Program**

Category : **Social Worker**

Issue Areas/Comments

OPPS: Partial Hospitalization

To whom it may concern, I urge you to stop this change from being made. This will again reduce our ability to treat the severely mentally ill as we move to the future.

CMS-1392-P-846 **Medicare**

Submitter : **Dr. Justin Vigil** **Date & Time: 09/13/2007**

Organization : **Hill Country Pain Associates**

Category : **Physician**

Issue Areas/Comments

ASC Impact

Dear Mr. Kuhn,
I practice in several rural communities. Many of my patients depend on medicare and medicaid to obtain medical services. There are few physicians that accept Medicaid in my area of practice. I continue to accept because I am serving a community and I have a duty to the citizens. Further Cuts in medicare and medicaid will make it impossible to serve these communities. Many patinents have limited means of transportation nor can aford to travel for health care. Access to care is critical in many situations. Thank you for your consideration.

Sincerely,

Justin J. Vigil MD

Hill Country Pain Associates

CMS-1392-P-847 **Medicare**

Submitter : **Ms. Mary Sun** **Date & Time: 09/13/2007**

Organization : **None**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Dear Mr. Weems:

I appreciate CMS's effort in seeking improvement in patient care access while keeping down related costs and preventing service abuses. However, as a blepharospasm and apraxia (forms of dystonia) patient, I am very concerned about CMS's proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive botulinum toxin injections regularly to alleviate the debilitating dystonic symptoms. These injections are critical to my ability to function. I RESPECTFULLY REQUEST THAT CMS NOT CHANBE THE PAYMENT FORMULA FOR PHYSICIAN-INJECTABLE DRUGS FOR 2008, AND INSTEAD MAINTAIN THE CURRENT PAYMENT FORMULA. Any reimbursement reduction will lead to fewer injectors in an area where we already have too few knowledgeable injectors in the first place(Not everyone can inject botulinum toxin successfully to give patient relief). Note that this policy change would destroy the payment uniformity across settings that ensures there are no economic rewards or penalities to providers, depending on where the injections are given.

Thank you for your attention.

CMS-1392-P-848 **Medicare**

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

Organization : **Gratiot Medical Center**

Category : **Hospital**

Issue Areas/Comments

OPPS: Partial Hospitalization

I am very concerned regarding the proposals for the per diem rate for psychiatric partial hospitalization and urge you to re-examine the issue. See attachment.

CMS-1392-P-849 **Medicare**

Submitter : **Mr. David McClure** **Date & Time:** **09/13/2007**

Organization : **Tennessee Hospital Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

See Attachment

#849

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 Gratiot Medical Center, we appreciate the opportunity to submit comments regarding CMS's proposed OPPS rates concerning APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient Psychiatric Services

Gratiot Medical Center is deeply concerned about the direct impact a fourth consecutive rate reduction will have on partial hospitalization and hospital outpatient services. We believe this rate cut will jeopardize the very existence of the partial hospitalization benefit itself.

I am a member of The Association of Ambulatory Behavioral Healthcare (AABH) and 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. Gratiot Medical Center 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,

Susan E. Malone, Director
Dept. Psychiatry & Behavioral Medicine
Gratiot Medical Center

CMS-1392-P-850 **Medicare**

Submitter : **Dr. Raj Bothra** **Date & Time:** **09/13/2007**

Organization : **THE PAIN CENTER USA PLLC**

Category : **Physician**

Issue Areas/Comments

GENERAL

aTTACHMENT

#850

September 10, 2007

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

Re: CMS-1392-P

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the Proposed Rule CMS-1392-P, "Proposed Changes to the Hospital Outpatient P rospective Payment System (HOPPS) and CY 2008 Payment Rates" (the Proposed Rule) published in the *Federal Register* on August 2, 2007. My comments cover two main issues related to the HOPPS and ambulatory surgery center (ASC) payment methodologies.

I. ASC Procedures

There are several specific procedure issues we ask CMS to review and address. I believe that two procedures that have not been included on the ASC payment list, but that are paid under the HOPPS and should also be included on the ASC list. These procedures are described by CPT codes 22526 (percutaneous intradiscal electrothermal annuloplasty, single level) and 22527 (percutaneous intradiscal electrothermal annuloplasty, one or more additional levels). There is no reason why ASCs should not be entitled to payment for these two procedures. The procedures are safely done in ASCs, and they are not procedures routinely performed in a physician's office. I ask CMS to include both procedures on the ASC list in the final rule.

ASIPP also is concerned that procedures 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography – lumbar - radiological supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. These services are payable separately in the HOPD in certain circumstances and I believe the same should be true for ASCs.

Lastly, I ask CMS recalculate the payment rate of CPT code 64517. The proposed payment rate for this procedure is $178 for CY 2008. While I do recognize that the payment for the procedure following the transition period will be $295, a payment of $178 seems too low.

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

I ask that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on

the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

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

I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

While I recognize the difference in median costs does not create a two times rule violation, the difference in median cost is not insignificant. CMS has assigned pass-through devices to a new APC or to a different, existing APC in absence of a "two-times" rule violation and for median costs differences significantly less than $1,000. I urge CMS to take a similar approach here. The creation of two separate APCs would result in more appropriate payment for both types of procedures—rechargeable and non-rechargeable neurostimulator procedures—based on their relative costs. To implement our recommendation, we further recommend that CMS create a G-Code to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator.

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all

settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary my recommendations to CMS are:

- Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
- Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
- Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,

CMS-1392-P-851 **Medicare**

Submitter : **Mr. Rick Failing** **Date & Time: 09/13/2007**

Organization : **North Dakota Hospital Consortium**

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

See Attachment

#851

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North Dakota Hospital Consortium Office
150 2nd St. SW, Suite 1 P:701-845-1900
Valley City, ND 58072 F:701-845-1911

September 13, 2007

Kerry Weems
Acting 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, 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:

The North Dakota Hospital Consortium appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar (CY) 2008 outpatient prospective payment system (PPS). The North Dakota Hospital Consortium including Carrington Health Center, Oakes Community Hospital, Lisbon Area Health Services and Mercy Hospital of Valley City are Critical Access Hospitals located in Carrington, Oakes, Lisbon and Valley City, N.D.

We support the comments submitted to CMS by the Catholic Health Association and the American Hospital Association. But we would like to add the following comments on an issue of particular concern to us and the communities we serve:

Necessary Provider Critical Access Hospitals (CAH)
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 believes 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. In the case of a necessary provider CAH that violates the proposed 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.

Approximately 850 of the 1300 CAHs nationally are necessary provider CAHs and are therefore within 35 miles of another hospital or CAH. Catholic Health Initiatives, our parent organization, operates 21 CAHs and several of them are necessary providers. These hospitals operate numerous rural health clinics and other provider-based facilities. In some cases, additional sites or relocation of existing off-campus sites will be needed to better serve the needs of patients in these rural communities.

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150 2nd St. SW, Suite 1 P:701-845-1900
Valley City, ND 58072 F:701-845-1911

If this proposal is adopted, North Dakota Hospital Consortium will be significantly limited in or prohibited from opening new off campus provider-based sites, or converting existing sites to provider-based status. CMS states in the proposed regulation that these new restrictions are "consistent with our belief that the intent of the CAH program is to maintain hospital-level services in rural communities while ensuring access to care." **These arbitrary limitations on provider-based service locations will have the exact opposite effect – access to services will be reduced.**

CAH provider-based entities are located in different places for various reasons. Hospitals consider available land, natural boundaries, increased need, preference of physicians and other practitioners, etc. While community members may be willing to travel a distance to a hospital for urgent care or services not available elsewhere, beneficiaries may need something closer to home for more routine visits, therapy, lab work, etc. By forcing CAHs to have services on-campus, CMS will be leaving some community members without access to services. The proposed rule will also prevent CAHs from replacing outdated facilities with new, more modern provider-based facilities in locations that best suit the needs of their population.

We are particularly concerned that CMS does not appear to exclude rural health clinics from the proposed rule. Clinics are often a way that CAHs recruit physicians to practice in the area. By hiring a physician at one of the CAHs' provider-based clinics, the CAH guarantees that there is a physician in the area to serve on the medical staff of the hospital. There are small communities nationwide that would not have a physician without a rural health clinic.

It should be noted that many state necessary provider plans, which were approved by CMS, used criteria such as population, income and age demographics for areas to determine if a hospital could qualify as a necessary provider. It would seem reasonable that new off-campus sites within geographic areas used to establish necessary provider status should not affect continuing necessary provider status.

We urge CMS to rescind this proposal to avoid limiting access to health care services in rural areas.

Thank you for providing us with an opportunity to comment. Please contact me at 701-845-1900 for additional information.

Sincerely,

Rick Failing
President/CEO

CMS-1392-P-852 **Medicare**

Submitter : **Mrs. Michele Steri** **Date & Time: 09/13/2007**

Organization : **none**

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 leader of the Pittsburgh Area Dystonia Support Group and one who represents so many people with 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. The majority of my members receive botulinum toxin to alleviate the debilitating and often painful dystonic symptoms. These injections are critically important to their ability to function normally and also, to continue working in whatever fields of employment. Without Botox, they could go from gainful employment to receiving disability payments.

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

Thank you for allowing me to express these comments.

CMS-1392-P-853 **Medicare**

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

Organization :

Category : **Hospital**

Issue Areas/Comments

Payment for Diagnostic Radiopharmaceuticals

This comment concerning payment for diagnostic radiopharmaceuticals is also part of our comprehensive comment on the section concerning packaged services. Thank you.

#853

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

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

Proposed payment for Diagnostic Radiopharmaceuticals

The Provider Roundtable (PRT) generally endorses the concept of CMS' expanded packaging proposal, but has reservations about the manner in which CMS selected services to package and what these services were specifically packaged into. We are fundamentally concerned with this since CMS' proposal will result in providers losing separate APC reimbursement for over 200 codes which currently generate separate payment. Therefore, we need to be certain that the costs associated with these proposed packaged services have been appropriately accounted for in the OPPS system. Specifically, our review of the APC proposed payment rates for a number of procedures which presumably would now include packaged charges are simply lower, and in some cases much lower, than the payment we receive today for all of the services through separate APC payment. We are deeply concerned that CMS may have understated some of the median costs, and in other cases, the packaged services may not have been accounted for at all if they were not present on the claim or if they were present on multiple procedure claims. Despite our concerns, we support CMS' implementation of the general packaging concept for 2008, but to a limited extent as we describe below.

On a separate note, the PRT is disappointed with the overarching tone and theme of this proposed rule, which implies that hospitals provide whatever services they wish at whatever cost, with their only concern being reimbursement for the service, and that reimbursement would motivate hospitals to report services on separate claims just to be paid more. We further note that existing requirements found at 42 CFR 411.15 (m) provide that hospitals must furnish and bill for services necessary to complete an outpatient hospital encounter. Therefore, repetitive language throughout the proposed rule stating that hospitals would potentially respond to packaging proposals by delivering part of the service at one hospital and the remainder of the service at another hospital would be a violation of existing CMS regulations.

CMS has identified seven service areas for packaging for CY 2008. The PRT recommends that CMS delay implementing packaging relating to some of these areas as outlined below. We strongly encourage CMS to conduct further analysis in these service areas to ensure that the rate-setting logic accurately accounts for the packaged dollars associated with these tests and procedures before it proceeds to package them.

We further note that CMS' assumption that this packaging initiative will "*create enhanced incentives for hospitals to provide only necessary, high quality care and to provide that care as efficiently as possible*" and that the packaging "*would create incentives for efficiency and volume control, while providing hospitals with flexibility to provide care in the most appropriate way for each Medicare beneficiary*" is incorrect and invalid. Hospitals provide services only upon order of a physician. Therefore, it is the physician community that drives the volume and selection of tests, as well as deciding the most appropriate care for patients. Hospitals must provide resources to complete the ordered tests based on the direction of the physician or refer the patient to another facility that can provide the ordered services. Hospitals may make suggestions to a physician regarding the reasonableness of one particular modality vs. another; however, the ultimate decision for the ordered service remains under the purview of the physician. Physicians and the community in general expect hospitals to keep abreast of advances in medical practice and to provide services that are ordered. Innovation and best practices definitely have associated increased costs. To base packaging policy on the frequency of service and to suppress payments to hospitals because CMS suspects that hospitals are "*over-providing*" services contributes to the further deterioration of hospitals' abilities to provide state-of-the-art care to Medicare beneficiaries.

If CMS' intent to expand the packaging concept is to succeed without causing huge financial risk for hospitals and beneficiary access to care problems, then the PRT believes CMS must strive to use correctly coded claims for rate setting, even if those claims are multiple procedure claims. Furthermore, CMS should discard incorrectly coded claims even if those claims are single procedure claims. In order to calculate accurate payment rates for what CMS characterizes as the "independent procedure or service," CMS must use only correctly coded claims for rate setting. Without accounting for the presence or absence of a packaged service on a claim, CMS will underestimate the median cost for the independent procedure or service and thereby reduce hospital APC payments. Based on CMS' existing rate-setting methodology it is clear that only single or pseudo single claims were utilized and where packaged services could be packaged they were packaged, without any regard to the appropriateness of the packaging. In addition, we are concerned about the distribution of packaged charges on multiple procedure claims since these claims are not

used for setting APC payment rates. We understand that CMS believes that packaged services appear with relatively equal frequency and quantity on single versus multiple procedure claims; however that still does not mean that CMS has appropriately allocated the packaged services, if at all, on multiple procedure claims. We believe CMS needs to work towards refining its packaging logic to allow for more packaged charges to be included in the rate-setting process and to allocate those packaged dollars using specific logic so that providers have a greater comfort level of what services are packaged into other services. We ask CMS to release additional data shedding light on the percentage of packaged services/dollars allocated to each separately payable APC and a listing of the codes and their frequency so we can better understand where the packaged dollars were assigned. We cannot fully support what appears to be a hasty decision on CMS' part to drastically change the OPPS system without additional data and analyses from CMS. Packaging for the sake of packaging or to introduce what CMS believes to be a set of efficiency and flexibility incentives for hospitals is irresponsible and to a large extent unfair to providers if packaging has only been marginally done. Furthermore, CMS has not addressed what the PRT believes will be a significant down stream effect of more packaging, which is a deterioration in the quality of future claims data, which in turn will impact 2010 APC payment rates.

As providers, we need a greater level of proof that currently paid services now proposed to be packaged have in fact been packaged to the most appropriate services and that these charges have not been lost altogether from the OPPS system. We are not confident that this is the case for all of the service areas CMS proposes to package in 2008 and strongly recommend that CMS further evaluate its data. The PRT urges CMS to proceed with caution to prevent negatively impacting hospital service lines that are integral to providing high quality patient care. We offer our specific thoughts by service area below.

DIAGNOSTIC RADIOPHARMACEUTICALS

These have been packaged and unpackaged over time and the reported line item codes and charges are likely to be susceptible to the same issues described above under contrast agents. CMS states that most of the single procedure nuclear medicine claims had a radiopharmaceutical present, but cannot comment on the appropriateness of the billed radiopharmaceutical with the particular nuclear medicine procedure. We believe CMS should have performed some sort of clinical and resource homogeneity analysis before simply deciding to package all diagnostic radiopharmaceuticals as we do not believe this is appropriate.

Radiopharmaceuticals have a short half-life and are administered based on the specific patient's disease and situation. These products, which are considered drugs rather than supplies by our hospitals, are not ordered in bulk and do not sit on a shelf waiting to be used. Neither are they interchangeable despite CMS' assertion that packaging these will give providers flexibility in selecting the most efficient products, services, care delivery, etc. For example, a patient that presents for a bone study requires a radiopharmaceutical that is appropriate for that study even if it is more expensive than a radiopharmaceutical for a soft tissue study. CMS must recognize that hospitals simply cannot select the least expensive radiopharmaceutical as a substitute for a more expensive one – unless of course we stop seeing certain types of patients altogether. The incentive

CMS is attempting to create is misguided and inappropriate and could result in serious access to care problems. Additionally, if a patient does not show up for the scheduled test or service, the hospital must absorb the cost for the radiopharmaceutical that was ordered for that study. These agents are very costly to the hospital and again, patient specific.

For the reasons cited above, the PRT recommends that CMS delay its proposal to package radiopharmaceuticals for at least one year. It may be possible for CMS to create groupings of radiopharmaceuticals rather than paying for each one separately as an attempt to move closer to packaging but without tying non-substitutable radiopharmaceuticals to procedures. Therefore, CMS should continue to provide separate reimbursement under the current reimbursement methodology for all radiopharmaceutical HCPCS codes.

Finally, the PRT supports the APC Advisory Panel's recommendation that CMS provide data on the percentage of diagnostic nuclear medicine study claims that were reported with and without a corresponding radiopharmaceutical. We believe this data will provide vital information concerning hospital reporting trends for these services and agents. Based on the analysis, it can be determined whether an edit is indicated for reporting these services either on the front-end through the Outpatient Code Editor or on the back-end in CMS' rate-setting logic. For diagnostic radiopharmaceuticals, an OCE edit could be added that would require the reporting of a radiopharmaceutical when a nuclear medicine test is reported. This edit could be constructed at the revenue code level since diagnostic radiopharmaceuticals should be reported under revenue code 0343 and diagnostic nuclear medicine procedures are reported under revenue code 0340 or 0341. This edit would support CMS' packaging initiative by improving the available cost data for these services. It would also demonstrate to CMS that radiopharmaceuticals are not interchangeable; services being interchangeable and providing the same result regardless of the modality is a basic, recurring concept in CMS' packaging methodology stated throughout this proposed rule, yet we disagree with it with respect to radiopharmaceutical use in nuclear medicine studies.

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

Sincerely yours,

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

CMS-1392-P-854 **Medicare**

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

Organization : **Medical Management Options**

Category : **Health Care Provider/Association**

Issue Areas/Comments

OPPS: Partial Hospitalization

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

Subject: CMS-1392-P □ Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Dear Deputy Administrator Kuhn:

I am writing in response to the proposed rule referenced above, specifically in regards to proposals made affecting Partial Hospitalization Programs. I am the CEO of Medical Management Options in Baton Rouge, Louisiana.

