CMS-1392-P-834 **Medicare**

Submitter : **Dr. Jimmy Ponder, Jr.,** **Date & Time: 09/13/2007**

Organization : **Headache & Pain Center, AMC & Day Surgery, Inc.**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

GENERAL

See Attachment

#834

September 10, 2007

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

Re: CMS-1392-P

Dear Mr. Kuhn:

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

I. ASC Procedures

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

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

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

II. IMPLANTATION OF SPINAL NEUROSTIMULATORS

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

We are concerned that the CMS proposal to pay rechargeable and non-rechargeable neurostimulator procedures under the same APC (0222) ($12,314 in hospital outpatient departments and $10,925 in ASCs) will impair Medicare Beneficiaries access to neurostimulation

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

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

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

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

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

Moreover, ensuring the payment rate is appropriate under the HOPPS system will result more appropriate payment in the ASC setting. Today, ASCs receive reimbursement for rechargeable generators through the DMEPOS fee schedule (L8689- rechargeable generator). With the current

proposal ASC reimbursement will be based on 100% of the device component and approximately 65% of the service component of the APC payment. If the device component, as determined from the OPPS claims data, is based on a mix of rechargeable and non-rechargeable device costs, payments to ASCs will vastly underpay for the actual equipment, which costs the same in all settings. Now that the two payments systems are inextricably linked it is even more incumbent upon CMS to ensure that payments are adequate under the HOPPS or Medicare beneficiaries may be left without an option to have this procedure performed at a HOPD or an ASC.

In summary our recommendations to CMS are:

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

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Thank you for your consideration of our comments.

Sincerely,
Jimmy N. Ponder, Jr., MD
Brandon S. Brooks, MD
Adolfo J. Cuadra, MD
Jimmy N. Ponder, Sr., PhD
Staff of Headache and Pain Center, AMC, 123 Frontage Rd. A, Gray, LA 70359 & Day Surgery, Inc., 151 Frontage Rd., A, Gray, LA 70359: Lynsie Alston, Gwen Battaglia, Tiffany Bertrand, Maudie Borne, Sherri Matherne, Ruth Bourgeois, Denise Cambre, Christy Carlin, John Clark, Jacqueline DeLange, Lacey Dempster, Rosetta Dempster, Kathryn Dressel, Ashley Falgoust, Denise Folse, Mary Folse, April Foret, Theresa Freyou, Michelle Gonsoulin, Heather Granier, Susan Gr emillion, S hari Gui llot, S helly H arris, D usti L abiche, M ary L anassa,Louise L ancon, Brittany Louviere, Monica Louviere, Brad Manual, Ronnie Oliver, Leslie Pecot, Erika Rodrigue, Sherry Rodrigue, Misty Romero, Natasha Romero, Michelle Songe, Jane Thibodeaux, Gretchen Thibodeaux, Christine Thistlethwaite, Lyndy Toups, Marilyn Wilson, Melissa Witzell

CMS-1392-P-835 **Medicare**

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

Organization : **The Ohio State University Medical Center**

Category : **Hospital**

Issue Areas/Comments

Cardiac Rehabilitation Services

" CMS proposes to change the current CPT code used for Cardiac Rehab to a new Level II HCPCS code. COMMENT TO SUBMIT: CMS□s proposal to change its long standing coding requirement for cardiac rehabilitation from a □per session□ to a □per hour□ code. The reason stated for this change is that CMS believes the □per hour□ descriptor is more reflective of how hospitals provide this service and it would make the billing for this service more straightforward. We request that CMS reconsider this recommendation because it would, in fact, make billing more complicated as most payers would require the □per session□ CPT code but CMS would require the □per hour□ HCPCS code. Operationally, this would create an administrative burden on facilities because their billing systems are not designed to accommodate two different time frames for the same service. The clinical staff frequently assigning the charge codes would have to distinguish between insurers in order to use the correct code or mapping tables would have to be created in the billing process to accommodate this requirement.

Device-Dependent APCs

" CMS proposes changes to the rule for partial credits or upgrades to devices. COMMENT TO SUBMIT: CMS for 2008 is proposing a new policy for partial credits that would require facilities to assign a new HCPCS modifier if the device listed in Table 39 is replaced with partial credit from the manufacturer that is equal to or greater than 20% of the cost of the replacement device. It is our belief that this requirement will place an operational burden on facilities to track these situations. Clinical staff who are submitting charges for devices are not aware of partial credit situations and do not have a method to determine the actual percentage credit. We ask CMS to reconsider this change.

Drug Administration

" CMS proposes to capture pharmacy handling/overhead cost associated with separately payable drugs by breaking out this cost from the drug line item charge. COMMENT TO SUBMIT: CMS□s proposal to capture pharmacy handling and overhead cost associated with separately payable drugs by breaking out this cost from the drug line item charge presents significant billing challenges to hospitals. Most hospitals do not store their pharmacy cost and charge data in their Charge Description Master file. This data is stored and managed in their pharmacy system and the price is passed to the billing system. Most pharmacy systems are not designed to accommodate sending two charges for specific drugs and major reprogramming would have to occur for this to be possible. It is highly unlikely that most hospitals could meet a January 1, 2008 dead line for this revision. As a result, there would be significant manual manipulation of claims to be able to submit them in the

required format. Additionally, this requirement will create billing issues with non-Medicare payers who do not want to have overhead removed from one charge type only. CMS has not presented a clear plan on how it intends to use this data even if hospitals were able to meet this requirement in some way for 2008. We ask that CMS remove this requirement from the 2008 final rule. If CMS feels it is necessary to have this data broken out to achieve its objective, then hospitals must be given adequate time to program such a significant change on such a substantial portion of its

charges.

GENERAL

" No National Guidelines for clinic or ED visits for 2008 COMMENT TO SUBMIT: For 2008, CMS has chosen not to establish national E&M guidelines but has released □principles□ to assist hospitals in establishing their own set of guidelines. As a facility we support the use of internally developed E&M guidelines. We also support the use of five levels of payment but feel the distinction between new and established patients creates operational issues. The ability of first line registrars or clinical staff to ascertain □if the patient has a medical record created in the past 3 years□ makes the application of this definition difficult. Furthermore, the 3 year period makes little clinical sense as far as distinguishing hospital resource utilization to compensate for the increased staff time used during the evaluation of what is typically considered a new hospital clinic patient. We believe the 3 year period needs to be reconsidered and either a more clinically appropriate time period or a different indicator be adopted. If not, the distinction between the new and established patients should be dropped. Providers are being required to do additional work to make the distinction between new and established patients but are not appropriately receiving additional compensation because the 3 year timeline does not reflect typical hospital clinical guidelines for new verses established patients.

