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September 15, 2005

Centers for Medicare & Medicaid Services  
Department for Health and Human Services  
Attention: CMS-1500-P  
P.O. Box 8011  
Baltimore, MD 21244-1850

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Ritter  
Burley  
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Hostetter  
Collins  
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Hart  
Bazell

**Re: CMS-1501-P — Medicare Program; Changes to the Outpatient Prospective Payment System and 2006 Rates; Proposed Rule, July 25, 2005 Federal Register**

Dear Dr. McClellan:

On behalf of its 6 member hospitals, the Detroit Medical Center welcomes this opportunity to comment to the Centers for Medicare & Medicaid Services regarding the proposed rule to update the Medicare Outpatient Prospective Payment System for calendar year 2006, as published in the July 25, 2005 *Federal Register*.

The adequacy of Medicare payments to cover the cost of services provided is crucial for ensuring the future viability of the Detroit Medical Center hospitals. Based on the 2004 cost report data, the Detroit Medical Center hospitals experienced a negative margin of 30.7% or \$22.5 million loss on all Medicare outpatient services.

The proposed changes will further threaten the future viability of the Detroit Medical Center hospitals and access to healthcare services for Medicare beneficiaries. **We strongly urge the CMS to incorporate revisions to prevent a further decline in Medicare payment levels.**

**HOSPITAL MARKET BASKET INCREASE**  
(*Federal Register Page 42694-42695*)

The hospital update is based on a "marketbasket" factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish patient care. These price changes must be projected forward to estimate increases for the subsequent year so that an appropriate marketbasket update can be determined in advance of payment. The payment system is prospective, and the update is not retroactively reconciled to reflect actual price increases for the year. Therefore, a reliable projection methodology is vital to ensure equitable payments.

For the hospital inpatient PPS, the FY 2006 inpatient proposed rule included a 3.2 percent update, with the actual increase in the final rule set at 3.7 percent, based upon a change in methodology. **The DMC requests that the CMS revise the marketbasket update included in the final OPSS rule to include a 3.7 percent marketbasket update, consistent with the inpatient final rule.**

## **COST OUTLIER PAYMENT THRESHOLDS**

*(Federal Register pages 42701- 42702)*

The CMS provides outlier payments for individual services or procedures with extraordinarily high costs compared to the payment rates of the APC group. For the 2005 OPSS, outlier payments are made for services with costs that exceed 1.75 times the APC payment rate and the APC rate plus a \$1,175 fixed-dollar threshold. This dual test was intended to eliminate outlier payments for low-cost services and provide higher outlier payments for more expensive procedures.

Since implementation of the OPSS in August 2000, the CMS has set aside a targeted outlier payment pool of 2.0 percent of total OPSS payments. In the proposed rule, the CMS cited the Medicare Payment Advisory Commission's (MedPAC) March 2004 report, which suggests Congress should eliminate the outlier policy under the OPSS. The CMS states that, although elimination of outlier payments would require a statutory change, many of the reasons cited by MedPAC justify a reduction in the size of the outlier payment pool.

For 2006, the CMS is proposing to set a projected target for aggregate outlier payments at 1.0 percent of aggregate total payments under the OPSS. In order to ensure that estimated 2006 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under OPSS, the CMS is proposing that the outlier threshold be modified so that outlier payments are made when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a \$1,575 fixed dollar threshold, which is \$400 more than the current threshold. The CMS will continue to pay 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate when the cost of a hospital outpatient service exceeds these thresholds. The proposed change to reduce the outlier pool by 1 percent will be implemented in a budget-neutral manner by increasing the APC conversion factor by 1 percent.

The DMC is concerned about the re-distributional impact of this change, which we believe is inappropriate. In the inpatient final rule, the CMS indicated its charge estimate was too high, and lowered the threshold considerably in the final rule. If the CMS is using the same charge estimates for purposes of the OPSS proposed rule, then the agency should make a similar adjustment to the methodology used to calculate the threshold in the OPSS final rule. In addition, for the past four years, the CMS set aside two percent of total estimated OPSS payments to fund hospital outlier payments. For 2006, the CMS is proposing to set aside only one percent for outlier payments. However, the agency does not publicly release data regarding how much of the established outlier pool was actually spent in prior years in the *Federal Register* or on its website. Due to the significant changes to outlier policies proposed for 2006, the DMC is concerned that Medicare may not actually spend the entire one percent pool. Therefore, **the DMC strongly recommends that in the final rule, the CMS publish data regarding actual**

**outlier payments made in 2004 and prior years, and to report this data in the future.** We also seek further clarification from the CMS regarding how the \$1,575 fixed dollar threshold was calculated. In addition, we **urge the CMS to maintain the outlier threshold at the current level and to maintain the total outlier pool at the current 2.0 of aggregate OPPS payments.**

## **MULTIPLE DIAGNOSTIC IMAGING PROCEDURES**

*(Federal Register pages 42748 - 42751)*

Currently, hospitals receive a full APC payment for each diagnostic imaging procedure on a claim, regardless of how many procedures are performed using a single imaging modality and whether or not contiguous areas of the body are studied during the same encounter.

In its March 2005 Report to Congress, MedPAC recommended improved Medicare coding edits that would detect unbundled diagnostic imaging services and reduce the technical component payment for multiple imaging services when they are performed on contiguous areas of the body. Currently, payment rates are based on each service being provided independently and the rates do not account for efficiencies that may be gained when multiple studies using the same imaging modality are performed in the same session. For surgical procedures, the OPSS has a longstanding policy of reducing payment for multiple procedures performed on the same patient during the same operative session. In such cases, full payment is made for the procedure with the highest APC payment rate, and each subsequent procedure is paid at 50 percent of its respective APC payment rate.

For 2006, the CMS is proposing to pay 100 percent for the diagnostic imaging procedure with the highest APC payment rate, and pay only 50-percent for each additional imaging procedure when all the procedures are performed during a single patient encounter and all are within an identified "family" of procedures that are commonly billed on the same day. The CMS identified 11 "families" of imaging procedures by imaging modality and by contiguous body area. The agency is proposing to apply the multiple imaging procedure reduction to individual services described by codes within one Family, not across Families. For example, no reduction would apply to an MRI of the brain (CPT code 70552) in code Family 5, when performed in the same session as an MRI of the spinal canal and contents (CPT code 72142) in code Family 6. The CMS is proposing to make full payment for the procedure with the highest APC payment rate, and payment at 50 percent of the applicable APC payment rate for each additional procedure, when performed in the same session. In developing this policy, the CMS did not examine hospital cost data but relied on Medicare physician fee schedule practice expense data for determining the discount level. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the appropriate level of efficiencies obtained by hospitals, if they even exist.

**The DMC opposes moving forward with this policy without solid justification, and more substantial, hospital-based data to support the policy.** We note that the APC Advisory panel came to the same conclusion. Additional concerns include:

- how this policy would be applied; use of the Medicare physician fee schedule practice expense data for determining the level of the discount;
- the policy lacks detail and justification for the 50 percent discount;

- how the CMS would define the “same session”. In some circumstances a patient may have a procedure performed earlier in the day and subsequently on the same day have another procedure that may fall within the same family and incorrectly be subject to the discount.
- how the CMS would ensure that this change is budget neutral.