Our agency has suffered over 21% reduction in reimbursement over the past two years, while costs have skyrocketed due to the after effects of hurricane□s Katrina and Rita. I spend most of my time talking with vendors about when our company will be able to pay our bills due to the extreme cuts we have already experienced. If this cut occurs and my programs and others are forced to close, the patients we currently serve will most likely be incarcerated or die.

Mental Health Services in Louisiana were in a dire situation prior to the hurricanes and we now require resources to respond to the mental health needs of its citizens.

We simply cannot provide services at the proposed rate. The proposed cut of 23.7% is excess and will effectively destroy the Mental Health System in Louisiana.

Due to these concerns, I respectively ask that you withdraw the provisions in this rule pertaining to Partial Hospitalization Programs. As stated above, such provisions would be devastating!

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

Sincerely,

Robert L. Miller
CEO, Medical Management Options

CMS-1392-P-855 **Medicare**

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

Organization : **Allegheny General Hospital**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

See Attachment

#855

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 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*

[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 contact me if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

David Seigneur, MS
Program Director
Dr. Dean Ornish Program for Reversing Heart Disease
Allegheny General Hospital
Pittsburgh, PA
Phone: 412-486-5366
E-mail: dseigneu@wpahs.org

CMS-1392-P-856 **Medicare**

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

Organization : The Provider Roundtable

Category : Hospital

Issue Areas/Comments

GENERAL

Please see attached comment from The Provider Roundtable. We have also uploaded our comments under the specific headings that are applicable for each section. We also submit this copy of our comment in total. Thank you.

#856

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

September 13, 2007

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

Re: File Code CMS-1392-P

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers from around the country who gathered to provide comments on the 2008 Outpatient Prospective Payment (OPPS) Proposed Rule, as published in the *Federal Register* on August 2, 2007.

Introduction

The Provider Roundtable (PRT) is a group of providers representing 19 different health systems from around the country. The members of the PRT collaborated to provide substantive comments with an operational focus which CMS' staff should consider during the OPPS policymaking and recalibration process each year. PRT members are employees of hospitals. As such, they have financial interest in fair and proper payment for hospital services under OPPS, but no specific financial relationship with vendors.

We appreciate the opportunity to provide CMS with our comments, and recognize that providers must become involved in the comment process if OPPS is to improve with time. A full list of the current PRT members is provided in **Appendix A.**

OPPS: Packaged Services

The Provider Roundtable (PRT) generally endorses the concept of CMS' expanded packaging proposal, but has reservations about the manner in which CMS selected services to package and what these services were specifically packaged into. We are fundamentally concerned with this since CMS' proposal will result in providers losing separate APC reimbursement for over 200 codes which currently generate separate payment. Therefore, we need to be certain that the costs associated with these proposed packaged services have been appropriately accounted for in the OPPS system. Specifically, our review of the APC proposed payment rates for a number of procedures which presumably would now include packaged charges are simply lower, and in some cases much lower, than the payment we receive today for all of the services through separate APC payment. We are deeply concerned that CMS may have understated some of the median costs, and in other cases, the packaged services may not have been accounted for at all if they were not present on the claim or if they were present on multiple procedure claims. Despite our concerns, we support CMS' implementation of the general packaging concept for 2008, but to a limited extent as we describe below.

On a separate note, the PRT is disappointed with the overarching tone and theme of this proposed rule, which implies that hospitals provide whatever services they wish at whatever cost, with their only concern being reimbursement for the service, and that reimbursement would motivate hospitals to report services on separate claims just to be paid more. We further note that existing requirements found at 42 CFR 411.15 (m) provide that hospitals must furnish and bill for services necessary to complete an outpatient hospital encounter. Therefore, repetitive language throughout the proposed rule stating that hospitals would potentially respond to packaging proposals by delivering part of the service at one hospital and the remainder of the service at another hospital would be a violation of existing CMS regulations.

CMS has identified seven service areas for packaging for CY 2008. The PRT recommends that CMS delay implementing packaging relating to some of these areas as outlined below. We strongly encourage CMS to conduct further analysis in these service areas to ensure that the rate-setting logic accurately accounts for the packaged dollars associated with these tests and procedures before it proceeds to package them.

We further note that CMS' assumption that this packaging initiative will "*create enhanced incentives for hospitals to provide only necessary, high quality care and to provide that care as efficiently as possible*" and that the packaging "*would create incentives for efficiency and volume control, while providing hospitals with flexibility to provide care in the most appropriate way for each Medicare beneficiary*" is incorrect and invalid. Hospitals provide services only upon order of a physician. Therefore, it is the physician community that drives the volume and selection of tests, as well as deciding the most appropriate care for patients. Hospitals must provide resources to complete the ordered tests based on the direction of the physician or refer the patient to another facility that can provide the ordered services. Hospitals may make suggestions to a physician regarding the reasonableness of one particular modality vs. another; however, the ultimate decision for the ordered service remains under the purview of the physician. Physicians and the community

in general expect hospitals to keep abreast of advances in medical practice and to provide services that are ordered. Innovation and best practices definitely have associated increased costs. To base packaging policy on the frequency of service and to suppress payments to hospitals because CMS suspects that hospitals are "*over-providing*" services contributes to the further deterioration of hospitals' abilities to provide state-of-the-art care to Medicare beneficiaries.

If CMS' intent to expand the packaging concept is to succeed without causing huge financial risk for hospitals and beneficiary access to care problems, then the PRT believes CMS must strive to use correctly coded claims for rate setting, even if those claims are multiple procedure claims. Furthermore, CMS should discard incorrectly coded claims even if those claims are single procedure claims. In order to calculate accurate payment rates for what CMS characterizes as the "independent procedure or service," CMS must use only correctly coded claims for rate setting. Without accounting for the presence or absence of a packaged service on a claim, CMS will underestimate the median cost for the independent procedure or service and thereby reduce hospital APC payments. Based on CMS' existing rate-setting methodology it is clear that only single or pseudo single claims were utilized and where packaged services could be packaged they were packaged, without any regard to the appropriateness of the packaging. In addition, we are concerned about the distribution of packaged charges on multiple procedure claims since these claims are not used for setting APC payment rates. We understand that CMS believes that packaged services appear with relatively equal frequency and quantity on single versus multiple procedure claims; however that still does not mean that CMS has appropriately allocated the packaged services, if at all, on multiple procedure claims. We believe CMS needs to work towards refining its packaging logic to allow for more packaged charges to be included in the rate-setting process and to allocate those packaged dollars using specific logic so that providers have a greater comfort level of what services are packaged into other services. We ask CMS to release additional data shedding light on the percentage of packaged services/dollars allocated to each separately payable APC and a listing of the codes and their frequency so we can better understand where the packaged dollars were assigned. We cannot fully support what appears to be a hasty decision on CMS' part to drastically change the OPPS system without additional data and analyses from CMS. Packaging for the sake of packaging or to introduce what CMS believes to be a set of efficiency and flexibility incentives for hospitals is irresponsible and to a large extent unfair to providers if packaging has only been marginally done. Furthermore, CMS has not addressed what the PRT believes will be a significant down stream effect of more packaging, which is a deterioration in the quality of future claims data, which in turn will impact 2010 APC payment rates.

As providers, we need a greater level of proof that currently paid services now proposed to be packaged have in fact been packaged to the most appropriate services and that these charges have not been lost altogether from the OPPS system. We are not confident that this is the case for all of the service areas CMS proposes to package in 2008 and strongly recommend that CMS further evaluate its data. The PRT urges CMS to proceed with caution to prevent negatively impacting hospital service lines that are integral to providing high quality patient care. We offer our specific thoughts by service area below.

GUIDANCE SERVICES

The PRT acknowledges that based on CMS' definition, guidance services are dependent services as they are not performed alone but as an adjunct to another procedure that can be performed independently. Because the other procedure can be performed alone, it is appropriate to package the guidance service into that individual procedure based on the manner in which the claims data reflect the dependent procedure having occurred with the independent procedure. For example, we agree that ultrasound guidance for a biopsy can be packaged, but we ask CMS to review whether it was appropriately packaged into a biopsy procedure or whether it was also packaged to other procedures that it should never be packaged to simply because of how the claim was submitted. In other words, does CMS use only those claims containing the biopsy CPT code and the guidance CPT code for rate setting? Another example is fluoroscopic guidance for inserting a tunneled central venous catheter. We agree that this can be appropriately packaged into the insertion procedure, but again ask CMS to review how many times it was packaged into this appropriate procedure versus another random procedure where the packaged dollars should never be assigned. We believe that CMS' existing rate-setting logic allows inappropriate packaging to occur. We understand from the rule that there is no assurance that the guidance would ONLY be packaged into the specific procedure(s) that require guidance and this is the significant issue that concerns us. If the packaging of a dependent procedure is not directed to one or more specific independent procedures, then we believe CMS will underestimate the median cost for the independent APC services, and potentially overestimate others (those that received packaged dollars but should not have). Once CMS appropriately matches dependent guidance services with only the appropriate independent procedures (and we believe that the claims data was likely reported more accurately than not), the PRT will then support the packaging of guidance services for the majority of modalities.

IMAGE PROCESSING SERVICES

The PRT agrees with the proposal to package image processing services with one hesitation. The fact that CMS states "*Resource cost was not a factor we considered when proposing to package supportive image processing services*" is troublesome. Many facilities do not have the resources to provide image processing "in house" and must contract with an outside provider. Excluding resource cost in making this decision is irresponsible on CMS' part and goes against the principles upon which this prospective payment system is predicated. The PRT strongly urges CMS to revisit the resource cost associated with these services in order to ensure appropriate payment for these services under OPPS but more important to assure that hospitals can continue to provide these services to beneficiaries. These services provide very important data in the care and diagnosis of all patients and not considering the cost to hospitals will result in these services being less available.

INTRA-OPERATIVE SERVICES

The PRT agrees with the packaging of the majority of codes listed in table 12 of the proposed rule. However, two of the codes are unlisted procedures and could be reported as independent procedures and therefore cannot be considered dependent. CPT codes 92999 (Unlisted neurological or neuromuscular diagnostic procedure) and 37299 (unlisted [eye] procedure, posterior segment)

should not be packaged. Under CPT rules, unlisted codes are reported when a specific CPT code does not exist for a procedure. Based on this rationale coupled with the fact that these codes are not designated as add-on codes, they are not candidates for packaging as there is no indication that all procedures reported with these codes are dependent in nature. These are the only unlisted codes on the proposed packaging list for intraoperative services and should be removed and separate APC payment continues. The PRT supports the APC Advisory Panel's recommendation to assign CPT code 96020 (functional brain mapping) to status indicator Q. The PRT wishes to commend CMS on excluding diagnostic services that are independent themselves, but are sometimes provided in association with other independent procedures. Once again, however, the PRT is concerned that CMS did not, but should, consider resource costs involved when making the decision to package certain intra-operative services.

IMAGING SUPERVISION AND INTERPRETATION SERVICES

The PRT adamantly opposes CMS proposal for packaging imaging supervision and interpretation services, as we do not believe that CMS conducted a thorough enough analysis of the many ways that CPT codes can be reported for multi-faceted services, that is services where there could be more than just one surgical CPT and one radiology S&I CPT. For instance, there is great variety in coding for Interventional Radiology services, and the current CPT coding system is set up on a "component" basis (S&I plus surgical) for this very reason. Otherwise, it would require hundreds of additional unique CPT codes to cover all the potential combinations of procedures that could be performed.

Furthermore, this is an area where the current cost center to revenue coding mapping is problematic. Hospitals report the surgical CPT component for most Interventional Radiology services under revenue code 0361 and this revenue code is mapped to the surgery cost center. Most of these procedures are performed in the radiology department or the heart catheterization laboratory, therefore, CMS' median cost calculation using the surgery CCR is highly suspect.

Also, based on current status indicators assigned to non-S&I procedures and CMS' packaging proposal, there will be times when two services are reported together and both are packaged services. If one service has a status indicator of Q, this is the service that will be reimbursed, which indicates that no consideration was given to an appropriate packaging methodology, but just packaging because of the code descriptor. There will be other instances when none of the codes on a claim are classified as a significant procedure, but only status indicator T which triggers reduced payment depending on the status indicator of the other procedures on the claim. In addition, it could result in a claim with packaged services only thereby resulting in no payment for a particular service that was rendered.

As an alternative to Table 13 in the proposed rule, where CMS shows a positive payment outcome for a simplistic CT/myelogram case, we would like to provide a scenario for CMS to consider involving an extensive angiography case (including only the procedure charges) as follows:

CPT CODE	CODE DESCRIP	2007 SI	2007 APC PAYMENT	2008 SI	2008 APC PAYMENT
	DX ANGIOGRAPHY W/ PTA SFA				
75625	ABDOMINAL AORTOGRAPHY	S	1,279.92	Q	
75716	ANGIOGRAPHY EXTREMITY BILATERAL	S	1,279.92	Q	
75774	SELECTIVE ANGIOGRAPHY EA ADDL VESSEL	S	584.32	N	
75774	SELECTIVE ANGIOGRAPHY EA ADDL VESSEL	S	584.32	N	
36247	3RD ORDER SELECTIVE CATHETER PLACEMENT	N		N	
35474	ANGIOPLASTY FEM-POP EA VESSEL	T	2,639.19	T	2,934.24
35474	ANGIOPLASTY FEM-POP EA VESSEL	T	1,319.60	T	1,467.12
75962	ANGIOPLASTY FEM-POP S&I	S	383.95	Q	
75964	ANGIOPLASTY FEM-POP EA ADDL VESSEL S&I	S	383.95	N	
	TOTAL APC PAYMENT		**8,455.17**		**4,401.36**

As evidenced in the example above, it is not conceivable that the S&I codes have been properly accounted for within the surgical codes. The proposed packaging concept for S&I codes will result in excessive and extreme decreases in reimbursement that will be detrimental to hospitals. The PRT agrees with the APC Advisory Panel's recommendations that CMS delay the packaging of these services and study the impact of this proposal in greater detail; ensure that services are not packaged into other services that are already packaged; and review alternative packaging options for these services. We also urge CMS to study the impact of the cost center to revenue code center mapping and charge compression in relation to these services.

CONTRAST MEDIA

The PRT notes that in the past, some of the items proposed for packaging have been packaged and unpackaged and then packaged again. For example, contrast media was separately reportable, then included in the procedure being performed; at which time some hospitals included the charge for the contrast in the charge for the procedure. Later, contrast media again was designated as separately reportable and separately payable, and some hospitals may have broken out the contrast charge and reported it separately while others may have left it packaged into the procedure charge despite the fact that separate payment was at stake and likely lost to the provider if they did not report the contrast HCPCS code separately. This is just one example of how frequent status indicator changes from packaged to separately payable and back to packaged again can cause provider billing problems, all of which can result in poor and inconsistent data being reported to CMS. Additionally, such frequent short-lived changes cause an enormous operational burden for providers.

Despite the above, the PRT does support CMS' proposal and the APC Advisory Panel's recommendation to package contrast media in 2008. As noted previously, we believe CMS should develop some claims logic or parameters for establishing into which procedures the contrast media is packaged and only use procedure line items for median cost calculation that have contrast packaged into them. Not doing so will undervalue the overall median cost for the procedure line item. For example, we agree that it is appropriate to package contrast into the procedure code for a

cardiac catheterization and radiology procedures that indicate they are performed with contrast, but if a CT scan of the brain with contrast and a chest x-ray are reported on the same claim. We believe CMS should use logic that assigns the contrast to the CT scan rather than allowing this to remain as a multiple procedure claim which is how we understand CMS treats it today.

DIAGNOSTIC RADIOPHARMACEUTICALS

These have been packaged and unpackaged over time and the reported line item codes and charges are likely to be susceptible to the same issues described above under contrast agents. CMS states that most of the single procedure nuclear medicine claims had a radiopharmaceutical present, but cannot comment on the appropriateness of the billed radiopharmaceutical with the particular nuclear medicine procedure. We believe CMS should have performed some sort of clinical and resource homogeneity analysis before simply deciding to package all diagnostic radiopharmaceuticals as we do not believe this is appropriate.

Radiopharmaceuticals have a short half-life and are administered based on the specific patient's disease and situation. These products, which are considered drugs rather than supplies by our hospitals, are not ordered in bulk and do not sit on a shelf waiting to be used. Neither are they interchangeable despite CMS' assertion that packaging these will give providers flexibility in selecting the most efficient products, services, care delivery, etc. For example, a patient that presents for a bone study requires a radiopharmaceutical that is appropriate for that study even if it is more expensive than a radiopharmaceutical for a soft tissue study. CMS must recognize that hospitals simply cannot select the least expensive radiopharmaceutical as a substitute for a more expensive one – unless of course we stop seeing certain types of patients altogether. The incentive CMS is attempting to create is misguided and inappropriate and could result in serious access to care problems. Additionally, if a patient does not show up for the scheduled test or service, the hospital must absorb the cost for the radiopharmaceutical that was ordered for that study. These agents are very costly to the hospital and again, patient specific.

For the reasons cited above, the PRT recommends that CMS delay its proposal to package radiopharmaceuticals for at least one year. It may be possible for CMS to create groupings of radiopharmaceuticals rather than paying for each one separately as an attempt to move closer to packaging but without tying non-substitutable radiopharmaceuticals to procedures. Therefore, CMS should continue to provide separate reimbursement under the current reimbursement methodology for all radiopharmaceutical HCPCS codes.

Finally, the PRT supports the APC Advisory Panel's recommendation that CMS provide data on the percentage of diagnostic nuclear medicine study claims that were reported with and without a corresponding radiopharmaceutical. We believe this data will provide vital information concerning hospital reporting trends for these services and agents. Based on the analysis, it can be determined whether an edit is indicated for reporting these services either on the front-end through the Outpatient Code Editor or on the back-end in CMS' rate-setting logic. For diagnostic radiopharmaceuticals, an OCE edit could be added that would require the reporting of a radiopharmaceutical when a nuclear medicine test is reported. This edit could be constructed at the

revenue code level since diagnostic radiopharmaceuticals should be reported under revenue code 0343 and diagnostic nuclear medicine procedures are reported under revenue code 0340 or 0341. This edit would support CMS' packaging initiative by improving the available cost data for these services. It would also demonstrate to CMS that radiopharmaceuticals are not interchangeable; services being interchangeable and providing the same result regardless of the modality is a basic, recurring concept in CMS' packaging methodology stated throughout this proposed rule, yet we disagree with it with respect to radiopharmaceutical use in nuclear medicine studies.