" Clarification of guidelines to distinguish between Type A and Type B emergency room visits. (IX B. 2) COMMENT TO SUBMIT: CMS solicited comment on providing further clarification on the guidelines to distinguish between Type A and Type B emergency room visits. Specifically we are asking for clarification of the case where during a specific limited time of the day (i.e. 8am to 10 pm) a process exists for routing less acute patients to certain rooms within an ED to expedite their care. The ED is open and staffed for 24 hours but during certain hours (to facilitate patient flow) less acute cases are sent to certain rooms where their less emergent condition is treated and they are released. Additional staff is available during these times but may work in any room with any patient as needed. We feel CMS has not adequately addressed whether this is considered to be a Type A or Type B visit.

Implantation of Spinal Neurostimulators

" CMS proposes to eliminate the pass-through payments for rechargeable neurostimulators. COMMENT TO SUBMIT: CMS has proposed to eliminate the pass-through payment for rechargeable neurostimulators. We ask CMS to reconsider this proposal as there are substantial clinical improvements afforded by rechargeable neurostimulaors when used in the proper patient population. We feel this will create financial disincentives to hospitals and potentially limit patient access to this beneficial technology if CMS groups rechargeable and non- rechargeable

neurostimulators as they propose to do.

Inpatient Procedures

" CMS proposes revisions to the Inpatient Only List. COMMENT TO SUBMIT: For 2008, CMS proposes to remove an additional 13 procedures from the inpatient only list. While we support the removal of these codes from the list we ask that CMS consider further reducing the list by also eliminating CPT codes 43420, 50727, 20660, and 27886.

OPPS: Packaged Services

" Packaging of 7 categories of service into the primary APC. COMMENT TO SUBMIT: While we understand CMS□s goal of increasing the number of packaged services paid under the OPPS, we question whether these are the correct services to package and we question what appears to be inconsistent packaging by CMS. We believe that random packaging of services is a serious flaw in CMS□s median cost methodology and results in underestimated APC payment rates. Potentially reduced reimbursement results from providers failing to routinely report packaged

services, the high volume of unusable multiple procedure claims, and CMS□s failure to consistently include the cost of both the procedure and the packaged item. Current calculations estimate that the impact to large urban teaching hospitals will range from an overall increase of 0.1 to 0.5. We would ask that if CMS adopts packaging of the seven service categories identified in the proposed rule, then procedures be put in place to validate the impact estimates with actual claims data. If actual claims data varies significantly then we ask that CMS reconsider their approach or their payment rates for these services.

OPPS: Partial Hospitalization

" CMS proposes a reduction in payment for partial hospitalization services based on claims data that indicates that some facilities are reporting fewer than CMS□s intended number of services per day. COMMENT TO SUBMIT: CMS has questioned the reported lower cost for the Partial Hospitalization Program (PHP) for the past few years and has revised it□s method of calculating the daily cost. For 2008, CMS is planning to significantly reduce the per diem payment based on the determination that facilities are frequently reporting fewer than 4 units of service per day under PHP. We ask that CMS consider a two level per diem for partial hospitalization. A full per diem payment for 5 or more units of service with a reduced payment for 4 or fewer units of service reported. This will allow adequate reimbursement for more intensive services and an appropriate reduction for patient care during the transition to less intensive outpatient services.

Offset Costs

" CMS proposes changes to the rule for partial credits or upgrades to devices. COMMENT TO SUBMIT: CMS for 2008 is proposing a new policy for partial credits that would require facilities to assign a new HCPCS modifier if the device listed in Table 39 is replaced with partial credit from the manufacturer that is equal to or greater than 20% of the cost of the replacement device. It is our belief that this requirement will place an operational burden on facilities to track these situations. Clinical staff who are submitting charges for devices are not aware of partial credit situations and do not have a method to determine the actual percentage credit. We ask CMS to reconsider this

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CMS-1392-P-836 **Medicare**

Submitter : **Miss. Charlene Ruvo** **Date & Time: 09/13/2007**

Organization : **MUSC**

Category : **Other Health Care Professional**

Issue Areas/Comments

OPPS Impact

I am a sonographer at the Medical University of SC and I use contrast agents. If separate payment for echo contrast agents is eliminated for hospital outpatients I believe it will reduce patient access to echo contrast agents.Please consider this and contrast to be of benefit to patients.

CMS-1392-P-837 **Medicare**

Submitter : **Dr. Vivian Auerbach** **Date & Time: 09/13/2007**

Organization : **Patients Against Lymphoma**

Category : **Individual**

Issue Areas/Comments

Payment for Therapeutic Radiopharmaceuticals

As a patient with lymphoma who is on Medicare due to disability, government sponsored coverage for lymphoma treatments is crucial for me. The type of lymphoma I have is incurable and must be managed over and over again by treatments which become less effective until death occurs. I have been through several chemotherapy treatments and have been told by several oncologists that the next likely therapy will involve a radiolabelled monoclonal antibody (Bexxar or Zevalin). These agents are effective, specific and far less toxic than other options and many oncologists now advocate their use earlier in the treatment course to optimize patients quality of life for as long as possible. Patients have a need and right to utilize such existing therapies and many of us will face dire consequences if reimbursement for them is cut. PLEASE don't condemn us.

CMS-1392-P-838 **Medicare**

Submitter : **Mr. Michael A. Pelc** **Date & Time: 09/13/2007**

Organization : **Detroit Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

SEE ATTACHMENT

#838

September 12, 2007

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

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

Dear Sir:

On behalf the Detroit Medical Center (DMC) hospitals – Children's Hospital of Michigan, Detroit Receiving Hospital, Harper-Hutzel Hospital, Huron Valley Hospital, Rehabilitation Institute of Michigan and Sinai-Grace Hospital – the DMC appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 2008 proposed rule to update the Medicare outpatient prospective payment system (OPPS). The DMC is concerned about policy changes that would reduce Medicare outpatient payments to the DMC hospitals since this would further threaten the financial viability of hospitals. This is particularly concerning since the latest data available indicates that the DMC hospitals have a negative margin of 38 percent for outpatient services and lose approximately $22 million annually on OPPS services provided to Medicare beneficiaries. **The DMC hospitals cannot sustain these losses and remain financially viable as the commercial insurers and self-pay patients are unwilling to absorb the cost of government under funding.**

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

In order for hospitals to receive the full OPPS payment update for services furnished in 2009, the CMS proposes to require that hospitals submit data on ten measures, effective Jan. 1, 2008. Hospitals that do not participate in the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), withdraw from the program, or fail to meet its requirements will receive an update that is reduced by 2.0 percentage points for the affected payment year. To participate

in the HOP QDRP for 2009 and subsequent years, hospitals must meet administrative, data collection/submission and data validation requirements. For the most part, these procedures and requirements mirror those currently in place under the IPPS RHQDAPU program.