**PHARMACY OVERHEAD & DRUG HANDLING – PAYMENT RATE ADJUSTMENT**  
*(Federal Register pages 42728 – 42731)*

The MMA required MedPAC to submit a report to the HHS Secretary on adjusting the APC rates for specified covered outpatient drugs, taking into account overhead and related expenses, such as pharmacy services and handling costs. The provision required a recommendation as to whether payment adjustment should be made; and the methodology for adjusting payment, if an adjustment is recommended. MedPAC concluded that the handling costs for drugs, biologicals, and radiopharmaceuticals delivered in the hospital outpatient setting are significant, as medications administered in outpatient departments generally require greater pharmacy preparation time that those provided in the inpatient setting.

For 2006, the CMS did not propose to create separate handling categories for radiopharmaceutical agents. However, for drugs and biologicals, the CMS proposes to establish three distinct HCPCS C-codes and corresponding APCs for drug handling categories to differentiate overhead costs for drugs and biologicals and instruct hospitals to charge the appropriate pharmacy overhead C-code for overhead costs associated with administration of each separately payable drug and biological based on the code description that best reflects the service required by the hospital in preparing the pharmaceutical product for administering to a patient. Since the CMS does not have separate hospital charge data for pharmacy overhead, for 2006, they propose to pay for these costs based on two percent of the Average Sales Price (ASP). This would result in overall drug payments, including the drug itself and the associated handling payment, of ASP + 8 percent which is a rate that the CMS states is equivalent, on average, to the mean cost for drugs derived from hospital claims data.

The DMC agrees with the MedPAC finding that handling costs for drugs and biologicals delivered in the hospital outpatient department are significant and should be reimbursed by Medicare. We believe that, while imperfect, the ASP + 2 percent adjustment for drug handling would be appropriate as a temporary measure. In the future, the CMS should work with hospital and pharmacy stakeholders to develop an approach to establish differential add-on payments for drug handling costs to account for a wide variety of drug handling categories.

The DMC is strongly opposed to the CMS’ proposal to require hospitals to establish separate charges for pharmacy overhead for separately payable drugs and biologicals and to utilize the three proposed C-codes for charging these overhead costs. This would be extremely burdensome for hospitals to implement. There are many complex issues and administratively burdensome aspects to adopting the CMS proposal for charging drug handling through the use of these new C-codes. These issues include:

- Hospitals will have to evaluate the normal mark-up formula for all pharmacy items and pull out the handling costs for some, but not all, of these drugs and biologicals. That is, hospitals would have to identify and strip out the handling charges for separately payable drugs under Medicare while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug.
- For each separately payable drug, hospitals will need to assign the handling charge to one of the CMS' proposed new drug handling C-codes. These codes are only recognized by and acceptable to Medicare, but not other payers. Hospitals will therefore have to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims but bill them as a single line item for other payers. This may be impossible for hospitals to implement as they have uniform charging policies for all payors. In addition, drug pricing is generated via a pharmacy charging system that is often outside the hospital's normal charging system and may not be able to accommodate the CMS proposed C-codes.
- There is confusion regarding how the handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient.
- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, there are questions regarding how the CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

The DMC strongly opposes this expansion of the drug handling C-coding proposal to packaged drugs. This would exponentially increase the coding and administrative burden on hospitals due to the sheer number of drugs that would require special charging practices for Medicare purposes. In addition, we strongly recommend that the CMS does not implement the proposed drug handling C-codes in 2006, but we suggest that the CMS work with stakeholder groups to collect further data and develop alternative and simplified solutions for ensuring that hospitals are appropriately paid for their pharmacy overhead and drug handling costs and the CMS obtains the information that it desires. If the CMS decides to proceed with implementing this burdensome drug-handling C-codes policy, then the DMC strongly suggests that the CMS provide a grace period of no less than 90 days after implementation of the 2006 OPPI, or until April 1, 2006, to allow hospitals to make necessary system changes, educate pharmacy staff, finance staff and coders on the required use of the drug handling "C" codes.

#### **INPATIENT ONLY PROCEDURES LISTING** (*Federal Register pages 42745 – 42746*)

The CMS proposes to remove 25 codes from the "inpatient only" listing—a listing that identifies services for which Medicare does not provide payment if they are performed in an outpatient setting and assigns them to clinically appropriate APCs.

The DMC continues to urge that the CMS entirely eliminate the "inpatient only" list, which undermines clinical decision-making. Physicians, not hospitals, determine where procedures can

be safely performed, as well as whether a patient's medical condition warrants an inpatient admission. If a physician determines that a service can be safely performed in an outpatient setting, under current rules, the hospital is penalized if that procedure is on the "inpatient only" listing. If the "inpatient only" list is not eliminated for 2006, the CMS should consider establishing an appeals process to address circumstances in which payment for a service provided on an outpatient basis is denied because it is on the "inpatient only" list. This would allow the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allowed the patient to safely be sent home without an inpatient admission.

#### **APC RELATIVE WEIGHTS**

*(Federal Register pages 42680 – 42692)*

While the DMC continues to support the use of the most recent claims and cost report data and the inclusion of multi-procedure claims, we request that the CMS provide a public use file that would indicate the impact of each individual proposed methodology change. This would allow health care providers to review the file and determine the specific impact on their own operations while also providing a stronger, more solid basis for helpful comments to the CMS.

#### **PARTIAL HOSPITALIZATION**

*(Federal Register pages 42692 – 42694)*

The DMC is concerned that the 15 percent reduction in the per diem payment rate for partial hospitalization services that the CMS proposed for 2006 could have serious negative consequences on the financial viability of partial hospitalization services in hospitals and health care systems which could endanger Medicare beneficiary access to these vital services. This is particularly concerning since these services are already vulnerable, with many programs closing or drastically limiting the number of patients accepted during recent years.

While we recognize the CMS's proposal was made in order to avoid an even more significant reduction in the payment rate for these services, we do not believe that hospitals that offer partial hospitalization services should be penalized for the instability in data reporting that stems from community mental health center (CMHC) based services. Instead, the DMC recommends that in the final rule for 2006, the CMS freeze payment rates for partial hospitalization services at the 2005 levels. This approach will provide for payment stability for these services while protecting beneficiary access and allowing the CMS adequate time to address the instability in the CMHC data.

#### **BLOOD & BLOOD PRODUCTS**

*(Federal Register pages 42740 – 42742)*

The CMS proposes to continue making separate payments for blood and blood products through individual APCs for each product. The agency also proposes to establish payment rates for blood and blood products based on their 2004 claims data, utilizing an actual or simulated hospital blood-specific cost-to-charge ratio to convert charges to costs for blood and blood products. For blood and blood products whose 2006 simulated medians would experience a

decrease of more than 10 percent in comparison to their 2005 payment medians, the CMS is proposing to limit the decrease in medians to 10 percent.

While this approach results in modest payment increases for many blood and blood product APCs, the payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition cost for blood, most notably for leukocyte-reduced red blood cells, and, with the introduction of additional blood safety measures, it is likely that the cost of these products will continue to increase, making the proposed Medicare payment rate even more inadequate.

**To ensure continued beneficiary access to all blood and blood products, the DMC recommends that CMS set 2006 rates at *the greater of*: (1) the simulated medians calculated using the 2004 claims data; or (2) the 2005 APC payment medians for these products.**

## **OBSERVATION SERVICES**

*(Federal Register pages 42742 – 42745)*

Currently, Medicare provides a separate observation care payment for patients with congestive heart failure (CHF), chest pain, and asthma. In order to reduce administrative burden on hospitals when attempting to differentiate between packaged and separately payable observation services, the CMS proposes to discontinue current HCPCS codes for observation services (G0244, G0263, and G0264) and instead create two new HCPCS codes to be used by hospitals to report all observation services: GXXXX (Hospital observation services, per hour) and GYYYY (Direct admission of patient for hospital observation care). The CMS would shift determination of whether or not observation services are separately payable under APC 0339 from the hospital billing department to the outpatient PPS claims processing logic contained in the Outpatient Code Editor (OCE) system.