OBSERVATION SERVICES

The Provider Roundtable (PRT) believes that based on CMS' own definition, observation is not a dependent service. CMS has defined observation care as "*a well defined set of specific, clinically appropriate services which include ongoing, short-term treatment, assessment and reassessment, that are furnished while a decision is being made regarding whether a patient will require further treatment as a hospital inpatient or if the individual is able to be discharged from the hospital.*" The ongoing assessment and monitoring is an active process that occurs during the observation stay. The medical monitoring itself becomes the primary independent service, and the other ancillary services become dependent to this active ongoing assessment.
The PRT realizes that CMS is alarmed by the rapid increase of separately payable observation service claims. However, we believe that this is directly related to the positive changes CMS made to the reporting system in response to work done by the APC Panel and other provider groups over the past several years. CMS listened to the operational burdens facing hospitals and responded with a simplified reporting and payment system. The PRT and the APC Panel reported to CMS that hospitals were likely under-reporting observation care in the past due to the complexity of billing rules prior to the changes made in 2006. We believe that the claims data generated under the simplified reporting and payment system support this information and is the primary reason CMS has seen an increase in the frequency of the separately payable observation APC. The PRT believes that claims data will stabilize and the upward trend will vanish with 2007 and later claims data.

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

CMS states in the proposed rule: "*We are also concerned that the current criteria for separate payment for observation services may provide disincentives for efficiency. In order for observation services to be separately payable, they must last at least 8 hours. While this criterion was put in place to ensure that separate payment is made only for observation services of a substantial duration, it may create a financial disincentive for an HOPD to make a timely determination regarding a patient's safe disposition after observation care ends. By packaging payment for all observation services, regardless of their duration, we would provide incentives for more efficient delivery of services and timely decision making.....To the extent that hospitals could change their*

behavior and cease providing observation services, refer patients elsewhere for that care, or increase the frequency of observation services, the data would show such a change in practice in future years and that change would be reflected in future budget neutrality adjustment..... We believe it is unlikely that hospitals would cease providing medically necessary observation care or refer patients elsewhere for that care if they were unable to reach a decision that the patient could be safely discharged from the outpatient department."

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

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

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

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

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

SUMMARY

In summary, the PRT strongly encourages the APC Advisory Panel and CMS to further evaluate non-specific packaging of services and ensure the use of correctly coded claims while discarding incorrectly coded claims (i.e., those where a packaged service would be expected to be reported but is missing) when calculating the independent procedure median costs. Without this level of specificity, if the associated packaged service is missing, an inappropriate allocation will occur and may ultimately compromise the integrity of the future APC rate-setting process. We agree with and support the majority of the APC Advisory Panel's recommendations as we also believe that sweeping changes of this magnitude require detailed analysis prior to broad-scale implementation and this level of analysis simply cannot be thoroughly accomplished during one regulatory cycle. If CMS proceeds with making such radical changes, it may place hospitals and beneficiaries at risk for very important services. We cannot state strongly enough that it is absolutely essential that CMS conduct an analysis regarding which independent services should have dependent services packaged into them.

IVIG Pre-administration-Related Services

The Provider Roundtable compliments CMS on the proposal to continue separate payment for IVIG pre-administration services for CY 2008. We also agree with the clinical APC assignment of G0332 as noted in the proposed rule.

However, we have significant concerns with the $38.52 proposed payment rate for 2008 given that we are currently paid $75 for this service. The 2008 proposed payment rate for G0332 is derived from 2006 provider claims data, which is likely flawed as G0332 was first introduced in 2006. The PRT believes a variety of factors may be distorting the proposed payment rate such as revenue code selection by individual hospitals, differences in the cost-to-charge ratios (CCRs) mapped to those revenue codes, and the actual dollar charge reported by providers. A survey of our member hospitals reflected a variety of revenue codes assigned for this service, although most are reporting this service under revenue code 260. Table 1 below shows the different revenue codes and corresponding CCRs reported by our members and it is clear that there is wide variation in the CCRs that influences the cost derived from reported charges.

Hospital	Rev code	CCR
Hospital 1	260	0.2645
Hospital 2	260	0.2889
Hospital 3	761	1.2400
Hospital 4	260	0.1674
Hospital 5	260	0.1640
Hospital 6	260	0.3200
Hospital 7	260	0.4940
Hospital 8	949	0.3370
Hospital 9	260, 636	0.1642
Hospital 10	636	0.2419
Hospital 11	260	0.0923
Hospital 12	260, 636	0.1925
Hospital 13	636	0.5174
Hospital 14	636	0.1622
Hospital 15	260, 636	0.1778
Hospital 16	260	0.1470
Hospital 17	260	0.2801
Hospital 18	260	0.3463
Hospital 19	636	0.1765

Moreover, we understand CMS had a large number of single claims available for rate setting. However, we know many providers simply reported a line item charge of $75 which is equal to the APC payment rate and others likely reported even lower charges. In both cases, the CCRs typically associated with the most frequently billed revenue codes would result in very low cost estimates for this important service. Therefore, the PRT requests that CMS verify that line items of G0332 with a charge of $75.00 were excluded from the rate setting process based on the following statement from the CY2007 OPPS final rule: "We also deleted claims for which the charges equal the revenue center payment (that is, the Medicare payment) on the assumption that where the charge equals the payment, to apply a CCR to the charge would not yield a valid estimate of relative provider cost" (page 87 CMS-1506-FC). When new codes are introduced it takes hospitals time to appropriately determine the cost and hence what the reported charge should be. If hospitals randomly selected a charge amount for this service during the early months of 2006 without giving thoughtful consideration to the resources involved, then CMS more than likely has many claims with inappropriately low charges (i.e., $75 or less) that we believe should be excluded from rate setting. While it is not specifically stated in the rule, we believe it would be appropriate for CMS to exclude line-items from the rate-setting process where the reported charge is less than the OPPS payment rate. The PRT asks CMS to comment on this issue and to verify whether it excluded line-items from the rate-setting process for this service where the reported charge was less than or equal to $75.

The PRT recommends CMS continue to pay IVIG pre-administration at the current rate of $75 for at least one more year so that it has the ability to evaluate 2007 claims data to verify at that time if

in fact the 2007 claims data would support a reduction in payment for OPPS in 2009. Until such verification with at least two years of claims data can be done, we do not believe it is prudent for CMS to decrease the payment rate by almost 50% as this will place a financial burden on our hospitals for this important service.

Implantation of Cardioverter Defibrillators

The Provider Roundtable supports CMS' proposal to recognize CPT codes 33240 and 33249 for the implantation of cardioverter defibrillators and discontinue the HCPCS codes G0297, G0298, G0299, and G0300.

Proposed Payment when Devices are Replaced with Partial Credit to the Hospital

The Provider Roundtable (PRT) agrees that beneficiaries should get the benefit of reduced device costs when replaced at full or partial credit to the hospital. However, we have several comments concerning the proposed payment policy, particularly in comparison to the Inpatient Prospective Payment System (IPPS) policy in this area and the operational implications.

On page 371 of the display copy, CMS states "*some hospitals have told us that they do not reduce charges for the device being implanted or used in the procedure in cases in which they receive a partial credit for the device, even in cases in which the credit is as much as 50 percent of the cost of an expensive device.*" The PRT is highly concerned with this statement because we believe such hospitals are already in violation of CMS policy stated at PRRM Section 2204.4 which reads: "*Medicare charges refer to the regular rates for various covered services which are charged to beneficiaries for inpatient or outpatient services. The Medicare charge for a specific service must be the same as the charge made to non-Medicare patients (including Medicaid, CHAMPUS, private, etc.), must be recorded in the respective income accounts of the facility,* ***and must be related to the cost of the service.*** "[emphasis added]. A charge for a device that has received a credit cannot be related to the cost of the device if it is charged the same amount as a device which received no credit. The PRT believes that CMS merely needs to re-emphasize existing policy with regard to hospital charge practices and instruct hospitals to reduce their charge for devices if there is a manufacturer credit.

CMS states that the median cost for device-dependent APCs used by CMS does not reflect full or partial credits because claims with modifier FB and token device charges were excluded. However, the PRT notes that to the extent the provider's cost of devices in their Medicare cost report reflects reduced costs due to credits, full and partial, the CCR used to reduce charges to cost does include the impact of credits. If the hospital did not reduce their billed charge for a credit, then the CCR for that department will be lower and the median cost calculation lowered. For example, if the hospital used one device and their charge is $200 and their normal cost is $100, then the CCR would be 0.50. If they received a 50% credit on the one device implanted and retained their billed charge of

$200.00, then their CCR would drop to 0.25 ($50.00/$200.00). If the hospital does reduce its billed charge, then the CCR will also reflect credits and the median cost calculation using the CCR will reflect the credit.

For OPPS, CMS proposes to reduce the device-dependent APC payment by 50 percent of the offset that would apply if the device were replaced at no cost, but only if the credit is 20% or more of the cost of the new replacement device. Note that the offset percentage is the percentage of the APC payment that is attributable to the cost of the device. Also, note that under PRRM Section 2302.6, hospitals must charge the same amount for the same service to inpatients and outpatients, so this offset amount should appropriately represent the value of the device under both OPPS and IPPS.

Under CMS' proposal, when a hospital receives a credit of 20% or more of the new device, CMS will reduce the payment for that device by 50%, a direct loss to the provider of up to 30% of the cost of the device. The PRT notes that this was the original policy proposed by CMS for the Inpatient Prospective Payment System, but later changed to 50 percent as discussed on page 479 of the display copy of the IPPS Final Rule for 2008. We note that CMS does not explicitly describe the type of DRG payment reduction to apply when a full or partial credit is received by a hospital for a device as evidenced by the presence of condition codes 49 and/or 50 on a claim. Rather, CMS leaves the logistics of this situation up to individual Fiscal Intermediaries and contractors up to and including the hospital having to produce an invoice for the device to the contractor upon request.

Finally, CMS requests that hospitals report a unique modifier if the credit on a replacement device is 20% or more of the cost of the replacement device. CMS states that requiring hospitals to reduce charges may be burdensome. Given that CMS already has policy in place that would require a hospital to reduce charges when its cost is reduced (i.e., PRRM Section 2204.4), it seems administratively burdensome to add an additional modifier when that modifier will not completely provide CMS with the information that it seeks (i.e., the amount of the device credit). Furthermore, adding modifiers is a coding requirement, whereby adjusting charges is a departmental requirement and the value of a credit is known to a department, not necessarily to a coder.

The PRT notes that the IPPS and OPPS policies are inconsistent and operationally untenable and likely to provide poor claims data for CMS to base future policies. Furthermore, CMS has not published the calculation or amounts of device reductions to apply under IPPS and neither have they published the savings to beneficiaries in their deductible if they are hospitalized as an inpatient and receive a replacement device at full or partial credit. In other words, how will the beneficiary benefit from the DRG payment reduction CMS plans to take?

For these various reasons, the PRT proposes the following to bring consistency to the two payment programs for these devices and which provides CMS with the information it needs in a manner that has the least reporting/administrative burden.

PRT Recommendations	IPPS	OPPS	Needed CMS Action
Provider charges for the device must reflect cost as per PRRM Section 2204.4	Provider charges must be reduced by the percentage of the credit. If 100% replacement, then token charge for the device only.	Provider charges must be reduced by the percentage of the credit. If 100% replacement, then token charge for the device only.	Restate policy per PRRM Section 2204.4 and instruct hospitals to reduce their charges for devices replaced at no or partial credit by the amount of the reduction.
Provider reports condition code 49 and/or 50 for full credit	Provider notes 100% credit in remarks field	Provider notes 100% credit in remarks field	Change policy to require hospitals to report the percentage of the credit in the remarks field on the UB04 claim when condition code 49 or 50 is reported.
Provider reports condition code 49 and/or 50 for partial credit of 50% or more	Provider notes percentage of credit in remarks field	Provider notes percentage of credit in remarks field	Change policy to require hospitals to report the percentage of the credit in the remarks field on the UB04 claim when condition code 49 or 50 is reported.
CMS Payment adjustment for a device with 100% credit	CMS reduces DRG payment by 100% of the applicable OPPS device offset (represented in dollars, not as a percentage) as calculated under OPPS	CMS reduces the APC payment by 100% of the device offset (current 2007 policy)	CMS uses the device cost calculations from OPPS to make payment reductions under both OPPS and IPPS.
CMS Payment adjustment for devices with 50% or more credit to the device	CMS reduces DRG payment by 50% of the applicable OPPS device offset (represented in dollars, not as a percentage) as calculated under OPPS	CMS reduces the APC payment by 50% of the device offset	CMS uses the device cost calculations from OPPS to make payment reductions under both OPPS and IPPS.

The advantages to the PRT recommendations are as follows:

1) The hospital will know ahead of time the amount of the reduction for both OPPS and IPPS.
2) The hospital does not have to report a special modifier under OPPS in addition to modifier FB and also condition code 49 and/or 50
3) The hospital communicates the exact amount of the device credit to CMS to allow CMS to track this issue.
4) The payment reduction for partial credit is consistent between OPPS and IPPS (i.e., 50 percent) and the amount of payment reduction known in advance to the hospital.
5) Fiscal Intermediaries can conduct audits to ensure hospitals are correctly reporting percentage credits, but hospitals do not have to provide invoices before an IPPS claim with a partial credit is processed for payment and this will allow the CMS contractors to process claims more readily.

Pharmacy Handling and Separately Payable Drug Payments

Pharmacy Handling and Overhead

The Provider Roundtable (PRT) has significant and grave concerns about the proposed reporting of pharmacy handling. CMS is bound by the statutory language of "average drug acquisition cost" and the PRT acknowledges CMS' directive to pay according to the statutory provision. The PRT suggests that defining pharmacy payment with terminology such as "ASP + X%" does separate drug cost from overhead/handling and meets the statutory requirement. The PRT also understands that CMS is attempting to remove the discrepancy between payment systems but also suggests that CMS has not factored into the equation the additional requirements that hospital pharmacies face when compared to retail pharmacies and physician's offices. Retail pharmacy systems have the capability of reporting drug acquisition cost separate from handling as retail pharmacies are reimbursed for handling/dispensing. For hospitals, there is no way to quantify handling easily and no way to automate the process. The proposed methodology of reporting pharmacy handling is unreasonable and presents HUGE operational issues for hospitals.

Operational concerns:

While CMS believes the uncoded revenue code is operationally easier than the prior C-code idea, the PRT disagrees and believes the new proposal is even worse in several ways. We understand that for one category of drugs – SCODs - CMS needs to address the statute by paying average acquisition cost and also pay for overhead/handling, but we do not believe the statute dictates separation of these payments. Primarily, the concept of separating overhead/handing from acquisition costs of drugs is an operational nightmare with significant financial risk to hospitals.

The first concern is calculating pharmacy handling consistently because there are many variables that prevent a quick and easy calculation. Each drug will have a different handling charge

depending on the route of administration. For example, the same drug may be given orally, IV push or via IV infusion. This creates three separate and unique calculations in order to reflect the accurate handling charge for a single drug with multiple preparations. The PRT asks CMS to imagine the resources required by our pharmacy departments to develop such charges for all of the drugs we currently administer, let alone all of their preparations.

Another issue that CMS should understand is that existing pharmacy systems cannot handle the explosion of charges and billing systems cannot automatically split one line item charge into multiple line items. To accommodate the reporting of a separate handling charge, hospitals will have to double the size of the Charge Description Master (CDM) or add items that can be "edited" so the individual handling charge can be added for each drug. Once this is completed, there is more manual intervention in order to insure that the correct charge is added to the individual claim. EACH account will have to be reviewed in order to know which drugs have been charged. The handling charge must be calculated individually (for editable CDM items) or the specific CDM number for the handling of that INDIVIDUAL drug must be selected. These items then have to be keyed in on the individual account. This process is just to get a claim out the door to Medicare. This will be a manual intervention nightmare for all providers!

Manual intervention correlates to a huge potential for errors. If charge corrections are required, someone has to remember to correct the handling charge also. This whole proposal creates a potential compliance risk for hospitals – if the correct handling charge is not rolled up to the correct drug line item, hospitals will inadvertently report incorrect data to private payers and have potentially billed a different individual drug charge to Medicare than to its private payers.

Most billing systems can combine charges by revenue code, grouping all items together for a single revenue code, but they cannot split line items out. Billing systems will not be able to allocate the handling charge to the individual drug line item charge. Additionally, billing systems are not able to allocate charges on a noncoded revenue line item to multiple revenue code lines. If pharmacy handling is reported under revenue code 259 (for example purposes only), and drugs are reported under revenue codes 636 and 250, it will be impossible for the billing system to know how much of the handling reported in revenue code 259 to allocate to revenue code 636 versus revenue code 250. Billing systems also do not combine HCPCS/CPT coded lines with noncoded lines for payment combination, even when reported under the same revenue code on the same date of service. Because revenue code 636 requires a HCPCS code, and the pharmacy handling will be a noncoded line item charge, there is no way to combine the two drug related charges onto one line item.

This creates a huge concern regarding cross-over claims. Once a hospital submits a claim to the primary payer, the primary payer transmits the claim to the secondary payer in many circumstances. If one of the payers is Medicare, this creates a huge potential for denied claims. Will Medicare's system be able to correctly report the charges to the non-Medicare secondary payer? If Medicare is the secondary payer, will Medicare accept the claim from the primary payer who doesn't accept separated line items and has no concern about what amount should be left on the drug line and what amount should be split out for pharmacy handling? How will each payer administer cross-over claims or will the hospital simply be penalized by delayed or denied payment?

CMS mentions in the proposed rule that *"So long as hospitals provide the same total charge to all payers, it would be acceptable to report that charge as a line item for one payer and two (or more) line items for another payer."* While we don't necessarily disagree with this statement, this will be a reporting burden for providers. Several non-Medicare payers have requirements that medications must be billed at the negotiated rate with no additional fee to cover pharmacy overhead. Many payers and some states require hospitals to submit a complete CDM on an annual basis. There is a high likelihood that these payers and states will see those separate charges for pharmacy overhead and disallow those detailed line items altogether on audit (even if the provider did roll them together on the claim to a single line item), because when a claim is audited, it is audited from the detail bill, not the UB claim form. This structure will create a prime target for third party payer auditors to deny the pharmacy handling line item, and perhaps the entire drug charge since they will not be able to disaggregate the information in any automated manner. That means that providers would still have to maintain the single comprehensive charge in the CDM for the drug which includes the overhead component, and then outside of the CDM (most likely manually) providers will have to manipulate the Medicare claim form. So this reporting requirement could become an entirely back-end manipulative process as noted previously in this comment.