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

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

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

PAYMENT FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Separate Reporting of Pharmacy Overhead Charges (Federal Register Pages 42733-42736)

For CY 2008, CMS is proposing to instruct hospitals to remove the pharmacy overhead charge from the charge for the drug or biological with which it is associated and instead report the pharmacy charge on an uncoded revenue code line on the claim. CMS intends to collect pharmacy overhead costs and package them into payment for the procedure associated with administering the drug or biological rather than into the payment for the drug or biological. The Agency believes this proposal would improve its packaging efforts.

The DMC appreciates CMS's effort to try to find better ways to account for pharmacy handling costs. However, the proposed policy of removing the handling charges from the charge for the drug or biological and report it on an uncoded revenue code line will not accomplish this goal. This is because the proposed policy is practically untenable due to the administrative burden it imposes on hospitals and is likely to result in poor data.

This proposed policy, if implemented, would require a major overhaul of coding and billing systems for the DMC hospitals. If hospitals are required to report handling charges separately from the charge of the drug, it would require hospitals to invest in separate stand-alone computer systems, that would maintain two charges for each of the potentially thousands of drugs to be charged for outpatient Medicare only patients. For bills to non-Medicare payers, this stand-alone system would have to add the two charges together before posting to the bill, while for Medicare bills, the system would simply pass the individual charges for each drug to the bill, and add together all of the overhead charges and pass this latter charge to an un-coded line on the Medicare bill.

The systems hospitals have now are not set-up differently based on the type of payer and it is unlikely that they could be, at least in the short term. Making the changes envisioned by the proposed rule would be expensive, administratively burdensome and would take time to implement as hospitals would have to determine how to establish new charges for pharmacy overhead and to develop extensive training programs to educate the staff in all areas of the hospitals where drugs are administered and dispensed. This requirement would only apply to outpatient Medicare patients.

Furthermore, the proposed rule does not include any guidance as to what constitutes overhead and handling costs. Thus, without knowing what revenue codes should be used to report the information on the uncoded line, each hospital may use different revenue codes, resulting in highly variable and inaccurate data for the purpose of determining overhead and handling costs.

In sum, while we support CMS's effort to continue to determine pharmacy overhead costs, we strongly oppose the proposed separate reporting of pharmacy overhead costs.

Proposed Payment for Separately Payable Drugs and Biologicals (Federal Register Pages 42741-42743)

Relying on hospital cost reports and outpatient claims data to estimate costs, CMS is proposing to pay for separately payable drugs and biologicals at the average sales price (ASP) plus five percent. This constitutes a one percent payment reduction from the payment rate hospitals receive in 2007. It also is lower than the physician office setting payment rate of ASP plus six percent.

We urge the Agency to continue to provide payment for separately payable drugs and biologicals at ASP plus six percent. This would provide a consistent payment policy across providers and increase the likelihood that hospitals receive adequate payment that covers drugs and biologicals and their associated handling costs. Providing consistent payments across providers has been CMS's long-standing policy that was implemented in part to discourage providers to treat patients in one setting over another.

The DMC remains concerned however, that even the current rate of ASP plus six percent is inadequate at covering the acquisition and handling costs of separately payable drugs and biologicals and urges CMS to conduct further analyses of its methodology for setting payment rates based on acquisition costs.

DEVICE-DEPENDENT APCs (Federal Register 42719-42727)

In recent years, some devices have been recalled and the manufacturers have offered replacement devices at no cost to the hospital or a credit for the device being replaced if the patient received a more expensive device. Thus, for CY 2007, in order to identify devices for which the hospital incurs no expense for a defective device that has been replaced, and to set payment rates for device-dependent APCs that contain such devices,
CMS requires hospitals to use modifier "FB" for procedures that use these devices and applies a payment reduction to those procedures that is based on an estimate of the device cost.

CMS is proposing to expand its policy to reduce the APC payment for selected device-dependent APCs when the hospital receives a partial credit when a defective device is replaced. Thus, under the proposed rule, the Agency would require hospitals to report a modifier for those cases in which a hospital receives a partial credit toward the replacement of a defective device.

The proposed rule would reduce the payment for the device-dependent APCs associated with devices for which hospitals have received partial credit for their replacement by half the reduction (half the offset amount) that applies when the hospital receives a device at no cost or receives full credit. CMS is proposing to apply this policy only in those cases in which the amount of the device is greater than or equal to 20 percent of the cost of the new replacement device being implanted.

While we understand the rationale for this proposal, especially since it was implemented in 2007 for replacement devices without cost to the hospital or when the hospital receives a full credit for the device, we believe that the additional administrative burden imposed by this proposal on

hospitals, in the form of the significant number of claims that must be re-billed in conjunction with replacement devices for which the hospital receives only partial credit is not justified by the potentially insignificant savings to the OPPS program as a whole. On page 42724 (72 Fed. Reg.) of the proposed rule, in the discussion of hospitals that do not reduce charges for devices upon which they receive partial credit, CMS states, "It is likely that the reduced hospital costs associated with steady, low volume warranty replacements of implantable devices may never be reflected in the cost-to-charge ratios (CCRs) used to adjust charges to costs for devices, because those CCRs are overwhelmed by the volume of other items attributed to the cost centers." This statement seems to suggest that credits for replacement devices are insignificant in relation to the median costs for the all devices being adjusted.

The additional reporting burden on hospitals arises from probability that 50% or more of all situations involving replacement devices for which the hospital receives partial credit will require the hospital to re-bill the procedure to Medicare. Many vendors require the failed device be returned to them for examination and evaluation before any credit is granted to the hospital. Thus, at the time a hospital bills Medicare for a procedure to replace a failed device, the hospital does not know the amount of a possible credit it may or may not receive on the returned device. The hospital does not know the amount of any such credits for one to three months after the procedure is performed, and thus will have to re-bill Medicare when the credit is received. The whole process of applying billing adjustments for such "device return credits" is highly manual. The common billing and charge systems used by most hospitals do not have an automated interface with the materials management systems which may track and record the device returns and credits. Also, given the infrequency of these returns, it is highly unlikely that most materials management systems track these returns and credits in an automated fashion at all. It is not common for material management departments to routinely match purchases and return data with specific patients, which must be done to apply billing adjustments required by the Medicare billing requirement implemented for 2007. This proposal would make the billing requirements even more burdensome for hospitals without resulting in significant savings for the Medicare program.