**The DMC supports the concept of allowing the OCE logic to determine whether services are separately payable as this will result in a simpler and less burdensome process for ensuring payment for the provision of covered outpatient observation services.** The existing G codes for observation services, with their long, complex descriptors that encompassed all variables required for claim processing into a single code, create a significant administrative burden for hospital coders and billers. We are pleased that CMS has found a method to reduce the burden by simplifying the G codes required for observation services and making changes to the OCE logic.

**However, we believe that the OCE logic could be used even more efficiently by making the HCPCS code GYYYY (Direct admission of patient for hospital observation care) unnecessary.** If the hospital bills the GXXXX code and the claim *does not* include a 45X (emergency department) or 516 (urgent care center) revenue code, then OCE logic should determine that this was a direct admission to observation care. If the hospital bills the GXXXX code with a 45X or 516 revenue code, then it is clear that the patient came in through ED or

urgent care center. Once such logic is programmed into the OCE, it would be up to the system to determine whether the observation is a result of a direct admission or not and pay accordingly.

**The DMC seeks clarification regarding the reference to inpatient status in the statement on page 42743 in the proposed rule that states “That is, hospitals would bill GXXXX when observation services are provided to any patient admitted to ‘observation status,’ regardless of the patient’s status as an *inpatient* [emphasis added] or outpatient.”** We are concerned about this statement because if a patient is admitted as an inpatient, the hospital would not report HCPCS codes, but instead would be using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes since ICD-9-CM is the Health Insurance Portability and Accountability Act code set standard for reporting procedures for hospital inpatient reporting.

### **PAYMENT FOR INTERRUPTED PROCEDURES** *(Federal Register pages 42751 – 42753)*

The CMS proposes to decrease payment from 100 percent to 50 percent for interrupted procedures coded with modifiers 52 (discontinued procedure, no anesthesia provided) or 74 (procedure discontinued after administration of anesthesia). However, no analysis was conducted to support the reduction.

These modifiers cannot be used for elective cancellations; therefore, the procedures generally have been interrupted due to clinical reasons. In the event that a procedure is interrupted because a patient is having medical problems, costs may actually increase, not decrease, as the team addresses the patient’s needs. Detailed claims analysis is needed to determine whether these additional costs could be covered through additional billed services or not. In any event, much of the hospital’s costs have already been incurred at this point. For example, the operating room will have been occupied during the start of the procedure and must still be prepared for the next patient. Similarly, sterile supplies will have been opened and will either be disposed of or be reprocessed at additional cost.

**The DMC believes that before the CMS establishes reductions in payments for procedures billed using these modifiers, there must be evidence supporting the need for payment reductions and the level of reductions that would be applied.**

### **PHYSICIAN OVERSIGHT OF NON-PHYSICIAN PRACTITIONERS** *(Federal Register pages 42753 – 42754)*

**The DMC supports the CMS’s proposal to defer to State law regarding the need for physicians to review and sign the medical records for outpatients cared for by non-physician practitioners in critical access hospitals (CAHs). However, we also recommend that the CMS extend the application of this policy to physician review of inpatient records for patients cared for by non-physician practitioners.** If state law permits these practitioners to practice independently, the CMS should not require physician oversight in either the outpatient or inpatient setting. We agree that State laws providing independent practice authority

generate sufficient control and oversight of these non-physician practitioners and we do not believe that quality of care is reduced by non-physician practitioners.

The DMC also supports the additional flexibility the CMS adds under this proposed policy for those states that do not allow for independent practice of non-physician practitioners – in particular permitting the facility to establish policy regarding the sample size of outpatient records to be reviewed and signed, consistent with current standards of practice.

Thank you for your review and consideration of these comments. If you have any questions, please contact me at (313) 578-2820 or via email at [mpelc@dmc.org](mailto:mpelc@dmc.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Pelc". The signature is fluid and cursive, with the first name being the most prominent.

Michael A. Pelc  
Vice President, Finance  
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September 1, 2005

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**Re: CMS-1501-P; Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule; Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status (Non Pass-Throughs)**

Dear Administrator McClellan:

Amgen is writing to comment on the calendar year 2006 Medicare hospital outpatient prospective payment system (OPPS) proposed rule (Proposed Rule), which the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register on July 25, 2005.<sup>1</sup> As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals (collectively referred to in this letter as "drugs" following the agency's convention) for Medicare beneficiaries. For this reason, our comments address the "Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status" section of the Proposed Rule as it applies to all separately payable drugs and to our innovative biological product, Aranesp<sup>®</sup> (darbepoetin alfa), in particular.<sup>2</sup>

Amgen commends the agency on its proposal to use a free market-based approach to set the OPPS payment rates for separately payable drugs, including Aranesp<sup>®</sup>. The proposed payment methodology for all separately payable drugs would allow the payment rates for these products to reflect market dynamics and would encourage the desired market adaptations that manufacturers and hospitals make to remain competitive. Regarding Aranesp<sup>®</sup> in particular, CMS accurately notes in the Proposed Rule that "the ASP [average sales price] data represents market prices for this biological" and that using the ASP methodology to establish the 2006 OPPS payment rate for Aranesp<sup>®</sup> "will permit market forces to determine the appropriate payment for this biological."<sup>3</sup> For these reasons, CMS

<sup>1</sup> 70 Fed. Reg. 42674.

<sup>2</sup> Aranesp<sup>®</sup> is indicated for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies and for the treatment of anemia associated with chronic renal failure, including patients either on dialysis or not on dialysis.

<sup>3</sup> 70 Fed. Reg. 42727.

has proposed not to apply an "equitable adjustment" under Section 1833(t)(2)(E) of the Social Security Act to the payment rate of Aranesp<sup>®</sup> in 2006. We recommend that CMS finalize these proposals as they appear in the Proposed Rule.

Below, we provide our comments on the proposed payment methodology for separately payable drugs. Additionally, we present further evidence to support the treatment of Aranesp<sup>®</sup> under the Proposed Rule.

***We support the proposed payment of ASP+6 percent for separately payable outpatient drugs and encourage CMS to finalize this proposal.***

We are pleased that CMS is attempting to pay hospitals at rates reflective of the costs that they incur to purchase drugs and biologicals. Because reported ASP data are based on the prices paid in the market for drugs and biologicals, we support the CMS proposal to set payment at ASP+6 percent and to add an additional percentage to reflect pharmacy handling costs. Section 1847A of the Social Security Act mandated the implementation in 2005 of the ASP+6 percent methodology for drugs and biologicals covered in the physician office setting, and CMS has recently proposed paying for all separately payable drugs administered in dialysis facilities at ASP+6 percent.<sup>4</sup> By expanding this payment methodology to separately payable drugs covered under OPSS in 2006, payment rates would be made consistent across these three primary settings of outpatient care. For these reasons, Amgen encourages CMS to finalize this proposal as it appears in the Proposed Rule.