Data Issues from the proposed rule:

From a data collection, or more important from a data integrity standpoint, the PRT is concerned about what will happen with the overhead costs in the larger context of multi-procedure claims as CMS looks to the rate-setting process in future years. First and foremost, we are having a difficult time evaluating specifically what will be required to produce a final claim since CMS' proposal does not name a specific revenue code for all providers to use to report the pharmacy handling charges; coupled with the fact that the rule also does not specify what constitutes pharmacy handling...it is left up to providers to decide.

But in the bigger picture, the concern is that additional lines of uncoded charges within the universe of claims will result in even more data being lost within the packaging hole as we believe CMS will see more and more drug charges, both the separately payable drug and the packaged pharmacy handling drugs charges on multiple procedure claims. Many drug charges already appear on multi-procedure claims and are currently not accounted for in the rate-setting process, therefore this proposal will simply compound CMS' inability to allocate packaged dollars correctly to procedures. CMS even reiterates in this proposed rule that "*we are unable to ensure that packaged costs can be appropriately allocated across multiple procedures performed on the same date of service.*" If CMS can't use the claim then the packaged dollars for handling fall completely out of the rate-setting process which will result in even lower aggregate drug reimbursement in the future.

By leaving the door open for providers to decide whether or not they want to report the overhead charge on a per drug or per episode basis, claims data will reflect wildly differing charges which bear no relationship whatsoever to the procedure or procedures being performed. The question is: what if there is a multi-procedure claim for drug administration (for instance one that includes both chemo and non-chemo infusion, as well as an injection), and assume the claim could be

manipulated in some way to become a pseudo-single---if that provider chooses to report overhead on per-episode basis (which means only one line item), how would the "*per-episode*" overhead be allocated to the individual drug administration procedures or is this irrelevant to CMS or in all likelihood will CMS simply view this as a multiple procedure claim for rate-setting purposes and not include it in future APC rate setting?

Another situation that happens very frequently in the outpatient hospital setting is that drug administration services are not reported on all claims that have pharmacy charges. Where will the pharmacy handling costs be packaged on these claims? Currently, drug administration services are not reported separately with surgery procedures as drug administration is considered to be part of the surgical procedure. Why should hospitals have the administrative burden of separating the two costs just to have them packaged into the procedure where they are going to be packaged anyway? If handling line items are excluded, then CMS' claims data is seriously flawed and will negatively affect future APC payment calculation.

CMS will never get 100% accurate data on separation of acquisition cost and handling. They will get a blend of both costs. Since there is no literally defined information for pharmacy handling, CMS is not going to get real information but only approximations. Many facilities will set a flat fee for handling which will reflect an average which will be overstated for some drugs and understated for others. CMS will also have to reconstruct their use of CCR. If hospitals bill one line based on acquisition cost, CMS cannot apply the current CCR because it is based on claims data and cost report information for a combined charge under this proposal. What was once a one line item charge has been split into at least two separate line items.

If the ultimate intent is to keep overhead packaged, the PRT fails to see the necessity of splitting out the two and reporting them on separate line items. The PRT believes that pharmacy handling is currently packaged in the most appropriate place – the pharmacy and with the drug, and should remain there. So we support CMS' "second" option as presented in the rule, which is to continue to provide a single bundled payment, representing combined acquisition and overhead, and make no changes to the reporting. And, as is mentioned in the proposed rule, this method still is consistent with your broader packaging efforts.

Should CMS move forward with the proposed structure of reporting pharmacy handling, it is absolutely impossible for hospitals to report this by January 1, 2008. This proposal would have to be delayed until such time as time and motion studies can be conducted by our pharmacists to establish appropriate pharmacy handling charges, To that end, CMS must issue a definition of pharmacy handling and manualize this definition; define the revenue code for reporting the handling charge (which should correspond to the pharmacy department so that cost matches expense), obtain NUBC approval for usage of a revenue code for this purpose, and issue guidance to assist hospitals in convincing the pharmacy and/or billing vendors that this process must be automated. The aforementioned documentation will possibly assist with explaining the charge structure to non-Medicare payers. The delay will have to allow for Medicare, Medicaid and other payers to alter their claims systems that deal with cross-over claims to prevent delays and denials of hospital services because of the differing reporting requirements. The delay will also have to allow for the

pharmacy and billing systems vendors to automate this function in their systems.

Separately payable drug APC payments based on ASP + 5%

The PRT cannot stress enough that we recommend CMS continue to use at a minimum ASP +6% as the payment method for average acquisition plus overhead/handling for all separately payable drugs. This formula elegantly covers average acquisition cost because average sales should equal average purchase costs and it retains consistency with payment for the same drug between sites of service (the hospital and the physician office setting), a principle CMS continues to promote. Prior studies by MedPac and data collected directly from hospitals indicates that ASP + 6% does not cover both acquisition and handling cost in the hospital setting. Despite this lack of appropriate reimbursement, the PRT and its member hospitals consider this more palatable than the proposed new reporting structure of carving out pharmacy handling separately from the drug charge. Making hospitals expend resources resulting from huge administrative costs to break out pharmacy overhead/handling with no apparent improvement to the payment system or to the quality of care or safety of medication administration is a direction that appears to be futile, and goes against CMS' stated goals of cost-containment, value-based purchasing, improvements in quality of care, and finally the flexibility it says in the proposed rule that it wants to give providers.

Reporting of All HCPCS codes for drugs

The Provider Roundtable supports CMS' proposal to recognize all HCPCS codes for drugs as an option but not a mandatory requirement. The option will allow greater flexibility and less operational burden on hospital processes.

Proposed Hospital Coding and Payment for Visits

Clinic Visits: New and Established Patient Visits

The 2008 proposed rule states: "*The AMA defines an established patient as 'one who has received professional services from the physician or another physician of the same specialty who belongs to the same group practice, within the past 3 years.' To apply this definition to hospital visits, we stated in the April 7, 2000 final rule with comment period (65 FR 18451) that the meanings of 'new' and 'established' pertain to whether or not the patient already has a hospital medical record number. If the patient has a hospital medical record that was created within the past 3 years, that patient is considered an established patient to the hospital. That same patient could be 'new' to the physician but an 'established' patient to the hospital.*"

The original definition in 2000 did not specify the three-year time frame; this was added in the 2006 OPPS final rule. This time frame is operationally difficult to apply for hospital providers. A hospital medical record number is created for the individual patient the first time that services are provided; this may be upon birth or the first time a patient seeks services from a specific provider. This unique number is utilized each time the patient presents for services and is never assigned to

any other patient. A multi-hospital system can choose to use the same medical record number at all of their facilities regardless to which campus the patient presents.

To the extent that hospitals expend additional resources evaluating and managing a new patient, these resources can be accounted for in each hospital's internal visit guidelines as is the case with consultation codes.

The PRT acknowledges that CMS' claims data indicates a new patient visit involves more resources than an established patient visit. However, we strongly believe this data may be flawed since it is almost impossible for hospitals to operationalize CMS' definition of a new patient and therefore the new patient visit codes may simply be reported as a matter of course, rather than through some thoughtful charging practice. In addition, we believe providers have reported new patient visits even when less than 3 years have transpired since the patient was last treated at the hospital, again contributing to the cost differences CMS is seeing. Simply put, we do not trust the data providers have reported to CMS given our own experiences and challenges in utilizing these codes and knowing that we do not report them very often. Despite the fact that keeping these codes in place and reporting them would result in better payment rates for some providers, the PRT members and its hospitals would prefer to take a reduction in APC payment rates by using only the established visit codes and having the median costs for new and established patients blended, rather than having to adhere to CMS' required definition of new patient. We truly believe that we are representative of all hospitals when we propose that CMS change its policy so that hospitals are only required to report the five established visit codes and CMS should continue to map these to five separate APC payment rates. Therefore, for 2008 and 2009 payment, the PRT proposes that CMS blend the median cost data for new and established visit codes and create five distinct levels of APC payment for these visit codes. We are willing to live with reduced payments over the next two years while reporting five visit codes but fully expect that CMS will receive much more accurate and robust cost data after two years at which time we believe APC payment rates for visits will stabilize and be more reflective of our resource consumption.

If CMS chooses to continue reporting both new and established visit codes, the PRT strongly urges CMS to change the definition of an established patient by removing the verbiage "created within the past 3 years" and return to the original definition published in 2000: "*If the patient has a hospital medical record, that patient is considered an established patient to the hospital.*"

Consultation Codes

The PRT supports CMS' proposal to inactivate CPT codes 99241 – 99245 for consultation visit codes under OPPS as these resources can be accounted for in each hospital's internal visit guidelines.

Type A and Type B Emergency Departments

CMS has specifically requested comments on the clarification needed to assist hospitals in determining whether an ED is a Type A or Type B, and on how this policy can be further clarified in light of hospitals' operational responsibilities to efficiently provide emergency services.

Providers are in full agreement and understanding of the application of Type B designation for "Fast Track" areas that are physically separate from the main ED; that have specific staff assigned for care of those patients; and that have specific hours (not 24/7) of operation. The Provider Roundtable (PRT) requests that CMS provide further clarification and specific guidance related to the necessity to "carve out" part of an Emergency Department for reporting as Type B.

Hospitals have an operational responsibility to efficiently provide services, and facilities work very hard to expedite patients through the system without compromising care. CMS notes throughout the proposed 2008 rule that they are specifically encouraging flexibility in resource utilization in order to provide quality care in the most cost effective manner possible. To that end, many hospitals are doing just this by finding a way to cluster patients in a specific set of rooms, identified as "fast track" rooms, which are housed within the main ED area. These rooms are used to treat both critical and non-critical patients. The staff that treats these patients are ED staff. The rooms used are available 24/7, but may not be used during all hours/days depending upon the census of the ED. The PRT contends that this "fast tracking" of patients is a process improvement initiative, and is not dependent upon the place of service. During peak patient visit hours, it is beneficial for some patients to be clustered in these "fast track" rooms rather than being spread throughout the ED. Facilities usually set specific hours when these rooms are "carved out" for fast tracking patients through the main ED due to historical data on ED census. The rooms may not be used outside these hours if they are not needed, but are functional for any ED patient when needed. Patients in a "fast track" room receive the same level of care as other patients: hospital staff floats between all ED rooms, although a specific nurse may be assigned to the "fast track" rooms during designated hours. As in any other nursing area, nurses receive a patient care assignment but ultimately have responsibility for all patients in that area. This is true for ED patients also, whether those patients are specifically assigned to a "fast track" room or not.

We believe the broad application of the "Type B" designation to include dual-use rooms within the ED walls has the unintended result of financially penalizing providers that utilize these "fast track" processes to improve patient care and reduce wait times. The PRT requests that CMS accept "fast track" as a process in this type of situation and refine the definition of Type B to exclude "carve out" rooms when the entire area as a whole meets the definition of a Type A Emergency Department.

Development of National E/M Guidelines

The Provider Roundtable (PRT) appreciates CMS not releasing national guidelines that are not functional in a hospital setting. We also appreciate CMS' acknowledging that providers have been

diligent in creating, refining, and maintaining internal guidelines. We understand CMS' current data indicates that hospitals' internal guidelines have produced stable visit level assignments without great fluctuation from year-to-year. However, we still believe it would be valuable in the future for CMS to move towards standardization and the development of national E/M guidelines. To that end, the PRT supports CMS' work toward the development of national E/M guidelines, but does not believe that there is a pressing need in the immediate future. The PRT provided analyses, modeling, and comments/recommendations to CMS earlier this year concerning development of national guidelines and hopes that information was useful in CMS' own analysis.

The PRT agrees that the initial six criteria, along with the additional five proposed E/M criteria form an excellent framework for the development of facility specific E/M guidelines. A poll was conducted among the PRT membership and all members note that the criteria proposed are reasonable and expect that most hospital's guidelines already meet these principles. We recommend that CMS define "great frequency" in the proposed criteria: "*The coding guidelines should not change with great frequency.*" The PRT applauds CMS for their continued efforts on this issue.

The PRT encourages CMS to work with and encourage the AMA to include these principles in the E/M section of the CPT book. Doing so would ensure easy access to the guidelines, promote consistency among all providers, and enable other payers to accept that CMS' use of the AMA CPT codes is different in the hospital setting versus physician setting.

The PRT has learned that some FIs are imposing their own unpublished E/M criteria upon providers rather than utilizing the provider's internally developed E/M guidelines during facility audits; these FIs are determining "reasonableness" of services as they relate to placement within various levels. When applied by the FI, these unpublished guidelines are detrimental to the hospital claims data as they are producing lower level calculations than the hospital's internal guidelines and more important, are in direct conflict with CMS' directive that requires providers to develop and use their own internally developed guidelines to report clinic and emergency department E/M visit codes. Hospital internal guidelines must be recognized by the FIs and to that end, the PRT vehemently urges CMS to provide clear direction to its FIs that they must use the individual facility's E/M internal guidelines when conducting a review or audit. CMS should explicitly state that an FI (or MAC) is not allowed to impose its own criteria upon the provider. The PRT asks that CMS make this explicit in instructions to FIs and MACs to be issued as soon as possible.

E&M ED Triage Issue

In the absence of national visit guidelines for Emergency Department services, the Provider Roundtable (PRT) would like clarification from CMS regarding the use of a low-level ED Visit code to cover the facility resources of a patient who is triaged and receives services, but leaves before receiving any physician or non-physician practitioner treatment. This question has been posed several times during the Hospital Open Door Forum calls yet remains unanswered despite the obvious need for clarification from CMS at a national level.

In this context, "triage" includes an initial assessment by a licensed practitioner (who is not a physician or non-physician practitioner) to ascertain whether the situation must be immediately managed (e.g., profuse bleeding, chest pain) or whether the situation is less life threatening (e.g.: sore throat, migraine headache).

Hospitals have an obligation under EMTALA to provide a Medical Screening Evaluation (MSE). However, some patients leave before receiving this MSE from a designated qualified provider (as dictated by state laws and/or hospital by-laws). We are concerned about the resource utilization associated with assessing patients who present to the hospital ED, but leave before receiving the MSE.

Technically, there is no coverage for the above scenario under the "incident-to" provisions for Hospital OP Therapeutic Services [100-02, Chap. 6, Section 20.4]: *"Therapeutic services which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services. To be covered as incident to physicians' services, the services and supplies must be furnished as an integral, although incidental, part of the physician's professional service in the course of diagnosis or treatment of an illness or injury. The services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician."*

Triage is not covered because a) there is no professional service for it to be integral to, nor alternatively b) there is not an order to provide the service. There is, however, an expectation that the service will be provided to ensure that the most critical patients are seen first. However, by nature of the presence of physicians within the ED, the "general assumption of supervision" is met on hospital premises.

However, it is also conceivable for triage services to be considered diagnostic services. Under section 20.3 in the manual [100-02, Chap. 6, Section 20.3] guidance is provided as follows: *"A service is 'diagnostic' if it is an* ***examination*** *or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury."* Additionally, *"Covered diagnostic services to outpatients include the services of nurses..."*

Historically CMS has alluded that the resource associated with a nursing assessment is commensurate with a low level E/M visit. Additionally, the ACEP model includes "triage" in the 99281 list of possible interventions. We believe that CMS recognizes that facility resources are expended for triage and did propose that triage be "payable" (though did not explicitly indicate that it is "covered") when CMS initially proposed HCPCS codes to replace E/M codes in 2002:

"Emergency Visits
Because, our data indicated that, in general, hospitals under the OPPS were reporting emergency visits appropriately, we believed that insofar as hospitals have existing guidelines for determining the level of emergency service, those guidelines reflected facility resource consumption. Therefore, we proposed that GXXX1— Level 1 Facility Emergency Services be reported when facilities deliver, and document, basic emergency department services. These services included registration, triage, initial nursing assessment, minimal monitoring in the emergency department (for example, one additional set of vital signs), minimal diagnostic and therapeutic services (for example, rapid strep test, urine dipstick), nursing discharge (including brief home instructions), and exam room set up/clean up. We expected that these services would be delivered to patients who present with minor problems of low acuity."

We believe that CMS has the authority to designate 99281 as a "nurse visit" under OPPS just as CMS has treated 99211 under the Medicare Physician's Fee Schedule (historically referred to as a "nurse visit" but listed in the current IOM 100-04, Chap. 12, Section 30.6.4) as follows: *"When evaluation and management services are furnished incident to a physician's service by a nonphysician employee of the physician, not as part of a physician service, the physician bills code 99211 for the service."*

In an environment where utilization of Emergency Room services is increasing annually, it is imperative that CMS define which hospital resource expenditures are reportable if the patient is not seen by the physician. Hospitals are required to accept all patients who present with a possible emergency condition and utilize resources to assess each patient. The PRT asks for clear instructions from CMS that these services are reportable. Providers have broached this question with different FIs and have received contradictory responses resulting in variable data being reported to CMS from providers around the country. The PRT presents several actual Emergency Department scenarios to facilitate answers by CMS. In all of these scenarios, it is given or assumed that the emergency physician is present in the emergency room meeting hospital physician supervision requirements.

1. A patient presents to the emergency room with a medical problem. Nursing performs and documents the initial assessment, including vital signs. The assessment process indicates the patient may wait in the waiting area until an ED bed becomes available. The patient leaves the hospital before receiving any other service. Are the expended hospital resources reportable with an appropriate emergency room E&M visit code based on the facility's own internally developed guidelines?

2. A patient presents to the emergency room with a medical problem. Nursing performs and documents the initial assessment, including vital signs. Based on the patient's clinical presentation, Emergency Room protocols allow the nurse to initiate diagnostic tests (for example, a patient presenting with chest pain may meet criteria to initiate a chest pain protocol which would instruct the nurse to draw cardiac enzymes, obtain an EKG, and possibly a CXR. The protocols are reviewed at regular intervals and approved by the ED

physicians). The protocol orders are documented on the patient's medical record. The patient leaves without any other service. Are the expended hospital resources reportable with an appropriate emergency room E&M visit code based on the facility's own internally developed guidelines?