Thus, we urge CMS to apply a similar policy to that adopted in the FY 2008 final inpatient rule. In that rule, CMS implemented a payment policy that reduces payment for DRGs in which the hospital receives credit equal to 50 percent or more of the cost of the device. In order to address hospitals' concerns regarding the administrative burden and proper billing, CMS gave hospitals two options: 1) submitting the claims immediately without the special condition code (Condition Code 49 under the inpatient PPS) and then submitting a claim adjustment with the condition code at a later date once the credit determination is made, or 2) holding the claim until a determination is made on the level of the credit. The DMC urges CMS to give hospitals the same billing options under the OPPS as they have under the inpatient prospective payment system.

NEW TECHNOLOGY APCS (Federal Register Pages 42703 – 42706)

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

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

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

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

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

For clinic visits in 2008, the CMS will continue to recognize the CPT codes for new and established patients under the OPPS. For ED visits, the CMS will continue to distinguish between Type A and B ED visits, with Type a visits continuing to be paid based on the five ED visit APCs, while type B ED visits would continue to be paid based on the five Clinic Visits APCs. (Hospitals that maintain an ED and have obligations to the EMTALA but do not operate a 24-hour ED are referred to as Type B EDs).

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

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

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

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

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

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

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

The CMS has indicated that the fixed dollar increase is largely due to the CMS' revised methodology used in calculating the overall cost-to-charge ratio (CCR), the APC recalibration and the proposed changes to packaging. The DMC is concerned that Medicare may not actually spend the outlier target set-aside. We believe the CMS should publish the annual outlier payments as a percent of total expenditures for previous years. **The DMC believes the outlier threshold increase should be limited to the increase in APC rates each year unless clear evidence exists that proves the outlier payments exceed the allocated pool.**

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

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

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

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

AN OPPS TEACHING ADJUSTMENT

The OPPS is the only major Medicare payment system that does not include a teaching adjustment. Teaching adjustments are included in the inpatient, psychiatric and rehabilitation facilities prospective payment systems. We urge CMS to conduct a study to determine whether teaching hospitals incur higher outpatient service costs compared to other hospital types, thereby supporting the addition of a teaching adjustment to the OPPS.

The outpatient department is critical to fulfilling the missions of teaching hospitals. In addition to providing a site for clinical education for all types of health professional trainees, teaching hospital outpatient departments provide an environment in which clinical research can flourish, and are a source for specialized, unique, and referral/standby services. Because of their education and research missions, teaching hospitals offer the newest and most advanced services and equipment, and care for the nation's sickest patients. In addition, teaching hospital outpatient departments often serve as a primary source of health care for low- income Medicare beneficiaries and other disadvantaged individuals.

In the initial OPPS Final Rule, published April 7, 2000, CMS stated that it would "conduct analyses and studies of cost and payment differential among different classes of hospitals, including teaching facilities, when sufficient data under the PPS have been submitted. We will

carefully consider whether permanent adjustments should be made in the system once the BBRA 1999 transition provisions expire." (65 Fed. Reg. at 18500). In addition, the Balanced Budget Act of 1997 requires the Secretary to establish adjustments "as determined to be necessary to ensure equitable payments . . . for certain classes of hospitals." (Section 4523 of the BBA).

In the 2006 final rule however, CMS asserted it does not believe "that a study of unit costs of teaching hospitals relative to other classes of hospitals is necessary at this time," because "such studies are especially warranted when hospitals experience a negative increase in payments" and for CY 2006 "major teaching hospitals are projected to experience an overall increase in payments of 1.0 percent." However, those statements were just that – assertions. We believe CMS has an obligation to do full data analysis because Medicare outpatient margins, while negative for all hospitals, are significantly lower for major teaching hospitals than for other teaching and non-teaching hospitals. For example, according to an internal analysis of 2004 hospital Medicare cost reports, the average outpatient margins were -20.2 percent for major teaching hospitals, -10.1 percent for other teaching hospitals and -11.8 percent for nonteaching hospitals.

In light of the negative margins, as well as the BBA requirement and CMS's commitment to make payment adjustments for classes of hospitals that may be negatively impacted by the OPPS, the DMC believes that it is incumbent upon CMS to conduct a comprehensive analysis that would include the impact of the costs associated with teaching hospitals' teaching and research missions on their outpatient cost structure. If such an analysis concludes that teaching hospitals have higher costs, we believe a teaching adjustment should be included.

Again, the DMC appreciates this opportunity to provide input to the CMS and urge you to modify the OPPS proposed rule based on our comments above. If you have questions or require additional information, please contact me at (313) 578-2820 or mpelc@dmc.org.

Sincerely,

Michael A. Pelc
Vice President, Finance
Reimbursement
Detroit Medical Center

CMS-1392-P-839 **Medicare**

Submitter : **Ms. Linda Saint Laurent** **Date & Time: 09/13/2007**

Organization : **Rhode Island Cardiology Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

OPPS Impact

Dear Sirs and Madam,
I am a practicing cardiac sonographer currently using contrast agents in a certain percentage of my daily patients. The contrast agents are employed when the ultrasound images obtained are uninterpretable due to body habitus, fibrosis from scarring, or chronic lung problems. They require more time, materials for intravenous insertion and nursing assistance in order to utilize them. If a separate charge for the use of a contrst agent is abolished they will most certainly be underutilized causing unnecessary and costly invasive procedures in the hospital. In most cases these are our sickest patients and most serious conditions being evaluated. Please consider that this may eliminate one of our needed tools to diagnose heart disease and in the long run burden the healthcare system more. Thank you. Linda Saint Laurent, RDCS, RVT

CMS-1392-P-840 **Medicare**

Submitter : **Nancy Valentine-Adams** **Date & Time: 09/13/2007**

Organization : **North Bronx Healthcare Network-Jacobi Med Ctr**

Category : **Hospital**

Issue Areas/Comments

Quality Data

I do not feel that enough time is being allowed for the processes that need to occur for the logistics of identifying patient populations for these quality outpatient indicators. The Specifications Manual for the quality indicators for the OPPS is still in a draft form. How can we develop the needed files for population identification based on a draft specifications manual? Systems needed to identify the patient populations for these indicators require coordination among different departments and should involve some quality checks to make sure the data is valid. The individual measures are varied and the file development is complicated. It is imperative that you reconsider the start date. The 'start date' for these measures of January 1, 2008 is too soon and will jeopardize participation.

