Submitter : Latinkic M. Mitchell **Date:** 10/10/2006

Organization : Proton Therapy Consortia

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-472-Attach-1.PDF

#172

PROTON THERAPY CONSORTIA

Loma Linda University Medical Center • Massachusetts General Hospital • The University of Texas M.D. Anderson Cancer Center • University of Florida Health Science Center • The Midwest Proton Radiotherapy Institute at Indiana University • University of Pennsylvania Medical Center/The Children's Hospital of Philadelphia • Arthur G. James Cancer Hospital/Ohio State University •Hampton University Proton Therapy Institute •Northern Illinois University

September 26, 2006

Hon. Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8011 and 8014
Baltimore, MD 21244

RE: Hospital Outpatient Prospective Payment System Calendar Year 2007 Rulemaking, Code CMS-1506-P; and Physician Fee Schedule and Practice Expense Rulemaking, Code CMS-1512-PN: Proton Therapy

Dear Dr. McClellan:

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which are noted below.

APC	CPT	CY'07 Proposed Payment Rate	CY'06 Payment Rate
0664	77520 and 77522	$1,136.83	$947.93
0667	77523 and 77525	$1,360.10	$1,134.08

These payment rates will ensure that further development of proton therapy continues as the clinical demand for this technology rises around the country.

As you know, the National Payment rates for proton therapy delivered in the Hospital Outpatient Hospital Department (HOPD) setting are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States.

Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

Freestanding Proton Therapy Centers

The Proton Therapy Consortia (Consortia) is concerned with the proposed treatment of the Freestanding Proton Therapy Centers by the Centers for Medicare and Medicaid Services (CMS) contracted Carriers in the State of Texas, Florida and Indiana. Contracted Carriers deviate significantly from the CMS National policy concerning proton beam therapy used to establish the existing payment rates as noted above for CY'06 and CY'07.

For Freestanding Proton Therapy Centers, CMS has given its contracted Carriers significant latitude with limited guidance from which to determine payment rates for proton therapy. As each State has its own Carrier, significant variations in payment rate determinations are occurring by State, as noted below.

Comparison of Freestanding Centers' Proton Therapy Rates by State			
	Indiana – Current	**Florida – Proposed 9/11/06**	**Texas – 9/1/06**
77520	-	$750.63	$652.75
77522	$516.36	$776.90	$653.90
77523	$782.43	$806.93	$783.79
77525	$782.43	$900.76	$954.41

Source: Indiana data provided by MPRI, as of September 29, 2006
University of Florida Health Sciences Center, as of September 11, 2006
TrailBlazer Health Enterprises, LLC provided to The University of Texas M.D. Anderson Cancer Center on September 1, 2006

Curtailing the development of proton beam therapy centers now through inadequate payment may have the negative long-term effect of precluding future cost reductions provided by proton beam therapy and not having this important therapy available to patients.

We are requesting that CMS direct its Carrier's on issues of payment of or for proton therapy for Free-Standing centers so that their rate setting approach is consistent with that of the CMS for HOPD.

Rationale for HOPD and Freestanding Payment Consistency: Capital Resources and Operating Costs

A typical proton beam therapy center will consist of 2-6 treatment rooms of which most include rotating gantry structures. Each gantry weighs in excess of 100 tons and is capable of rotating 360 degrees around the patient so as to deliver the proton beam therapy with sub-millimeter precision. Each facility requires up to $125 million and more than three years to develop.

A proton beam therapy center can be open up to 16 hours each day and employs radiation oncologists, physicists, nurses, medical dosimetrists, therapists and technical personnel.

For comparison, a typical conventional radiation therapy center, with 1-2 treatment vaults to accommodate a linear accelerator, gamma knife or cyber knife, will take 8-12 months to construct and prepare for clinical use. Capital requirements are between $4 and $6 million. Operating ramp-up for a conventional radiation therapy facility will usually require 2-3 months, or less in some instances.

It should be noted that due to the capital cost of proton therapy, both Freestanding and HOPD centers have similar costs for patient treatments.

Practice Expense Relative Unit Value

In addition, we believe that it is not appropriate for freestanding facilities to pursue a relative value unit (RVU) through the AMA-RUC process for proton beam therapy. Due to the limited availability of this technology in the Freestanding setting and the established coverage and payment policy established by CMS for HOPDs, we feel it is more appropriate to leverage the considerable work performed by CMS to establish payment for these setting across both hospital outpatient and freestanding facilities. The risk of not doing so may in effect limited the access of this technology to cancer patients around the country.

PROTON THERAPY CONSORTIA

Loma Linda University Medical Center • Massachusetts General Hospital • The University of Texas M.D. Anderson Cancer Center • University of Florida Health Science Center • The Midwest Proton Radiotherapy Institute at Indiana University • University of Pennsylvania Medical Center/The Children's Hospital of Philadelphia • Arthur G. James Cancer Hospital/Ohio State University •Hampton University Proton Therapy Institute •Northern Illinois University

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Proton Therapy Consortia

Proton beam therapy has been used in the clinical setting for more then 20 years, and employed in the hospital setting since 1990 to treat cancer patients (see Appendix 1 and 2). Positive clinical results from the use of proton beam therapy have stimulated worldwide interest in the clinical applications of proton beam therapy.

The Consortia consists of a group of premier cancer treatment centers in the United States that offer, or are in the process of building the capacity to offer, proton beam therapy. Members of the Consortia include nine institutions and contain both HOPDs and Freestanding centers, including:

Centers in Operations and Treating Patients:

- Loma Linda University Medical Center (October 1990): HOPD
- Massachusetts General Hospital (November 2001): HOPD
- Midwest Proton Radiotherapy Institute of Indiana University (February 2004): Freestanding
- The University of Texas M. D. Anderson Proton Therapy Center (May 2006): Freestanding
- The University of Florida Health Science Center (August 2006): Freestanding

Centers Currently Under Development:

- University of Pennsylvania Medical Center (planning stages): HOPD
- Arthur G. James Hospital / Ohio State University (planning stages): Freestanding
- Hampton University Proton Therapy Institute (planning stages): Freestanding
- Northern Illinois University (planning stages): Freestanding

Conclusion

Currently, over 40,000 patients have been treated with protons in many institutions around the world. In spite of the proven effectiveness of proton beam therapy, the development of a clinical proton beam therapy center is still challenged with the complexity, size and cost of the necessary equipment and physical facility.

Proton beam therapy is in an early stage of clinical adoption and the required equipment is significantly more expensive to purchase and maintain than standard radiation treatment equipment, which is a relatively more mature technology and has a large installed base and widespread clinical acceptance.

We strongly agree with CMS's proposed CY '07 payment rule for proton beam therapy for HOPDs.

We strongly urge CMS to direct its Carriers on matters concerning proton therapy medical coverage and payment so that Carrier determinations regarding proton therapy payment rates for Freestanding centers are made in a consistent manner with those currently in effect for HOPDs.

As always, please feel free to call upon us at (713) 563-2314 if you have any questions or if we can provided further data that can assist CMS's rule making.

Sincerely,

M. Mitchell Latinkic
Division Administrator
Division of Radiation Oncology
The University of Texas
M. D. Anderson Cancer Center

Allan Thornton, M.D.
Medical Director
Midwest Proton Radiotherapy Institute
at Indiana University

Appendix 1

UNDERSTANDING PROTON BEAM THERAPY

Principles of Radiation Oncology

The beneficial aspects of all forms of radiation oncology result from ionization. Because of ionization, radiation damages DNA within the cells. Damaging the DNA destroys specific cell functions. While both normal and cancerous cells go through a repair process, the ability of cancer cells to repair after injury is frequently inferior. As a result, higher levels of ionization in cancer cells will ensure that they sustain more permanent damage and subsequent cell death, minimizing ionization to normal cells will allow them to repair and survive. This selective cell destruction is the objective of all sound cancer therapies.

Increased Effectiveness and Utilization

Physicians have looked for ways to use radiation to treat cancer since the discovery of x-rays by Wilhelm Roentgen and radioactivity by Marie and Pierre Curie 100 years ago. Advances in technology and a better understanding of its effects on the body have made radiation therapy an important part of cancer treatment.
The first proposal for the medical use of protons was made in 1946 in a paper by physicist, Robert Wilson, Ph.D. By 1954, proton beams from a high-energy physics research accelerator were first used to treat humans.

Over the last decade, radiation therapy has grown in its utilization as a result of early detection and cancer awareness programs. With greater emphasis placed on organ preservation, quality of life and productivity, the role of radiation oncology is expected to increase.

In fact, according to the American Cancer Society, about half of all people with cancer will receive radiation during their cancer treatment.

Objectives of Radiation Therapy

The classic intent of radiation oncology is to deliver ionizing radiation only to diseased tissue. In practice, this ideal is compromised; normal tissue is always included in the radiation fields. The tolerance of the normal tissue in those fields often determines the dose the radiation oncologist can deliver; the resulting dose is frequently insufficient to control the cancer.

Radiation oncologists seek the lowest rate of side effects and complications as possible, consistent with the attempt to achieve the best possible local and local/regional cancer control. Complications include disability, disfigurement, dysfunction, and even death.

Conventional Radiation Therapy Constraints

Radiation therapy requires delivery of photons and electrons into the body in total doses sufficient to ensure that enough ionization events occur to damage all of the cancer cells.

Unlike protons, photons lack charge and mass, thus most of their energy is deposited in normal tissue near the body's surface, as they travel through tissue, and beyond the targeted cancer. This undesirable pattern of energy placement results in unnecessary damage to healthy tissues.

Attempting to overcome the inherent characteristics of photons and electrons, radiation oncologists employ multi-field treatment delivery arrangements to build up the tumor dose and spare as much of the normal tissue as possible by restricting the dose in those tissues to a tolerable level.

Rationale for Proton Beam Therapy

Protons, unlike photons or electrons, are energized to specific velocities. These energies determine how deeply in the body protons will deposit their maximum energy. The precise stopping point of protons in the body is where the highest radiation dose is released; this is called the Bragg Peak. Protons' favorable absorption characteristics result from their charge and heavy mass, which is 1,835 times that of an electron. These factors allow the physician to predict and control their depth of travel within the patient. The heavy mass of protons results in minimal travel deviation, which reduces unwanted side effects and improves treatment benefit.

Appendix 2

MAJOR COMPONENTS OF A PROTON BEAM THERAPY SYSTEM

A proton beam therapy treatment center consists of a number of distinct technical components. All of the components are based on an established accelerator, medical physics, control systems and software technologies. The proton beam treatment center typically consists of a separate building or designated space to house all of the proton beam therapy equipment coupled with up to four distinct patient treatment rooms.

Accelerator: High energy proton beams are generated by a synchrotron or cyclotron accelerator, a compact particle accelerator that accelerates protons that can be reduced to variable energies in the range from 70 to 250 MeV. The accelerator consists of a ring of magnet(s) having a circumference length of approximately 23 meters that constrains the protons to travel in a circumscribed path inside a high vacuum chamber. Accelerated protons are extracted into the beam transport line, which directs the proton beam to the patient treatment room.

Beam transport line: The proton beam travels through the beam transport system inside a vacuum tube. The beam transport line consists of a series of bending and focusing magnets, which control the beam's focus and position as it travels to the patient treatment rooms.

Rotating gantry treatment rooms: Gantries are massive rotating steel structures that support the bending and focusing magnets, vacuum system, nozzle, and all equipment necessary for controlling and monitoring patient treatment. This complex structure, three floors in height, weigh in excess of 100 tons and rotate 360 degrees around the patient with sub-millimeter precision. The gantry is rotated to prescribe angles around the patient, thus directing the proton beam toward the tumor from different directions. In this manner, multiple portals (or beam entry points) can be used during a treatment session while keeping the patient in a fixed position.

Horizontal, fixed-beam treatment room(s): A fixed, horizontal, non-moveable beam transport and delivery system and an adjustable patient treatment couch or chair are used for large-field treatments, including treatments of prostate, and head and neck cancers. A small-field treatment system is specially designed to treat tumors of the eye.

Treatment delivery nozzle: In each of the patient treatment rooms, a nozzle is located at the terminus of each beam line. The nozzle contains devices that shape, focus and direct the proton beam to the precise configuration of the involved area specified by each patient's treatment plan, thereby allowing three-dimensional conformal treatment to the exact tumor volume. Advanced nozzle designs include magnets that sweep a pencil-beam of protons through the tumor volume, while varying the intensity of the beam or the speed of the sweeping pattern. This advanced form of treatment, called intensity modulation, will offer the optimum radiation treatment for cancer.

Patient positioning system: The patient positioning system includes digitally controlled platforms that hold the patient in a secure treatment position and moves the patient to the exact position required for treatment. Advanced imaging systems provide necessary data for movement corrections that position patient's cancer in the treatment beam to within sub-millimeter accuracy.

Treatment control and safety systems: The treatment control system is a fully integrated hardware and software system that monitors and controls all aspects of beam production, transport and delivery. The control system includes monitoring devices and diagnostics software that provide rapid problem identification and error reporting. Additional software displays the patient's treatment field, setup information, patient-specific treatment device information, and real time monitoring and reporting of the delivered dose. The safety system operates independently of the control system. It has both software and hardware systems that monitor all of the critical elements of beam delivery.

Treatment planning, record-and-verify, and interface software: In addition to the foregoing, treatment planning, information and image management software systems and workstations are needed to integrate with the facility control system.

Development Period: The full proton beam therapy treatment system requires an extensive period of time to install, test and commission prior to first patient treatment. The building, up to approximately 85,000 square feet in size, needed to house the proton beam therapy hardware and software takes approximately 12 months to complete before equipment can be installed. Approximately 24 months, if not more, are required to install and commission the proton accelerator, beam transport lines and gantries, to install and integrate the software systems, and to finish, test and commission the resulting integrated system to clinical specifications.

Submitter : **Ellen Stovall** **Date: 10/10/2006**

Organization : **Cancer Leadership Council**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-473-Attach-1.DOC

#173

October 10, 2006

Filed Electronically

Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Hubert H. Humphrey Building
Room 314-G
Washington, D.C. 20201

Re: CMS-1506-P; Comments Regarding the Hospital Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

The undersigned members of the Cancer Leadership Council write to express their concerns regarding potential changes in payments for cancer therapies reflected in the proposed rule for the Hospital Outpatient Prospective Payment System (OPPS) for calendar year 2007. Modifications to payments for cancer drugs and radioimmunotherapies as proposed by the Centers for Medicare & Medicaid Services (CMS) could have a negative impact on patient access to potentially life-saving therapies.

If, as proposed, payment for cancer drugs is reduced from 106% of average sales price (ASP) to 105% of ASP, hospitals with a heavy concentration of cancer patients may suffer losses that could eventually exert a negative impact on individual patient access to these drugs. We understand that surveys of community cancer centers indicate that a number of cancer drugs would not be available for prices equal to or less than the proposed Medicare payment rate. Under such circumstances, cancer providers in the hospital outpatient setting will have a disincentive to utilize these drugs and, if the trend persists, these institutions will be disinclined to maintain the services provided to cancer patients. We urge CMS to reconsider the proposed reduction of payment for calendar year 2007 to ensure that patient access to cancer care in the outpatient setting is not compromised.

CMS proposes to set a fixed rate for radiopharmaceuticals in 2007. Although this modification in payment methodology may be advisable, we are concerned that the data that will be utilized to set the payment rate may not be complete and up-to-date. It is projected that the rate of payment may be cut in half from 2006 to 2007, a reduction that could have a significant impact on availability of radioimmunotherapies for treatment of non-Hodgkin's lymphoma. We recommend that this change be delayed until there are assurances that the data supporting the new payment rate are accurate and complete and that particular attention be given to high-cost radiopharmaceuticals, for which a special payment methodology may be necessary.

We urge CMS to carefully consider these issues that may affect patient access to cancer care in the outpatient setting.