3. A patient presents to the emergency room with a medical problem. Nursing performs and documents the initial assessment, including vital signs. Based on the patient's clinical presentation, Emergency Room protocols allow the nurse to initiate diagnostic tests (for example, a patient presenting with chest pain may meet criteria to initiate a chest pain protocol which would instruct the nurse to draw cardiac enzymes, obtain an EKG, and possibly a CXR. The protocols are reviewed at regular intervals and approved by the ED physicians). The protocol orders are documented on the patient's medical record. The patient leaves without any other service. The physician does not personally examine the patient, but personally reviews, authenticates and dates the encounter record in the chart. Are the expended hospital resources reportable with an appropriate emergency room E&M visit code based on the facility's own internally developed guidelines??

4. A patient presents to the emergency room with a medical problem. Nursing performs and documents the initial assessment, including vital signs. Based on the patient's clinical presentation, Emergency Room protocols allow the nurse to initiate diagnostic tests (for example, a patient presenting with chest pain may meet criteria to initiate a chest pain protocol which would instruct the nurse to draw cardiac enzymes, obtain an EKG, and possibly a CXR. The protocols are reviewed at regular intervals and approved by the ED physicians). The protocol orders are documented on the patient's medical record. The physician personally examines the patient, documents a note and authenticates and dates the encounter record in the chart. Are the expended hospital resources reportable with an appropriate emergency room E&M visit code based on the facility's own internally developed guidelines??

Cardiac Rehabilitation Services

The Provider Roundtable (PRT) does not support CMS' recommendation to change how cardiac rehabilitation services are reported. The proposed changes include creating new HCPCS codes for cardiac rehabilitation, and reporting charges on a per-hour rather than per-session basis.

The current CPT codes for cardiac rehab are:

- 93797 - Outpatient cardiac rehab; without continuous ECG monitoring (per session)
- 93798 – Outpatient cardiac rehab; with continuous ECG monitoring (per session)

The proposed new HCPCS codes are:

- GXXX1 - Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per hour)

- GXXX2 - Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per hour)

The PRT fails to see the rationale for changing from CPT to HCPCS coding, or from a non-time-based rate to a time-based rate. Cardiac Rehabilitation services are predominantly provided within a 45–90 minute time-frame per session. The increases in volume that have been seen over the last several years are attributable to inherent changes in the Medicare population's demographics.

The PRT believes that this proposed change presents a difficult problem for hospitals to meet Medicare requirements to bill all patients the same price for the same service. Hospitals would have to create per-hour charges to bill CMS while continuing to bill per-session charges to all other payers. Hospitals would bill one set of codes to Medicare and bill the current CPT codes to other payers which results in providers having to implement manual billing processes contributing to overhead and administrative cost and an increase in operational burden while doing nothing to advance the quality of the clinical care. We are concerned that hospitals will be vulnerable to compliance issues if they were to report different charges and codes to different payers for the same service.

In addition, the PRT questions how CMS formulated the proposed payment rates for the newly proposed "per hour G-codes" from the "per session CPT codes" present in the 2006 claims database. The PRT believes that implementing this coding change will impair future claims data as a result of the difficulties that hospitals will experience in attempting to implement two different coding systems for cardiac rehabilitation. We strongly feel that if CMS were to implement the proposed G-codes for Cardiac Rehabilitation services that it will simply see erroneous and aberrant claims data in the future as hospitals will certainly experience operational challenges in implementing these new G-codes for Medicare while continuing to report CPT codes to other payers. The fact is that two sets of codes will exist with totally different time elements for reporting the same cardiac rehabilitation services being provided. This will cause confusion for clinical as well as billing staff.

Further, this proposed rule change conflicts with CMS' stated goal of utilizing CPT codes rather than HCPCS codes and conflicts with current NCD guidelines which define cardiac rehabilitation services on a per-session basis. The PRT recommends that CMS rescind this proposal and continue to allow providers to report existing CPT codes for Cardiac Rehabilitation services.

Bone Marrow and Stem Cell Processing Services

The Provider Roundtable supports CMS' proposal for CY2008 to discontinue recognition of HCPCs code G0267 (Bone marrow or peripheral stem cell harvest) and to recognize the six CPT codes that are more specific. The PRT agrees that use of these codes will provide more specific claims data and more accurate payment, while also requiring one set of codes for all payers for these services.

ASC Impact: Proposed Update of the Revised Ambulatory Surgical Center Payment System

The PRT appreciates CMS' desire to remove site-of-service differentials that often result from the incentives created by different payment systems in place in different settings, such as hospitals and ambulatory surgery centers or hospitals and the physician office setting. However, while we are in favor of streamlining payment system differences, we are concerned that ASCs may underestimate the severity of certain types of patients and/or cases, particularly from the 700+ codes added to their list of available new services. It is the PRT's experience when ASCs provide services that they perhaps may not be fully equipped or staffed for, that hospitals and patients are the ones to suffer as patients are transferred to the hospital for continued care, either as prolonged recovery time or an observation stay. The PRT is concerned that while CMS is working to streamline payment inequities between the hospital and the ASC, it may simply end up reintroducing different inequities where hospitals lose money on patients transferred over from ASCs and patients who end up having to be seen and cared for by multiple providers. The PRT expects to see an increase in the number of patients transferred from ASCs in the future and we believe CMS will see an increase in the incidence of observation claims, or when the observation service does not meet medical necessity requirements, the hospital will be forced to issue an ABN to the beneficiary, thereby further adding to the beneficiary's cost.

The PRT encourages CMS to monitor this situation closely by collecting data. To this end, the PRT recommends that CMS develop one or more mechanisms for capturing transfers from the ASC to the hospital setting, and presents the following suggestions:

- Develop a discharge code for the ASC to indicate that the patient was sent to a hospital for recovery or observation; or
- Develop an admit source code for the hospital to indicate that the patient has come from an ASC; or
- Develop a separate G-code for hospitals to indicate a direct admit from an ASC.

The PRT members note that the preferred mechanism should be one that will work for all payers, and therefore prefer one of the first two options listed above as not all non-Medicare payers accept HCPCs codes.

In addition to correcting the site-of-service payment differentials, the PRT encourages CMS to develop consistent quality indicators between hospitals and ASCs. The PRT strongly believes that Medicare beneficiaries should receive the same high quality of care regardless of the site in which that service is provided.

Quality Data

The Provider Roundtable (PRT) understands -- and supports -- the need to report quality indicators for Medicare outpatients. These patients are typically in our hospitals for 24 hours or less. In that time, staff provides medical assessments, diagnostic studies, treatments, and evaluations to determine if admission is warranted. Thus, information required by CMS on quality indicators must be very specific and related to the patient's current visit.

The PRT agrees that the five proposed ED-AMI indicators should be reported by the transferring facility. PRT members that represent smaller facilities note that their facilities have the mechanisms and resources to provide care for ED-AMI patients pertaining to these indicators, but that they may not have the resources required for data collection and reporting on these indicators. While CMS did not specifically state that the reporting mandate is applicable to CAHs, the PRT strongly recommends that this information should be included in the data submission for the ED-AMI indicators.

The PRT believes that CMS has not clearly explained how the five proposed PQRI indicators will be captured. Given the proposed rule's definition of an "outpatient encounter", we anticipate that the volume related to these five PQIs will be nearly unmanageable. We request that CMS clarify several areas, including the type of services or conditions to be included and, given the tremendous volume of outpatients, whether hospitals would be allowed to provide a sampling of patients.

The PRT also asks CMS to clarify whether it expects facilities to report on outpatient services that include diagnostic studies. For example, a patient who has a diagnosis of CHF and presents to the hospital with a physician order for CXR would be an outpatient service. If the presenting problem is a secondary condition rather than CHF, would CMS require data reporting? In addition, CMS should clarify the expectations for data reporting on patients with CHF who frequently recur and return to the outpatient clinic. Further, if these patients are on an ACE inhibitor, CMS should clarify if this is to be reported for *each* encounter.

As another example, peri-operative care and timing of antibiotics are currently captured for inpatients and would be a reporting indicator that could be considered for surgical cases. The proposed rule is unclear concerning whether these indicators are for specific surgical procedures, or if interventional procedures are also to be included. Likewise, clarification is needed concerning whether specific types of prophylactic antibiotics are to be identified and if sampling will be allowed. We believe that the population related to these two indicators will be overwhelmingly large to manage without sampling.

The pneumonia PQRI appears to be a logical condition for measuring quality related to antibiotic administration in the Emergency Room and observation status. PQRI for A1C would not be measured in an acute care facility, in the ED, or in observation status. The A1C test is frequently ordered on newly diagnosed diabetics in order to help determine how elevated their uncontrolled blood glucose levels have been. The test may be ordered several times while control is being achieved, and then several times a year after that time, in order to verify maintenance of good

control. This indicator applies primarily to a provider-based diabetic clinic or a physician's office, not a facility.

AMI patients who present to smaller hospital Emergency Rooms are treated and then transferred to other acute care facilities for continued care. At the moment, quality indicators for these transferred patients are not included in the reporting structure in the receiving facility, since the initial treatment was not provided by the receiving facility. The PRT understands and supports CMS initiative to obtain this missing information for these transferred patients.

The PRT reviewed the remaining 30 proposed quality indicators and concurred that their focus is primarily for physician offices or a physician-based clinic -- rather than for hospital outpatient facilities. The PRT urges CMS not to implement these indicators until they have been further refined and made more specific to the hospital outpatient setting.

The proposed rule indicates that the CY 2009 payment reduction will be based on outpatient data validation as of January 2008 discharges. The PRT would like CMS to clarify if the proposed payment reduction would apply for all services reported in CY 2009. We feel there should be a grace period of data collection not directly tied to the next year's payments, which would be more closely allied to how IPPS indicators were collected and validated. CMS should remain mindful of the timeframe for implementation to train staff, and allow vendors to set up their products.

Conclusion

The Provider Roundtable would sincerely like to thank CMS and its staff for reviewing and considering our comments. The PRT members are very encouraged by the policy-making process and appreciate how our input can have an impact on future year's rules and policies. We are very grateful to CMS for considering our comments in past years as well as again this year. We hope the operational issues we have outlined will be helpful to CMS in considering future system changes. If you have any questions or require additional information, please contact our spokesperson:

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A full list of the provider roundtable members is included below in Appendix A.

Sincerely yours,

Members of the Provider Roundtable

Appendix A: Current Members of the Provider Roundtable

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CMS-1392-P-857 **Medicare**

Submitter : **Mr. Joseph Kappel** **Date & Time: 09/13/2007**

Organization : **PET/CT Services of Florida**

Category : **Health Care Industry**

Issue Areas/Comments

PET/CT Scans

(1) After trying to absorb an approximate 64% REDUCTION in the technical reimbursement for codes 78814,78815 & 78816 in 2007, it appears that these codes will be REDUCED again if the FDG-18 radiopharmaceutical (code A9552) is included in the new rate for 2008. This will likely cause many additional closures of Independent Testing Facilities (IDTF'S), and limit access to necessary imaging - especially for Senior Citizens (Medicare Patients). We are currently struggling to breakeven from a cash flow position, let alone earn enough to cover the replacement cost of the expensive PET/CT equipment - where a fully-equipped PET/CT Center costs approx. $2.5 million. Further reducing rates in 2008 will be disastrous, and cause even more Group Oncology Practices to acquire their own PET/CT equipment - where they can now purchase used/repossessed equipment at a fraction of the cost of new - and proceed to 'script' their way to profitability by ordering enough procedures to keep the equipment running at maximum capacity. I believe that the Group Practice Exception to Stark regarding imaging invites massive abuse(and overuse) of the technology - just the opposite of the supposed intent of the Deficit Reduction Act reductions in Part B reimbursements.

(2) I notice that codes 78811, 78812 & 78813 (i.e., PET only (without CT) are proposed at IDENTICAL reimbursements as the PET/CT codes noted above. This is absurd, for why did our business spend $1 million+/- to add the CT component to PET - and provide the best imaging available in the industry? We believe that there should be a SIGNIFICANT difference in the PET-only reimbursement versus PET/CT - just due to the 40+% increase in capital investment and much higher ongoing maintenence and operating costs of PET/CT. The CT portion consumes a tremendous amount of electrical power for operating, and for the additional cooling of the heat generated, not to mention the dual-certified technologists required and much higher insurance/other costs on the equipment. The difference in technical reimbursements should reflect that fact - and be in the neighborhood of a 40% REDUCTION for PET-only - and not the approx. $95.00/procedure difference in 2007.

Thank you. My direct dial number is 412-292-2728, and I would be most appreciative of further input on these matters.

Joseph J. Kappel
President
PET/CT Services of Florida

CMS-1392-P-858 **Medicare**

Submitter : **Mr. Barry Liss** **Date & Time:** **09/13/2007**

Organization : **Carlinville Area Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

See Attachment

#858

September 14, 2007

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

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

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

Dear Deputy Administrator Kuhn:

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

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

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

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

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

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

Sincerely,

Kenneth G. Reid, FACHE
President/CEO

CMS-1392-P-859 **Medicare**

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

Organization : **John Manter**

Category : **Nurse**

Issue Areas/Comments

OPPS: Packaged Services

I am requesting that you keep the same guidelines which have been in place in OPPS since 2000, namely to recognize and pay for significant costs for items that normally would be packaged. In the April 7, 2000 Federal Register, which established fundamental rules for OPPS, you stated " packaging payment for certain expensive items and services into a APC group rate could have such a potentially negative impact as to jeopardize beneficiary access to these items " This is an abrupt change in policy, and should be phased in if necessary. However, the costs of paired services may change independently or one another over time, and paying separately for each varying cost would promote more accurate future payment. While I wish OPPS had started out as a per encounter payment system, using a combination of ICD-9 diagnoses ad CPT codes, such was not the case. Typically several CPT/HCPCS codes are assigned for most encounters, and typically more than one APC is paid per encounter. Your proposals for universal packaging are too extreme a change in my opinion. OPPS should continue to recognize and pay for significant costs, not just in pharmacy, but in all areas to be consistent and fair. In particular, I take exception to packaging all CPT add on codes, since such codes were created specially for extra effort and costs, that may or may not be done in addition to the root CPT code. Also, in some proposed imaging services paying the same for single vs. multiple views creates pressure to minimize diagnostic data. Excessive packaging could impact Medicare patients negatively, as you stated in April 2000.

CMS-1392-P-860 **Medicare**

Submitter : **Ms. Shirley Eigenbrot** **Date & Time: 09/13/2007**

Organization : **Mills Peninsula Health Services**

Category : **Social Worker**

Issue Areas/Comments

Partial Hospitalization

I am a social worker/coordinator of an outpatient behavioral health program for seniors in the San Francisco Bay area. I have been working in this program for the past 14 years and believe we offer an excellent program for our patients which allows them to return to functional and meaninful lives as they recover from their mental health disabilities.
I am very concerned about the proposal to reduce the rate of medicare reimbursement for our and similar programs. Since I been working in this field we have dealt with increasing demands for accountability and ever more paperwork. I believe we have taken this in stride and that our program has improved as a result. However, even with the current rate of reimbursement we are operating at our capacity. I believe that, if the reimbursement rates are reduced, we will be forced to modify our program by reducing program hours, reducing services to our patients and that there is a real possibility of our program being unable to sustain itself and being forced to close its doors.
Our program is specifically for seniors of whom the majority have medicare as their health insurance carrier. This makes our program particularly vulnerable to medicare cuts. There are very few programs around, and none other than ours in this area, specifically for seniors. We supply a critical need in our area and I believe that it is imperative that we continue to serve the needs of our vulnerable seniors. We will not be able to do this with the proposed reductions in reimbursement.
I ask you, beg you, to reconsider these cuts. Our seniors demand our support.
Thanks you,
with regards,
Shirley Eigenbrot, LCSW

CMS-1392-P-861 **Medicare**

Submitter : **Mrs. Virginia McCann** **Date & Time: 09/13/2007**

Organization : **Hi-Desert Behavioral Health Cenrtre**

Category : **Health Care Provider/Association**

Issue Areas/Comments

OPPS: Partial Hospitalization

I am currently the Director of the Hi-Desert Behavioral Health Centre. I have been the Director here for over 7 years and every year has been a challenge to make the financial ends meet. When I first took over gasoline was $1.00 a gallon, today it is over $3.00. We provide transportation to patients who otherwise would not be able to get here for help. We serve the most chronic mentally ill patients. Every year the cost of doing business goes up, vans break down or need replacing, salaries rise, gasoline prices rise - everything goes up. Now we are facing more cuts. I will tell you that we do everything we can to keep this Program open. Fortunately we are a rural non-profit District Hospital which allows us to operate without making any money. If further cuts are made this will probably become impossible and we will have to close. In this area we have lost 2 major psychiatric hospitals and now are taking care of their patients. If we close - there will be nothing for these ill patients. There are no further financial cuts that can be made in a Program like this. I employ interns, encourage staff to clock in late and leave early. There is no more that I can do. Please, please do not cut payments to Programs such as this any more, we are not making it as it is.

CMS-1392-P-862 **Medicare**

Submitter : **Ms. Theresa Wiegmann** **Date & Time: 09/13/2007**

Organization : **AABB**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Blood and Blood Products

see attachment

Bone Marrow and Stem Cell Processing Services

see attachment

#862

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-863 **Medicare**

Submitter : **Mrs. Michele Steri** **Date & Time: 09/13/2007**

Organization : **none**

Category : **Individual**

Issue Areas/Comments

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as leader of the Pittsburgh Area Dystonia Support Group and one who represents so many people with dystonia, (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS's proposal to bundle the payment rate to hospitals for physician-injected drugs. The majority of my members receive the botulinum toxin to alleviate the debilitating, incapacitating, and often painful dystonic symptoms. These injections are critically important to their ability to function normally and also, to continue to work in whatever fields of employment. Without Botox, they could go from gainful employment to receiving disability payments. Therefore, both the guidance service and botulinum toxin injections they receive are eqully important for people to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and therefore, result in the injections being ineffective because it does not get to the right muscles to have benefit. Again, the guidance service is critically important for this treatment to be effective.

Thank you for allowing me to express these comments.