CMS-1392-P-841 **Medicare**

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

Organization : **William Caster**

Category : **Individual**

Issue Areas/Comments

OPPS: Packaged Services

Dear Mr. Weems:
Regarding: CMS-1392-P, OPPS: Packaged Services
I would like to commend CMS for seeking to improve patient access to care while simultaneously keeping down the related costs and trying to eliminate abuse of services. However, as a patient with (list the form dystonia you have), (dystonia is a movement disorder resulting from sustained involuntary muscle spasms), I have serious concerns about CMS□s proposal to bundle the payment rate to hospitals for physician-injected drugs. I receive injections of botulinum toxin to alleviate the debilitating dystonic symptoms. Both the guidance service and the botulinum toxin injections I receive are critically important for my ability to function normally and have relief of the pain associated with dystonia.
1. I respectfully request that CMS not package the payment of these services together but continue to pay for them separately. The proposed change may result in hospitals pressuring doctors not to utilize this equipment and the injections being ineffective because it does not get to the right muscles to have benefit for me. The guidance service is critically important for this treatment to be effective.
2. Thank you for allowing me to provide these comments.

CMS-1392-P-842 **Medicare**

Submitter : **Dr. Jon Parks** **Date & Time:** **09/13/2007**

Organization : **Dr. Jon Parks**

Category : **Physician**

Issue Areas/Comments

GENERAL

see attachment

 #812

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

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

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

CMS-1392-P-843 **Medicare**

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

Organization : **The Resource Group**

Category : **Individual**

Issue Areas/Comments

GENERAL

Comments regarding more than one aspect of the proposed rule have been submitted within the attached letter.

#843

(on letterhead)

September 14, 2007

By Electronic Delivery

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

Re: CMS-1392-P; Medicare Program Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Proposed Rule

Dear Mr. Weems:

The Resource Group welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates" published in the August 2, 2007 Federal Register.[1] The Resource Group is a healthcare consulting firm with a specific focus on resource consumption and its relationship to payment methodologies among and between the various sites of care. We consult nationally and have the opportunity to observe the perplexity existing among providers concerning payment issues. Thus we speak from a broad perspective of provider views. This letter provides comments on three sections of the rule: (1) OPPS: Specified Covered Outpatient Drugs; (2) APC Relative Weights, and (3) Quality Data.

I. OPPS: SPECIFIED COVERED OUTPATIENT DRUGS (SCODs)

We present three points regarding SCODs as follows.

A. CMS Should Maintain Payment at ASP+6% For Non-Pass-Through Drugs and Biologics, Including Pharmacy Overhead, In CY 2008

CMS proposes to reduce reimbursement for drugs and biologicals without pass-through status in 2008 to Average Sales Price (ASP) plus five percent versus the current rate of ASP plus six percent.[2] Furthermore, CMS also states that the reduced rate of ASP plus five percent is sufficient to account for both the acquisition costs and the pharmacy overhead costs. We believe the reduced rate would result in inadequate payment to hospitals, thus threatening patient access to life-giving therapies.

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[1] 72 Fed. Reg. 42627 (Aug. 2, 2007).

[2] Id at 42736.

CMS assumes that pharmacy overhead costs are typically built into hospital charges for drugs and biologicals, but this assumption is not supported by survey data. The Resource Group has conducted two surveys concerning this issue as follows.

- In 2004, The Resource Group conducted a survey of 1,500 hospitals. Of this sample, 386 hospitals responded to the question "does the pharmacy charge include an amount for anything other than the drug?" with 220 hospitals, or 57%, reporting that they did not include non-product costs, such as administrative and overhead costs, as a component of their drug charges.[3] Only 166 hospitals, or 43% of respondents, replied affirmatively to that question. This finding is contrary to the CMS assumption that pharmacy overhead costs are uniformly built into hospital charges for drugs and biologics.

- In late 2006 and early 2007, The Resource Group conducted a survey[4] of 3,100 hospital decision-makers. Respondents were asked "... which of the following are reflected in your pharmacy charge structure: storage; preparation; transport; disposal; record keeping and other departmental overhead?" Of the 313 respondents, 63% reported that their systems identified some of these six overhead components, but none reported all six categories. There were also major differences in the combinations of components reported between and among the various hospital respondents. Notably, only 63% of the respondents reported they could identify any of the overhead components. This means, of course, that the remaining 37% of respondents had systems that did not identify any overhead component as being reflected in their charge structure.[5]

The Government Accountability Office (GAO) has conducted a survey that found similar results.

- In 2004 the GAO conducted a survey of 113 hospitals. This survey found that 58% of hospitals reported they did not include non-product costs, such as administrative and overhead costs, as a portion of their drug charges. The GAO report recommended that CMS analyze variations in hospital charge-setting to determine if the OPPS payment rates uniformly reflect hospitals' costs for

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[3] Three hundred and eighty-six hospitals responded to this survey question. The Resource Group study surveyed a random sample of 1,500 hospitals selected from all hospitals (except psychiatric facilities) present in the CMS Providers of Service database, as adjusted for duplicate entries and terminated facilities. At a 95% confidence interval, plus or minus 5% error, the number of desired responses, rounded upward, was 400, or a 28% response rate. This response rate was achieved.

[4] *See Exhibit A,* The Resource Group, "Hospital Pharmacy Chargemaster Survey," (Jan. 24, 2007).

[5] Three hundred and thirteen hospitals responded to this subsequent survey that was descriptive and/or explanatory rather than predictive. The Resource Group drew a sample representing 3,100 hospital pharmacy decision-makers from two sources: chief financial officers and controllers from the membership of the Healthcare Financial Managers Association (HFMA), and directors of pharmacy and assistant directors of pharmacy form the membership of the Association of Health-System Pharmacists (ASHP). Data were collected in late 2006 and early 2007 via a self-reporting survey instrument distributed by first class mail.

providing outpatient services and, if they do not, to make appropriate changes to the methodology.[6]

Until CMS can perform a more complete analysis of hospital overhead cost issues related to pharmacy services, we urge the agency to maintain a rate of at least ASP plus six percent in the Final Rule for these therapies.

B. CMS's Current Proposal for Tracking Pharmacy Overhead Is Burdensome to Facilities and Potentially Unworkable

For CY 2008 CMS proposes to require hospitals to remove pharmacy overhead charges from the charges for drugs and report those charges on an uncoded revenue line item on each applicable claim. Hospitals would have the option of reporting charges per drug or per episode. The agency expects to then use the data to package pharmacy charges into associated procedures in the future.

To determine a separate overhead charge for each drug provided on each claim would require major information systems work for each and every hospital. Furthermore, without specific guidance hospitals are like to use widely varying methodologies and report widely disparate charges. Consequently any data that could be collected would be virtually unusable for purposes of future rate-setting.