Sincerely,

Cancer Leadership Council

American Psychosocial Oncology Society
American Society of Clinical Oncology
C3: Colorectal Cancer Coalition
Cancer Care
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Sarcoma Foundation of America
Us TOO International Prostate Cancer Education and Support Network
Y-ME National Breast Cancer Organization

Contact Information:

Ellen Stovall
1010 Wayne Drive – Suite 770
Silver Spring, MD 20910
Phone: 301/650-9127
Fax: 301/565-9670
E-mail: estovall@canceradvocacy.org

Submitter : Mr. Michael Ruggiero **Date:** 10/10/2006

Organization : Astellas Pharma US

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-474-Attach-1.PDF

#474

October 10, 2006

Dr. Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1506-P: Comments Regarding the Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Dr. McClellan:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to comment on the hospital outpatient prospective payment system (OPPS) proposed rule for calendar year 2007, published by the Centers for Medicare and Medicaid Services (CMS). Astellas is among the top 20 global pharmaceutical companies, with North American product lines that focus on the therapeutic areas of immunology, cardiology, dermatology, infectious disease, and urology. Our drugs and biologicals are used to treat Medicare beneficiaries in a variety of settings, including hospital outpatient departments.

As we noted in our comments on the physician fee schedule proposed rule, Astellas is aware of the significant challenges facing CMS in devising payment systems that facilitate patient access to care in the most appropriate setting. We support CMS' efforts to sustain the fiscal integrity of the Medicare program while providing Medicare beneficiaries with the same level of access to new and established therapies as their privately insured counterparts. Our comments are designed to assist CMS in balancing these goals, as well as to preserve incentives for therapeutic innovation. This is especially important for hospital outpatient centers, which are generally best equipped to incorporate new and effective therapies into their care standards earlier than the small and mid-size physician practices providing primary care to the Medicare population. Our comments below focus on three key issues, and can be briefly summarized as follows:

(1) **Payment for Specified Covered Outpatient Drugs (SCODs).** CMS should revise its proposal to pay for SCODs at 105% of Average Sales Price (ASP), which likely understates hospitals' acquisition and handling costs and creates access risks. Instead, CMS should adopt the 106% of ASP payment rate it set for SCODs in 2006.

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[1] 71 Fed. Reg. 49506 (Aug. 23, 2006).

(2) **Payment for pass-through drugs (and other new drugs with HCPCS Codes).** CMS should revisit its proposal to pay hospital outpatient departments for these drugs at the Competitive Acquisition Program (CAP) price when they are included in CAP. CAP prices (which are based on the CAP vendor's bid) fall well below the 106% of ASP payment rate that applies to other new drugs, and there is no evidence that these prices will be sufficient to cover hospitals' acquisition and handling costs for new drugs. CMS should therefore set the 2007 payment amount for pass-through drugs included in CAP (and other new drugs with HCPCS codes included in CAP) at 106% of ASP.

(3) **Drug administration fees and appropriate coding mechanisms.** To help ensure adequate reimbursement for drug administration services, CMS should instruct its contractors to pay hospitals for administration of biological response modifiers using the codes applicable to anti-cancer therapies.

* * *

I. Payment For Specified Covered Outpatient Drugs

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) defined a SCOD as a drug for which a separate APC had been established and that is either a radiopharmaceutical agent or is a drug or biological for which pass-through payment was made on or before December 31, 2002 (subject to certain exceptions).[2] Since implementation of the MMA payment provisions, CMS has treated products that have come off "pass-through" status as SCODs for payment purposes. The MMA directed that payment for SCODs in 2006 and subsequent years equal the "average acquisition cost for the drug for that year . . . as determined by the Secretary," subject to adjustment for overhead costs.[3] Where hospital acquisition cost data is not available, payment must equal "the average price for the drug in the year established under [SSA]

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[2] Social Security Act (SSA) § 1833(t)(14)(B)(i).

[3] SSA § 1833(t)(14)(A)(iii).

section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph."[4]

CMS paid for SCODs at 106% of ASP in 2006, and proposes to pay 105% of ASP for 2007. CMS compared two sources of data -- ASP data from the fourth quarter of CY 2005 and mean "costs [of drugs] derived from the CY 2005 hospital claims data" -- and concluded that using mean cost to set SCOD payment rates would be "equivalent to basing their payment rates, on average, at ASP+5 percent."[5] Citing a MedPAC survey indicating that hospitals set charges for drugs "high enough to reflect their pharmacy handling costs as well as their acquisition costs," CMS reasoned that "the mean costs calculated using charges from hospital claims data converted to costs are representative of hospital acquisition costs for these products, as well as their related pharmacy overhead costs."[6] CMS thus concluded that "payment for drugs . . . and pharmacy overhead at a combined ASP+5 percent rate would serve as the best proxy for the combined acquisition and overhead costs of . . . these products."[7]

As discussed below, Astellas is concerned that due to several problems with this analysis, 105% of ASP would be inadequate to cover hospitals' acquisition and overhead costs and could thus jeopardize beneficiary access. Accordingly, we urge CMS to revisit this proposal and set 2007 SCOD payments at the 106% of ASP payment rate CMS set for 2006.

CMS reasons that if hospitals set charges for drugs high enough to "reflect" handling costs and acquisition costs, a payment rate determined by reducing charges to costs would cover drug handling and acquisition costs. However, the assumption that charges are adequate to cover handling and acquisition costs only implies that payment at charges would be adequate -- not that payment at charges-reduced-to-costs would be adequate. Further, the MedPAC findings CMS cites appear not to be based on a systematic survey, but on informal MedPAC "consultations" with hospital pharmacy directors and administrators[8], which may not provide a representative sample of charging

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[4] Id.

[5] 71 Fed. Reg. at 69584.

[6] Id.

[7] Id.

[8] MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, Ch 6, Payment for Pharmacy Handling Costs in Hospital Outpatient Departments, 139 (Jun. 2005)

practices. Moreover, CMS did not adequately explain how it derived its average reimbursement of 105% of ASP from charges reduced to costs. For example, CMS stated that 105% of ASP for the fourth quarter 2005 was equal to the mean "costs [of drugs] derived from the CY 2005 hospital claims data" (i.e., charges reduced to costs), but did not discuss whether all CY 2005 data or only fourth quarter 2005 claims data were considered.

Finally, the MMA's OPPS payment provisions were designed to replace the previous system of using the complex methodology of deriving cost data from hospital charges. The cost-to-charge methodology was replaced largely due to its ineffectiveness in setting payment levels that reflected hospitals' acquisition and handling costs for all products. CMS' reliance on informal consultations between MedPAC and select hospital pharmacy directors and administrators, as well as the conclusions derived from the MedPAC report, do not capture the variability in "charges" for individual products (e.g., charge compression for higher-cost therapies) or the divergent charging practices between hospitals. Astellas believes that reinjecting the complexities of the pre-MMA payment methodology is a step backward from the 2006 streamlined approach to setting payment rates for separately paid OPPS drugs and biologicals. Moreover, implementing the 105% of ASP change would contravene MedPAC's overriding principle of consistency in payment rates across sites of service. Accordingly, we urge CMS to adopt a 106% payment rate for SCODs in the 2007 OPPS final rule.

II. Payment For New Drugs And Biologicals

CMS proposes to pay for drugs and biologicals with pass-through status, and new drugs and biologicals with product-specific HCPCS code but no claims data, at 106% of ASP or (if applicable) the CAP payment amount.

Astellas believes that setting the OPPS payment rate for new drugs at the CAP payment rate (for drugs included in CAP) could underpay hospitals for these important therapies and create beneficiary access problems. Hospital outpatient departments cannot acquire drugs through CAP. CAP payment rates are based on the CAP vendor's bid, and fall significantly below the 106% of ASP rate that physicians would be paid for these drugs (and that applies to other new drugs in the OPPS setting). There is no evidence to conclude that CAP payment rates are representative of hospital acquisition costs, let alone the combined acquisition and pharmacy overhead costs incurred by hospital outpatient departments.

Moreover, there is no need for CMS to set payments for pass-through drugs that are covered by CAP at the rate set for the drug in the CAP program; the MMA does not require this. Rather, the statute sets the "additional payment" for a pass-through drug that is covered by CAP at the amount by which the average CAP price exceeds the portion of the relevant fee schedule amount for the drug.[9] Thus, the OPPS payment amount for a pass-through drug included in CAP generally is the otherwise applicable fee schedule amount (unless the drug's CAP price exceeds that amount, in which case an extra "pass-through" payment is made in the amount that the CAP price exceeds the fee schedule amount). CMS itself sets the otherwise applicable fee schedule amount (which the Agency considers to be the payment for new drugs without pass-through status but with HCPCS codes).[10] If that amount does not exceed the CAP price, then the "pass-through payment" is zero and the drug would simply be paid at the relevant fee schedule amount.

Consequently, CMS can ensure that pass-through drugs included in CAP (and other new drugs with HCPCS codes included in CAP) are reimbursed adequately merely by establishing an adequate fee schedule amount (which, as noted above, is an amount set by CMS in its discretion). To reduce the risk that new therapies are paid inadequately and may be unavailable to Medicare beneficiaries in the hospital outpatient setting, CMS should set a fee schedule amount equal to 106% of ASP (the same payment that physicians who do not participate in CAP would receive for those drugs).[11] Astellas urges CMS to adopt this approach in its final OPPS rule for 2007.

III. Drug Administration Fees And Appropriate Coding Mechanisms

Astellas reiterates the concerns expressed in its comments to the Physician Fee Schedule proposed rule with respect to payment for administration of drugs and biologicals. We recognize that CMS has undertaken several initiatives to ensure adequate reimbursement for physician services associated with administration of Part B drugs and biologicals. The Agency's commitment to adjust historically inadequate payment amounts was evident in its 2005 adoption of the AMA's revisions to the CPT codes for these services (in the physician office setting, but not in hospital outpatient centers) a year earlier than the 2006 effective date of the CPT revisions. Specifically,

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[9] SSA § 1833(t)(3)(D)(i).

[10] 71 Fed. Reg. at 49581.

[11] We note that CMS also could use its equitable adjustment authority under SSA § 1833(t)(2)(E) to set an adequate payment for pass-through drugs included in CAP.

CMS created a set of G codes that, in part, incorporated the CPT panel recommendation to pay for complex biologicals utilizing the codes applicable to anti-cancer therapies.

Clearly, CMS and its contractors had the authority to interpret these G codes on a product-specific basis at the national or local contractor level. Many contractors did not apply these codes to biological response modifiers. Unfortunately, the various interpretations made by each contractor, for the most part, remain in effect even after the 2006 effective date of the CPT revision. These "policies" have not yet fully or uniformly operationalized the AMA's incorporation of biological response modifiers into the definition of products that fall within the chemotherapy administration codes. Astellas is concerned that these limitations will continue to apply to products administered in the hospital outpatient setting.

CMS' longstanding policy has been to defer to the AMA on CPT code interpretation. Biological response modifiers clearly fall within the AMA's definition of products eligible for administration under the chemotherapy codes. CMS should therefore instruct its contractors to pay for administration of biological response modifiers under these codes. We suggest that CMS also invite biological manufacturers to provide product information and other guidance to the various contractors that identifies specific complex biologicals as biological response modifiers.

* * *

Astellas appreciates the opportunity to provide these comments. If you have any questions or require further information, please contact me at (847) 405-1640 or via email Michael.Ruggiero@us.astellas.com.

Sincerely,

Michael J. Ruggiero
Senior Director, Government Policy
and External Affairs

Submitter : Dr. Samuel Masket **Date:** 10/10/2006

Organization : Amer. Society of Cataract and Refractive Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-475-Attach-1.PDF

#1175

ASCRS OUTPATIENT OPHTHALMIC SURGERY SOCIETY, INC.

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

via Electronic Mail

October 10, 2006

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1478-P
P.O. Box 8013
Baltimore, MD 21244-8012

RE: CMS-1506-P; CMS-4125-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Ambulatory Surgical Center List of Covered Procedures; Ambulatory Surgical Center Payments System and CY2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient PPS Annual Payment Update Program—HCAHPS Survey, SCIP, and Mortality)

Dear Dr. McClellan:

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association representing over 1000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective outpatient surgical environments, particularly ambulatory surgical centers (ASC).

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing over 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of cataract procedures performed annually in ASCs and hospitals.

On behalf of OOSS and ASCRS, we are taking this opportunity to comment on the 2007 proposed Ambulatory Surgical Center Covered Procedures List, the New Technology Intraocular Lens (NTIOL) proposal, and elements of the Hospital Outpatient Prospective Payment System (HOPPS) rule, all of which were published in the August 23, 2006 Federal Register. We will provide further extensive comments on the FY 2008 ASC payment proposal, with respect to which comments are due on November 5, 2006.

New Technology Intraocular Lenses (NTIOL)

OOSS and ASCRS, as representatives of surgeons who operate in high-quality, lower-cost, and patient-friendly operative environments, are dedicated to ensuring that ophthalmologists are able to offer to our patients state-of-the-art vision-restoring technology, including intraocular lenses (IOL). Our organizations were integrally involved in the enactment of legislation and the promulgation of regulations to implement the NTIOL benefit that provides ASCs with an additional payment enabling ophthalmic surgeons to implant IOLs with advanced and innovative characteristics that offer patients improved surgical outcomes and quality of life. Through the NTIOL program, our patients have been afforded access to the Allergan AMO Array Multifocal lens, the STAAR Surgical Elastic Ultraviolet-Absorbing Silicone Posterior Chamber IOL with Toric Optic, and the AMO Tecnis and Alcon Acrysof IQ lenses, both of which reduce spherical aberration. Generally speaking, we support the changes CMS is proposing to modify the processes through the agency notifies the public regarding NTIOL approvals and revises the content of applications requesting NTIOL status. We do offer the following recommendations:

- OOSS and ASCRS agree that requiring additional information within the application for NTIOL status should enable CMS to more comprehensively assess the clinical benefits of applicants' NTIOL products, facilitating the adoption of appropriate designations and payment adjustments. However, application of these requirements by CMS should be guided by promoting, not inhibiting, access of patients to new technology.

- The enabling NTIOL regulation established a $50 additional payment for implantation of an NTIOL during cataract surgery. We believe that, in light of advances in cataract surgery technique and the availability of exceptional IOL products whose research, development and production costs exceed those of conventional lenses, the regulations should permit sponsors of new lens technologies to apply for payment adjustments that are greater than $50. Unless NTIOL payments adequately account for inflation in surgery centers' IOL acquisition costs, our patients will be denied optimal potential surgical outcomes. The proposed modifications to the NTIOL application and payment adjustment process should enable the agency to complete the requisite evaluation of an NTIOL's characteristics and costs. We would suggest that manufacturers of new lens products be afforded the opportunity of presenting to CMS dual submissions for agency review: (1) a request for approval of the applicant IOL to be approved for NTIOL status; and, (2) a request, based upon the submission of appropriate documentation, for the particular class of NTIOL to be eligible for a higher payment adjustment. In order to ensure maximum patient access to NTIOLs, the approval of a higher payment for a new NTIOL class, or a new lens within an existing class, should not affect the status of, or beneficiary access to, existing classes or lenses paid for at the standard $50 rate.

- We are not recommending herein that an NTIOL category be extended beyond the five-year period embodied within the original regulation. However, it is imperative that, consistent with the HOPPS pass-through process, the base ASC facility payments for cataract surgery be upwardly adjusted after the five-year period, to appropriately reflect the adoption rates of these more costly lenses within the ASC setting.