CMS-1392-P-864 **Medicare**

Submitter : **Ms. Theresa Wiegmann** **Date & Time: 09/13/2007**

Organization : **AABB**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Blood and Blood Products

see attachment

Bone Marrow and Stem Cell Processing Services

see attachment

#864

Advancing Transfusion and
Cellular Therapies Worldwide

September 12, 2007

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

Re: CMS 1392-P, Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Rates – Bone Marrow and Stem Cell Processing Services and Blood and Blood Products

Dear Mr. Kuhn:

AABB appreciates the opportunity to comment on the proposed changes to the hospital outpatient prospective payment system for 2008. AABB (formerly known as the American Association of Blood Banks) is a professional association dedicated to advancing transfusion medicine and cellular therapies. AABB's members include approximately 1,800 institutions, including hospital-based blood banks and laboratories, transfusion services and blood and bone marrow collection facilities, as well as approximately 8,000 individuals involved in blood, bone marrow, cord blood and peripheral blood stem cell collection, processing, storage and infusion.

Bone Marrow and Stem Cell Processing Services

AABB is concerned about the APC assignment and the proposed payment levels for the bone marrow and stem cell processing procedures, **codes 38207-38215**. These services involve the processing of bone marrow and stem cells prior to transplantation, such as removing certain undesirable cells. From the inception of the hospital outpatient prospective payment system (HOPPS) program until the present time, the Centers for Medicare and Medicaid Services (CMS) has not recognized these CPT codes. Rather, three "G" codes were established to report these services. G0265, Cryopreservation, freezing and storage of cells for therapeutic use, and G0266, Thawing and expansion of frozen cells for therapeutic use, were erroneously classified as clinical diagnostic laboratory tests and excluded from the HOPPS. G0267, Bone Marrow or peripheral stem

cell harvest, modification or treatment to eliminate cell type(s) (e.g., T-cells, metatastic carcinoma), was covered under HOPPS.

After several years of discussion with the agency, AABB was very pleased when CMS announced in the proposed rule that Codes 38207-38215 would be recognized under HOPPS. However, we are concerned about the payment grouping to which the codes have been assigned.

First, codes 38207-38209 were assigned to APC 0344, Level IV Pathology, with a proposed payment rate of $54.69. This APC consists of various anatomic pathology services including Codes 88307 and 88309. However, the steps that are involved in cryopreserving, thawing and washing bone marrow/stem cells which will be used for a potentially life-saving transplant are very different and cost significantly more than handling and preparing pathology specimens for microscopic evaluation. The former involves the collection of much larger volumes (e.g., a liter vs. a few milliliters), testing required by the Food and Drug Administration, sterile equipment and supplies, etc., none of which are needed for diagnostic testing. The bone marrow/stem cells are products to be transplanted into humans, not specimens that will be discarded.

AABB, along with other interested societies, recently initiated a survey of hospital centers that perform bone marrow transplantation services. The survey requested data from the centers on direct costs—clinical labor and supplies and reagents. Based on the results received from seven institutions, the mean and median direct costs of performing these services are as follows:

Code 38207, Cryopreservation and storage – mean $809 and median $500
Code 38208, Thawing w/o washing – mean $206 and median $144
Code 38209, Thawing w/ washing – mean $325 and median $206

Assuming direct costs are about 50 percent of total costs, this would indicate that total costs are about double the direct cost estimates. This would raise the estimate of total costs to:

Code 38207, Cryopreservation and storage – mean $1,618, median $1,000
Code 38208, Thawing w/o washing – mean $412, median $288
Code 38209, Thawing w/ washing – mean $650 and median $412

AABB recognizes that ultimately CMS will have charge and cost data when there is reporting under this series of codes. However, these data will not be available until at least the payment rates are established for CY 2010, when payments will be based on CY 2008 claims. In the interim, AABB urges CMS to place these codes in an APC that pays substantially more than $54, which will cover only a small fraction of the costs. We would suggest that APC 0111, Blood Product Exchange (paying $776), would be an appropriate initial payment level. It would pay substantially less than the costs of freezing and storing the product and somewhat more than the average cost of thawing the same material. However, on average, this APC would be a reasonable interim APC until better data are available in two years.

Second, as noted above, G0267 is currently paid for under HOPPS and is assigned to APC 0110. This is the blood transfusion APC and CMS proposes to assign all the cell depletion codes, codes 38210-38215, to this APC which has a payment rate of $222.44. These are very low volume codes, particularly in the Medicare population. The median cost data for G0267 indicate only 194 single claims were billed (438 total claims) with a median cost of $405.84. It must be emphasized that this is for all the various cell depletion services. However, there are extremely wide differences in the costs of the various cell depletion activities and we are confident that most of the billings within G0267 are for the lower cost services such as red blood cell removal (code 38212). Two of the codes, 38210 (T-cell depletion) and 38211 (tumor cell depletion) are extremely costly services which are performed by only a limited number of facilities and very rarely in the Medicare age group. We have data for five facilities that indicate that the reagent kits alone for codes 38210 and 38211 used for these services cost from $5,913 to $7,968 per patient with clinical staff costs from $270 to $1,344. Thus, the $222 payment rate would cover only a miniscule portion of the costs. AABB, therefore, asks that these two codes be placed into a much higher paying APC and would suggest, APC 0112, Apheresis and Stem Cell Procedures, with a payment rate of $2.035.93 would be a reasonable interim rate.

Alternatively, AABB proposes that CMS reimburse CPT codes 38210 and 38211 using a cost-based payment methodology by providing payment for these services at a hospital's charges reduced to cost using existing cost-to-charge methodologies for blood products. This would allow time for hospitals to adapt to the new codes and CMS to collect improved claims data.

For the other cell depletion codes, 38212-38215, we request that these codes be placed in a separate APC using the median cost data for G0267. (We are confident that the data CMS has on G0267 is overwhelmingly for codes 38212-38215 services.) This would raise the payment level to the $400 level from the proposed $220 rate based on the transfusion codes. When CMS has adequate claims data for the individual codes it might be appropriate to adjust the APC grouping further.

Blood Products

AABB appreciates CMS' continued attention to payments for life-saving blood products. AABB is pleased that CMS has proposed increased payments for most commonly transfused blood products. However, it should be noted that CMS' proposed payments in 2008 continue to lag behind actual acquisition cost data for the most commonly transfused blood product, leukocyte-reduced red blood cells (RBCs) in 2004, the most recent year for which comprehensive national blood cost data were collected.

AABB conducted the *2005 Nationwide Blood Collection and Utilization Survey* under a contract with the Department of Health and Human Services to collect data on a number of issues relating to blood supply and utilization, including cost issues. In this nationwide survey, data were collected from approximately 1,600 hospitals. Hospitals provided information regarding the average amount paid by hospitals in 2004 for blood products.

AABB is particularly concerned about the proposed payment for APC 0954, leukocyte-reduced RBCs, which is by far the highest volume blood product reimbursed under Medicare. In 2004, a unit of leukoreduced RBCs cost $201.07 and yet CMS is proposing to pay only $188.47 for this critical product in 2008. Implementation of the proposed APC rate will mean that most hospitals will incur a financial loss in providing blood and blood products to Medicare patients.

The costs of blood products continue to increase with new safety advances and increasingly expensive donor recruitment and retention efforts. Recent safety measures include a new screening test for Chagas' disease, initiatives to mitigate the risk of transfusion related acute lung injury (TRALI) – the leading reported cause of transfusion related death – and the movement toward improved, ISBT 128, labeling of blood products.

Given these safety advances, AABB believes it is reasonable to estimate that the average amount hospitals will pay for leukoreduced RBCs in 2008 will have increased from the 2004 $201 acquisition cost. It should be noted that this rate reflects the cost of acquiring the blood product and does not include any allowance for the cost incurred by hospitals for overhead, storage, handling and wastage due to shelf-life limitations. Thus, it is clear that the proposed APC rates will not cover the cost of this and other critical blood products. AABB therefore recommends that CMS continue to increase payments for blood products, including leukoreduced RBCs, to bridge the gap between Medicare payments and the actual costs incurred by hospitals.

Thank you again for the opportunity to offer these comments. If you have questions or require additional information, please contact me at 301-215-6554 or theresa_l@aabb.org.

Sincerely,

Theresa L. Wiegmann, JD
Director, Public Policy

CMS-1392-P-865 **Medicare**

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

Organization : **Missouri Hospital Association**

Category : **Other Association**

Issue Areas/Comments

Quality Data

See attached letter.

#865

MISSOURI HOSPITAL ASSOCIATION

Marc D. Smith, Ph.D., President

September 12, 2007

Kerry N. Weens
Deputy Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1392-P
P. O. Box 8011
Baltimore, Maryland 21244-1850

RE: CMS-1392-P Outpatient Quality Data

Dear Mr. Weens:

On behalf of its 142 member hospitals, the Missouri Hospital Association welcomes the opportunity to share its comments and concerns on the proposed outpatient hospital quality data reporting requirements contained in the Centers for Medicare & Medicaid Services' 2008 outpatient prospective payment system proposed rule.

Technical Specifications

The 2008 OPPS rule proposes implementing the outpatient hospital quality data reporting project January 1, 2008, but the technical specifications for this project were released August 29, 2007. The delay in the technical specifications is a significant problem for vendors and hospitals. The MHA Management Services Corporation is a Hospital Quality Alliance data collection vendor. MSC's experience as a vendor indicates new measure sets require significant time for hospitals and vendors to implement. With the delay in the release of the technical specifications, vendors have not as yet developed the necessary data abstraction and submission tools, as well as educational materials and programs. Hospitals also are unable to determine plan processes and evaluation criteria required to implement such a large project.

It also is difficult for MHA and its members to provide comments about the quality measures when the definitions were unavailable for review. MHA believes it is important to allow ample time for reviewing technical specifications and measure definitions before implementing a new or revised project.

Outpatient Measures

MHA commends the CMS for recognizing the need to use standardized measures endorsed by an organization such as the National Quality Forum. However, we are concerned the 10 measures proposed for data collection on January 2008 have not received final endorsement by the NQF.

The proposal seeks to extend the acute myocardial infarction (AMI) measures to the emergency department data collection project because a large portion of the AMI cases are not captured in the current inpatient data collection project. In the current inpatient prospective payment system (IPPS), transfers from an emergency department to another facility are excluded from the abstraction criteria. This will increase the volume of cases in the AMI data collection project. However, we note that the ED measures may place an undue burden on small rural hospitals due to their limited resources.

MHA has reviewed the more recent research on utilization of median times versus mean times for certain data elements. We conclude that this may be the reason three of the five emergency department measures use median time calculation. We question why an AMI measure such as median time to ECG is included in the outpatient data collection but is excluded from the inpatient measures. Ideally, to meet the CMS' goal of "harmonizing" measures, this would be a logical next step for IPPS.

The two measures for outpatient surgery — PQRI #20 and PWRI #21 — are consistent with measures for the surgery care improvement project, as well as the outpatient heart failure and pneumonia measures. MHA strongly encourages the CMS to diligently work toward **identical** data definitions for both outpatient and inpatient measures. The HQA has experienced significant issues when data definitions are **similar but not identical**. Hopefully, the CMS will continue to use experiences with HQA data collection to improve the quality of the outpatient project.

Measure Selection and Development

MHA agrees with the CMS' prior statements about the need to continuously evaluate and develop measure sets, including retiring or suspending measures. MHA recommends the following.

- The CMS should incorporate a mechanism for an annual review to determine necessary changes, retirement or suspension of measures.

- A time line should be developed for implementing additional measures affecting hospital reimbursement, with a **minimum of 12 months** allocated for hospital planning and implementation.

These recommendations will ensure the current clinical practice guidelines are being used for public reporting and pay-for-performance projects. They also provide adequate time for hospitals to implement new measures.

MHA suggests the proposed outpatient measures not be tied to hospital payment sanctions for the initial 12 months of data collection. After field testing, MHA will support their use for public reporting and annual payment update.

Time Line

MHA's greatest concern with the outpatient quality data reporting project is the extremely compressed implementation time line. Hospitals will have less than four months to implement a new project for outpatient services that is tied to reimbursement. This is problematic and unfair to acute care hospitals. MHA understands that the CMS believes the integration between inpatient and outpatient services is so similar that there is no need for additional implementation time.

Missouri hospitals disagree with this assessment. Outpatient services are structured differently and operate independently of inpatient services in most hospitals.

The abstraction and submission time line of January 2008 outpatient data is **75 days** earlier than the time line used for IPPS. MHA is aware CMS chose to do this because of the time line required for data collection by the Tax Relief and Health Care Act of 2006. However, the act only mandates data collection and reporting; it does not require data collection validation.

MHA strongly opposes tying January 2008 data submission and validation requirements to the outpatient APU, without additional implementation time. For hospitals to verify January 2008 claim data for the affected populations, the CMS would be required to have this data posted on the QualityNet Web site for hospital review 75 days earlier than the current display requirement. Historically, CMS has been unsuccessful in meeting the current time line. How successfully will CMS implement the Web site 75 days earlier?

Data Sample

MHA strongly opposes using only one month of abstracted data to determine the annual payment update for outpatient services, especially if that month of data is collected without any field testing.

An integral part of the data collection validation is developing accurate sampling procedures to ensure the correct number of cases is submitted to the CMS. In addition, those cases must correspond to population estimates that are based on claim data submitted in the same time period, which the technical specifications data release affects.

New Outpatient Project

The CMS believes the addition of outpatient quality data collection is not a significant issue for acute care hospitals, because the hospitals already have been submitting data on the impatient side for similar measures. As a data collection vendor, our experience is that many hospitals needed approximately two years to establish consistent, successful processes implementing new measure sets.

The outpatient measures will have different documentation issues, forms and criteria. When the surgical care improvement project was added as a measure set, it was a struggle for many hospitals because it was different from the other HQA population sets. For some hospitals, SCIP brought in a "new" group of surgery staff to work on the project, and the learning curve was significant. We have no reason to believe outpatient quality measures will not require the same lengthy learning curve.

It is likely hospital staff who will work on the outpatient project will be different than the individuals who worked on the inpatient project. This mirrors CMS' own practices. According to senior CMS operational staff, the outpatient project likely will involve a different group of CMS staff than those currently working on the inpatient project because of differences between the two data collection projects.

Infrastructure and Data Submission Issues

Typically, there are technical difficulties and delays associated with a new quality data project and with the initial data submission to a new data warehouse. MHA is concerned that the CMS is proposing to use

only the first month of data collection, submission and validation to determine a hospital's outpatient APU for the next fiscal year. With the inpatient project, hospitals were not penalized for submission and validation issues until two years after the project began, allowing time for establishing processes and resolving technical issues.

Our concern is that the CMS has been unable to consistently implement the necessary ongoing changes with the current HQA IPPS project. In first quarter 2007, the CMS HQA data collection tool, CART, did not have the most recent version of the ICD-9 codes that were implemented with October 1, 2006, discharges. As a result, hospitals abstracted SCIP cases for six months using an obsolete coding set.

Another example of the CMS' lack of infrastructure and information technology resources involved adding the "present on arrival" digit to diagnostic codes. Before CMS announced that this project's implementation would be delayed until January 2008, vendors worked to implement the UB-04 data changes required for POA implementation. Vendors who made the changes were notified by CMS that the POA code would have to be stripped from submission files before submitting data to the QualityNet warehouse. The reason for the delay — the CMS was not able to meet the deadline for the programming changes necessary for this new data code.

Similar issues occurred during data submissions with third and fourth quarter 2006 and first quarter 2007 data submissions to the QualityNet warehouse. Hospitals and vendors were not notified of issues until after data submission had begun. Vendors following the CMS' instructions to submit early and often were essentially penalized because QualityNet had not yet incorporated technical specification changes made in April and October 2006. In the third and fourth quarters, the data submission deadline had to be extended. MHA recommends the CMS create a mechanism to address these and similar technical problems.

Submission deadlines have been extended whenever the CMS has technical errors or issues. However, when a vendor has technical difficulties submitting the data, there is no recourse for the hospital. MHA recommends incorporating an appeal process when data are not correctly submitted by vendors because of technical errors. Vendors' technical submission issues are not under a hospital's direct control.

The QualityNet warehouse and the CMS' data collection tool, CART, have not been able to keep up with the pace of the current IPPS program and the HQA's deadlines. MHA is concerned the addition of the proposed outpatient project with significantly shortened time lines will jeopardize the integrity of the current inpatient and proposed outpatient projects.

MHA believes the technical limitations of QualityNet require further evaluation and review. At a minimum, technical resources and limitations with the data warehouse must be considered during the measure set development, implementation process and time frame. We further believe QualityNet should be held accountable to the same time line expectations and requirements for HQA technical specifications as third-party vendors.

Validation

MHA applauds the CMS for recognizing that the current infrastructure and validation processes used for IPPS have been problematic and need improvement. MHA agrees the current process for IPPS chart

validation is not sufficient to ensure the quality of the abstracted data. The current process has unresolved problems including the volume of reviewed cases required for statistical validity and performance scores.

There have been significant issues with the validation and reconsideration process for IPPS. Until these issues are resolved, MHA opposes the shortened validation time line proposed for the outpatient project. We also recommend that any Clinical Data Abstraction Center request for medical records explicitly state the records are being requested for re-abstraction to prevent failures caused by omissions or the submission of incorrect records.

MHA appreciates the CMS' agreement to allow each hospital to preview data on the QualityNet Web site before its public release.

Ambulatory Surgical Centers

MHA is disappointed the OPPS quality data reporting initiative is not being implemented simultaneously for hospital-based outpatient services and ambulatory surgical centers. We are aware of the many DRG changes affecting ASCs but do not believe hospital outpatient services should have a different implementation process than ASCs. MHA believes this may give ASCs an unintended advantage over hospital outpatient surgery services.

Reconsideration and Appeal Procedures

For the current appeal process, MHA encourages the CMS to proceed with a data resubmission policy. The Joint Commission's policy allowing hospitals to resubmit data to correct known errors has proven to be effective in improving the reliability and accuracy of the data submitted.

As an ORYX® vendor working with hospitals to submit their data to the CMS' QualityNet, we found that the reconsideration and appeal processes for fiscal year 2007 were not smooth. Hospitals waited for months after they were told the appeal process would take only a few weeks. Adjudication was not complete until the fiscal year already had begun. MHA believes the appeal process must be completed before implementing any financial sanctions including withholding the APU. The appeal process must be clear to hospitals before implementing a final rule that affects reimbursement.