The difficulty with this approach is further emphasized by a MedPAC-authorized survey. This survey found that hospital pharmacy charges are often not closely tied to costs, as follows.

- This 2005 Medicare Payment Advisory Commission (MedPAC) study performed by The Lewin Group found that ". . .The fact that charges are often not closely tied to costs implies that the current Medicare payment systems may not be closely tied to resource utilization. The findings from this study suggest that in certain instances, relative charges may not accurately proxy relative costs. Therefore, the impact of using charges to set payment rates in Medicare should be investigated more closely." [7]
  (This conclusion is further strengthened by the Lewin report's observation that the sample was biased toward hospitals with sophisticated pharmacies that may be more likely to reflect overall costs than those used by the broader population of hospitals.)[8]

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[6] After surveying 113 hospitals, the GAO report stated that 24 of the 57 (42%) hospitals responding to this question reported that they include non-product costs as a portion of their drug charges. We may therefore conclude that the remaining 33 hospitals, or 58%, do not include non-product cost as a portion of their drug charges. See U.S. Government Accountability Office, Medicare: Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services, GAO-04-772, Appendix II (Sept. 17, 2004), available at: http://www.gpoaccess.gov/gaoreports/index.html.

[7] The Lewin Group, "A Study of Hospital Charge Setting Practices," (Dec. 2005) at vi, available at: www.medpac.gov/publications/contractor_reports/Dec05_Charge_setting.pdf.

8 Id at Appendix A-Screener Protocol, Q3, 26-27.

Supporting testimony from a number of hospital representatives attending the September, 2007 APC Panel Advisory meeting emphasized the burden that would be placed on facilities should they be required to track pharmacy overhead on a separate, non paid revenue line. Still other testimony from hospital representatives concerned serious coding and payment issues arising from commercial payers' response to this proposed methodology. In view of these responses, we ask that CMS retract this proposed approach.

C. CMS Should Re-Consider The Stakeholder Approach To Payment of Pharmacy Overhead Presented To The APC Panel In March 2007

An alternative approach to payment of pharmacy overhead was presented to the APC Panel in March 2007. In Phase One of this approach, CMS would make a flat overhead payment for each separately billable drug identified with a HCPCS code. CMS would define categories of drugs according to the complexity of preparation required. A code would be assigned to each category. (A suggested listing of drugs by categories has already been provided to the agency.)

Under this approach, each hospital would not have to determine pharmacy overhead charges. Instead, the billing software would be programmed to bill these codes automatically with each reported drug. The flat payment rate for each category would be calculated using claims data from recent years and recent surveys of hospital pharmacy costs. An important aspect of this approach is that pharmacy overhead remains associated with drug charges. Furthermore it automates the reporting process, thereby decreasing provider administrative burden.

We ask that CMS re-consider this automatic and much simpler method of gathering necessary pharmacy overhead information from hospital claims.

II. QUALITY DATA

The proposed Hospital Outpatient Quality Data Reporting Program (HOP QDRP) introduces outpatient specific indicators, acknowledging the uniqueness of patient care within this setting and links provider performance to the annual payment update factor. Consistent with the current IPPS quality initiative (RHQDAPU) the proposed outpatient quality indicators require endorsement by one of the national consensus building entities.

The ten quality measures that are proposed as the initial starter set address care provided to a large number of adult patients, across a diverse set of conditions, and are relevant to all hospitals.[9] Within that set there are nine process indicators: five focusing on acute myocardial infarction (AMI) care in the emergency department (ED); one related to heart failure treatment; two related to perioperative care and one for pneumonia management. The tenth indicator in the starter set is an *outcome indicator*.[10]

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[9] 72 Fed. Reg. 42800 (Aug. 2, 2007).

[10] Hemoglobin A1c Poor Control in Type I or 2 Diabetes Mellitus. The proposed 2008 rule describes this as "an intermediate outcome measure that has not been risk-adjusted"

The Resource Group supports the concept of hospital outpatient-specific quality measures and commends CMS for selection of indicators that are harmonious with those currently in use for IPPS, as these categories are consistent with the common hospital patient populations. We ask that CMS provide adequate guidance and education to providers in order to minimize administrative burden as the process is introduced to the hospital outpatient site of care.

Additionally we ask that the measures for this introductory year be held to process indicators, as they were initially for the inpatient setting, and that the HemoglobinA1c outcome indicator be eliminated during this implementation year. We further request that additional consideration and process transparency be applied to the development of and requirement for any outcome measures, and that endorsement by a national consensus building entity continue to be required.

III. APC RELATIVE WEIGHTS

CMS is proposing to expand packaging and to create payment bundles for groups of services with the goal of promoting greater provider efficiency while preserving flexibility. Specifically there is intent to package payment for HCPCS codes that describe the dependent items and services in seven categories into the payment for the independent services with which they are furnished.[11] Additionally the proposed rule introduces two composite APCs, indicating movement toward encounter or episode-based payment methodology.[12]

The Resource Group understands the role of packaging within a prospective payment system and generally supports this direction. However we urge CMS to be cautious in the overzealous application of bundling. We request that careful consideration be given to each packaging recommendation and that the agency continue to collect complete and accurate data on the items and services provided in the hospital outpatient department in order to design appropriate APCs with adequate payment rates in the future.

[11] Id at 42653

[12] Id at 42677

IV. CONCLUSION

We appreciate the opportunity to comment on the important issues raised by CMS's Proposed Rule. Please contact us at via phone or e-mail (contact information below) should you require any clarification or additional information.

Respectfully yours,

Judith J. Baker, PhD, CPA
Partner and Executive Director
The Resource Group
Editor, Journal of Health Care Finance

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Exhibit A

Hospital Pharmacy Charge Master Survey

January 24, 2007

Conducted For:
Centocor, Inc.

Conducted By:
The Resource Group

Hospital Pharmacy Charge Master Survey

Table of Contents

Survey Fact Sheet

Survey Purpose

- To determine how hospital pharmacy charges vary, and
- To determine whether the CMS presumption that pharmacy overhead costs are already built into the pharmacy charges for drugs and biologicals is accurate.

Survey Distribution

- 3,100 surveys distributed: approximately 95% by U.S. Mail and 5% by email (email utilized upon respondents' request)

- Surveys sent to Chief Financial Officers and Controllers, utilizing purchased membership lists of the Healthcare Financial Managers Association (HFMA), and to Directors of Pharmacy and Assistant Directors of Pharmacy, utilizing purchased membership lists of the Association of Health-System Pharmacists (ASHP).