- We support the agency's objective to codify the NTIOL review process to render it consistent with the annual notice and comment period that is proposed to be applied to the annual establishment of new payment rates for ASC services. We appreciate CMS' need for ample time to review NTIOL applications and support, where absolutely necessary, the extension of the NTIOL review period from 30 to 90 days. However, as discussed below, we would expect that NTIOL sponsor/agency contact during the course of new product development and study should mitigate the need for CMS to avail itself of review time in excess of 30 days. Regardless of the review time, upon completion of application review, patients should have immediate access to NTIOL products in the ASC. It appears that the agency is proposing that NTIOL application approvals be "batched" into one annual payment rule and effective date. To ensure timely beneficiary access to approved NTIOLs, our organizations believe that the agency should implement a process similar to the new technology pass-through system applicable to hospital outpatient surgical services under which newly designated NTIOLs are available to patients upon CMS approval throughout the course of the year.

- As noted above, it is imperative that patients enjoy expeditious access to advances in IOL technology; this is contingent upon manufacturers of these products being afforded timely access to all NTIOL submission requirements and a meaningful agency review of their applications. CMS is proposing to post NTIOL requirements on its website. We are concerned that lags in website updates may compromise an NTIOL sponsor's ability to design and implement requisite studies and generate data that will adequately support timely consideration and approval of an application. We would recommend that the proposed rule be reflective of CMS' practice of meeting with manufacturers throughout the study design and application processes to ensure that the agency's demands for documentation of an IOL's benefits are fully understood by applicants and are met upon submission of the application. Alternatively, the agency should review an NTIOL application under the criteria published on the CMS website at the time of submission. We believe any changes to the rule or criteria should be made only under notice and comment rulemaking as announced in the Federal Register.

CY 2007 Update to List of Covered Procedures

In our comments submitted to CMS with respect to the 2005 procedures list update, we objected to CMS' decision not to include **CPT Code 66990** (use of ophthalmic endoscope) on the list of

approved procedures. We reiterate our objection today with respect to the proposed rule. 66990 is an add-on code for a specific endoscopic surgical approach and does constitute surgery. It is reported on conjunction with many ophthalmic surgical services that are permitted and reimbursed in the ASC environment. Failure to include the code will result in these services being performed in the hospital inpatient or outpatient environments, at greater cost to the Medicare program and inconvenience to the beneficiary. We recommend that 66990 be added to the ASC list.

*****

Thank you for providing our organizations with the opportunity to present our comments on these important issues. We look forward to providing more extensive comments next month with respect to the proposed 2008 ASC payment system. Should you have any questions, please do not hesitate to contact our Washington representatives: Michael Romansky, Washington Counsel, OOSS at mromansky@ooss.org or at 302.332.6474; or Emily Graham, RHIT, CCS-P, CPC, ASCRS Manager of Regulatory Affairs at egraham@ascrs.org or 703-591-2220.

Sincerely,

Samuel Masket, MD
President, ASCRS

William Fishkind, MD
President, OOSS

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY
P.O. Box 5256 • Johnson City, TN 37602-5256 • 866-246-9880 • Facsimile (423) 282-9712

Submitter : Ms. Katherine Browne **Date:** 10/10/2006

Organization : Consumer-Purchaser Disclosure Project

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See attached comment letter and supporting document.

CMS-1506-P-476-Attach-1.DOC

CMS-1506-P-476-Attach-2.DOC

Consumer-Purchaser
DISCLOSURE
PROJECT Improving Health Care Quality through Public Reporting of Performance

October 10, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., NW
Washington, DC 20201

File Code: CMS-1506-P

RE: Hospital Outpatient and Inpatient Payment Changes

Dear Dr. McClellan:

Thank you for the opportunity to comment on the proposed changes to the Hospital Outpatient and Inpatient Prospective Payment System. We applaud your efforts to promote and foster increased transparency and we believe that Medicare should lead the way to promoting a market that recognizes and rewards high-quality, efficient, equitable, and patient-centered care. Publicly reporting hospital performance will allow: 1) consumers to make informed decisions about their health care; 2) insurers and purchasers to make value-based contracting decisions and use differential payments as incentives; and 3) providers' improvement efforts to be supported with better information. To that end, we strongly support Medicare using public reporting and "value-based purchasing" as strategies to promote better quality of care and more effective use of resources. (See the attached material underscoring the broad support for this effort across consumers, purchasers, and labor.)

What follows are specific comments on the three sections of the proposed rule (CMS-1506-P) that address hospital quality data, promoting effective use of health information technology, and the transparency of health care information.

SECTION XX: HOSPITAL QUALITY DATA

Outpatient Prospective Payment System (OPPS)
We support CMS' proposal to apply the 21 inpatient measures for heart attack, heart failure, pneumonia, and surgical care to the annual outpatient payment update. This would, in effect, reduce a hospital's outpatient payment by 2% if inpatient performance data were not reported. We also support tying additional performance measures, such as those suggested for the inpatient FY 2008 payment, to the outpatient payment update. We believe a reduction to a hospital's outpatient payments will be an incentive to spur submission of performance data for public reporting. However we recommend that CMS evaluate the effectiveness and consider increasing and/or shifting the reduction to reflect performance instead of merely reporting.

C/O National Partnership for Women & Families
1875 Connecticut Avenue, NW Suite 650
Washington, DC 20009
202.986.2600 • 202.986.2539 (fax) • healthcaredisclosure.org

Outpatient-Specific Measure Development
We understand that tying the reporting of inpatient measures to the outpatient payment update is an interim step as CMS works with stakeholders to develop and ultimately expand the number and type of quality and cost of care measures that are most appropriate and applicable to the hospital outpatient setting. Because of the lack of well-specified and endorsed measures that meet consumers' and purchasers' needs, the federal government should specifically support the rapid development of measures that are:

- **Reasonably Scientifically Acceptable:** Consumers and purchasers want measures to be scientifically sound and evidence based, but do not want the pursuit of perfection to delay the availability of good and useful information.
- **Feasible to Implement:** Rapid reporting necessitates measures that are constructed and specified so that the data needed are currently available or can be collected with limited reporting burden.
- **Relevant to Consumers and Purchasers:** The needs of consumers and purchasers for important and actionable information should drive the development of measures.
- **Reflect the Continuum of Care/Care Coordination from a Patient's Perspective:** Measures should address the extent to which comprehensive, patient-centered care is delivered, often by multiple providers and across multiple settings.

We strongly urge that HHS or CMS also fund measure development in areas where gaps are identified and provide core operating support for the National Quality Forum (NQF) to ensure ongoing, independent consensus process for the review, endorsement, and updating of measures so as to enable the availability of comparative information and the reduction of provider reporting burden. We are encouraged by the statement that fully developed, well-tested outpatient-specific measures could be implemented as early as January 1, 2009.

Reporting Cost of Care
Consumers are increasingly faced with a multitude of decisions and choices – such as estimating aggregate costs for a year based on plan or benefit design, and selecting a health plan, physician, medical group, hospital, health plan or treatment. Enabling consumers to make well-informed, value-based decisions means that the presentation of health care cost information should be linked to quality information and should be actionable. In general, the following two core principles should guide the presentation of cost information to consumers:

1. **Link Cost to Quality Information:** Whenever possible, cost information should be directly linked to quality measures (e.g., outcomes, patient experience, and compliance with evidence-based medicine). Linking cost and quality information facilitates the consumer's consideration of the total value of the choice they are making. When it is not possible to provide a direct link to quality information or when quality of care is not variable (e.g., receiving a flu shot), the presentation of costs should include contextual information and a general description of quality considerations (including that higher price does not necessarily correlate to better quality).

2. **Make Cost Information Actionable:** Information provided to consumers needs to be easy to comprehend (**Understandable**), easy to retrieve at the time a consumer needs to make a decision (**Timely and Accessible**) and useful in the context of a consumer's particular circumstance and needs (**Relevant**).

    - **Understandable**: Information should be easy to comprehend by the consumer. Health industry jargon should be avoided, and material should be tested for both the health and financial literacy skills of the targeted audience(s).

- **Timely and Accessible**: Cost information needs to be easily accessible at the time the consumer is making their decision. Effective dissemination and promotion of cost information is critical, as is ensuring that the information is available on-line without barriers and designed for ease of use.

- **Relevant:** To be actionable by a consumer, cost information should be as specific as possible to the consumer's circumstances (e.g., health status, insurance coverage and benefit design). Cost information should reflect the specific choice being made (e.g., the annual choice of health plan, provider selection, treatment choice) and account for an individual's or family's particular health coverage and health status. Information should include comparisons of providers and/or treatments based on quality and cost; information on possible alternatives; and potentially provide additional information related to contacting the provider or learning more about the condition. The information should predict likely expenses accurately and/or have a clear explanation of the reason for the range of cost variation and how a consumer's circumstances would likely cause them to fall within that range.

Planning for Implementing Value-Based Purchasing
As CMS embarks on the planning process mandated by the Deficit Reduction Act of 2005 for implementation of value-based purchasing by FY 2009, we would encourage the inclusion of all hospital services, both inpatient and outpatient. Going forward, CMS should:

- Continue to rapidly expand the number and type of measures that hospitals must report to obtain annual payment update. In the near term, this expansion serves as a good building block for comprehensive hospital payment reform in 2009.
- Ensure that the amount of payment linked to performance is substantial.
- Phase in a system that differentially pays providers based on nationally standardized measures, but ensure that the portion of money that is tied to performance increases over time in conjunction with the performance measures upon which hospitals are assessed.
- Construct incentives so that they take into account performance on high clinical quality, patient-centered, and efficient care, as recommended by the 2006 Institute of Medicine report on *Rewarding Provider Performance: Aligning Incentives in Medicare.*
- Ensure that provider incentives should be budget-neutral and, in the near-term, based on a combination of improvement and meeting thresholds.

In addition, both efficiency and equity represent large gaps in which there are few, if any, nationally standardized measures or approaches. During this planning phase, CMS has an opportunity to support national standards on relative use of resources and disparities in care.

SECTION XXI: PROMOTING EFFECTIVE USE OF HEALTH INFORMATION TECHNOLOGY (page 542)
Health information technology (HIT) – which includes software applications for care management (EMR, EHR, practice management systems, registries) – has the potential to dramatically improve the quality and efficiency of health care. In addition, if appropriately implemented, HIT can and should serve as the platform for the collection of information to supply future performance measurement, reporting and payment systems. To date, implementation has been exceedingly slow. The Secretary can spur HIT adoption and ensure that the data necessary for quality measures are captured, by using conditions of participation that require hospitals to implement HIT that:

- Complies with interoperability standards;
- Adequately protects privacy and confidentiality of patient data;

- Enables standardized quality, performance, and efficiency measurement as a routine by-product of their use; and
- Enables the merger of data with others in both the public and private sectors for the purpose of facilitating the production of standardized quality, performance, and efficiency information.

[NOTE: Adapted from AQA Data Sharing and Aggregation Subgroup on HIT: www.ambulatoryqualityalliance.org/files/PrinciplesforHITandMeasAgg-May06.doc]

Further, the Secretary should tie the annual hospital payment update to the reporting of hospitals' progress toward implementing Computerized Provider Order Entry (CPOE) as was noted in the 2005 Institute of Medicine's report *Performance Measurement: Accelerating Improvement.*

Until HIT becomes wide-spread the Secretary can enable much more robust hospital performance reporting by requiring hospitals to augment claims data with additional clinical data elements. The public reporting of quality and cost information would benefit greatly from claims data with richer detail. For example, accurately assessing provider performance would be greatly enhanced if the severity of the patient's condition could be captured from administrative claims data. Adding the following data elements to the inpatient paper and electronic claim forms would enable better quality and efficiency reporting:

- Unique physician identifier for each coded procedure;
- Referring/ordering physician for each coded procedure;
- Vital signs (heart rate, blood pressure, temperature, and respiratory rate) recorded at presentation;
- Key lab values (BUN, hematocrit, platelets, WBC, sodium, potassium, and creatinine) if obtained at the time of admission, excluding hospitalizations for psychiatric, obstetrical and newborn services;
- Do Not Resuscitate order present (including date and time), if recorded during first 24 hours of patient presenting; and
- Time of day of admission, discharge, and each procedure.

SECTION XXII: TRANSPARENCY OF HEALTH CARE INFORMATION (page 545)

As the Department builds upon its current transparency efforts, we would encourage the Secretary to increase both the scope and breadth of consumer-friendly cost and quality information by employing the action listed below. The critical need to directly link, wherever possible, consumers' cost information with quality information reinforces the importance of the federal government supporting the development and endorsement of a robust set of hospital (and other provider) performance measures.

Actions the federal government should take to increase the breadth and scope of performance information available to the public include:

- Make available physician-identifiable Medicare claims data (fully protecting patient privacy), to allow for better performance reporting.
- Continue to allow private-sector organizations to download provider performance information from the CMS Compare websites.
- Release the Medicare risk-adjusted DRG rates for every hospital (and rates for physicians), by region in easily accessible formats.
- Develop BOTH total costs of episodes of care AND total estimated beneficiary out-of-pocket costs for episodes of care (with estimates for beneficiaries with and without Medigap supplemental coverage).

CMS/HHS should consider using the following mechanisms to further enhance transparency of quality and cost information by:

- Establishing conditions of participation for hospitals that require posting of prices and policies regarding discounts and other payment options for uninsured patients. For insured individuals, health plans will likely be the primary vehicle for information that is specific to beneficiaries' condition or coverage, but CMS should play a central role in ensuring that the uninsured have access to information that is relevant to their circumstances. Informed consumer decision-making will require actionable tools and true transparency.
- The Administration through its various contracting mechanisms with health plans (via OPM or Medicare), should require that they provide tools for their enrollees to make informed choices, considering both quality and costs.

SECTION XXIII: FY 2008 IPPS RHQDAPU (Additional Quality Measures and Procedures for Hospital Reporting of Quality Data for the FY 2008 Inpatient Annual Payment Update)

To qualify for the FY 2007 annual payment update, hospitals will have to report 11 additional measures for heart attack, heart failure, pneumonia, and surgical care infection prevention. For the FY 2008 update, hospitals would have to report the following measures:

- HCAHPS;
- 30-day mortality rates for heart failure, heart attack and pneumonia; and
- Three surgical care infection prevention measures
  - VTE prophylaxis ordered for surgical patient
  - VTE prophylaxis within 24 hours pre/post surgery
  - Appropriate selection of antibiotics

For public reporting purposes, each of the seven domains within the HCAHPS survey will have a composite score, i.e., there will be seven composites and two overall ratings displayed on the Hospital Compare website. We support this approach as it provides consumers with valuable information that is easy to understand, however we urge CMS to retain the ability for consumers to drill down so that they can assess the hospital's performance related to a single question. We would also ask CMS to continue to allow private-sector organizations to have full access to provider performance information from the CMS Compare website and that the performance information for each question (rather than just the composite scores) on HCAHPS survey be available for download. Further, we applaud CMS' interest in determining a way to identify those hospitals that share a Medicare provider number and move toward displaying performance information by campus rather than by hospital system as it provides consumers with more actionable information about where to obtain services.

We support the expanded FY 2008 measurement set, but would also urge CMS to add the structural measures that were included in the 2005 Institute of Medicine's report *Performance Measurement: Accelerating Improvement*: (1) implementation of computerized provider order entry for prescriptions; (2) staffing of intensive care units with intensivists; and (3) evidence-based hospital referrals. All three measures are endorsed by the National Quality Forum as Safe Practices and are widely collected across the United States.

In selecting measures to adopt for FY 2008 and thereafter, CMS is proposing to add standardized measures that "have been adopted by or endorsed by a national consensus-building entity that utilizes a national consensus building process." The proposed rule goes on to identify the National Quality Forum as one such consensus building entity. In addition, the rule notes that the Hospital Quality Alliance (HQA) is another such entity. We whole-heartedly agree that the National Quality Forum is a consensus building entity and indeed adheres to the

definition of a consensus standards-setting organization as defined by the National Technology Transfer and Advancement Act of 1995 (Public Law 104-11) and Office of Management and Budget (OMB) Circular A-119. We are also very supportive of the Hospital Quality Alliance and its work to implement NQF-endorsed measures through a collaborative, public-private partnership. However, while the HQA has been instrumental in advancing hospital performance reporting via the Hospital Compare website, we do not view it as adhering to the same consensus-building process that the NQF utilizes. The roles of these two entities are distinct, though complementary. Each entity has its purpose and both are very integral to advancing the transparency of quality and cost information.