***We also support additional payments for pharmacy overhead costs.***

As the Medicare Payment Advisory Commission (MedPAC) recommended in its June 2005 report to the U.S. Congress, separate payment for pharmacy costs is needed because these costs would not be accounted for in acquisition-based payment for drugs under OPSS in 2006. The Commission correctly concluded that hospital handling costs for drugs, biologicals, and radiopharmaceuticals are "not insignificant."<sup>5</sup> Therefore, the CMS proposal is a positive step towards providing more appropriate payment for the costs associated with providing drugs in the hospital outpatient setting, and we urge the agency to implement the proposal to pay hospitals separately for pharmacy overhead costs.

***By implementing market-based pricing and eliminating the "equitable adjustment" for Aranesp<sup>®</sup>, as CMS proposes, Medicare and its beneficiaries will pay less for comparable clinical outcomes.***

In past years, OPSS payments for separately payable drugs have been determined under different methodologies, and CMS has applied an "equitable adjustment" using a dose conversion ratio despite extensive submissions showing the clinical comparability of Aranesp<sup>®</sup> and Procrit<sup>®</sup> as well as lower costs of Aranesp<sup>®</sup>. With the implementation of the proposed market-based payment rates for all separately payable drugs, including Aranesp<sup>®</sup>, it is clear that an "equitable adjustment" is not needed in 2006. CMS correctly notes this fact in the Proposed Rule.<sup>6</sup>

<sup>4</sup> 70 Fed. Reg. 45846.

<sup>5</sup> MedPAC (2005). *Report to the Congress: Issues in a Modernized Medicare Program*.  
[http://www.medpac.gov/publications/congressional\\_reports/June05\\_Entire\\_report.pdf](http://www.medpac.gov/publications/congressional_reports/June05_Entire_report.pdf).

<sup>6</sup> 70 Fed. Reg. 42727.

By setting payment rates using market-based prices that reflect the value that other payers, physicians, and, in other settings, even the Medicare program ascribe to products, there is no need for CMS to impose its regulatory authority to adjust pricing in the case of Aranesp<sup>®</sup> and Procrit<sup>®</sup> in 2006. In fact, such a measure merely would create distortions in the market, which are not needed given the agency's clearly stated position that the ASP+6 payment system reflects market-based pricing. Furthermore, as we will demonstrate below, there are clear and compelling clinical and economic data to support the agency's proposal not to apply an "equitable adjustment" in 2006.

***Clinical practice guidelines support the clinical comparability of Aranesp<sup>®</sup> and Procrit<sup>®</sup> at commonly administered doses.***

The treatment of Aranesp<sup>®</sup> under the Proposed Rule is fully consistent with well-established clinical practice guidelines, which have been validated by randomized, comparative clinical trials. Most notably, the National Comprehensive Cancer Network (NCCN) *Clinical Practice Guidelines in Oncology<sup>™</sup>: Cancer and Treatment-Related Anemia* and the U.S. Pharmacopeia Drug Information (USP DI<sup>®</sup>) monograph list the commonly used initial dose of Aranesp<sup>®</sup> at approximately 200 micrograms (mcg) every other week (Q2W).<sup>7</sup> Amgen's clinical submissions to CMS in 2003 and 2004 demonstrated that Aranesp<sup>®</sup> under these guidelines achieve comparable clinical outcomes to commonly administered doses of Procrit<sup>®</sup>.<sup>8,9</sup>

***Definitive head-to-head, randomized controlled trials of Aranesp<sup>®</sup> and Procrit<sup>®</sup> confirm the validity of the clinical practice guidelines.***

CMS should also be aware that Amgen's 2003 and 2004 submissions have now been validated by randomized, head-to-head clinical trials, which represent the highest standard of evidence to evaluate comparative effectiveness.<sup>10,11</sup> These new trials have been added to the established evidence base regarding the comparability of clinical outcomes of Aranesp<sup>®</sup> 200 mcg Q2W and Procrit<sup>®</sup> 40,000 international units (IUs) every week (QW) for chemotherapy-induced anemia patients. Among these studies is a properly powered, 1,200-person, non-inferiority trial that represents the optimal methodology to address the question of clinical comparability. These studies demonstrated the following key points:

- Comparable clinical outcomes between Aranesp<sup>®</sup> and Procrit<sup>®</sup> were observed in clinically relevant, well-established endpoints, indicating that the products are comparable at 200 mcg Q2W and 40,000 IUs QW, respectively;

<sup>7</sup> Sabbatini (2004). *Clinical Practice Guidelines in Oncology<sup>™</sup>: Cancer and Treatment-related Anemia*. [http://www.nccn.org/professionals/physician\\_gls/f\\_guidelines.asp](http://www.nccn.org/professionals/physician_gls/f_guidelines.asp); Klasco, R, Ed. (2004). Darbepoetin alfa (systemic). *USP DI<sup>®</sup> Drug Information for the Healthcare Professional*. Greenwood Village, Colorado, Thomson Micromedex. Note that the USP DI<sup>®</sup> monograph references weight-based dosing.

<sup>8</sup> "Darbepoetin Alfa Briefing Document" prepared for the meeting between Amgen and CMS on April 28, 2003.

<sup>9</sup> Data from Amgen Inc., submission on the 2005 OPPTS proposed rule, dated October 7, 2004.

<sup>10</sup> Glaspy, J., R. Berg, et al. (2005). Final results of a phase 3, randomized, open-label study of darbepoetin alfa 200 mcg Q2W versus epoetin alfa 40,000 IUs QW in patients with chemotherapy-induced anemia. 41st Annual Meeting. Orlando, FL, American Society of Clinical Oncology: Presented at the 41st Annual Meeting of the American Society of Clinical Oncology.

<sup>11</sup> Schwartzberg, L., L. Yee, et al. (2004). "A randomized comparison of every-2-week darbepoetin alfa and weekly epoetin alfa for the treatment of chemotherapy-induced anemia in patients with breast, lung, or gynecologic cancer." *Oncologist* 9(6): 696-707.

- Aranesp<sup>®</sup> was also shown to be clinically comparable (as defined by the pre-specified non-inferiority margin) to Procrit<sup>®</sup> with respect to transfusion requirements, the sole clinical factor recognized by the U.S. Food and Drug Administration, as well as other standard, validated clinical factors, including hemoglobin outcomes; and
- Patients and the Medicare program receive substantial economic and other benefits from the convenient once every-2-week dosing schedule with Aranesp<sup>®</sup>, which requires half the number of injections than Procrit<sup>®</sup>.

Amgen will continue to share new clinical developments regarding Aranesp<sup>®</sup> with CMS.

***Aranesp<sup>®</sup> costs Medicare and beneficiaries less than Procrit<sup>®</sup>.***

Aranesp<sup>®</sup> is less expensive than Procrit<sup>®</sup> at the payment rates that CMS published in the Proposed Rule, as noted in Table 1. By applying the proposed payment rates for doses based on the aforementioned clinical guidelines and validated in randomized controlled trials, the Medicare program will pay less for Aranesp<sup>®</sup> than Procrit<sup>®</sup> and achieve the same clinical outcomes.