The Survey

- Is descriptive and/or explanatory rather than predictive.
- Was conducted during the fall of 2006, with follow-up in early 2007
- 313 individuals responded
- Responses arrived from 45 states
- Response was voluntary, with no remuneration

* * *

Hospital Pharmacy
Charge Master Survey
Data Summary
n=313

Q1a In your opinion, is the current CMS reimbursement of ASP+6% for separately payable hospital outpatient drugs an adequate amount overall to cover both the drug acquisition cost and the pharmacy overhead?

	#	%
Yes	13	4.2
No	251	80.2
Don't know	39	12.5
No response	10	3.1
Total	313	100.0

Q2a Does your hospital's pharmacy charge include amounts for anything other than the drug's acquisition cost, such as pharmacy handling costs and/or overhead?

	#	%
Yes	187	59.7
No	109	34.8
Don't know	13	4.2
No response	4	1.3
Total	313	100.0

Q2b If yes, does the additional amount represent costs of: (check all that apply)

	#	%
Storage	128	15.8
Preparation	172	21.3
Transport	144	17.8
Disposal	114	14.1
Record keeping	138	17.0
Other departmental overhead	113	14.0
Total	809*	100.0

* Respondents allowed to indicate more than one choice.

Q2c If yes, is the additional amount designated as a:

	#	%
Dispensing or material management fee	77	47.3
Compounding or mixing fee	24	14.7
Other	62	38.0
Total	163*	100.0

* Respondents allowed to indicate more than one choice.

Q3a If your pharmacy charge master records charges with a mark-up, is the mark-up based on:

	#	%
Direct acquisition cost	97	31.0
Net acquisition cost after discounts/rebates	11	3.5
Medicare's ASP	6	1.9
AWP	175	55.9
Standard cost	7	2.3
Other	6	1.9
No response	11	3.5
Total	313	100.0

Q4a If your charge master records a mark-up, is your hospital charge master's mark-up for drugs at a:

	#	%
Uniform rate	84	26.8
Variable rate	193	61.7
Consistent fixed dollar amount	13	4.2
No response	23	7.3
Total	313	100.0

Q5 If your pharmacy charge master records a mark-up at a variable rate (different percentages depending on the cost of the item), please answer CMS's questions as follows:

Q5a Does your pharmacy charge master apply differential mark-ups only above some threshold (such as $1,000)?

	#	%
Yes	94	50.0
No	94	50.0
Total	188*	100.0

* Plus 125 "non-applicable" or "no response" equals n of 313.

Q5b Does the mark-up change in some uniform fashion with the cost of the service?

	#	%
Yes	93	66.0
No	48	34.0
Total	141	100.0

* Plus 125 "non-applicable" or "no response" equals n of 313.

Q6 [Indicates detail of various mark-up levels and respective dollar ranges]

Q7 Do all drugs charged separately ("drugs charged to patients") reside in the pharmacy section of charge master, rather than being split among various sections?

	#	%
Yes	266	85.0
No	28	9.0
No response	19	6.0
Total	313	100.0

Q8 Which of the following best describes who authorizes changes to your charge master system?

	#	%
Required by corporate home office	56	17.9
Recommended by corporate home office	11	3.5
Determined by individual hospital	211	67.4
Other	24	7.7
No response	11	3.5
Total	313	100.0

Q9 How often are the updates for line item drug products reviewed and changed?

	#	%
Real-time	58	18.6
Monthly	53	16.9
Quarterly	66	21.1
Semi-annually	17	5.4
Annually	89	28.4
Other	18	5.8
No response	12	3.8
Total	313	100.0

Q10a How often is base source for mark-up percentages (such as AWP, ASP, etc) reviewed and changed?

	#	%
Less than one year ago	153	48.9
1-2 years ago	52	16.6
2-5 years ago	19	6.1
More than 5 years ago	41	13.1
Annually	-0-	-0-
Don't know	30	9.6
No response	18	5.7
Total	313	100.0

Q10b How often has the charge master methodology used by your hospital to mark up percentages been reviewed and changed?

	#	%
Less than one year ago	137	43.8
1-2 years ago	54	17.3
2-5 years ago	33	10.5
More than 5 years ago	53	16.9
Annually	-0-	-0-
Don't know	25	8.0
No response	11	3.5
Total	313	100.0

Respondents' Demographics

Q11 Hospital location by Census area:

	#	%
Northeast	63	20.1
Midwest	88	28.1
South	88	28.1
West	52	16.7
No response	22	7.0
Total	313*	100.0

* Responses identified from 45 states.

Q12a Is your hospital location urban or rural?

	#	%
Urban	158	50.5
Rural	155	49.5
Total	313	100.0

Q13a Does your hospital have teaching status?

	#	%
Yes	91	29.1
No	215	68.7
No response	7	.2.2
Total	313	100.0

Q14a Hospital size (# beds)

	#	%
0-99	110	35.1
100-199	62	19.8
200-299	43	13.8
300-499	41	13.1
500+	46	14.7
No response	11	3.5
Total	313	100.0

Q15a Is your hospital a member of a multi-hospital system?

	#	%
Yes	141	45.1
No	167	53.3
No response	5	1.6
Total	313	100.0

Q16a Is your hospital a member of an integrated delivery system (IDS)?

	#	%
Yes	96	30.7
No	202	64.5
No response	15	4.8
Total	313	100.0

Q17a Does your hospital qualify as a DSH hospital?

	#	%
Yes	118	37.7
No	172	55.0
No response	23	7.3
Total	313	100.0

Q18 Which of the following best describes your hospital's structure?

	#	%
Not-for-profit, non-secular	148	47.3
Not-for-profit, secular	65	20.8
Governmental	57	18.2
For-profit	36	11.5
No response	7	2.2
Total	313	100.0

Appendix #1: Cover Letter

[on letterhead]

September 2006

We need your help!

As you may be aware, Medicare payments for drugs under the hospital outpatient prospective payment system and ambulatory payment classifications (APCs) have been significantly reduced during the past few years. The current payment method reflects certain assumptions by the Centers for Medicare and Medicaid Services (CMS) regarding how hospital pharmacies handle charges for complex drugs and biologics.

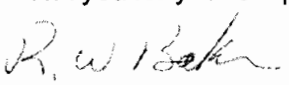
The purpose of the survey is to determine how hospital pharmacy charges vary, and to determine whether the CMS statement ***"...pharmacy overhead costs are already built into the (pharmacy) charges for drugs, biologicals, and radiopharmaceuticals"***[1] *is accurate.*

CMS believes that the current reimbursement for separately payable hospital outpatient drugs of Average Sales Price (ASP) + 6% pays too much for the combined acquisition and overhead costs of hospital pharmacies. As a result, ***CMS has proposed to reduce reimbursement for separately payable hospital outpatient drugs and pharmacy overhead from ASP+6% to ASP+5% commencing January 1, 2007.***

To assess the validity of the CMS assumptions, it is necessary to collect data that can be analyzed and presented to CMS administrators and policymakers. We need your help to obtain this information. Our experience indicates the attached survey can be completed in less than 10 minutes.