Again, thank you for the opportunity to comment. If you have any questions please contact either one of us.

Sincerely,

Peter V. Lee
Disclosure Project Co-Chair
Chief Executive Officer
Pacific Business Group on Health

Debra L. Ness
Disclosure Project Co-Chair
President
National Partnership for Women & Families

#4760-2

Consumer-Purchaser
DISCLOSURE
PROJECT Improving Health Care Quality through Public Reporting of Performance

CONTACT: Theresa Wheeler
Perry Communications Group
916-658-0144 or theresa@perrycom.com

Consumers, Employers and Labor Groups Call for Medicare Overhaul:

Measurement, Public Reporting and Payment Changes Recommended

Washington, DC (June 30, 2005) — Today, a broad cross-section of consumer and employer organizations, representing more than 100 million Americans, have called for an overhaul of Medicare's measurement, reporting, and payment systems for all levels of care. For the first time, the nation's leading consumer, purchaser and labor organizations announced their endorsement of principles that call for Medicare to publicly report and pay physicians, hospitals, health plans and other providers on how well they provide high-quality, efficient and patient-centered care.

This change would represent a dramatic departure from Medicare's current role and its relationship with health care providers and plans. These principles reinforce MedPAC's recent recommendation that the federal government drive improvement in the health care system, and reflect a growing consensus that Medicare – as the single, largest purchaser of health care services in America – must play a more active role in promoting a market that rewards better performance.

These principles come at a time when Medicare has been expanding its early, incremental steps to launch demonstration and pilot programs, and legislators are increasingly recognizing that more transformational change is required. "The current Medicare payment system provides little to no incentive for either better quality or controlling costs," said Peter Lee, president and CEO of the Pacific Business Group on Health and co-chair of the *Disclosure Project*. "We must move beyond a system that is performance-blind to one that rewards better quality and gives consumers tools to make informed choices. With these principles, representatives of millions of Americans are calling on Medicare to build on its early work and implement public reporting and pay-for-performance nationally."

"Medicare must first measure and then go one step further and provide the public and other purchasers with comparative information on provider performance," said Debra Ness, president of the National Partnership for Women & Families and *Disclosure Project* co-chair. "All Americans should have access to objective information that allows them to choose the best surgeon for their bypass surgery, the physician who will do the best job of keeping their diabetes under control, the pediatrician who will best treat their child's asthma so they can avoid trips to the emergency room, the safest hospital for giving birth, or the nursing home that is most likely to provide attentive care. The only way for Americans to make informed health care decisions is to ensure that they have access to standardize performance reports about hospitals, physicians and other providers."

There are currently over 100 private-sector performance measurement and incentive programs, in addition to Medicare's own demonstration projects in areas such as nursing homes, hospitals and physicians that have paved the way for Medicare to make measuring, reporting, and rewarding core elements of its modernization efforts.

This will foster improvements that will ripple through the entire health care system. Medicare not only has a national geographic reach, but it has the service density in virtually every community to provide Americans with a robust picture of the performance of most health care providers.

According to the *Disclosure Project's* principles, Medicare should evaluate the performance of each health care provider that bills Medicare using nationally-endorsed and scientifically-valid measures that address:

- Clinical quality (safe, timely and effective care);
- Efficiency (prices and resource use over time);
- Equity (gender, race, ethnicity);
- Patient experience;
- Use of quality-enhancing information technology.

The principles also recommend that Medicare phase in a system that makes the results of this measurement public and that pays providers based on overall performance and improvement. In addition to building on the recent recommendations of MedPAC, these principles reinforce the call made by the Institute of Medicine report, *Leadership by Example*. Increasing transparency and implementing financial incentives are a critical strategy to address the rising health care costs and quality gaps that touch all Americans.

Attachment

For more information go to: www.healthcaredisclosure.org

About the Disclosure Project

The Consumer-Purchaser Disclosure Project is a group of leading employer, consumer, and labor organizations working toward a common goal to ensure that all Americans have access to publicly reported health care performance information by January 1, 2007. Our shared vision is that Americans will be able to select hospitals, physicians, and treatments based on nationally standardized measures for clinical quality, consumer experience, equity, and efficiency. The Disclosure Project is supported by a grant from the Robert Wood Johnson Foundation and the Leapfrog Group.

Consumer-Purchaser
DISCLOSURE
PROJECT Improving Health Care Quality through Public Reporting of Performance

Consumer and Purchaser Principles for Making Medicare Payments Performance-Sensitive

June 2005

America's health care providers are increasingly focusing their commitment, competence and compassion on addressing the acknowledged chasm between the care delivered and what patients need. In the face of these important efforts, however, it is unacceptable that:

- Americans get the right care at the right time only 55 percent of the time.
- Over 100,000 Americans die each year of avoidable errors.
- Inefficient resource use in the health care industry represents more than thirty percent of health care spending, at a time when health care costs are straining individuals, employers and the federal budget.
- Individuals choose health care providers with little to no comparative information on quality or resources used.
- Rising costs are a key driver to the increasing number of uninsured.
- Payment systems provide little to no incentives for higher quality care and efficiency, and frequently actually reward lower quality, less efficient care.

Medicare should lead the way to promoting a market that rewards higher-quality, efficient, and patient-centered care through the following policies:

Measure: Medicare should evaluate the performance of each health care provider that bills Medicare, using nationally-endorsed, scientifically-valid, risk-adjusted, and regularly-updated measures that address:

- Clinical quality (safe, timely, and effective care);
- Efficiency (prices and resource use over time);
- Equity;
- Patient experience;
- Use of quality-enhancing information technology.

Report: Medicare should provide the public and other purchasers with the information on provider performance described above, in a manner that protects patient confidentiality.

Reward: Medicare should phase in a system that differentially pays providers, based on overall performance and improvement.

C/O National Partnership for Women & Families
1875 Connecticut Avenue, NW Suite 650
Washington, DC 20009
202.986.2600 • 202.986.2539 (fax) • healthcaredisclosure.org

Consumer and Purchaser Principles for Making Medicare Payments Performance-Sensitive

Endorsing Organizations

As of July 28, 2005

AFL-CIO
American Benefits Council
American Hospice Foundation
Bridges to Excellence
Carlson Companies
CalPERS
Chevron
Cisco
Consumers' CHECKBOOK
Corporate Health Care Coalition
Employer Health Care Alliance Cooperative
ERISA Industry Committee
General Electric
General Motors
Health Policy Corporation of Iowa
HealthCare 21
HR Policy Association
Intel
International Association of Machinists
Massachusetts Group Insurance Commission
Maternity Center Association
Motorola
National Association of Manufacturers
National Business Coalition on Health
National Coalition for Cancer Survivorship
National Partnership for Women & Families
Pacific Business Group on Health
Service Employees International Union
Sprint
Sysco
U.S. Chamber of Commerce
Wells Fargo
Xerox

Submitter : **Mrs. Maria Murphy** **Date: 10/10/2006**

Organization : **Murphy's Plus, Corp**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Partial Hospitalization

Partial Hospitalization

We are very disturbed by the proposed cuts for 2007 for the Partial Hospitalization Program. There is a true need in our community for this type of program and I truly believe it will be a detriment to the mental health patient who requires this type of treatment.

Respectfully,
Maria E. Murphy

Submitter : Mr. Jayson Slotnik **Date:** 10/10/2006

Organization : Biotechnology Industry Organization

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-478-Attach-1.PDF

CMS-1506-P-478-Attach-2.PDF

#418

October 10, 2006

BY ELECTRONIC DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1506-P (Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule)

Dear Administrator McClellan:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding revisions to the hospital outpatient prospective payment system (OPPS) and 2007 payment rates, published in the Federal Register on August 23, 2006 (the "Proposed Rule").[1] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States.

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[1] 71 Fed. Reg. 49506 (August 23, 2006).

Representing an industry that is devoted to discovering new therapies and ensuring patient access to them, BIO is troubled that CMS' proposal to reduce reimbursement for many separately paid drugs and biologicals will harm hospitals' ability to provide these important therapies to Medicare beneficiaries. We are concerned that the proposed rates of average sales price (ASP) plus five percent for drugs and biological products without pass-through status are not sufficient to reimburse hospitals for their acquisition costs, much less their pharmacy service costs. Our analysis of the claims data has found serious flaws in the OPPS rate-setting methodology that indicate that Medicare is not paying appropriately for all of the costs of providing drugs and biologicals.

To ensure that hospitals are reimbursed appropriately for providing advanced drugs and biologicals to Medicare beneficiaries, we recommend the following measures:

1) Medicare should set reimbursement under the OPPS for drugs and biological products at no less than ASP plus six percent, the rate applicable in physicians' offices;
2) CMS should continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs;
3) CMS should eliminate the bundling threshold and pay separately for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes as it does in the physician office setting;
4) CMS should continue to use the methodology implemented in 2006 for payment of radiopharmaceuticals;
5) CMS should not apply an equitable adjustment to any drugs or biologicals;
6) CMS should finalize its proposed drug administration ambulatory payment classifications (APCs) to ensure that hospitals are paid appropriately for the second and subsequent hours of infusion services;
7) CMS should pay for a second or subsequent intravenous push of the same drug;
8) CMS should provide payments for all intravenous pushes and therapeutic injections for pain management and other clinical conditions, regardless of the setting in which they are administered;
9) CMS should allow hospitals to separately bill and receive payments for therapeutic infusions and hydration infusions provided in the same encounter; and
10) CMS should continue to pay for preadministration-related services for intravenous immune globulin (IVIG).

We discuss these comments in more detail below.

I. CMS must not finalize its proposed reimbursement for drugs, biologicals, and radiopharmaceuticals because these rates are not adequate to reimburse hospitals for all of the costs of providing these therapies. [OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals]

A. Payment for Drugs and Biological Products

1. CMS must reimburse hospitals adequately for their acquisition and pharmacy service costs.

For 2007, CMS proposes to reduce reimbursement for drugs and biological products without pass-through status[2] to ASP plus five percent from the current rate of ASP plus six percent.[3] BIO remains concerned that reimbursement at ASP plus six percent may not be adequate to ensure beneficiary access to appropriate therapies, and we believe that reducing payment to ASP plus five percent will place additional burdens on hospitals that already are straining to provide drugs and biologicals. As the Medicare Payment Advisory Commission (MedPAC) recently testified to the House Ways and Means Subcommittee on Health, in some parts of the country, hospital outpatient departments are taking on larger patient loads as physicians are unable to provide chemotherapy in their offices at Medicare's current reimbursement rates. In particular, patients who do not have supplemental insurance coverage are being sent to hospital outpatient departments for cancer care. If hospitals are not appropriately reimbursed for providing care, these patients will have nowhere to turn for treatment. Reducing Medicare's payments to hospitals also will exacerbate the access problems for IVIG that currently exist under the ASP plus six percent payment methodology.

Not only does CMS propose to reduce reimbursement for drugs and biologicals, but it also asserts that the proposed rates are sufficient to cover hospitals' pharmacy handling costs. We strongly disagree with this assertion. Pharmacy services can be complex and are labor and resource intensive. They range from basic mixings and reconstitutions to more advanced compounding requiring a clean room, trained and certified personnel, and ancillary supplies. Complex therapies, such as advanced biologicals, must be stored and prepared under carefully controlled conditions to protect them from changes caused by

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2 This proposed reduction will also apply to clotting factors.
3 Id. at 49585.

variations in temperature and light. In addition to preparing drugs and biologicals for administration, pharmacists and pharmacy technicians consult with physicians about the appropriate selection, dosage, and administration of drugs, perform quality assurance measures to verify that therapies are correctly prepared, and safely dispose of any unused medications. The costs associated with providing these services include salaries and benefits for pharmacists and pharmacy technicians, supplies, equipment, and renovations required to comply with recent changes in pharmacy regulations. Without these quality and safety protections, errors involving these therapies are likely to occur. Medicare payment for all aspects of providing drug and biological therapies, including preparing drugs, performing quality control, and administering drugs, must be adequate to protect hospitals' ability to satisfy patients' needs and continue to provide quality care.

2. CMS' proposed rates are based on flawed assumptions and analyses.

BIO believes that CMS' proposal to set reimbursement for these therapies at ASP plus five percent is based on several flawed assumptions and analyses. First, although MedPAC noted in its June 2005 report that hospital officials believed they set their charges high enough to account for pharmacy handling costs, MedPAC also noted that most hospitals do not set charges for handling costs and lack precise information about the magnitude of these expenses.[4] In the aggregate for all the drugs and biologicals dispensed by the pharmacy department, both inpatient and outpatient, charges may include overhead costs. Hospital charges are not likely to reflect overhead on a product-by-product basis, however.

Second, because overhead costs are not distributed evenly to all drugs, CMS' use of the claims data for only separately paid drugs and biologicals to calculate that the total cost of pharmacy services, including acquisition and overhead, vastly underestimates total overhead costs. We believe these costs are substantially greater than five percent of ASP.

As we have explained in comments on prior OPPS rules, CMS' application of a constant cost-to-charge ratio (CCR) to pharmacy charges results in inaccurate calculations of costs for specific drugs and biologicals. Hospitals tend to mark up their charges for higher cost items by a smaller percentage than lower

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[4] Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.

cost items. When CMS applies a single CCR to these items, the charge of the higher cost item may be reduced below its cost, while the estimated cost of the lower cost item may exceed its actual cost.[5] As a result, CMS' estimated unit costs and the Medicare payment rates based on those costs bear no relation to the actual costs of drugs and biological products. Our analysis of CMS' methodology for determining average acquisition costs for drugs and biological products found that these average costs, stated as a percentage of ASP, range from ASP minus 100 percent to ASP plus 2395 percent. These wide variations indicate that CMS' methods for calculating average acquisition cost produce inaccurate, unpredictable, and unreasonable results.[6] CMS itself acknowledged in the final inpatient prospective payment system rule for fiscal year 2007 that charge compression might cause distortions in Medicare's payment systems, and the agency has engaged a contractor to study the phenomenon.[7]

Further, CMS used these mean unit costs for only separately paid drugs and biologicals in the estimate of the total costs for drugs compared to the total costs using ASP. This causes CMS to underestimate the overhead costs associated with those therapies. If all drugs and biological products had HCPCS codes and were included in this calculation, the handling costs included in hospitals' charges would be accounted for in an estimate of total costs, although the share of total handling costs assigned to each therapy might be inaccurate. In the OPPS, however, drugs and biological products whose costs are below the $55 per day packaging threshold are not separately reimbursed. Additionally, there are many very low cost drugs that do not have HCPCS codes or ASPs, but do have charges reported under general pharmacy department revenue codes. Because CMS excluded these therapies from its analysis of average acquisition costs, it failed to capture the disproportionately large share of pharmacy service costs allocated to packaged drugs. When we included HCPCS-coded packaged drugs with reported ASPs in our calculations, we found that the mean unit cost, on average, is far higher than ASP plus five. The difference between mean unit cost and ASP was double the amount we calculated without these packaged drugs. This finding does not account for overhead charges for many lower cost drugs without

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5 MJ Braid, KF Forbes, DW Moran. "Pharmaceutical Charge Compression under the Medicare Outpatient Prospective Payment System" *Journal of Health Care Finance* Spring 2004, p. 21-33.

6 See also, Government Accountability Office (GAO), Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, GAO-04-772, September 2004, at 16 ("CMS's methodology does not recognize hospitals' variability in setting charges, and, therefore, the costs of services used to set payment rates may be under or overestimated.").