**Table 1: Comparison of Proposed Weekly OPPS Payments for Aranesp<sup>®</sup> and Procrit<sup>®</sup>**

	<b>Procrit<sup>®</sup></b>	<b>Aranesp<sup>®</sup></b>
<b>Weekly Dose</b>	40,000 IUs (40,000 IUs QW)	100 mcg (200 mcg Q2W)
<b>Dosing Assumption Source</b>	Clinical Guidelines and Head-to-Head, Randomized Controlled Trials	Clinical Guidelines and Head-to-Head, Randomized Controlled Trials
<b>Proposed OPSS Payment</b>	\$9.99 per 1,000 IUs (Proposed Rate for Q0136 <sup>12</sup> )	\$3.28 per 1 mcg (Proposed Rate for Q0137 <sup>12</sup> )
<b>Total Weekly Payment</b>	\$399.60 (\$9.99 x 40)	\$328.00 (\$3.28 x 100)
<b>Payment Comparison</b>	<b>Medicare and Beneficiary Payments are \$71.60 Less per Week, per Patient with Aranesp<sup>®</sup> on Average</b>	

Based on dosing referenced in clinical guidelines, the Medicare payment would be, on average, \$71.60 less per week, per patient for Aranesp<sup>®</sup> than Procrit<sup>®</sup>. Of that total amount, beneficiaries would be responsible for \$14.32 less per week in Part B copayments. Additionally, due to the less frequent dosing pattern of Aranesp<sup>®</sup>, Medicare and its beneficiaries would also pay less for drug administration and related hospital outpatient services for Aranesp<sup>®</sup> than for Procrit<sup>®</sup>, as shown in Table 2.

<sup>12</sup> 70 Fed. Reg. 50880.

**Table 2: Comparison Including the Proposed Weekly OPPS Payment Amounts for Services Related to Aranesp® and Procrit®**

<b>Assumptions<sup>13</sup></b>	<b>Procrit®</b>	<b>Aranesp®</b>
<b>Drug Administration Services</b>	<b>CPT® code 90782 (injection SC/IM)</b>	
<i>Injections (APC 0353) per 2 weeks<sup>14</sup></i>	2 at \$23.46	1 at \$23.46
<i>Total Medicare payment</i>	\$46.92	\$23.46
<b>Hospital Outpatient Visits</b>	<b>CPT® code 99211/2 (outpatient visit, established)</b>	
<i>Visits (APC 0600) per 2 weeks<sup>15</sup></i>	2 at \$51.56	1 at \$51.56
<i>Total Medicare payment</i>	\$103.12	\$51.56
<b>Total 2-Week Service Payments</b>	\$150.04	\$75.02
<b>Total 2-Week Payment Comparison Including Services and Product Doses</b>	<b>Medicare and Beneficiary Payments are <u>\$218.22 Less</u> per Patient, per 2 Weeks with Aranesp® on Average</b>	
<b>Weekly Payment Comparison Including Product Doses</b>	<b>Medicare and Beneficiary Payments are <u>\$109.11 Less</u> per Patient, per Week with Aranesp® on Average</b>	

Based on the lower costs of Aranesp® as outlined in Table 2, the Medicare program and its beneficiaries would pay about an estimated \$15.3 million less for Aranesp® vs. Procrit® in 2006.<sup>16</sup> In light on the clearly demonstrated lower costs of Aranesp®, CMS should finalize the proposed payment rate for the product.

***In summary, we agree with the agency's proposal for Aranesp® and other separately payable drugs.***

As CMS prepares to finalize changes to OPPS for 2006, we recommend the following:

- adopt the market-based ASP+6 percent methodology to set payment rates for separately payable drugs,
- implement the proposal to pay hospitals separately for pharmacy overhead costs, and
- finalize the proposed market-based treatment of Aranesp® in order to achieve significant Medicare payment reductions and savings for beneficiaries.

<sup>13</sup> This comparison assumes the provision of one administration service and one hospital outpatient visit on the date that the drug is delivered. Because actual services rendered depend on the needs of specific patients, patients may receive an administration service, an outpatient visit, both services, or some other combination of services on a particular date of service.

<sup>14</sup> The amount used in this analysis represents the 2006 proposed national average Medicare payment allowable, including the beneficiary copayment for APC 0353. 70 Fed. Reg. 50811.

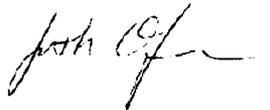
<sup>15</sup> The amount used in this analysis represents the 2006 proposed national average Medicare payment allowable, including the beneficiary copayment for AP6 0600. The most commonly billed levels of outpatient visits on the same dates of service with Procrit® injections are CPT® 99211 and 99212, which both map to APC 0600. 70 Fed. Reg. 50822.

<sup>16</sup> Estimate based on data from an independent analysis of 2004 OPPS claims conducted by The Moran Company. Data on file.

\* \* \* \* \*

Amgen appreciates this opportunity to comment on the important issues raised in the Proposed Rule and looks forward to working with you to ensure that Medicare beneficiaries treated in the hospital outpatient setting continue to have access to new and important biological therapies. Please contact Chris Mancill by phone at (202) 585-9618 or by email at [cmancill@amgen.com](mailto:cmancill@amgen.com) to arrange a meeting or if you have any questions regarding our comments. Thank you for your attention to this important matter.

Regards,



Joshua J. Ofman, MD, MSHS  
Vice President,  
Reimbursement and Payment Policy



David Beier  
Senior Vice President,  
Global Government Affairs

cc: Ms. Leslie Norwalk, Deputy Administrator, CMS  
Mr. Herbert Kuhn, Director, Center for Medicare Management, CMS  
Ms. Elizabeth Richter, Director, Hospital and Ambulatory Policy Group, CMS  
Dr. Barry Straube, Acting Chief Medical Officer, Acting Director of the Office of Clinical Standards and Quality, CMS  
Dr. Peter Bach, Senior Advisor, Office of the Administrator, CMS  
Dr. Steve Phurrough, Director, Coverage and Analysis Group, CMS  
Mr. Jim Hart, Director, Division of Outpatient Care, CMS  
Ms. Joan Sanow, Deputy Director, Division of Outpatient Care, CMS  
Dr. Carol Bazell, Medical Officer, Hospital and Ambulatory Policy Group, CMS  
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M. Cory Zwerling  
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CCRS  
NPT/P/R/R

September 14, 2005

Ritter  
Ahmed  
Kane  
Sarnow  
Hart  
Bazell

Mark McClellan, M.D., Ph.D.  
Administrator, Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Rm. 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: CMS-1501-P Proposed Changes to the Hospital Outpatient Prospective Payment System: Radiopharmaceuticals and Medical Imaging Drugs - Non-Pass Throughs**

Dear Administrator McClellan:

On behalf of Bristol-Myers Squibb Medical Imaging Inc., I appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule: Medicare Program, Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Calendar Year 2006 Payment Rates. (70 Fed. Reg. 42,674; July 25, 2005)

As one of the leading manufacturers of radiopharmaceuticals and other medical imaging drugs, Bristol-Myers Squibb Medical Imaging has a keen interest in CMS's proposed changes in HOPPS for 2006. In addition, we support CMS's efforts to maintain consistency in payment for radiopharmaceuticals to preserve beneficiary access and recognize the complexity of radiopharmaceuticals especially with respect to handling and overhead costs.

Bristol-Myers Squibb Medical Imaging is concerned, however, that CMS has not fully integrated the unique features of radiopharmaceuticals into workable reimbursement methods under a cost-to-charge ratio approach in 2006, or an ASP approach in 2007. Further refinements and alternatives are needed. Bristol-Myers Squibb Medical Imaging agrees with CMS that any changes should avoid drastic reductions in payment for radiopharmaceuticals from 2005 to 2006 and thus preserve beneficiary access to radiopharmaceuticals and nuclear medicine procedures. Our comments and recommendations are summarized in section I and discussed in greater detail in the following sections.