In the current process, a critical error in copying a medical record may result in failed validation and a subsequent 12-month loss of the APU. We believe this penalty is too severe for this quality data collection and hospital performance measurement project. MHA does not believe the federal government intended for hospitals to lose payment for minor technical process errors that have no effect on the quality of patient care or hospital performance.

In addition, all hospitals should have the ability to appeal all validation cases whenever the validation scores could affect a potential loss of the APU. Hospitals must have opportunities to appeal human errors in transcription, copying or mailing medical records to the CDAC for validation.

The reconsideration process should include the following.

- a defined appeal process that clearly outlined all necessary steps
- clearly established time lines for each step or process for appeals

- clearly established time lines for the CMS to respond to appeals
- the ability to appeal any item within any quarter that may affect the loss of the APU

Factors we believe should be appealable include the following.

- population size variance from submitted claim data
- vendor submission errors affecting a hospital's compliance
- an incorrect medical record submitted to CDAC
- the medical record was not received by CDAC

The chief executive officer, chief operating officer or chief financial officer should have the opportunity to submit an appeal on a hospital's behalf.

Proposed Measures for 2010

In our view, the additional 30 measures proposed for 2010 should not be included in the calendar year 2008 data collection project. Only the 10 measures proposed for 2008 should be considered.

The 30 measures proposed for later implementation should be ranked by sub-topic according to the most immediate critical interventions for hospital outpatient care. Many of the indicators listed are more applicable to inpatient care or physician office practice and not hospital outpatient care. For example, fall risk (3) and antidepressant medication during acute phase with new episode of major depression (4) are items you would expect to see in acute care settings. The two diabetes measures related to low density lipoprotein control and blood pressure control are quality measures more appropriate for physician office practice.

The proposed asthma pharmacologic therapy measures include patients ages 5-40. Currently, the inpatient measures only include patients ages 18 or older. Does this mean the pediatric population will be included in the hospital outpatient measures? This would be a significant change from the inpatient measures and warrants further review.

Again, MHA recommends the CMS move deliberately in implementing the hospital outpatient measures.

Attestation for Data Completeness and Accuracy

Having quarterly attestation of data completeness and accuracy by hospital staff seems like an improvement in the accountability processes. Operationally, without an automated electronic record that interfaces with the billing system, this attestation is difficult to ensure.

In closing, MHA recognizes that employers and purchasers of health care are interested in the rapid implementation and public reporting of new measures and hospital performance scores. However, **we urge the CMS to cautiously move forward with this complex endeavor to ensure a smooth transition, accurate and useful quality data for consumers, payers and providers, and, ultimately, quality patient care.**

MHA appreciates the opportunity to submit comments on fiscal year 2008 and fiscal year 2009 data quality measures. We are eager to work with the CMS on future performance measurement activities before implementation.

If you have any questions or comments, please contact me at 573/893-3700, ext. 1349 or dlandon@mail.mhanet.com or Wanda F. Marvel, R.N., M.S., director of performance measurement and accreditation, at ext. 1325 or wmarvel@mail.mhanet.com.

Sincerely,

Daniel Landon
Senior Vice President of Governmental Relations

dl/vb

CMS-1392-P-866 **Medicare**

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

Organization : Imaging Healthcare Specialists, LLC

Category : Other Health Care Professional

Issue Areas/Comments

Payment for Diagnostic Radiopharmaceuticals

The preliminary decision by CMS to bundle the reimbursement for all radiopharmaceutical procedures regardless of cost to the facility will have a detrimental effect on imaging centers as well as reduce the availability of these tests for patients. Our costs for some drugs is over $500, and profit margin is less than this cost. If imaging centers are forced to absorb this cost, especially in the area of PET which has already been reduced by 45% due to the Defecit Reduction Act, centers may not be able to continue providing these services to patients. The revised recommendation of only reimbursing drugs over $200 is slightly improved, but we must remember that often the operating costs of an imaging center do not even allow for this kind of cut in a profit margin. In short, adopting this ruling will effect patient care as it reduces the ability of radiologists and imaging centers to effectively provide this service. Thank you.

CMS-1392-P-867 **Medicare**

Submitter : **Mr. Gene Gotbaum** **Date & Time: 09/13/2007**

Organization : **Medical University of South Carolina**

Category : **Other Health Care Professional**

Issue Areas/Comments

OPPS Impact

I am a practicing "cardiac ultrasonographer" at MUSC in Charleston, SC.I have been in the medical field for almost 30 years.I have heard that CMS is proposing to eliminate separate payment for contrast agents used in echo procedures performed in hospital outpatient settings beginning in 2008.Payment for contrast agents would be packaged into the amount received for the principal procedure billed with the contrast agent.Since the same amount would be paid for the procedure whether or not contrast is used, this proposal would create a financial disincentive to use a contrast agent, even when its use would be medically appropriate.I believe that this proposal should be dropped and that contrast agents should continue to be eligible for separate payment.These are the key points for my opinion; Contrast agents already may be underutilized, and the proposal will increase the financial disincentive to use contrast, even when its use is medically appropriate. Underutilization of contrast agents is not in the best interests of Medicare patients or the Medicare program since inconclusive diagnosis may result in the performance of more invasive and costly diagnostic tests. Contrast agents are relatively costly in comparison with the echo procedures with which they are to be packaged, which increases the financial disincentive created by packaging these agents with the underlying echo procedures.Please don't criple healthcare facilities in our ability to provide care to a population that needs this. Consider yourself in this expensive situation. Thank you for taking the time to read and consider my opinion on this matter.
Gene Gotbaum, BHS, RDCS

CMS-1392-P-868 **Medicare**

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

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

OPPS Impact

Contrast agents need to be at the sonographers and Physicians disposal to make the best diagnosis possible. It is already not used in all of the situations when it would make a better study. Not getting paid for these contrast agents makes it even less likely that they will be used when it is needed. Using the agent will help make diagnoses and therefore stop the patient from having a multitude of other tests to figure out what is going on.

CMS-1392-P-869 **Medicare**

Submitter : **Mr. James Hiserodt** **Date & Time: 09/13/2007**

Organization : **Soldiers**

Category : **Critical Access Hospital**

Issue Areas/Comments

Necessary Provider CAHs

See Attached Letter Regarding CAH with off site clinics

#869

Soldiers & Sailors Memorial Hospital
418 North Main Street • Penn Yan, New York 14527-1085 • (315) 531-2000

September 14, 2007

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

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 VP & Site Administrator at Soldiers & Sailors Memorial Hospital in Penn Yan, NY.

Our hospital converted to a Critical Access Hospital in 2005 as a result of being designated by New York State as a necessary provider. Soldiers and Sailors Memorial Hospital currently operates two distinct off-site clinics to serve behavioral health patients in the Yates County area and also an outpatient clinic and lab draw station in Dundee, NY. Both clinics service our federally designated underserved area. Closure of these clinics would have a definite affect on the health of this community. Currently, there is a shortage of primary care physicians in the area. The clinics are providing the access for patients in the community.

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

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

Sincerely,

James R. Hiserodt
VP & Site Administrator

CMS-1392-P-870 **Medicare**

Submitter : **Dr. Michael Repka** **Date & Time: 09/13/2007**

Organization : **American Academy of Ophthalmology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

See comments attached

#870

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Suite 700
1101 Vermont Avenue NW
Washington, DC 20005-3570

Tel. 202.737.6662
Fax 202.737.7061
http://www.aao.org

Federal Affairs Department

September 13, 2007

Via Electronic Mail
Mr. Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates.

Dear Acting Administrator Weems:

The American Academy of Ophthalmology is writing to share our comments regarding the CY2008 Proposed Hospital Outpatient Payment System and the related Final ASC Payment Rule. The Academy is the world's largest association of eye physicians and surgeons—Eye M.D.s—with more than 18,000 members in the U.S.

We appreciate this opportunity to comment on the proposed rule published in the Federal Register on August 2, 2007, which proposes, among other changes, CY 2008 payment rates for procedures performed in an ambulatory surgery center (ASC). We reiterate our support for the revised ASC payment system, and commend CMS for its efforts in developing the new system.

Eye procedures are one of the most frequently and safely performed procedures in ASCs in this country. In 2003, the Office of the Inspector General reported that Medicare could save more than $1 billion if hospital outpatient (HOPD) and ASC payments were equalized. According to the OIG, nearly half of those savings would come from eye procedures (*http://oig.hhs.gov/oei/reports/oei-05-00-00340.pdf*).

General ASC Comments: List Expansion
The Academy would like to commend CMS for taking into account the comments and recommendations from the ASC community as it moves forward to finalize a new payment system for this care setting. As noted in our proposed rule comments, the Academy applauds the finalization of the new exclusive list that would only eliminate those procedures that are not safe to perform due to patient safety reasons. For ophthalmology, this means the addition of nearly 70 procedures that can now be performed in the ASC. This will expand patient access to the exceptional care in ophthalmic ASCs. We would note that there are additional ocular plastic procedures that meet the patient safety requirements and should be added to the list. We focus on those procedures in another section.

General ASC Comments: Alignment and Budget Neutrality

CMS continued its steps at alignment in its final ASC rule and in the proposed CY2008 OPPS rule. The Academy commends the changes made which demonstrate that alignment of the ASC setting can be more directly tied to the HOPPS. **While the steps taken recognize the linkage, a more equitable and direct linkage to the outpatient setting is necessary in order to continue to expand patient access and the savings to the program by increased use of the ambulatory surgical setting.**

- **We strongly recommend that CMS provide the same annual update mechanism for both settings. Currently, CMS is proposing that ASC updates be based on CPI-U while the HOPD rate is tied to the hospital market basket. Such a disparity is contrary to alignment.** Inflationary costs for facility services, supplies, and medical device costs affect ASCs no differently than they affect hospitals. This part of the proposal will create greater disparity in the reimbursement for services performed in the hospital outpatient and ASC settings without any evidence that hospital costs increase at rates in excess of those of ambulatory surgery centers.

The Academy recognizes that the statutory language in DRA 2005 mandates that the initial calculation of the payment rate for ASCs be budget neutral. However, we strongly disagree with the manner in which such neutrality was applied. In looking at targeted outpatient aggregate expenditures, the Academy urges CMS to consider all Medicare expenditures for outpatient surgical services irrespective of setting, not just those of ASCs. Again this would fit in with CMS's goal to better align these two systems and creates a more transparent methodology for calculating the budget neutrality adjustment.

- **The currently proposed conversion factor derived through a budget neutrality adjustment that pays ASC at a rate that is nearly 35-33% (over a four year transition) less then HOPPS is unfair and this differential is not an accurate reflection of the true cost differences of providing care in these two settings.**

- **The Academy remains concerned that the agency underestimated the volume of migration of certain procedures into or out of the ASC that will occur when payments are about 35% less for the ASC than the OPPS. By making these incorrect migration estimates CMS has underestimated the payment rate for ASCs at which budget neutrality will be achieved.**

- **At a minimum, ASCs should receive a percent of the HOPD fee schedule that is in the range of 75% for all covered procedures as called for in legislation introduced in 2005 and supported by the Academy.**

- **This inequity is especially apparent with the move to eliminate the separate payment for many high cost supplies and devices.** Our comments will discuss specific examples of procedures that are impacted by these bundling requirements. In several cases, there are procedures that are currently being successfully performed in the ASC setting that will now move back to HOPD because their costs will not be covered under the new payment methodology. In another case, current problems already being experienced in the OPD system will be compounded in the new ASC system.

Implantable Devices Under the OPPS

Positive steps were taken by CMS in its efforts to improve the manner in which Medicare plans to pay for device-intensive procedures under the new ASC payment system. However, the Academy has identified a definite problem/oversight in the proposed payment method for procedures that also have associated Level II HCPCS codes and/or associated DMEPOS fee schedule payments today, but do not appear to qualify for the proposed "device-intensive" designation.

With the publication of the final ASC rule and the 2008 proposed OPPS rule an aberration has been created that will result in some implantable devices that are currently paid for in ASCs through the DMEPOS fee schedule to now be considered as bundled into the transitional rate that is being used for phasing in the new ASC payment methodology. For most devices the OPPS rate includes the cost of the device and the bundling is acceptable. However, the Academy has found some instances where, because of the transition, the device cost is inadequately covered until the final rate is achieved in four years.

The transition to the new payment rate will occur over four years with a blended rate of 75% of the current rate and 25% of the final rate (67%) for the first year, 50%/50% for the second year, 25%/75% the third year and then 100% of full 67% rate in 2011. For some higher cost implantable devices that did not make the list of procedures that are considered device-intensive (the cost of the device is at least 50% of the cost of the service) this will have an extremely negative impact.

- **Ophthalmic Specific Procedure Issues Created By the Proposed OPD and Final ASC Payment Systems**

  1) **Proposed CY 2008 ASC Payment for CPT 66180**

For ophthalmology, the glaucoma code 66180 commonly known as a placement of a Glaucoma Drainage Implant (e.g., Baerveldt, Molteno, Ahmed shunts) procedure was performed successfully 40% of the time in the ASC setting in 2005 (nearly 2750 times out of 7800 done overall). For the sickest glaucoma patients who are facing irreversible vision loss, medical therapy is no longer useful and the standard trabeculectomy procedure typically performed to move fluid out of the eye and relieve pressure may not be an option, or has been tried and failed. For them another procedure, inserting a shunt to relieve the intraocular pressure, is necessary. For some of these high-risk patients there may be other medical reasons, such as anatomic anomalies or scarring, why a shunt would be necessary.

Under the new ASC system the aqueous shunt device and the scleral tissue graft that is used in these cases will no longer be able to be separately billed on the DMEPOS schedule as CMS asserts that the costs of these are included in the payment rate for the OPPS APC. CMS also has not included 66180 on the list of device-intensive procedures.

The total expected payment in the ASC for code 66180 in 2008 is only $940.81. On average, the typical shunt device costs approximately $650 and the pericardium graft tissue that is used to cover the tube shunt is an additional $255 for a total device cost of $905. Previously the ASC facility payment for this service was $717 plus the DME payments for the devices which typically covered their costs in most instances.

2) Proposed CY2008 ASC Payments for Certain Ocular Plastic Implants

Similarly there are at least four oculoplastic procedures that have an implant whose costs will cause a significant shortfall based on the proposed 2008 ASC payment rate. These include: CPT code 65105 (enucleation of eye; with implant, muscles attached to implant); 65140 (insertion of ocular implant secondary; after enucleation, muscles attached to implant); 65155 (reinsertion of ocular implant; with use of foreign material for reinforcement and/or attachment of muscles to implant); and 67912 (correction of lagophthalmos, with implantation of upper eyelid lid load).

Facilities typically use L8610 for both the gold weight used with 67912 and the hydroxyapatite implant used with the other procedures. The price for the gold weight is $200 or $240 depending on the size (platinum weights are required in gold-intolerant patients and cost $300 or $400 depending on the size). The specification "muscles attached to implant" in the above codes indicates the use of a special, costly ocular implant (typically a hydroxyapatite implant) that accommodates attachment of the extraocular muscles following removal of the eye. These implants typically cost $695. Wrapping the implant with another product such as pericardium (also coded with L8610) adds additional cost (see above discussion regarding glaucoma shunts)."

3) Proposed CY 2008 ASC Payment for CPT 65780, amniotic membrane transplant

Addendum B of the Proposed HOPD Rule will assign an "N" status indicator to V2790, the HCPCS Level II code assigned to human amniotic membrane tissue. Accordingly, payment of V2790 is bundled with its related procedure, CPT 65780, amniotic membrane transplant. For the same reasons already discussed, the bundling of V2790 results in a payment rate for CPT 65780 that does not cover the cost of the tissue supplied in the procedure. In order to continue to make this innovative tissue and treatment available, the payment rate must accurately reflect the cost of obtaining, processing and distributing the tissue as well as performing the procedure.

- **Potential solutions to these payment shortfall problem**

We offer two ways in which CMS can compensate for the payment shortfalls:

1) Pay the fully implemented rate in 2008

CMS has already calculated the fully transitioned ASC payment for 2008. The difference between the actual 2008 payment rate and fully transitioned rate adequately accounts for the device. Applying the fully implemented payment to these codes for 2008 would be an administratively simple solution to the problem because CMS has already calculated these values.

2) Include the 2007 device payment in the transition year payment calculation

Another approach to account for the device in the 2008 payment would be to include the current payment for the device in the 2007 payment rate that is used to calculate 75% of the transition payment. Although this payment is generally lower than the fully implemented payment amount suggested in #1 above, it accounts for the device and would allow ophthalmologists to continue to perform these procedure in the ASC during 2008 without suffering a significant financial loss on each case. Alternatively, we ask that CMS create a separate APC for amniotic membrane transplantation procedures for the ocular surface that accurately reflects the cost of amniotic membrane tissue.

Additional Ophthalmic Issues with the revised ASC List

- **Patient Safety Exclusions**

CMS indicates that it is establishing beneficiary safety and the need for an overnight stay as the principal clinical considerations in determining procedures that should be excluded from payment of an ASC facility fee. However, if CMS is to exclude procedures in addition to those on the inpatient only list for payment in the ASC, it should fully explain the clinical basis for the exclusion. In addition, as we have supported previously, CMS should develop an advisory group of clinically-trained ASC experts which will work with CMS staff prior to release of the proposed rule to review and provide clinical safety and procedure data on procedures CMS may initially deem a safety risk.

- **Addition of Oculoplastic Codes to the ASC List**

The specialty of ophthalmology includes oculofacial plastic surgery. This combines orbital and periocular surgery with facial plastic surgery and includes the clinical practice of aesthetic plastic and reconstructive surgery of the face, orbit, eyelid and lacrimal system. With this unique combination of skills, ophthalmologists perform facial plastic surgery, eyelid surgery, orbital surgery and lacrimal surgery. Outpatient care is the majority site of service for many ocular plastic procedures.