7 71 Fed. Reg. 47870, 47897, (August 18, 2006).

HCPCS codes, which, if it were possible to include, could result in an even wider disparity between CMS' proposed rate and hospitals' actual costs.

It is possible that if all drugs and biologicals could be included in the calculation of pharmacy overhead costs that CMS would find these costs to be comparable to those found by MedPAC. MedPAC reported that pharmacy department wages, salaries, fringe benefits, and supplies made up 26 to 28 percent of pharmacy department direct costs.[8] Overhead costs of 28 percent would result in a calculation of hospital acquisition and handling costs of ASP plus 39 percent, assuming that all hospitals could purchase covered drugs and biologicals at ASP.

In a separate analysis we found that while approximately half of the packaged drug and biological costs (HCPCS coded and revenue coded) were included on 'single' bills and used for rate-setting, the vast majority of these were on claims for procedures other than pharmacy administration services. Only 5 percent of packaged drug costs were included in drug administration code median cost calculations. Both the product and handling costs for packaged drugs are spread throughout the APC system and are not being reimbursed as separate drug payments or under the drug administration codes.

3. CMS should include all drugs and biologicals with HCPCS codes in its calculations of pharmacy costs and should reimburse separately payable drugs at no less than ASP plus six percent in 2007.

We look forward to the results of the study of the effects of charge compression on the inpatient PPS and we hope any lessons learned from it can be applied to the OPPS. Until the charge compression study is completed, we recommend that CMS recalculate the total costs of pharmacy services, including acquisition and overhead, using costs for all drugs and biologicals with HCPCS codes, not just the separately paid therapies, to ensure that all pharmacy overhead costs are included in the agency's calculation. In no event should CMS set payment for drugs and biological products at less than ASP plus six percent, the rate applicable in physician's offices. This is consistent with what the Advisory Panel on APC Groups ("APC Panel") recommended at its August meeting.

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[8] Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 140.

4. CMS should continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs.

In the longer term, we urge CMS to continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs. We recommend that CMS not make any reductions to payment for drugs and biologicals until it develops such a method. As we explain above, we believe that the claims and cost report data are inadequate to calculate accurate payments for the acquisition and handling costs for each drug or biological. To improve the accuracy of these data, CMS should provide hospitals with clear guidance on how to report their pharmacy costs and set charges for all pharmacy services. CMS also should consider mechanisms to provide more accurate reimbursement for pharmacy service costs, such as payment for medication therapy management codes or the use of codes for pharmacy handling services similar to those proposed for use in the OPPS in 2006.[9]

5. CMS should pay separately for all drugs and biological products with HCPCS codes.

CMS also should pay separately for all drugs and biological products with HCPCS codes to ensure that hospitals are reimbursed appropriately for all of the therapies they provide. CMS proposes to increase the packaging threshold from $50 per day to $55.[10] BIO opposes this proposal. Instead, we support the APC Panel's recommendation to eliminate the packaging threshold for all drugs and biologicals with HCPCS codes.[11] Paying separately for these therapies will remove the incentives currently built into the OPPS that discourage hospitals from using packaged therapies that might be the most appropriate clinically. It also would help to ensure that all services provided in hospital outpatient departments are appropriately reimbursed. Our analysis found that most of the costs of packaged drugs are not included in drug administration payments. Only four percent of packaged drug lines and five percent of packaged drug costs are on drug administration single claims. However, 43 percent of packaged drug lines and 44 percent of costs were on single claims for other procedures, while the remaining 53 percent of lines and 51 percent of costs were not used in CMS' analysis. Therefore,

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9 70 Fed. Reg. 42674, 42730 (July 25, 2005).

10 71 Fed. Reg. at 49582.

11 Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

although packaged drug costs are included in the OPPS, they are not included in charges for drug administration services. Unpackaging payment for these drugs and biologicals would improve the accuracy of OPPS rates for all services in which drugs and biologicals are used.

Separately reimbursing all drugs and biologicals with HCPCS codes also would not increase hospitals' administrative burdens because hospitals are strongly encouraged to code for these drugs currently.[12] Our analysis of claims data indicates that hospitals are indeed coding for many of these therapies. In fact, paying separately for these therapies should only further encourage hospitals to code correctly, improving the data upon which future rates will be set. Moreover, such treatment is consistent with payment in the physician office setting and would be more equitable for hospitals. In the past, CMS has expressed concern that differences in reimbursement methodologies should not drive patient care from one setting to another. Yet this is precisely what will occur if all drugs and biological products with HCPCS codes are reimbursed at ASP plus six percent in the physician office but only certain drugs are paid separately in the hospital outpatient department, and the reimbursement rate for those drugs is one percent of ASP less.

B. CMS should continue to use the methodology implemented in 2006 for the payment of radiopharmaceuticals.

For 2007, CMS proposes to establish prospective payment rates for radiopharmaceuticals in 2007 using mean costs derived from calendar year 2005 claims data through the application of hospital-specific departmental cost-to-charge ratios.[13] BIO believes that this methodology is deeply flawed and will deny beneficiaries access to therapeutic and diagnostic radiopharmaceuticals by setting reimbursement rates that are below acquisition cost and impairing CMS' ability to set more appropriate rates in the future. We urge CMS to continue to use the methodology it implemented in 2006 to protect against "rapid reductions [that] could adversely affect beneficiary access to services utilizing radiopharmaceuticals"[14] and to allow the agency to continue to collect data that reflect all of the costs of providing these potentially lifesaving therapies.

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12 January 2006 Update of the OPPS: Summary of Payment Policy Changes, OPPS PRICER Logic Changes, and Instructions for Updating the Outpatient Provider Specific File (OPSF), Transmittal 804, Change Request 4250, Jan. 3, 2006, at 12.

13 71 Fed. Reg. at 49587.

14 70 Fed. Reg. 68515, 68653 (November 10, 2005).

The proposed payment methodology will cause drastic cuts in reimbursement for therapeutic radiopharmaceuticals, such as Zevalin® and Bexxar®. The proposed 2007 rate for Y-90 Zevalin® is $12,130.20, a 42 percent reduction from the 2005 level of $20,948.25, and 38 percent less than the average purchase price reported by the Government Accountability Office in 2005.[15] Bexxar®'s payment would fall by 39 percent, from $19,422 in 2005 to $11,868.78 in 2007. In addition, CMS proposes substantial cuts to reimbursement for the administration codes for these therapies as they are moved from new technology APCs to clinical APCs.[16] The combined effect of these cuts will make it difficult for hospitals to continue to offer these therapies to patients.

CMS states that its proposed methodology for radiopharmaceuticals "is consistent with how payment rates for other services are determined under the OPPS" and that the rates it establishes "serve as appropriate proxies for the average acquisition costs of radiopharmaceuticals along with their handling costs."[17] We agree that this methodology offers consistency across the OPPS, but it also would create inaccurate payments for radiopharmaceuticals just as it does for drugs and biologicals. As we describe above, basing payments on mean charges reduced to cost can lead to inaccurate rates that do not include all of the costs of providing a therapy. Additionally, because hospitals did not report their overhead costs accurately or uniformly in the past, as indicated in comments on the 2006 OPPS proposed rule[18] and the June 2005 MedPAC report,[19] using data from prior years will not capture the full costs of providing therapeutic radiopharmaceuticals.

In 2006, CMS attempted to set appropriate and stable rates for radiopharmaceuticals by basing payment on each hospital's charge reduced to cost.[20] To ensure that "payments under the OPPS can accurately reflect all of the actual costs associated with providing these products to hospital outpatients," CMS also clarified that "it is appropriate for hospitals to set charges for these agents in 2006 based on all costs associated with the acquisition, preparation, and handling

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15 GAO, Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting, GAO-05-733R, July 14, 2005, at 6.

16 71 Fed. Reg. at 49556. Payment for 79403 (hematopoietic nuclear therapy) would be reduced by 43 percent and payment for G3001 (administration and supply of tostitumomab) would be reduced by 32 percent.

17 Id. at 49587.

18 70 Fed. Reg. at 68654.

19 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.

20 70 Fed. Reg. at 68653.

of these products."[21] This is particularly important for therapeutic radiopharmaceuticals, such as Bexxar® and Zevalin®, and certain diagnostic radiopharmaceuticals that require the most resources of all drugs to prepare due to additional safety and quality assurance requirements.[22] These costs include the resources needed to shield patients and staff from radiation exposure and comply with regulations regarding the safe administration, transport, and disposal of radioactive isotopes. If hospitals followed CMS' guidance to implement new charges for 2006, CMS could have appropriate data for use in setting rates in 2008. In the likely event that many hospitals were not able to update their charges for 2006, CMS will need to wait even longer to be sure that it has sufficient accurate data to set rates for these therapies.

Instead of using a flawed ratesetting methodology and data that do not reflect all of the costs of providing therapeutic and diagnostic radiopharmaceuticals, we recommend that CMS continue to use the payment methodology it implemented for radiopharmaceuticals in 2006. When CMS implemented this methodology, it noted that it is "the best available proxy for average acquisition costs of the radiopharmaceuticals along with their handling costs."[23] The agency acknowledges again in the Proposed Rule that it is an acceptable proxy for these costs,[24] and the APC Panel recommends that CMS continue to use this methodology.[25] Continuing to use this methodology will protect beneficiary access to these therapies while creating the stability necessary to allow CMS to continue to collect more accurate data for use in setting future rates. We urge CMS to use the 2006 methodology for at least one more year and evaluate the quality of the data next year to decide how to set rates for 2008.

C. CMS should not apply an equitable adjustment to any drugs or biologicals.

BIO supports CMS' decision not to propose to apply an "equitable adjustment" to any drug or biological for 2007. Continuation of a policy of market-based reimbursement via the ASP-based methodology for all therapies is consistent with Congress's intent in the Medicare Prescription Drug, Improvement,

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21 Id.
22 Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 145-146.
23 70 Fed. Reg. at 68653.
24 71 Fed. Reg. at 49587.
25 Advisory Panel on Ambulatory Payment Classification (APC) Groups, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

and Modernization Act of 2003 (MMA). By not including any language or discussion proposing to adjust payment for one drug or biological based on another drug or biological, CMS can continue to allow the market to determine the appropriate payment for therapies, not arbitrary government price-setting. We applaud CMS on this point and recommend that CMS not apply an equitable adjustment to any drug or biological products in the final rule.

II. CMS should clarify the payment rates that will apply to drugs and biologicals with pass-through status that are covered under the Competitive Acquisition Program. [Pass-Through Drugs]

CMS proposes to continue to reimburse pass-through drugs and biological products at ASP plus six percent, except that drugs that also are included in the Competitive Acquisition Program (CAP) will be reimbursed at the CAP rate.[26] CMS states that two drugs and biologicals with pass-through status are covered under the CAP and will be reimbursed at the "amounts determined under the competitive acquisition program."[27] We ask CMS to clarify that it will base payment for these therapies on their individual payment rates under the CAP, as required by the statute, and not the aggregate payment for all drugs covered under the CAP.

III. CMS should finalize its proposed new APCs for drug administration, implement the APC Panel's recommendations regarding drug administration services, and continue to make payments for preadministration-related services for IVIG. [OPPS Drug Administration]

BIO is pleased that CMS proposes to create six new APCs for drug administration services and to make separate payment for additional hours of drug administration services. BIO has long urged CMS to adopt such policies. We are hopeful that these changes, combined with the new rates CMS has proposed based on more precise coding, will help to improve the adequacy of Medicare's payments for administration of advanced drugs and biologicals. We thank CMS for its hard work on these proposals and urge the agency to implement them in the final rule.

We are concerned about the significant reduction in payment for the first hour of administration services, however, and we ask the agency to verify that

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[26] 71 Fed. Reg. at 49580.
[27] Id. at 49581.

its calculations are correct. In reviewing these codes, CMS should bear in mind that very few claims for packaged drugs are submitted with a claim for a drug administration service. Therefore, even though CMS intends for payment for drug administration services to include the costs of packaged drugs, its claims data do not include these costs. Unless CMS implements our recommendation to pay separately for all drugs with HCPCS codes, its proposed drug administration codes may be too low to include both the costs of the administration service and the drug.

In addition, we support the APC Panel's recommendation to make payment for a second or subsequent intravenous push of the same drug by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology in CY 2007.[28] Under the current coding guidance and the proposed new drug administration APCs, CMS will make payment for a second or subsequent intravenous push only if it is used to administer a different drug. This policy fails to recognize that the second push requires the same amount of work and resources as the first push. Furthermore, if payment for the drug is packaged, the hospital is reimbursed for neither the second push nor the additional dose of the drug. When combined with the recommendation to make separate payment for all drugs and biological products with HCPCS codes, implementing the APC Panel's recommendation also will help to ensure that hospitals are appropriately reimbursed for all drugs and biologicals and their administration services.

In addition, the APC Panel recommended that CMS provide payments for all intravenous pushes and therapeutic injections for pain management and other clinical conditions, regardless of the setting. We agree with this recommendation and ask CMS to implement it. As we explained above, most single claims for packaged drugs are made with a service other than drug administration. This could be explained by the Current Procedural Terminology's[29] (CPT's) instructions for use of drug administration codes. The CPT instructs providers not to report injection or infusion codes with codes for which an IV push or infusion is an inherent part of the procedure, such as administration of contrast material for an imaging study. There may be situations, however, when it is appropriate to bill a drug administration code, yet hospitals are not doing so.

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[28] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

[29] Current Procedural Terminology, or CPT, is a trademark of the American Medical Association.

There also may be procedures for which the associated drug administration costs are not included in the claims data. For example, Medicare makes separate payment for echocardiographic imaging drugs that are used to enhance images, but does not pay separately for their intravenous administration. The echocardiography procedure codes do not mention use of contrast agents, and the resources supporting payment for these procedures do not include the contrast agents or their administration. CMS should remove any edits from the Outpatient Code Editor and the hospital version of the Correct Coding Initiative that package intravenous injection codes into codes for echocardiography procedures. Clarifying the coding guidance and allowing payment for drug administration services in all settings will help to ensure that hospitals code appropriately for all services and will help to set more accurate payment rates in the future.

We also support the APC Panel's recommendation to allow hospitals to separately bill and receive payments for therapeutic infusions and hydration infusions provided in the same encounter.[30] For payment under the OPPS, CMS currently has a single code assigned to the first hour of a therapeutic or diagnostic infusion. Under guidance issued in 2006, CMS allows hospitals to report a first hour for each different type of infusion provided when the infusions can be reported using different codes, and they meet the requirements for billing an hour of each type of infusion.[31] Under the Proposed Rule, if a hospital provides an hour of therapeutic, non-chemotherapy infusion and an hour of hydration infusions, the first hour would be paid using code C8950, assigned to APC 440, and the second hour would be paid using code C8951, assigned to APC 437. To ensure that hospitals are reimbursed appropriately for these services, we ask CMS to implement the APC Panel's recommendation to allow hospitals to be paid using first hour codes when both a hydration infusion and a non-chemotherapy infusion are provided in the same visit.

In addition, we ask CMS to make a clarification to its guidance on coding and payment for drug administration services under the OPPS. Consistent with the CPT's guidance for the chemotherapy codes used in physician offices, the guidance explains that "hospitals are to report chemotherapy drug administration

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[30] Advisory Panel on APC Groups, Panel Recommendations, August 23-24, 2006, Panel Recommendations, http://www.cms.hhs.gov/FACA/Downloads/apcmeeting8_2006.zip.

[31] January 2006 Update of Hospital Outpatient Prospective Payment System Manual Instruction: Changes to Coding and Payment for Drug Administration, Transmittal 785, Change Request 4258, Dec. 16, 2005 (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2).