**I. Summary Recommendations**

**Payment for Radiopharmaceuticals in 2006**

- **Consider cost-to-charge ratio (CCR) methodology an "interim" basis for payment.** CMS has proposed using CCR methodology in 2006 to pay for radiopharmaceuticals. In comments on HOPPS in previous years, many stakeholders have provided detailed evidence of the "charge compression" problem by which CCR-based estimates of cost fall substantially below actual costs for many radiopharmaceuticals. Using CCRs may result in serious payment distortions for many radiopharmaceuticals—some hospitals will be paid significantly less than their actual costs while others may be paid in excess of their costs. **For this reason, we recommend that CMS:**

1. **Use the CCR applicable to the overall hospital and not department specific CCR;**
  2. **Publish the CCRs that will be used to calculate the hospital outpatient payment for radiopharmaceuticals; and**
  3. **Use the 2005 payment rates for radiopharmaceuticals as the default for payment if a hospital's charge reduced to cost falls below 95 percent of the 2005 payment rates.**
- **Ensure access to radiopharmaceuticals and nuclear medicine procedures by implementing the payment adjustments described above when necessary.**

### **Payment for Radiopharmaceutical Handling Costs**

The MedPAC Report on Pharmacy Handling Costs in Hospital Outpatient Departments noted that, on average, pharmacy handling and overhead costs for drugs ranged from 25 to 28 percent.<sup>1</sup> The MedPAC Report recommended seven categories of drugs for which CMS should pay "handling" costs. Of the seven categories, radiopharmaceuticals had the highest handling costs of all drugs. In the proposed rule, CMS proposed to create three categories for drug handling costs and requested comments on categories for radiopharmaceuticals. In the interim, CMS has proposed paying an additional two percent for drugs (but not radiopharmaceuticals) to cover handling costs until the claim file data becomes available.

Handling costs for radiopharmaceuticals are not accurately reflected in hospitals' charges for the product. **For this reason, CMS should:**

- **Adjust payments to include an additional 25 to 28 percent for handling costs of radiopharmaceuticals until hospital charge data are available.**

New HCPCS codes will be needed for CMS to establish payment for handling costs in 2007 and beyond. Therefore, if CMS proceeds with its proposal to implement HCPCS codes to report handling for other pharmaceuticals beginning in 2006, we recommend that **CMS also adopt parallel codes to report radiopharmaceutical handling costs** (preferably G codes that could be used on claims for all payers). If, however, CMS delays implementation of these codes to consider comments from hospitals about the feasibility of requiring institutions to report these charges separately, then it would be appropriate to delay the adoption of codes for radiopharmaceutical handling until these issues can be resolved.

- **Eliminate threshold for separate payment of radiopharmaceuticals** to facilitate appropriate payment for the pharmacy handling costs associated with radiopharmaceuticals.
- **Require hospitals to report HCPCS codes for all radiopharmaceuticals** to help ensure that the costs and charges for these products, as well as the associated handling costs, are considered in establishing payment rates under HOPPS.

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<sup>1</sup> MedPAC Report to the Congress, Chapter 6 at 140, June 2005.

### **Payment for Radiopharmaceuticals Beyond 2006**

CMS proposes to require radiopharmaceutical manufacturers to report ASP beginning in 2006 and proposes to pay for radiopharmaceuticals using ASP data beginning in 2007.

- ASP reporting by radiopharmaceutical manufacturers and the determination of payment based on ASP presents some unique challenges and raises significant problems that need to be fully addressed if any type of ASP system is to be utilized. Therefore, **we recommend that CMS continue payment based on CCR until these ASP issues are fully explored and discussed with all stakeholders.**

Looking ahead, if some form of ASP data is used as a basis for payment, CMS should:

- Qualify manufacturer reporting—i.e., manufacturers cannot certify sales prices by radiopharmacies;
  - Use a weighted average that includes manufacturer and radiopharmacy ASP data;
  - Conduct surveys of the relationship between end-user acquisition cost at the HCPCS level (from independent radiopharmacies and hospital radiopharmacies) and the manufacturer-reported ASPs;
  - Work with stakeholders to determine the appropriate cross-walk between NDCs and HCPCS; and
  - Develop a specific proposal regarding the appropriate methodology for reporting and using ASP data for the payment of radiopharmaceuticals and allow stakeholders the opportunity to comment upon the proposal before it is finalized.
- 
- **Establish HCPCS descriptors based on “per-dose” units for radiopharmaceuticals** so that charges and costs can be tracked in a more effective, accurate manner. Specifically, we urge CMS hospital outpatient staff to work with the HCPCS coding team to implement recommendations submitted by the Council on Radionuclides and Radiopharmaceuticals (CORAR) to modify HCPCS descriptors and we ask that CMS publish these changes in the Final Rule.
  - **Implement new HCPCS codes for contrast echocardiography drugs, including DEFINITY<sup>®</sup>, Vial for (Perflutren Lipid Microsphere) Injectable Suspension, which will be effective January 1, 2006,** to facilitate uniform billing for all contrast echocardiography drugs across all sites of service.
  - **Confirm payment for contrast echocardiography drugs will be based on ASP + six percent + an appropriate amount to reflect handling (no less than two percent)** so that payment for these drugs is consistent with all other separately paid drugs under HOPPS.

## **II. DETAILED COMMENTS AND RECOMMENDATIONS**

### **A. Payment Options for Radiopharmaceuticals in 2006 - CCR**

HOPPS payment for radiopharmaceuticals is currently based on a percentage of average wholesale price and/or median cost data. For 2006, CMS is required to pay separately for

specified covered outpatient drugs, including radiopharmaceuticals on the basis of average acquisition cost. To facilitate this transition, Congress required GAO to conduct a survey to gather average acquisition price information for CMS's consideration in establishing payment rates. Congress also specified that CMS could vary payment based on hospital group or other relevant characteristics. If hospital acquisition cost data were unavailable, CMS has discretion to set payment based on § 1842(o) which is the Medicare Part B payment methodology for drugs. Depending upon the type of drug, Part B payment may be based on the lesser of ASP or wholesale acquisition cost, or competitive acquisition in 2006. There was special authority in the Medicare Modernization Act of 2003 (Section 303(h)) to continue the payment methodologies for radiopharmaceuticals, including the use of invoice pricing by Medicare carriers. CMS acknowledged in its ASP regulations that radiopharmaceuticals were exempt from reporting ASP.

CMS has indicated that it will not use the GAO data for traditional drugs or radiopharmaceuticals to establish payment rates. This may be appropriate for most traditional drugs because CMS has more current ASP data as compared to the GAO data. However, since radiopharmaceuticals are not paid based on ASP, CMS had not required manufacturers to report ASP, recognizing the challenges associated with these unique products. Consequently, as an alternative to ASP, CMS has proposed using cost-to-charge (CCR) methodology.

The CCR payment methodology presents many significant challenges for hospitals, including: setting appropriate charges consistent with the hospital specific CCR; maintaining contracts based on charges in light of this change in Medicare policy; and whether CMS uses a particular hospital's overall CCR or the department specific CCR. Department specific CCRs reflect charge practices for radiology, pharmacy or medical supply products that are quite different than radiopharmaceuticals. Typically, the ratios for these departments do not reflect the costs and complexity of radiopharmaceuticals. In addition, implementing and managing payments based on department CCRs will be a tremendous administrative burden to hospitals and CMS.