By completing the survey you and your hospital will greatly assist the effort to help CMS staff understand HOPD cost structures. A stamped preaddressed envelope is enclosed for your convenience in returning the survey.

Thank you for your cooperation.



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[1] 71 Federal Register 49586 (August 23, 2006).

Appendix #2: Questionnaire

Pharmacy Charges Survey

Your hospital has been selected through a random process to receive this survey. The data will be used for research purposes only. Only aggregated results will be released, thus ensuring that all responses will remain anonymous. Return of the completed questionnaire signifies your agreement to participate in the study.

The purpose of the survey is to determine how hospital pharmacy charges vary, and to determine whether the CMS statement ***"...pharmacy overhead costs are already built into the (pharmacy) charges for drugs, biologicals, and radiopharmaceuticals"***[1] is accurate.

CMS believes that the current reimbursement for separately payable hospital outpatient drugs of Average Sales Price (ASP) + 6% pays too much for the combined acquisition and overhead costs of hospital pharmacies. As a result, ***CMS has proposed to reduce reimbursement for separately payable hospital outpatient drugs and pharmacy overhead from ASP+6% to ASP+5% commencing January 1, 2007. To help us explain the issue, please answer the following.***

1) (a) In your opinion, is the current CMS reimbursement of ASP+6% for separately payable hospital outpatient drugs an adequate amount overall to cover both the drug acquisition cost and the pharmacy overhead? ☐Yes ☐No ☐Don't know

2)(a) Does your hospital's pharmacy charge include amounts for anything other than the drug's acquisition cost, such as pharmacy handling costs and/or overhead?
☐Yes ☐No ☐Don't know

(b) If yes, does the additional amount represent costs of (check all that apply):
- ☐ Storage?
- ☐ Preparation?
- ☐ Transport?
- ☐ Disposal?
- ☐ Record keeping?
- ☐ Other departmental overhead?

(c) If yes, is the additional amount designated as a:
- ☐ Dispensing fee or materiel management fee?
- ☐ Compounding or mixing fee?
- ☐ Other (please explain) _____

3) (a) If your pharmacy charge master records charges with a mark-up, is the mark-up based on:
- ☐ Your direct acquisition cost?
- ☐ Your net acquisition cost after group purchasing discounts or rebates?
- ☐ Medicare's Average Sales Price as listed on the CMS web site?
- ☐ Average Wholesale Price (AWP) as listed in the Red Book or FirstDataBank?
- ☐ Standard cost? (please explain_____)
- ☐ Other? (please explain _____)

3) (b) If your answer to 3(a) above was ASP, how often is the ASP updated in your charge master :

- ☐ Quarterly
- ☐ Semi-annually
- ☐ Annually
- ☐ Other (please indicate) _____

4) (a) If your charge master records a mark-up, is your hospital charge master's mark up for drugs:

(choose one):

- ☐ At a uniform rate (the same percentage for all drugs regardless of cost)
- ☐ At a variable rate (different percentages depending upon drug cost)
- ☐ A consistent fixed dollar amount

4) (b) If your pharmacy charge master records a mark-up at a uniform rate (the same percentage for all drugs regardless of cost), please indicate the mark-up percentage that is used for all drugs:

_____%

5) If your pharmacy charge master records a mark-up at a variable rate(different percentages depending on the cost of the item), please answer CMS's questions as follows:

(a) Does your pharmacy charge master apply differential mark-ups only above some threshold (such as $1,000)? ☐Yes ☐No

OR

(b) Does the mark-up change in some uniform fashion with the cost of the service? ☐Yes ☐No

6) Please list the various mark-up levels and their respective dollar ranges so we may include them in the aggregated survey results

Description of Item(s)	Mark-Up Levels	Dollar Range

7) Do all drugs charged separately ("drugs charged to patients") reside in the pharmacy section of the charge master, rather than being split among various sections? ☐Yes ☐No
(An example of being split among various sections might be chemotherapy drugs placed in the infusion therapy section of the charge master instead of the pharmacy section.)

8) Which of the following best describes who authorizes changes to your charge master system?

- ☐ Required by corporate home office level
- ☐ Recommended by corporate home office level
- ☐ Determined by individual hospital
- ☐ Other (please describe)

9) How often are the updates for line item drug products reviewed and changed?

- ☐ Real-time
- ☐ Monthly
- ☐ Quarterly
- ☐ Semi-annually
- ☐ Annually
- ☐ Other (please indicate) _____

10) (a) How often is the base source for the mark-up percentages (such as AWP, ASP, etc.) reviewed and changed?

- ☐ Less than one year ago
- ☐ 1 to 2 years ago
- ☐ 2 to 5 years ago
- ☐ More than five years ago
- ☐ Don't know

10) (b) How often has the charge master methodology used by your hospital to mark up percentages been reviewed and changed?

- ☐ Less than one year ago
- ☐ 1 to 2 years ago
- ☐ 2 to 5 years ago
- ☐ More than five years ago
- ☐ Don't know

11) State in which hospital is located: _____

12) Hospital location (check one) ☐ Urban ☐Rural

13) Does your hospital have teaching status? ☐Yes ☐No

14) Hospital size (number of beds) _____

15) Is your hospital a member of a multi-hospital system? ☐Yes ☐No

16) Is your hospital a member of an integrated delivery system? ☐Yes ☐No

17) Does your hospital qualify as a DSH hospital? ☐Yes ☐No

18) Which of the following best describes your hospital's structure? (check one)

- ☐ Not-for-profit, non-secular
- ☐ Not-for-profit, secular
- ☐ Governmental [taxing district; state-owned; etc.]
- ☐ For-profit

Comments:

_____

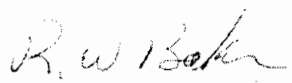
_____

_____

If you would like to receive a summary of this survey's results please fill in the following:

Your Name _____
Title _____
Department _____
Hospital/System _____
Street Address _____
City, State, Zip _____
Email address: _____

Thank you for your participation in this survey.



R.W. Baker, Project Director
The Resource Group

Please return the survey to this address:
Hospital Pharmacy Survey
P.O.Box 1685
Cedar Park, TX 78630

A stamped pre-addressed envelope has been enclosed for your convenience.