HCPCS codes when providing non-radionuclide anti-neoplastic drugs to treat cancer and when administering non-radionuclide anti-neoplastic drugs, anti-neoplastic agents, monoclonal antibody agents, and biologic response modifiers for treatment of noncancer diagnoses."[32] We appreciate this instruction and recommend that CMS clarify that it also applies to IVIG, hyperimmune IVIG, and DNA-or RNA-based therapies, which are all biological response modifiers, whose administration should be billed using chemotherapy administration codes.

Finally, we urge CMS to continue to make payment for preadministration-related services for IVIG. As you know, BIO has been very concerned about Medicare beneficiary access to IVIG over the past few years as a result of the changes to Medicare's payment methodologies for drugs and biologicals. BIO was pleased that CMS recognized the unique aspects of this therapy, as well as its importance to Medicare beneficiaries, through the establishment of a $75 payment for preadministration-related services for IVIG in last year's OPPS final rule. Unfortunately, CMS proposes to eliminate this payment for 2007.[33]

BIO is very disturbed by the proposed policy determination, especially coincident with a proposal to reduce the payment for IVIG by one percent. As noted above, we believe that CMS made positive strides in ensuring access to IVIG through the preadministration-related services payment. The elimination of the payment would be a significant step backward. All of the costs that CMS identified last year that hospitals incur related to IVIG will continue to be incurred next year, and CMS offers no evidence that these costs would not continue to be incurred. As such, the cost should continue to be reimbursed.

IV. Conclusion

In conclusion, BIO recommends that CMS take the following steps to protect Medicare beneficiaries' continued access to appropriate drug and biological therapies in hospital outpatient departments:

- Include all drugs and biologicals with HCPCS codes in its calculations of pharmacy costs and reimburse separately payable drugs at no less than ASP plus six percent in 2007;
- Continue to work with stakeholders to develop appropriate methods of reimbursing hospitals for pharmacy service and handling costs;

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[32] Id. (revising Medicare Claims Processing Manual (CMS Pub. 100-4), ch. 4, § 230.2.2).
[33] 71 Fed. Reg. at 49604.

- Pay separately for all drugs and biologicals with HCPCS codes;
- Continue to use the methodology implemented in 2006 for the payment of radiopharmaceuticals;
- Not apply an equitable adjustment to any drug or biological;
- Clarify the payment rates that will be apply to drugs and biologicals with pass-through status that are covered under the CAP; and
- Finalize the proposed new APCs for drug administration, implement the APC Panel's recommendations regarding drug administration services, and continue to make payments for preadmission-related services for IVIG.

BIO appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact me at 202-312-9273 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jayson Slotnik
Director, Medicare Reimbursement &
Economic Policy
Biotechnology Industry Organization (BIO)

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1655 N. FORT MYER DRIVE, SUITE 1250 ARLINGTON, VA 22209 (703) 465-9970 FAX (703) 465-9969

Memorandum October 6, 2006

TO: Jayson Slotnik, BIO

FROM: Mary Jo Braid-Forbes, The Moran Company

SUBJECT: Findings from our replication of the CMS ASP+5% calculation

There has been historical controversy about how overhead and handling costs are recorded for pharmaceuticals under the Hospital Outpatient Prospective Payment System (HOPPS).

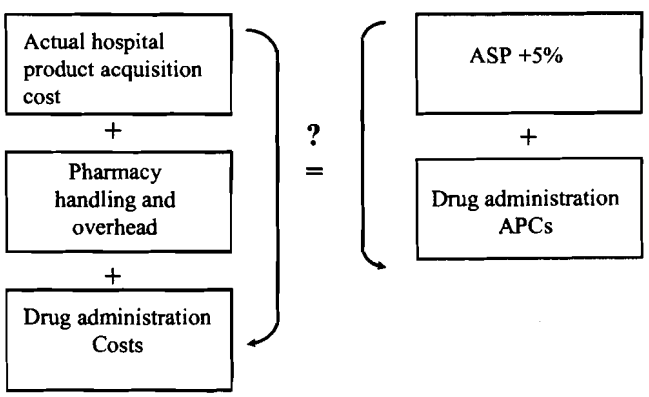
Questions that have arisen include:

- How much of the costs of the pharmacy department is overhead and handing and how much is product costs?
- Have hospitals included these costs in the charges for pharmaceuticals?
- Do all products have the same percentage allocation of overhead or is there a differential mark-up?

Some of the research conducted has on the surface seemed contradictory. Specifically, for the OPPS payment, CMS has calculated that overhead and handling costs are covered if payment for separately payable pharmaceuticals and biologics is set at Average Sales Price (ASP) plus 5%. However, several cost report analyses have concluded that overhead costs are between 25 and 33% of department costs, which would imply a mark-up over acquisition cost of between 33 and 50%.

From a payment system perspective the question becomes whether the costs of the product, pharmacy handling and overhead and drug administration are covered by the drug payment rates calculated at ASP plus 5% and drug administration APC payment rates. See figure 1.

Figure 1



Cost report analysis of overhead consistently has shown overhead costs are at least 25% of department costs. These studies have included the CMS contractor Kathpal Technologies (1999) report which analyzed 55 cost reports and found pharmacy overhead to be one-third of pharmacy costs. Using more recent cost report information and over 1,200 cost reports, MedPAC repeated this analysis and found that wages, salary and fringe benefits represented 25% of department costs (June 2006). This would seem to be lower bound on the overhead percentage, since there are additional costs that would be considered overhead and handling that are not direct personnel costs. MedPAC's analysis of more detailed Maryland hospital cost reports found direct personnel costs and non-drug supplies to be between 26 and 28 percent. We have conducted similar analyses on cost report data and had similar findings.

However, CMS calculations of pharmacy overhead costs calculated as a percentage above ASP have been much lower. CMS uses charges submitted by hospitals on their claims for separately payable drugs and biologicals and estimates the cost of these products by applying a cost-to-charge ratio derived from the hospitals' cost reports. Arriving at an average cost per unit using this methodology and weighting that by the observed unit volume, CMS arrives at a pool of dollars that represent their estimate of product cost and overhead. This is compared to the pool of dollars for these same drugs weighted by the ASP.

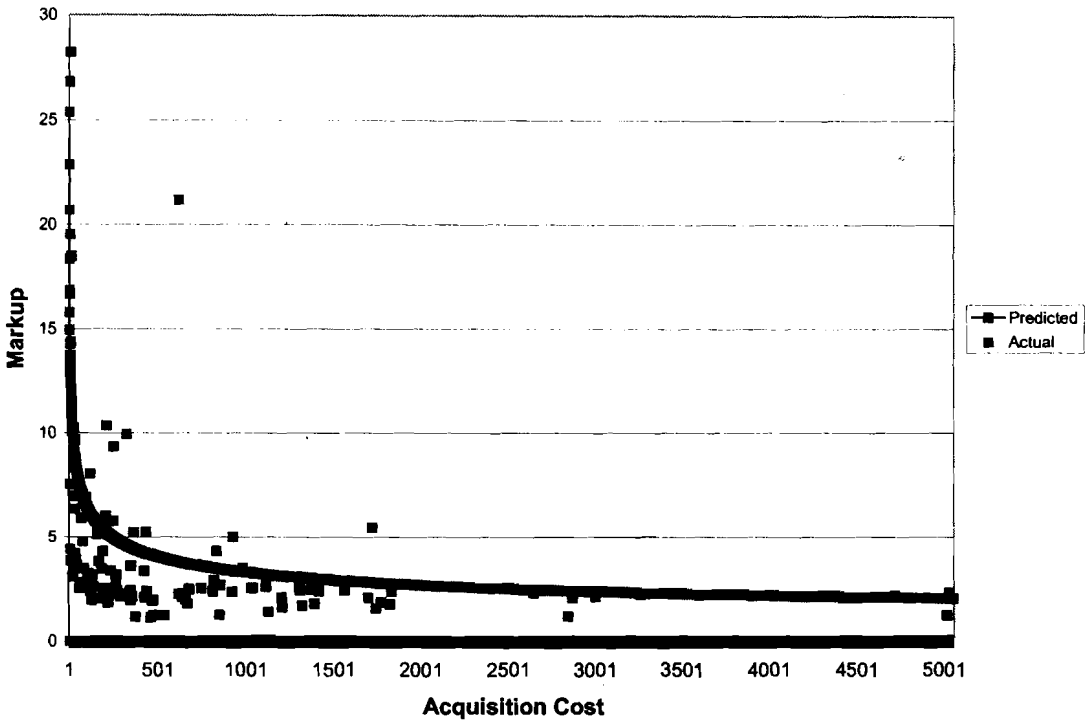
In its 2006 final rule, CMS calculated that hospital acquisition and handling costs amounted to ASP plus 6%. In the proposed rates for 2007, the calculation is 5% above ASP. Assuming ASP is a close approximation of actual hospital pharmacy product acquisition costs, there is a wide disparity between the calculations using the cost reports directly and CMS's calculations using essentially the same cost report data and comparing this to ASP.

A potential cause of this divergence could be that the cost report analyses have included the entire pharmacy department costs, while CMS's analyses use only separately paid, therefore higher cost, drugs. If overhead was allocated to all drugs dispensed from the pharmacy department, and these charges were marked-up at the same percentage, these two methodologies should produce the approximately the same results. However, if overhead is not allocated to all pharmacy products at the same rate then using a subset of drugs and biologicals for the calculation could result in a biased estimate of overhead.

In a previous study of actual acquisition cost and hospital charges, we found that relatively high cost products have lower mark-ups than lower cost products. [1] The relationship between acquisition cost and mark-up is log-log. Figure 2 below shows the study findings.

[1] MJ Braid, KF Forbes, DW Moran. "Pharmaceutical Charge Compression under the Medicare Outpatient Prospective Payment System" *Journal of Health Care Finance* Spring 2004, p. 21-33.

Figure 2



BIO asked us to analyze whether reimbursement at ASP plus 5% would fully capture drug and biological acquisition and handling costs in the Hospital Outpatient department. We repeated CMS's calculation of mean unit cost compared to ASP on a volume weighted basis using only separately payable drugs (SI=K). We then added the lower cost HCPCS coded packaged drugs (SI=N). We used CMS's own published mean costs and units volumes which are based on 2005 claims data. We also used the April 2006 ASP file that CMS stated was used in their calculations.

We found that when we added the lower cost, packaged drugs, our calculation of the necessary markup percentage of ASP to capture hospital acquisition and handling costs doubled. We hypothesize that if it was possible to add non-HCPCS coded pharmacy overhead, the calculation would be closer to the 33 to 50 percent markups implied by various cost report studies. Unfortunately this cannot be tested directly.

Interestingly, in our calculation of the ASP percentage, we found that on a drug-by drug basis the difference between the mean unit cost and ASP varies widely. The range of ASP percentages on a product by product basis, for separately paid drugs without coding changes between 2005 and 2006 was minus 100 to plus 2395. Consequently, the calculation of the ASP percentage can vary substantially based on which drugs are included or not included. Because there were some substantial code definition changes between 2005 and 2006 adjustments need to be made between the claims data which is 2005 data and the ASP data which is 2006 data. Whether some

or all products with coding changes are included, and if so how the adjustments are handled, can also make a material difference in the calculation of the ASP percentage.

In a separate analysis we found that while approximately half of the packaged drug and biological costs (HCPCS coded and revenue coded) were included on 'single' bills and used for rate-setting, the vast majority of these were on claims for procedures other than pharmacy administration services.[2] Only 5 percent of packaged drug and biological costs were included in drug administration code median cost calculations. Both the product and handling costs for packaged drugs and biologicals are spread throughout the APC system and are not being reimbursed as separate drug payments or under the drug administration codes. Table 1 below shows the results of this analysis.

Table 1: Summary of Packaged Drug and Drug Administration in OPPS

	LINES		COSTS $		cost per line
All packaged drugs					
(HCPCS and rev code 25x)					
singles on drug admin	1,371,568	4%	$ 44,382,385	5%	$ 32.36
singles not on drug admin	14,741,503	43%	$ 436,181,814	44%	$ 29.59
not used	17,893,353	53%	$ 503,173,980	51%	$ 28.12
total	34,006,424	100%	983,738,179	100%	$ 28.93
(HCPCS only)					
singles on drug admin	478,644	3%	$ 10,962,485	4%	$ 22.90
singles not on drug admin	6,162,022	43%	$ 111,420,064	42%	$ 18.08
not used	7,613,907	53%	$ 143,838,249	54%	$ 18.89
total	14,254,573	100%	266,220,798	100%	$ 18.68
HCPCS coded as % of total	*42%*		*27%*		
Drug admin codes					
singles	2,262,438	49%	$ 241,801,861	51%	$ 106.88
not used	2,325,093	51%	$ 236,570,293	49%	$ 101.75
total	4,587,531	100%	478,372,155	100%	$ 104.28

For this analysis packaged drug lines included both HCPCS coded drugs with an "N" status indicator and lines with a pharmacy revenue code (25x) and no HCPCS code. Hospitals are coding packaged drugs with pharmacy revenue center codes more often and for more charges than HCPCS codes. HCPCS coded drug lines were only 42% of all the packaged drug lines and 27% of all the packaged drug costs.

[2] We replicated the methodology that CMS uses to create single procedure claims and calculate median costs. For the file overall we were within 3 percent of the CMS count of single claims for 78% of the claims. Calculating the median costs we are even closer, we are within 3% for 91% of the claims.

Summary Findings:

- In analyzing CMS's finding that mean unit costs in the aggregate were equal to ASP plus 5%, we compared mean unit costs to ASP on a product by product basis. We found a range of mean unit costs for separately paid drugs and biologicals without coding changes between 2005 and 2006 of ASP minus 100 to ASP plus 2395.
- Whether some or all products with coding changes are included, and if so how the adjustments are handled, can also make a material difference in the calculation of the ASP percentage.
- We found that when we added the lower cost, packaged drugs our calculation of the necessary markup percentage of ASP to capture hospital acquisition and handling costs doubled.
- We hypothesize that if it was possible to add non-HCPCS coded pharmacy overhead, the calculation would be closer to the 33 to 50 percent markups implied by various cost report studies. Unfortunately this cannot be tested directly.
- Only 5 percent of packaged drug costs were included in drug administration code median cost calculations.

Submitter : Mr. Dwight Fine **Date:** 10/10/2006

Organization : Missouri Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1506-P-479-Attach-1.DOC

#419

October 10, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program – HCAHPS Survey, SCIP, and Mortality (71 Federal Register 49506), August 23, 2006.

Dear Dr. McClellan:

On behalf of our member hospitals, health care systems, and other health care organizations, and our individual members, the Missouri Hospital Association (MHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule establishing new policies and payment rates for the hospital outpatient prospective payment system (PPS) for calendar year (CY) 2007. The rule also includes proposals on inpatient quality reporting for fiscal year (FY) 2008, ambulatory surgical center (ASC) payments for 2007 and 2008 and Medicare Administrative Contractors.

Many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2007 than in 2006. These changes make it extremely difficult for hospitals to plan and budget from year to year. We would expect that four years after the start of the outpatient PPS, the payment rates and associated payment-to-cost ratios would be much more stable.

Adding to this instability, outpatient PPS is under-funded, paying only 87 cents for every dollar of hospital outpatient care provided to Medicare beneficiaries. MHA will continue to work with Congress to address inadequate payment rates and updates in order to ensure access to hospital-based outpatient services for Medicare beneficiaries.

The proposed rule contains several significant policy changes in outpatient PPS and in other areas of Medicare policy.

LINKING THE OUTPATIENT PPS UPDATE TO INPATIENT QUALITY DATA REPORTING

MHA and our member hospitals are committed to public transparency of hospital quality information. Indeed, as a member of the Hospital Quality Alliance (HQA), MHA has worked toward increasing the amount of publicly available, reliable and useful quality data. We continue to work through HQA to identify and implement important clinical quality measurement activities for Missouri's hospitals. This work includes collaborating with AQA (formerly known as the Ambulatory Quality Alliance) to identify measures that are specifically appropriate for and applicable to the hospital outpatient setting.