As an alternative, CMS could consider current 2005 payment rates as a default payment standard, if use of the CCR results in a payment that falls below 95 percent of the current rate. This would accomplish CMS's goal of avoiding severe payment cuts and establishing a smoother transition from 2005 to 2006.

In light of these difficult challenges, and to ensure that Medicare patients continue to receive high quality cardiac diagnostic care that does not suffer from payment barriers, **we recommend that CMS:**

- 1. Use the CCR payment methodology as an "interim" approach;**
- 2. Use the overall hospital CCR to calculate payment;**
- 3. Publish the CCRs that will be used to calculate the hospital outpatient payment for radiopharmaceuticals; and**
- 4. Use the current 2005 payment rates for radiopharmaceuticals as the default for payment if a hospital's charge reduced to cost falls below 95 percent of the 2005 payment rates.**

Using the 2005 payment rates as the default payment is supported by CMS's findings that --

- Pharmacy handling costs for non-radiopharmaceutical drugs is 25 to 28 percent;
- Pharmacy handling and overhead costs for radiopharmaceuticals are higher than other drugs;

- ASP is a proxy for average acquisition costs; and
- Current payment rates represent ASP + 22 percent (presentation by CMS staff at meeting of Advisory Panel on Ambulatory Payment Classification Groups [August 17, 2005]).

Using the 2005 rates as the "default" for payment of radiopharmaceuticals (assuming the rates would represent ASP + 22 percent) is an especially equitable approach because MedPAC's study of hospital drug overhead costs confirmed that radiopharmaceuticals have the highest relative overhead costs of all the drugs studied.

Further, pharmacy handling, supply and labor costs are not included in the hospital charges for the radiopharmaceuticals. Even so, CMS presents an assumption, presented initially by MedPAC, which we believe incorrectly states that such overhead costs are included in the hospital reported charges. See 70 Fed. Reg. at 42,727. To ensure all assumptions about radiopharmaceuticals are correct, we strongly urge CMS to consider the clarifying letters sent to MedPAC by CORAR and the Society for Nuclear Medicine which state that in many cases, hospitals do not include such overhead costs in charges.

#### **B. Radiopharmaceutical Overhead Pharmacy Costs**

CMS proposes to establish three separate C-codes and make separate payment for drug handling costs for all drugs with the exception of radiopharmaceuticals. CMS is proposing to exempt radiopharmaceuticals from this handling cost provision for CY2006 because the agency believes that these costs will be captured under the proposed CCR radiopharmaceutical payment. However, because the handling costs would not be captured in future years under ASP payments, CMS has requested specific comments on the appropriate categories or C-codes for capturing radiopharmaceutical handling costs. According to CMS, the handling cost categories/codes should include all aspects of radiopharmaceutical handling and payment, including: transportation, storage, compounding, shielding, inventory management, revision of doses, short half-life, intended use of the product, and whether the product is prepared "in-house" or in a commercial radiopharmacy.

We agree fully with CMS's recognition of the complex drug handling and overhead costs associated with radiopharmaceuticals. CMS has not, however, translated this recognition into payment policy. We recommend that CMS establish four G-codes for radiopharmaceutical handling costs. Diagnostic radiopharmaceuticals should be categorized separately from therapeutic radiopharmaceuticals/radionuclides. Handling costs for radiopharmaceuticals prepared or compounded in the hospital and the handling costs for radiopharmaceuticals purchased by hospitals in unit dose preparations should also be differentiated. Overhead costs of radiopharmaceuticals are quite diverse because there are different models of how radiopharmaceuticals are prepared, patient and hospital staff safety costs, as well as survey costs and disposal. We understand, as reported by MedPAC, that overhead costs are higher for radiopharmaceuticals than other drugs and that overhead for drugs in general is about 25 to 28 percent.

Overhead and handling costs for radiopharmaceuticals that are compounded by hospitals include costs for special equipment needed for shielding, preparation, waste, disposal and safety. In addition, while perhaps less obvious, hospitals that purchase unit-dose preparations have significant overhead and handling costs. For example, hospitals must still order the product, receive and check in the product, a process that includes conducting dose calibration to ensure that the product, as delivered, contains the appropriate level of radioactivity. In

addition, following injection, hospitals must conduct radiation surveys of the patient area, document the use and/or wastage of the radiopharmaceutical. Hospitals also have special handling costs related to items that were in contact with the patient and were potentially soiled or contaminated with radioactive material. For example, hospitals must transfer, store in special lead-lined containers and dispose of IV tubing, patient gowns, sheets, etc. Proper disposal also entails unique costs and challenges.

**For this reason, we recommend CMS establish the following codes and APCs for capturing and reimbursing hospitals for their radiopharmaceutical handling costs.**

1. G1111 Diagnostic radiopharmaceutical (not compounded by hospital) requiring special handling, protective shielding and monitoring;
2. G2222 Therapeutic radiopharmaceutical (not compounded by hospital) requiring special handling, protective shielding and monitoring;
3. G3333 Diagnostic radiopharmaceutical (compounded and requiring calculations performed correctly and then compounded correctly by hospital) requiring special handling, protective shielding and monitoring; and
4. G4444 Therapeutic radiopharmaceutical (compounded and requiring calculations performed correctly and then administered correctly by hospital) requiring special handling, protective shielding and monitoring.

If CMS proceeds with its proposal to implement "C" or "G" codes to report handling for other pharmaceuticals beginning in 2006, we would recommend that CMS also adopt parallel "G" codes to report radiopharmaceutical handling costs. If, however, CMS delays implementation of these codes to consider comments from hospitals about the feasibility of requiring institutions to report these charges separately, then it would be appropriate to delay the adoption of codes for radiopharmaceutical handling until these issues can be resolved for ALL pharmaceuticals including radiopharmaceuticals.

### **C. ASP Reporting and ASP-Based Payment for Radiopharmaceuticals**

As noted above, radiopharmaceuticals/radionuclides are very specialized drugs used in diagnostic and therapeutic nuclear medicine procedures. Most radiopharmaceuticals are composed of two key components (radioactive and non-radioactive) that can be sold separately by different manufacturers. Radiopharmaceutical manufacturers typically sell radiopharmaceutical kits that can contain the first (non-radioactive) component to specialized radiopharmacies. In turn, the radiopharmacies may buy the second (radioactive) component separately from the same supplier or from another manufacturer. This is often the case with technetium (Tc 99m) based radiopharmaceuticals, such as Cardiolite<sup>®</sup> (Kit for the Preparation of Technetium Tc 99m Sestamibi for Injection). The radiopharmacy then prepares radiopharmaceutical unit doses, combining the two components, which are sold to the provider. In other cases, hospitals can also buy components from different suppliers.

As a result of the unique features of radiopharmaceuticals, including their preparation, radiopharmaceutical manufacturers generally do not have average sales prices for the finished end product that is described by the HCPCS billing code. In fact, Congress authorized the continuation of Medicare Part B payment for radiopharmaceuticals because manufacturers do not have ASPs for the HCPCS unit doses, which are the relevant unit under Medicare Part B for payment. For these reasons, we strongly believe that ASP reporting by manufacturers alone,

may not be a reasonable methodology for establishing "average hospital acquisition costs" of radiopharmaceuticals.