Currently there are several procedures that are not on the revised ASC list that the Academy supports including. CPT codes for the repair of orbital fractures encompassed in 21385 (Open treatment of orbital floor blowout fracture; transantral approach), 21386 (Open treatment of orbital floor blowout fracture; periorbital approach), 21387 (Open treatment of orbital floor blowout fracture; combined approach) are currently not on the list despite the fact that other related procedures such as 21390 (Open treatment of orbital floor blowout fracture; periorbital approach, with alloplastic or other implant), 21406 (Open treatment of fracture of orbit, except blowout; without implant) and 21407 (Open treatment of fracture of orbit, except blowout; with implant) are included. All of the codes that the Academy requests to add performed at least 40% of the time in the outpatient, ASC or physician setting currently. The physician work involved for 21386 is actually less intensive then code 21390 which was included on the ASC list. The related procedures CPT codes 21385 and 21387 should also be added for consistency with 21386 and 21390.

- **Exclusion of Unlisted Procedures from the ASC Setting**

CMS has indicated that without knowing the specific procedure, it is not possible to evaluate whether the procedure performed would have been excluded from ASC payment due to established safety criteria. In particular, CMS has stated that it would not be able to determine whether the procedure in question involved major blood vessels, major or prolonged invasion of body cavities, or extensive blood loss, or was emergent or life-threatening in nature. The Academy does not see why there would be a safety issue in the ASC but not in the HOPD or physician office. At a minimum, when all of the procedures that fall within the same section of CPT are covered services, then an associated unlisted code should also be eligible for payment in the ASC at the carrier's discretion.

The Academy supports the ASC Coalition's contention that while unlisted surgical CPT codes do not allow reporting of specific procedures, they do allow reporting of the anatomic region of the procedure. This anatomic location can be precisely defined especially for ocular procedures. In some instances, unlisted codes also identify a specific surgical technique or a specific medical condition. Knowing the anatomic location and occasionally the surgical technique and medical condition for which the procedure is performed, allows evaluation of safety of the entire spectrum of procedures reportable by the unlisted code. By considering the entire range of possible procedures for the particular anatomic location against

the safety criteria to be satisfied, a knowledgeable clinician can determine whether there is reason to exclude the unlisted code in question. Asking whether or not any procedure performed on the anatomic structure(s) in question would 1) involve major blood vessels, 2) require major or prolonged invasion of body cavities, 3) result in extensive blood loss, 4) be emergent or life-threatening in nature, 5) require systemic thrombolytic therapy, 6) be included on the inpatient list or 7) require an overnight stay allows a logical and comprehensive assessment of safety risk based on the criteria that CMS has established.

When looked at in this context, nearly all ophthalmic unlisted procedures as well as those for several other specialties would be allowed in the ASC setting. Again, if the agency desires alignment in these two settings, then it should apply uniform safety standards in the ASC and HOPD. The surgeon based on the patients needs should determine the best setting for safely performing the procedure(s) necessary.

Office Based Procedures

In the July 2007 ASC Final Rule, CMS adopted a policy on office-based surgical procedures. The policy provides that the payment for the facility resources associated with office-based procedures will not be greater when provided in ASCs than when provided in physician offices. Thus, payment for office-based surgical procedures performed at an ASC will be capped at the lesser of the Medicare physician fee schedule nonfacility amount, or the ASC rate developed according to the standard methodology of the revised ASC payment system.

The Academy is opposed to this policy because it will force physicians to send a surgical service to the more costly OPD setting that is better suited to an ASC than the office setting due to a particular patient medical issue. This is not only more costly to the Medicare program but also to the beneficiary. The inequity of this policy is exacerbated by the fact that the "lesser of" rule is not applied to payment to hospital outpatient departments. There are no data that the Academy is aware of that shows that procedures commonly performed in physicians' offices are more likely to migrate to an ASC than to a hospital outpatient department. Therefore, this "lesser of" rule should either be abandoned completely or be made to apply to payments to ASCs and hospital outpatient departments. As the Academy has supported consistently, the site of service should be determined by the surgeon's knowledge of the patient's condition and expertise.

Payment for Corneal Tissue

On behalf of our members that provide corneal transplantation, the Academy very much appreciates the CMS decision to finalize and retain the existing policy to include in the ASC Payment System the payment for corneal tissue on an acquisition cost basis, paid at reasonable cost. This action acknowledges that eye banking is no less variable in this present day as it was in 1998 when CMS acknowledged the role of community-based philanthropy and fund-raising utilized by most eye banks and the variable nature of the costs associated with obtaining this sight saving tissue. Of all the transplant surgery done today, corneal transplants are the most common and the most successful.

However, the Academy believes that Medicare Payment Policy must be consistent for All Tissue Processing for Ocular use under the HOPPS Payment. Currently, there are two HCPCS codes used to report services related to corneal tissue and amniotic membrane transplantation under HOPPS—V2785 (processing, preserving and transporting corneal tissue) and V2790 (amniotic membrane for surgical reconstruction, per procedure). There is a discrepancy in payment policy and status indicators for these two types of tissue which are both used for ocular surface reconstruction procedures. As a result, hospitals are paid separately—in addition to the APC rate—for costs associated with corneal tissue

transplantation, but not for costs associated with processing preserved amniotic membrane tissue for ocular surface transplants.

The Academy is concerned that this inequitable payment classification creates a financial disincentive for hospitals to promote the treatment of ocular surface diseases using amniotic membrane tissue, and impedes beneficiary access to this unique ocular reconstructive procedure.

We respectfully request that CMS revise the current HOPPS payment policy for amniotic membrane transplant procedures so that it is consistent with the policy to reimburse hospitals for costs associated with V2785 (processing, preserving and transporting corneal tissue). Or as previously stated, the Academy believes that an appropriate APC should be created for the amniotic membrane transplant. Should there also be a comment about the preparation of endothelial grafts for the newer endothelial keratoplasty procedures?

Comment Period for NTIOL Requests

As previously indicated, we generally agree with CMS's new NTIOL notice and comment process that is now aligned with the proposed and final OPPS/ASC annual rules. It should be monitored to ensure that an annual process does not slow or impede the consideration of these new technologies. For consistency with the rule process, the Academy requests that the comment periods also coincide. In the final rule, CMS indicates that the NTIOL process would be a 30-day comment period rather then the 60 days that is allocated for the payment rules.

Conclusion

We appreciate CMS's significant achievement in developing the new ASC payment system. We believe that CMS has the tools to address the issues discussed above so that ophthalmic patient care and surgery for Medicare beneficiaries is uninterrupted during 2008 and beyond. Thank you for your attention to these important matters.

Sincerely,

Michael X. Repka, M.D.
AAO Federal Affairs Secretary

CMS-1392-P-871 **Medicare**

Submitter : **Ms. Ginny Mitchell** **Date & Time: 09/13/2007**

Organization : **MUSC**

Category : **Hospital**

Issue Areas/Comments

OPPS: Packaged Services

I am a praticipating sonographer at the Medical University of South Carolina and I use echo contrast agents. If seperate payment for echo contrasts agents is eliminated for hospital outpatients I believe it will reduce patient access to echo contrast agents.

CMS-1392-P-872 **Medicare**

Submitter : **Dr. Hugo Torres** **Date & Time: 09/13/2007**

Organization : **Dr. Hugo Torres**

Category : **Physician**

Issue Areas/Comments

GENERAL

See Attachment.

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-873 **Medicare**

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

Organization : **Seton Medical Center**

Category : **Other Health Care Professional**

Issue Areas/Comments

Partial Hospitalization

September 14, 2007

RE: Calendar year 2008 Proposed Cut for Partial Hospitalization Programs (PHP) and Outpatient Services (OP).

Dear CMS,

I am writing to urge you to keep Medicare reimbursement to PHP and OP programs stable, at the 2007 rate. Over the past 19 years, a consistent decline of reimbursement rates offered to the nation□s mentally ill and elderly population has occurred. The proposed CMS per diem rate cut of 24% in CY 2008 would be devastating for those in need. It would result in a 44% cumulative cut in reimbursement over the past three years. Programs will be forced to shut down, forcing the mentally ill population into more expensive emergency room treatment.

The impact of the proposed CMS rate cut affects more than the consumers currently receiving Medicare benefits. The private insurance industry is likely to follow the standard that Medicare sets, which could mean lower rates across the board. If PHP and OP programs were forced to close due to financial hardship, the nation would potentially be flooded with an unstable mentally ill population, capable of taxing the healthcare, social service, and criminal justice systems even further. The nation would also be losing out on the potential for citizens to recover and return to gainful employment.

PHP and OP programs help to keep mental health consumers out of the hospital and more expensive, higher levels of care. They are fiscally responsible programs that do not have a track record of fraud. These programs provide necessary care to consumers at a relatively low cost, reducing the need for more costly, higher levels of care. By keeping the 2007 reimbursement rate stable and (avoiding the proposed 24% decrease), these programs can continue to provide valuable services that benefit mental health consumers, and society as a whole. I urge you to:

1. Suspend the current PHP and OP rate proposal and leave the current CY 2007 rate in place. Identify a reasonable inflation adjustment factor each year that is developed and legislated by Congress.
2. Develop a new PHP and OP rate Calculation Taskforce, which includes CMS staff and

representatives the Association of Ambulatory Behavioral Health (AABH), National Alliance for the Mentally Ill (NAMI) and other Psychiatric Healthcare Organizations.
3. Protect the integrity of the PHP and OP benefits that will ensure availability for the nation□s Mentally Ill population.

Sincerely,

Michael Korson, MFT
Program Manager,
Outpatient Mental Health
Seton Medical Center

CMS-1392-P-874 **Medicare**

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

Organization : **None**

Category : **Individual**

Issue Areas/Comments

OPPS: Packaged Services

Dear Mr. Weems:

Regarding: CMS-1392-P, OPPS: Packaged Services:

I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with Spasmodic Torticollis - Cervical Dystonia, (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMSs proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.

I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.

Thank you for allowing me to provide these comments.

Sincerely,

Lawrence Toporek

CMS-1392-P-875 **Medicare**

Submitter : **Ms. Millicent Pinckert** **Date & Time: 09/13/2007**

Organization : **none**

Category : **Individual**

Issue Areas/Comments

OPPS: Packaged Services

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

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

Thank you for allowing me to provide these comments.

CMS-1392-P-876 **Medicare**

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

Organization : **None**

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 Cervical Dystonia (a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMSs proposal to reduce the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. These injections are critically important to my ability to function normally.
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-877 **Medicare**

Submitter : **Dr. Sanford Silverman** **Date & Time: 09/13/2007**

Organization : **Comprehensive Pain Medicine**

Category : **Physician**

Issue Areas/Comments

GENERAL

see attachment

#877

Sanford M. Silverman, MD, PA

Comprehensive Pain Medicine

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Certified Pain Management American Board of Anesthesiology
Diplomate American Board of Pain Medicine
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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 and should also be included on the ASC list. These procedures are described by CPT codes 22526 (percutaneous intradiscal electrothermal annuloplasty, single level) and 22527 (percutaneous intradiscal electrothermal annuloplasty, one or more additional levels). There is no reason why ASCs should not be entitled to payment for these two procedures. The procedures are safely done in ASCs, and they are not procedures routinely performed in a physician's office. I ask CMS to include both procedures on the ASC list in the final rule.

ASIPP also is concerned that procedures 72285 (discography - cervical or thoracic - radiological supervision and interpretation) and 72295 (discography – lumbar - radiological supervision and interpretation) have been packaged in all circumstances under the ASC proposed rule. These services are payable separately in the HOPD in certain circumstances and I believe the same should be true for ASCs.

Lastly, I ask CMS recalculate the payment rate of CPT code 64517. The proposed payment rate for this procedure is $178 for CY 2008. While I do recognize that the payment for the procedure following the transition period will be $295, a payment of $178 seems too low.

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

I ask that CMS create a new APC for implanting rechargeable neurostimulators upon expiration of the new technology transitional pass-through payment at the end of 2007.

I am concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation therapy utilizing rechargeable devices. The proposed payment structure could lead to such financial pressures on the facilities purchasing these devices and ultimately cause the restrictive use of this technology despite the fact that rechargeable devices represent a major improvement in neurostimulation therapy for patients with chronic pain. If access to the rechargeable technology is inhibited than Medicare beneficiaries in need of this type of treatment for chronic pain will be relegated to non-rechargeable technology and subject to the risks and co-insurance costs associated with repeat surgical procedures for battery replacement. This outcome seems inconsistent with CMS's own determination that this technology offers beneficiaries substantial clinical improvement over non-rechargeable implantable which was evidenced by the decision to grant rechargeable implantable neurostimulators new technology pass-through payments for 2006 and 2007.

Implantable neurostimulators ensure that chronic pain patients have consistent pain control without interruption. The clinical benefit of the first generation non-rechargeable neurostimulator technologies is limited by the need for repeat surgical procedures for battery replacement any where from every two to four years depending on the usage of the device. Unfortunately, what we know from experience is that many physicians using non-rechargeable battery devices will utilize program settings that require less power in order to conserve the life of their non-rechargeable battery. This practice compromises the patient's opportunity to obtain optimal pain relief on a day-to-day basis; but patients choose this option as opposed to undergoing another surgical procedure. Rechargeable neurostimulators are capable of delivering continuous stimulation, even at high levels, to optimize patient relief without concern of rapid battery depletion.

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

I ask CMS to create an APC for procedures using rechargeable implantable neurostimulators that is separate and distinct from the proposed APC grouping (0222) to create greater resource consistency. While we appreciate that CMS wants to bundle similar procedures that may utilize a variety of devices with different costs, it is inappropriate to bundle procedures when the absolute difference in cost is so significant. CMS's own analysis of the claims data associated with APC 0222 (shown in Table 35 of the preamble) reveals significantly higher costs for procedures associated with rechargeable neurostimulators ($18,089 median cost) than non-rechargeable neurostimulators ($11,608 median cost).

While I recognize the difference in median costs does not create a two times rule violation, the difference in median cost is not insignificant. CMS has assigned pass-through devices to a new APC or to a different, existing APC in absence of a "two-times" rule violation and for median costs differences significantly less than $1,000. I urge CMS to take a similar approach here. The creation of two separate APCs would result in more appropriate payment for both types of procedures—rechargeable and non-rechargeable neurostimulator procedures—based on their relative costs. To implement our recommendation, we further recommend that CMS create a G-Code to distinguish between implanting a rechargeable and a non-rechargeable neurostimulator.

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

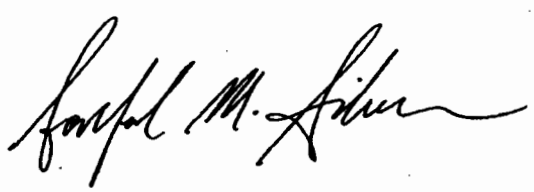
In summary my recommendations to CMS are:

- Create a new APC for procedures using rechargeable neurostimulators to recognize the full device and facility costs associated with these procedures.
- Establish new HCPCS II "G-codes" to differentiate between rechargeable and non-rechargeable neurostimulators.
- Alternatively, CMS could continue using the device C-code, C-1820, to assign rechargeable neurostimlutor procedures to a new APC.
- Maintain non-rechargeable neurostimulator procedures in APC 0222.

***

Thank you for your consideration of my comments.

Sincerely,



Sanford M. Silverman, MD

CMS-1392-P-878 **Medicare**

Submitter : **Dr. W Hansford Watford Jr** **Date & Time: 09/13/2007**

Organization : **Dr. W Hansford Watford Jr**

Category : **Physician**

Issue Areas/Comments

PET/CT Scans

I am writing to support the proposed changes in reimbursement or Cardiac PET stress scanning for codes 78459, 78491, and 78492.

PET scanniing is by far the most accurate assessment of the progrnosis of ischemic heart disease. The sensitivity and specificity of PET stress tests is between 90-95%. Such high percentages are unheard of in a screening test. Compared to SPECT Cardiolite stress testing, cardiac PET stress testing has has cut our group's rate of false positive catherterizations by 50%, producing a signifant cost savings for the health care system.

In 18 years of practice I've not seen any other advance that is more accurate, yet saves money to the system.

PET scanning is very expensive from an overhead standpoint, with large start-up and maintenance costs, while also requiring additional highly trained personnel that not only need to be certified for the handling and administraion of Nuclear material, but also proficient in CT scanning, something that nuclear technicians are not trained to do. Thus special CT-trained radiology technicians must also be hired.

The radionuclide we inject (Rubidium) is significantly more expensive than other stress nuclear agents, because we have to buy a generator that produces Rubidium from Strontium. One has to purchase an enormous amount of Strontium to decay into the useful dose of Rubidium, and these costs are substantial.

That said, adequate reimbursement for this special technology will save a lot of money for the health care system while safely delivering more accurate information for our patients and their physicians.

CMS-1392-P-879 **Medicare**

Submitter : **Ms. Millicent Pinckert** **Date & Time: 09/13/2007**

Organization : **none**

Category : **Individual**

Issue Areas/Comments

Specified Covered Outpatient Drugs

Dear Dr. Weems:

Regarding:CMS-1392-P, OPPS: Packaged Services

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

I respectfully request that CMS not package the payment of these services together, but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.

Thank you for allowing me to provide these comments.

CMS-1392-P-880 **Medicare**

Submitter : **Dr. Michael Glass** **Date & Time:** **09/13/2007**

Organization : **Dr. Michael Glass**

Category : **Physician**

Issue Areas/Comments

GENERAL

See attachment

#880

Michael L. Glass, M.D., F.A.C.O.G.
Amanda K. Levine, M.D.
Obstetrics and Gynecology

September 13, 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

405.341.9996 Fax. 405.330 3566 3815 S. Boulevard Edmond, OK 73013 mglass@drglassobgyn.com alevine@drglassobgyn.com

Michael L. Glass, M.D., F.A.C.O.G.
Amanda K. Levine, M.D.
Obstetrics and Gynecology

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

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

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

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

Respectfully,

Michael L. Glass M.D., F.A.C.O.G.
3815 S. Blvd.
Edmond, Oklahoma 73013

CMS-1392-P-881 **Medicare**

Submitter : **Dr. Amanda Levine** **Date & Time: 09/13/2007**

Organization : **Dr. Amanda Levine**

Category : **Physician**

Issue Areas/Comments

GENERAL

See Attachment regarding CMS 1392-P

#881

Michael L. Glass, M.D., F.A.C.O.G.
Amanda K. Levine, M.D.
Obstetrics and Gynecology

September 13, 2007

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

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Michael L. Glass, M.D., F.A.C.O.G.
Amanda K. Levine, M.D.
Obstetrics and Gynecology

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Respectfully,

Amanda K. Levine, M.D.

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