For CY 2007, CMS has proposed to use its authority under §1833(t)(2)(E) of the *Social Security Act* to reduce the outpatient PPS update for those hospitals that are required to report quality data under hospital inpatient PPS, but failed to do so. Specifically, CMS proposes that hospitals that failed to submit the required quality data for a full market basket update for inpatient PPS for FY 2007 would have their outpatient update also reduced by 2 percentage points.

We are troubled by CMS' proposal for many reasons: First, it simply makes no sense to link outpatient payments to inpatient measures of quality. Second, linking a reduction in the conversion factor to the submission of inpatient PPS data that have already been reported and made public does nothing to further CMS' stated goals of encouraging hospital accountability and quality improvement. Third, linking payment to data submission that predates the outpatient PPS rule is unfair and tantamount to retroactive rulemaking. Fourth, in linking outpatient payments to the reporting of quality data, CMS has exceeded its statutory authority.

FY 2008 INPATIENT QUALITY MEASURES

In the proposed rule, CMS announces the measures that hospitals paid under Medicare acute care hospital inpatient PPS must submit in order to receive the full inpatient update in FY 2008. MHA applauds CMS for adding to its requirements for a full inpatient update in FY 2008 measures that have been adopted by the HQA. **We urge CMS to continue to align its choices of measures to link to payment with the measures chosen by the HQA.**

We also commend CMS for proposing in August 2006 the measures that hospitals will be required to report to receive their full FY 2008 inpatient payments. This early notice allows hospitals sufficient time to establish the proper data collection processes. **We urge CMS to continue with this timely rulemaking as a mechanism to notify hospitals several months in advance of the inpatient PPS quality reporting requirements for the upcoming fiscal year.**

HOSPITAL CLINIC AND ED VISIT CODING

MHA is disappointed that in 2007 CMS proposes to establish new G codes to describe hospital clinic visits, emergency department (ED) visits and critical care services in the absence of national guidelines. Creating temporary G codes without a fully developed set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes – G codes for Medicare and current procedural terminology (CPT) codes for non-Medicare payers – without the benefit of a standardized methodology or better claims data. In contrast, MHA recommends that CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing ambulatory payment classifications (APCs) for hospital clinic and ED services until national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized. This would provide stability for hospitals in terms of coding and payment policy and allow CMS and stakeholders to focus on developing comprehensive national hospital visit guidelines that could be applied to a new set of hospital visit codes in the future.

Proposed Codes and Coding Policy for 2007. Despite CMS' previous assurances that it would not create new codes to replace existing CPT E/M codes until national guidelines were developed, in 2007 the agency proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, ED visits and critical care services. CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. Until national guidelines are adopted, CMS states that hospitals may continue to use their existing internal guidelines to determine the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

MHA opposes implementing new codes for hospital clinic and ED visits in the absence of accompanying national code definitions and national guidelines for their application. CMS should drop its proposal to create temporary level II G codes while requiring hospitals to apply their own internal guidelines to these codes. Instead, we recommend that CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized.

Creating temporary G codes without a fully developed set of national guidelines will increase confusion and require hospitals to manage two sets of codes – G codes for Medicare and CPT codes for non-Medicare payers – without the benefit of a standardized methodology or better claims data. In contrast, our approach would provide stability for hospitals in terms of coding and payment policy and allow CMS and stakeholders to focus on developing and fine-tuning a set of national hospital visit guidelines that could be applied to a new set of hospital visit codes in the future.

MHA recommends that once national guidelines are developed, a formal proposal should be presented to the AMA's CPT Editorial Panel to create CPT level I codes for hospital visits. Then hospitals could report these codes to all payers. We do not support the creation of temporary G codes as an interim step for a year or two, but prefer to wait for the implementation of CPT codes.

Proposed Payment Policy for 2007. CMS proposes to assign the new G codes to APCs for payment purposes as follows:

- Five new clinic visit G codes would be assigned to five new clinic visit APCs.
- Five new type A ED visit G codes assigned to five new type A emergency visit APCs. (Type A = open 24 hours a day, seven days a week – 24/7)
- Five new type B ED visit G codes assigned to the five new clinic visit APCs. (Type B = not open 24/7)
- One new critical care G code (hosp critical care, 30-74 min) assigned to the new critical care APC. The other critical care G code (hosp critical care, additional 30 min) would be packaged into other services or procedures performed during the visit.

CMS asserts that paying for type B ED visits at the clinic visit rate is consistent with the agency's current policy for services furnished in EDs that have an *Emergency Medical Treatment and Labor Act* (EMTALA) obligation but do not meet the CPT definition of ED to be reported using clinic codes. The agency states, "Under the outpatient PPS, we have restricted the billing of emergency department CPT codes to services furnished at facilities that meet this CPT definition. Facilities open less than 24 hours should not use the emergency department codes."

In the proposed rule, CMS requests comments regarding this policy because the agency is concerned with ensuring that necessary ED services are available to rural Medicare beneficiaries, recognizing that rural EDs sometimes operate on a less than 24/7 basis. Although MHA does not collect data on the hours of operation for hospital EDs, we believe there are very few EDs that are open less than 24/7. We are unaware of any rural hospital EDs that operate at anything less than 24/7. In fact, many rural hospitals are designated as critical access hospitals (CAHs) for which the Medicare conditions of participation require emergency services be available 24/7. Therefore, MHA believes that there are very few facilities that would currently meet the type B ED definition, and it is likely that most of these are remotely located EDs operated by hospitals with 24/7 on-site EDs. That said the level of services in EDs varies based on the availability of other hospitals, general population size and availability of physician specialists.

In addition, in the proposed rule, CMS notes that the reporting of specific G codes for emergency visits provided in type B EDs will permit the agency to collect and analyze the hospital resource costs of visits to these facilities in order to determine whether a proposal of an alternative payment policy may be warranted in the future. MHA believes that CMS' proposed policy to establish different sets of ED visit codes for type A and type B facilities will not provide adequate data to allow a useful analysis of comparative costs to charges associated with the operation of these facilities. Hospitals that have both an on-site 24/7 ED as well as one or more remote non-24/7 EDs would report costs for both types of EDs under a single service category – emergency services. Rolling costs into the same cost report line would make it impossible to distinguish between the services provided in the type A versus type B ED.

We recommend that CMS create a unique revenue code for reporting non-24/7 ED services and modify the cost report to create another service category to allow separate reporting of those costs. With this structure, the billed services provided in the on-site 24/7 ED could be captured using a different revenue code from the billed services provided in the satellite non-24/7 ED. This would allow the matching of costs to charges. This approach also would make it unnecessary to establish a separate set of codes for type B EDs. Over time, reviewing cost report data combined with patient level-of-care data will help determine whether the costs of non-24/7 EDs are more similar to those of a clinic, a 24/7 ED, or somewhere in-between.

We are concerned about CMS' proposed coding and payment structure. From a coding perspective, what should be taken into consideration are the services provided to individual patients. In addition to highlighting the traditional 24/7 availability of hospital EDs, we believe that the CPT description of ED services as requiring 24-hour services also may serve as a proxy for the level and

scope of care that the facility can provide. If an ED that is open less than 24/7 can provide the same level and scope of care that an ED open 24/7 can, then it should be paid at the ED rate. For instance, this may be the case if the non-24/7 ED:

- Operates as a provider-based facility at a different location than its main campus hospital, but essentially is an extension of the main campus 24/7 ED;
- Complies with EMTALA by virtue of meeting the criteria as a "dedicated emergency department;"
- Provides unscheduled care and maintains procedures to register and triage patients;
- Accepts patients from emergency medical services (EMS), including patients who are at risk of loss of life and/or limb and require emergency stabilization; and,
- Is staffed during hours of operation similar to the hospital's on-site 24/7 ED, and provides patients with access to the same type and range of services – including physician specialists, laboratory tests, imaging procedures and other services and procedures that are typical of emergency services provided by the on-site 24/7 ED.

From a payment policy perspective, assuming that the costs of these non-24/7 EDs are more similar to that of a clinic than a 24/7 ED is unfounded. After all, these are EDs that CMS has already defined as being subject to EMTALA by virtue of meeting the criteria as a "dedicated emergency department," including providing unscheduled emergency care and accepting ambulance patients. While these facilities may not bear the same staffing costs and "stand-by" expenses associated with 24-hour operation, they do bear these other costs and provide an intensity of service that make them closer to a 24/7 ED than an outpatient clinic.

Given the expected small number of non-24/7 EDs, and the fact that this is an interim policy pending evaluation of cost data, CMS should pay for ED visit services at these facilities at either the ED APC rate or, if appropriate, at a reasonable discount from the ED rate.

Proposed Treatment of Guidelines for 2007. MHA is pleased that CMS finds the AHA/AHIMA guidelines to be the most appropriate guidelines to use as the starting point for consideration in outpatient PPS. We further agree that the 2003 AHA/AHIMA guidelines require short-term refinement prior to full adoption and continued refinement over time. We are encouraged that CMS is providing the expert panel with the opportunity to refine the model and address CMS' and the industry's concerns.

We request that CMS release the detailed analysis by the Iowa Foundation for Medical Care of the AHA/AHIMA model so we can appropriately review the issues raised.

APC Relative Weights

Proposed Recalibration of APC Relative Weights for 2007. Current law requires CMS to review and revise the relative payment weights for APCs at least annually. MHA continues to support the agency's use of hospital data, rather than data from other sources, to set the payment rates, as this

information more accurately reflects the costs hospitals incur to provide outpatient services. However, since the August 2000 implementation of outpatient PPS, payment rates for specific APCs have fluctuated dramatically. For 2007, the proposed rates continue to show significant volatility.

In the proposed rule, CMS uses the most recent claims data for outpatient services to set the 2007 weights and rates. MHA continues to support use of the most recent claims and cost report data to set the 2007 payment weights and rates. We also continue to support the use of multi-procedure claims, as we believe these data improve hospital cost estimates. MHA also supports the expanded list of codes for bypass, as it appears unlikely that these codes would have charges that would be packaged into other services or procedures.

Proposed Revision to the Overall Cost-to-Charge Ratio (CCR) Calculation. The proposed rule includes a significant change in the way the overall hospital-specific CCR is calculated. CMS uses the overall hospital CCR to set outlier thresholds and to estimate outlier and pass-through payments and in other services paid based on charges reduced to costs. The fiscal intermediaries (FIs) use overall CCRs to determine outlier payments and payments for certain other services. CMS recently discovered that it calculates the overall hospital CCR differently than the FIs. Compared with the CMS "traditional" overall CCR calculation, the FIs' method includes allied health education costs and adds weighting by Medicare Part B charges. In the rule, CMS proposes to use features of both methods by excluding allied health education costs and adopting weighting by Medicare Part B charges.

It is important to have a consistent methodology for setting policy, modeling impacts and making outpatient PPS payments. The decisions to exclude allied health education costs and to adopt weighting by Medicare Part B charges are appropriate policy decisions. **MHA supports CMS' proposal to adopt a single overall CCR calculation that incorporates weighting by Medicare Part B charges and excludes allied health costs for modeling and payment.**

Proposed Changes to Packaged Services. MHA commends CMS and the APC Packaging Subcommittee for continuing to address provider concerns that many packaged services ("N" status code services) could be provided alone, without any other separately payable services on the claim. In the rare circumstances in which a hospital provides services described by these "N" status codes alone, there is no way for the hospital to be reimbursed for the cost of providing these services.

MHA supports the proposed designation of specific CPT codes as "special packaged codes" with status indicator "Q" that will be used for separate payment of these services when they are billed on a date of service without any other separately payable outpatient PPS service. We encourage CMS to continue to work with the APC Packaging Subcommittee to further review "N" status codes and identify those services that should be paid separately.

PARTIAL HOSPITALIZATION

MHA is concerned that an additional proposed 15 percent reduction in the per-diem payment rate for

partial hospitalization services could harm the financial viability of partial hospitalization services and could endanger Medicare beneficiary access to them. This will be the second consecutive year that the per-diem rate was reduced by 15 percent. Hospitals cannot sustain further reductions in the per-diem rates. These services are quite vulnerable, with many programs in recent years closing or limiting the number of patients they accept.

We share CMS' concern about the volatility of community mental health center (CMHC) data and support the agency's intent to monitor and work with CMHCs to improve their reporting.

MHA recognizes that CMS made the proposal to avoid an even more significant reduction in the payment rate for these services that would be derived from using the combined hospital-based and CMHC median per-diem cost; however, hospitals offering partial hospitalization services should not be penalized for instability in data reporting of CMHC-based services.

MHA recommends that in the final rule for 2007, CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65. This approach will provide payment stability for these services and protect beneficiary access while allowing CMS adequate time to address the instability in the CMHC data.

Rural Hospital Hold Harmless Transitional Payments

MHA is concerned about the impact that phase-out of transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. MHA supports S. 3606, *Save Our Safety (SOS) Net Act of 2006*, which would permanently extend hold harmless payments to small rural hospitals and sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.

Outlier Payments

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, CMS proposes to raise the fixed-dollar threshold to $1,875 – $625 more than in 2006 – to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from change in the CCR methodology. To qualify for outlier payment, the cost of a service would have to be more than 1.75 times the APC payment amount and at least $1,875 more than the APC payment amount.

We are concerned that CMS has set the threshold for outliers too high. With significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, MHA is concerned that Medicare may not spend the targeted outlier pool.

NEW TECHNOLOGY APCS

CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. CMS generally retains a service within a new technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, CMS proposes to assign some services that have been paid under new technology APCs for less than two years to clinically appropriate APCs. For example, positron emission tomography (PET)/computed tomography (CT) scans, which had been assigned to new technology APC 1514 in 2005, is scheduled to move to a clinical APC in 2007. Some hospitals that adopt these new technologies may be unable to quickly change their charge masters, including changing codes and setting charges that reflect actual costs of the new service. Data that CMS obtains in the first year or two of adoption of these technologies may not appropriately reflect the use and cost of these services because diffusion of new technologies can be slow, and waiting additional years for more hospitals to adopt and use new technology is important. **MHA recommends that when CMS assigns a new service to a new technology APC, the service should remain a new technology APC for at least two years until sufficient claims data are collected.**

RADIOLOGY PROCEDURES

In the proposed rule, CMS indicates that it will continue to defer the implementation of a multiple imaging procedure payment reduction policy pending further analyses. **MHA supports CMS' decision not to implement this policy.** As we commented last year, MHA opposes this policy without better justification and more substantial hospital-based data analyses. Hospital cost data currently reflect efficiencies gained when multiple images are performed, leading to lower cost estimates across all procedures.

In the proposed rule CMS requests comments on ways that hospitals can uniformly and consistently report charges and costs related to all cost centers that also acknowledge the tradeoff between a greater precision in developing CCRs and the administrative burden associated with reduced flexibility in hospital accounting practices.

MHA appreciates CMS' evenhanded presentation of this issue in the proposed rule. As CMS notes, any step taken to ensure greater uniformity in the reporting of costs and charges would have to carefully balance the additional administrative burden and loss of flexibility in a hospital's accounting system.

The difficulty in applying CCR ratios to arrive at cost is that it presupposes consistency in how HCPCS procedure codes relate to the service categories indicated on the cost report. The cost report relies on service categories that reflect the general descriptor of a provider's service departments. But other departments can now safely and effectively perform services that were once performed by a specialized departmental unit.

For instance, bedside lab tests are now performed in the ED; procedures can be furnished in an operating room, treatment room, or outpatient surgery area; and supplies cross multiple departments. Consequently, inconsistencies occur when determining the cost of a service if the CCR assignment is made to a different cost report service category.

CMS also must recognize the current limitations and inconsistencies in preparing the cost report. Today, providers must reconcile the Medicare Provider Statistical & Reimbursement reports to determine how FIs not only paid the claim but also how they recorded the units and revenue code assignment to the billed services. Often the FI makes changes that affect how the services and revenue matches are made. Such changes by the FI, however, fail to match revenue as reported by the provider on the cost report.

MHA urges CMS to proceed with care in this area. Hospitals need the flexibility to set charges and allocate costs in a manner that makes the most sense for the particular mix of services it offers. In addition, even relatively small changes in practices and procedures need to take into account the varying levels of sophistication of provider accounting systems. CMS must allow adequate time for dissemination of changes, and provider education on any changes is imperative.

OBSERVATION SERVICES

For 2007, CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. MHA continues to support CMS' concept of allowing the Outpatient Claims Editor logic to determine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

Now that the process for determining whether observation is separately payable is largely "automated," CMS should explore a narrow expansion in the diagnoses for which observation may be separately paid. **MHA recommends that CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment.** This is consistent with a recent recommendation from the Advisory Panel on APC Groups.

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove eight codes from the inpatient-only list, which identifies services that are ineligible for payment if performed in an outpatient setting, and assign them to clinically appropriate APCs.

MHA remains concerned about the inconsistency between Medicare payment policy for physicians and hospitals with regard to procedures on the inpatient-only list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient-only list are performed in outpatient settings, physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For

instance, because the inpatient-only list changes annually, physicians may not always be aware that a procedure they have scheduled in an outpatient department is on the inpatient-only list. There also may be other reasonable, but rare, clinical circumstances that may result in these procedures occurring in the absence of an inpatient admission.

MHA continues to recommend that CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient-only list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and circumstances that allow a particular patient to be sent home safely without an inpatient admission.

CAHs: Emergency Medical Screening

MHA supports CMS' proposal to change the CAH conditions of participation to allow registered nurses to serve as qualified medical personnel to screen individuals who present to a CAH emergency department, if the nature of the patient's request is within the registered nurse's scope of practice under state law and such screening is permitted by the CAH's bylaws.

This change provides hospitals with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services in CAHs. We note, however, there is an inconsistency between CMS' preamble language and the regulatory text proposed in this section. While the preamble indicates that the CAH would have to include this change in their bylaws, the regulatory text does not mention CAH bylaws.

Medicare Contracting Reform Mandate

In the rule, CMS proposes regulation changes required to implement Medicare contracting reform provisions of the MMA. Hospitals will be integral customers of Medicare Administrative Contractors (MACs), and a significant proportion of hospital revenue will depend on these contractors operating in a timely and judicious manner.

The MMA requires that the Secretary consult with providers on MAC performance requirements and standards, and MHA appreciates the many opportunities hospitals and other providers have had in contributing to this process. With the advent of competitive procedures for selection of MACs, MHA believes that such provider input is critical.

However, we encourage CMS to further include providers in the contractor selection and renewal process. Furthermore, to address any serious problems with selected MACs, providers also should be permitted to provide formal mid-contract reviews of their performance. We are concerned that with the introduction of competitive procedures for selection of MACs, some contractors may bid so low they may be unable to adequately perform at the level that HHS and providers require. Hospitals have had first-hand experience with contractors who submit "low-ball" bids and then cannot do their job adequately in the Medicaid program, where competitive bidding is used often to

select contractors. Therefore, hospitals should have input on both the selection and termination of MACs.

In addition, given that each defined Medicare A/B MAC jurisdiction will include several states, CMS must ensure that the chosen contractor is able to maintain a local presence. This includes the ability to work within different time zones, availability within typical hospital administrative hours of operation, and the ability to conduct face-to-face meetings and teleconferences with individual hospitals or groups of hospitals in each state on a regular basis.

CMS proposes to assign providers to the MAC that is contracted to administer the types of services billed by the provider within the geographic locale in which the provider is physically located. However, CMS also proposes to allow large national hospital chains that meet the agency's criteria as "qualified chain providers" to request an opportunity to consolidate their Medicare billing activities to the MAC with jurisdiction over the geographic locale in which the chain's home office is located. In addition, qualified chain providers that were formerly granted single FI status (prior to October 1, 2005) would not need to re-request such privileges at this time.

MHA is pleased that the proposed rule will allow chain-provider organizations to receive "single MAC" status. However, there should be an option for a chain provider with facilities in many A/B MAC jurisdictions to consolidate into a smaller number of MACs instead of a single MAC in the chain's home office location. This might apply to a chain provider that has its home office and several of its facilities within the same MAC jurisdiction but other facilities located in another MAC's jurisdiction. For a chain organization that includes multiple kinds of providers – hospitals, freestanding imaging centers, physician offices, etc. – there should be a mechanism to allow some facilities to stay with the MAC in their geographic locale while others migrate to the MAC of the chain's home office *if that be their choice.*

MHA also seeks clarification on how chain providers that currently report to a single intermediary will be managed in the coming stages of the MAC transition. If a chain hospital is in a jurisdiction that is transitioning to a MAC, but the chain's home office is not in that jurisdiction, may the chain hospital continue to report to the intermediary it has been using, or must it transition to the contracted MAC in its jurisdiction? **MHA recommends that CMS expeditiously provide instructions on how a chain organization may convert to a single MAC to avoid the need for multiple transitions for chain hospitals.**

HEALTH INFORMATION TECHNOLOGY

In the proposed rule, CMS repeats questions posed in the proposed inpatient PPS rule regarding:

- Its statutory authority to encourage adoption and use of information technology (IT);
- The appropriate role of IT in any value-based purchasing program; and
- The desirability of including use of certified health IT in hospital conditions of participation.

Health IT is a critical tool for improving the safety and quality of health care, and MHA's members are committed to adopting IT as part of their quality improvement strategies. They also view IT as a public good that requires a shared investment between the providers and purchasers of care.

As summarized in the final inpatient PPS rule, most commenters, including MHA, noted that health IT is a costly tool, requiring both upfront and ongoing spending. While providers bear the burden of those costs, the financial benefits of having IT systems often flow to payers and purchasers of care, including Medicare. **Given that they reap many of the financial benefits of IT, MHA believes that payers and purchasers of care should share in its costs.** An add-on payment to Medicare is one possible mechanism for doing so.

With regard to value-based purchasing, MHA believes that these programs should build on the consensus measures endorsed by the broad spectrum of organizations - including CMS - that participate in HQA. In general, HQA favors measures that address quality process and outcomes, rather than the tools used to get there. Health IT, however, can play a role in reducing the burden of quality reporting.

In the FY 2007 final inpatient PPS rule, CMS stated that it would not make use of certified interoperable health IT a condition of participation in Medicare, but might revisit the issue in future rulemaking. **MHA opposes including health IT in the Medicare conditions of payment for hospitals.** The conditions of participation address basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, current commercial healths IT applications do not always meet hospitals' needs, and certification efforts are in their infancy. As noted in a recent report by the Agency for Healthcare Research and Quality (AHRQ), evidence on health IT does not yet support this level of requirement. Imposing it would amount to an unfunded mandate.[1]

TRANSPARENCY OF HEALTH CARE INFORMATION

Significant progress has been made in making quality information more transparent. Several national health care organizations have partnered with CMS to form HQA. The work of HQA has led to voluntary reporting and sharing of 21 quality measures with the public on the *Hospital Compare* website, and more measures of hospital quality and patient satisfaction are planned for the future. This effort has been tremendously successful, with nearly all inpatient PPS hospitals voluntarily reporting quality information. Efforts to further expand public availability of hospital quality information must continue to be pursued through HQA.

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[1] "Costs and Benefits of Health Information Technology." Agency for Healthcare Research and Quality Publication No 06-E006 (April 2006).

While progress has been made regarding quality transparency, similar information on hospital pricing is less accessible. Consumers deserve meaningful information about the price of their hospital care, and hospitals are committed to sharing information that will help consumers make important decisions about their health care.

However, sharing pricing information is more challenging because hospital care is unique. Hospital prices can vary based on patient needs and the services they use; prices reflect the added costs of hospitals' public service role – like fire houses and police stations – serving the essential health care needs of a community 24/7; and most hospitals cannot yet provide prices that reflect important information from other key players, such as the price of physician care while in the hospital or how much of the bill a patient's insurance company may cover.

Providing *meaningful* information to consumers about the price of their hospital care is the most significant challenge hospitals and CMS face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

- Presenting information in a way that is easy for consumers to understand and use;
- Making information easy for consumers to access;
- Using common definitions and language to describe pricing information for consumers;
- Explaining to consumers how and why the price of their care can vary; and
- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

MHA is pleased that CMS acknowledged in its FY 2007 inpatient PPS final rule the complexities involved in presenting pricing information in an accurate and useful manner; and recognized that an educational effort will be required. We also are pleased that CMS plans to make pricing information available for other types of providers and services. Consumers should have information on physician services, and common procedures in hospital outpatient clinics and ambulatory surgery centers.

MHA makes the following recommendations:

- Federal requirement for states, working with state hospital associations, to expand existing efforts to make hospital charge information available to consumers.
- Federal requirement for states, working with insurers, to make available in advance of medical visits, information about an enrollee's expected out-of-pocket costs.
- Federal-led research effort to better understand what type of pricing information consumers want and would use in their health care decision-making.
- Hospital-led effort to create consumer-friendly pricing "language" – common terms, definitions and explanations to help consumers better understand the information provided.

More can and should be done to explain pricing information to consumers clearly and consistently. Hospitals will work together to create common terms, definitions and explanations of complex pricing information. HHS should provide incentives to states to improve transparency at the state and

local level; and, through AHRQ, complete research on what consumers want and would use in purchasing health care services.

MHA appreciates the opportunity to comment. If you have questions, please feel free to contact me or Gary Toliver, V.P. for Federal Relations, at 573/893-3700.

Sincerely,

Dwight L. Fine
Senior Vice President for Governmental Relations

Submitter : **Date: 10/10/2006**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-480-Attach-1.DOC

CMS-1506-P-480-Attach-2.DOC

CMS-1506-P-480-Attach-3.TXT

#480

October 10, 2006

Dear Congresswoman Wasserman Schultz,

I am a Program Director of a CMHC in South Florida. We provide a vital role to mental health consumers suffering from severe mental illness. Without sufficient benefits patients will experience difficulties maintaining stability in the community resulting in more frequent and costly inpatient stays. Individuals from all walks of life will be impacted greatly if CMS rates are cut, thereby defeating the purpose of serving the good of the general public and defeating attempts to reduce federal costs. Our profession and the services we provide are essential and I am in opposition to the proposed rate cut for CMS, as it would negatively impact both patients and professionals.

Respectfully Submitted,

Jennifer Beardman, MA

Submitter : Ms. Stephanie McDonald **Date:** 10/10/2006

Organization : Fairview Health Services

Category : Hospital

Issue Areas/Comments

Visits

Visits

see attachment

CMS-1506-P-481-Attach-1.DOC

October 6, 2006

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
PO Box 8011
Baltimore, MD 21244-1850

Re: Visits: Federal Register Notice 71 FR August 23 2006; Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates

Dear Sir or Madam:

Fairview Health Services, which has seven hospitals in Minnesota, including a large multi-specialty academic health center wishes to thank you for the opportunity to comment on the proposed rule for HOPPS 2007. In this letter, we wish to comment on section IX, Visits. Our comments are as follows:

We do not feel that the proposed categories fit any but the most basic model for health care and do not reflect how health care is currently handled in a hospital-based clinic setting. In fact, a good portion of the interventions is more appropriate in a home care setting.

The examples given are all geared to patient encounters that require nursing intervention. In most instances, they do not reflect the current delivery of care in a modern hospital setting, even a primary care clinic, much less in a hospital with multi-specialty clinics.

The examples are geared toward nursing, yet there is far more hospital staff engaged in caring for a patient's needs than nursing. It should be noted that with the current demands on physicians in modern health care, it is not the physician that is doing the assessments. The physicians refer the patients to qualified hospital staff to do assessments – these being nurses, therapists, nutritionists, social workers, diabetes educators, genetics counselors, psychiatric counselors, etc. In short, hospitals have far most cost tied to a patient visit than nursing. There are not always codes other than the E&M to describe what the other staff is doing. The code descriptions should include a sum total of all hospital staff involved face to face in the patient encounter, not just nursing.

Intervention vs. assessment and education: Not every visit requires an intervention. The proposed model requires intervention by the nurse before coding and charging can occur, yet possibly 8 of 10 visits in a tertiary care setting do not have any actual interventions, but assessments and education. Hospital staff can spend several hours with a chronic patient assessing every aspect of his/her condition(s), and then doing education or re-education to changes needed as the disease progresses. Under the models proposed, there is nothing we could charge for the time and effort by the hospital staff. An example would be the chronic Cystic fibrosis patient, some of who are now able to survive into middle adulthood. As the disease progresses, however, there are changes that need reassessment and re-education for the patient and caregivers. Hospital staff can spend 3 to 5 hours with one of these patients going over all of the various conditions involved with the condition, and yet would not actually do any interventions, other than possibly a venipuncture and some labs. According to your proposed model, we could only charge for the venipuncture and the labs.

Education: in addition, there are often shorter visits that require assessment and education, yet your model indicates that we could not charge until 60 minutes of education is done. Education happens at levels other than the higher levels, and hospital staff is performing the education. We could, in fact, have 4 patient appointments over an hour's time that require some assessment and education, and your model would not allow us to bill for any of them. We would not be able to recover any of our effort.

Services in other departments: if we have a patient who comes in for, as an example, physical therapy but when the patient arrives, the patient does not feel well. The therapist may spend a good deal of time assessing the patient's problems prior to determining that no therapy can take place. CMS previously told us to charge an E&M code for the time. Under the proposed codes, we would not be able to capture the effort, as there is no code for the therapist to use that describes the assessment. This can occur in other areas as well. This is not a rare occurrence that can be pushed off as a "cost of doing business".

Considering the time frame given for commenting, there is no way that we could take the model to the specialty clinics and have them try to work up and crosswalk examples of what assessments and/ or interventions they might do that would be similar to the levels CMS or AHA/AHIMA have proposed.

We feel that using the proposed guidelines will result in a potential loss of revenue as 8 of 10 visits will not be able to be billed because there are no interventions, but hospital staff has spent a great deal of time.

We appreciate efforts on the part of CMS, AHA and AHIMA to try to capture the efforts of hospital staff, and we most certainly agree that this is necessary to be recognized as more than just a charge for the hospital's "room" or "space". However, the proposal does not go far enough and does not capture the reality of anything but the most basic care.

Thank you for the opportunity to comment.

Sincerely,

Stephanie McDonald
Compliance Specialist
Fairview Health Services
Corporate Office
400 Stinson Blvd NE
Minneapolis, MN 55413

University of Minnesota Medical Center, Fairview
Fairview Southdale Hospital
Fairview Ridges Hospital
Fairview Northland Regional Hospital
Fairview Lakes Regional Medical Center
Fairview Red Wing Hospital
University Medical Center, Mesabi

Submitter : **Date: 10/10/2006**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P-482-Attach-1.DOC

#182

October 10, 2006

Dear Congresswoman Wasserman Schultz,

I am a Program Director of a CMHC in South Florida. We provide a vital role to mental health consumers suffering from severe mental illness. Without sufficient benefits patients will experience difficulties maintaining stability in the community resulting in more frequent and costly inpatient stays. Individuals from all walks of life will be impacted greatly if CMS rates are cut, thereby defeating the purpose of serving the good of the general public and defeating attempts to reduce federal costs. Our profession and the services we provide are essential and I am in opposition to the proposed rate cut for CMS, as it would negatively impact both patients and professionals.

Respectfully Submitted,

Jennifer Beardman, MA