**We believe that ASP could possibly be adapted to unique features of radiopharmaceuticals.** If, however, manufacturers are required to report ASP, distinct caveats which take into account the unique features of radiopharmaceuticals must be authorized to protect the manufacturer as well as the Medicare program's integrity. We would also reiterate and recommend that CMS consider another source of ASP-related data – independent radiopharmacies. Finally, if CMS is to utilize some form of ASP, it must:

- Qualify manufacturer reporting, i.e., that manufacturers cannot certify radiopharmacy pricing;
- Use a weighted average that includes manufacturer and radiopharmacy ASP data;
- Conduct surveys of the relationship between end-user acquisition cost at the HCPCS level (from independent radiopharmacies and hospital radiopharmacies) and the manufacturer-reported ASPs;
- Work with stakeholders to determine the appropriate cross-walk between NDCs and HCPCS; and
- Develop a specific proposal regarding the appropriate methodology for reporting and using ASP data for the payment of radiopharmaceuticals and allow stakeholders the opportunity to comment upon the proposal before it is finalized and implemented.

**We recommend that CMS continue to use CCR methodology for payment of radiopharmaceuticals beyond 2006 until the issues with ASP are fully explored and resolved.**

#### **D. Eliminate Threshold for Separate Radiopharmaceutical APCs**

The current \$50 threshold for separate payment of radiopharmaceuticals is too high and distorts the resource homogeneity of the nuclear medicine APCs. The \$50 threshold seems particularly inappropriate when compared to the overall payment rate for the associated procedures. For example, payment for one nuclear medicine APC is about \$90, while payment for another nuclear medicine APC is about \$145. With a \$50 threshold, payment for a nuclear medicine procedure may not be much more than the cost of the packaged radiopharmaceuticals (\$50).

To preserve the resource homogeneity of the nuclear medicine APCs and facilitate reporting and Medicare payment of radiopharmacy handling and overhead costs, we recommend **CMS make separate payments for all radiopharmaceuticals**. Such an approach would be consistent with the Part B payment setting for radiopharmaceuticals and consistent with CMS's policy for antiemetic drugs.

#### **E. Hospitals should Report HCPCS Codes for all Radiopharmaceuticals**

To facilitate accurate data collection and help ensure that the costs and charges of radiopharmaceuticals (as well as the associated handling costs) are considered in establishing payment rates under HOPPS, we recommend that CMS require hospitals to report HCPCS codes and charges for all radiopharmaceuticals.

This coding and billing approach would be consistent with CMS's policy for device-dependent APCs and coding for devices to ensure that claims and charges are being appropriately reported. In addition, it would provide more uniform claim file data that may be helpful as CMS reviews the data to establish payment rates for pharmacy overhead and handling costs.

**F. Establish Uniform "Per Dose" Descriptors for Radiopharmaceuticals**

In conjunction with the implementation of HOPPS, radiopharmaceuticals have been assigned a variety of HCPCS code descriptors from "per dose, per vial, per millicurie, and per microcurie." The descriptors have not always reflected the "unit" administered to patients. CMS has also changed the codes and descriptors for many products several times since HOPPS was implemented. These frequent changes have contributed to the complexity of billing under HOPPS and hospitals have had a difficult time keeping pace with the changes.

CORAR and the Society for Nuclear Medicine have recommended that CMS adopt uniform "per dose" HCPCS code descriptors for certain radiopharmaceuticals. Adoption of "per dose" descriptors would help facilitate a smoother transition as CMS moves to establish payment for radiopharmaceuticals based on average acquisition costs and pharmacy handling APCs. Accordingly, we support the coding recommendations submitted by CORAR and **we urge CMS to coordinate with the HCPCS working group to adopt "per dose" code descriptors for radiopharmaceuticals as appropriate.**

**G. Implement the New HCPCS Codes for Contrast Echocardiography Agents**

We understand that the HCPCS Working Group at CMS has established new HCPCS codes for echocontrast drugs, including DEFINITY<sup>®</sup>, Vial for (Perflutren Lipid Microsphere) Injectable Suspension, as well as new HCPCS codes for low osmolar contrast material (LOCM). These new codes will be effective January 1, 2006, and will be used by physicians to bill for echocontrast agents.

In the proposed HOPPS rule, CMS discussed the new codes for LOCM but did not mention the new codes for contrast echocardiography agents. To facilitate consistency in billing and claim processing, we recommend that CMS publish and implement the new HCPCS codes for contrast echocardiography just as CMS has proposed doing for LOCM.

**H. Payment for Contrast Echocardiography Drugs should include Pharmacy Handling Costs**

CMS is transitioning to ASP based payment in 2006 for all contrast echocardiography drugs. We support this transition for this class of drugs. However, we believe it is important to ensure that payment for contrast echocardiography drugs includes an appropriate amount to reflect handling costs and that payment for these drugs is consistent with all other separately paid drugs under HOPPS. Therefore, we request that CMS confirm payment for pharmacy overhead costs will be added to the ASP-based payment for contrast echocardiography drugs. We also recommend that CMS confirm this payment policy in the final HOPPS rule.

**III. CONCLUSION**

Bristol-Myers Squibb Medical Imaging is a member of the Council on Radionuclides and Radiopharmaceuticals (CORAR) and is supportive of the comments being developed by CORAR and the Nuclear Medicine APC Task Force. We appreciate this opportunity to submit comments on the proposed HOPPS rule for 2006, and we look forward to working with CMS directly and through CORAR and the Nuclear Medicine APC Task Force in order to make appropriate and accurate payment to hospitals for important diagnostic imaging procedures, medical imaging drugs, and radiopharmaceuticals.

Finally, Bristol-Myers Squibb Medical Imaging renews its commitment to work with CMS to advance payment and coding policies that accurately reflect important medical imaging drugs and procedures. We appreciate this opportunity to comment and would welcome further discussions with CMS on any of the recommendations above. We urge CMS to implement the recommendations presented above in the final rule, which will ensure high quality care for Medicare patients. If your staff has any questions regarding this comment letter, please contact Jack Slosky, Ph.D., M.B.A. at [jack.slosky@bms.com](mailto:jack.slosky@bms.com).

Thank you for your consideration.

Sincerely,



Cory Zwerling

President

cc: Elizabeth Richter, Director, Hospital and Ambulatory Policy Group  
James Hart, Director, Division of Outpatient Care, CMS  
Edith Hambrick, MD, JD, Chair, APC Advisory Panel, CMS



Eden Medical Center

A Sutter Health Affiliate

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PHP

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September 9<sup>th</sup>, 2005

We, the administrators of the Eden Medical Center Psychiatric Services are writing to strongly oppose the CMS proposal to cut the Partial Hospitalization Program reimbursement rate by 14% beginning Jan'06. There are two primary reasons we would like to challenge this plan.

First, the proposal was based on data that does not reflect the cost of operating programs in the Bay Area where staffing and overall operations costs are among the highest in the country. Our belief is that your proposal will likely eliminate all of the PHP programs in Northern California. We simply can not afford to meet the required staffing and programming at a 14% cut in revenue. The last 10 years of increased documentation and utilization review demands have contributed to the closure of multiple PHP's in California.

Second, Partial Hospitalization Program functions as the only step down from Inpatient Hospitalization. We simply do not have other services that can manage the high level of psychiatric symptom acuity with the short Inpatient length of stay (typically 6 days in California). Day Treatment programs no longer exist in the mental health system, Community Mental Health Centers function more as long term socialization agencies, and do little for symptom management. As you must be aware, services for people with Severe Mental Illnesses are cut every year statewide, and nationally. Currently our Partial Hospitalization Program and Outpatient Services continuum serves approximately 150 patients a year. The elimination of a terribly needed service for some of the most needy in our county would have grave results.

Please reconsider your proposal,

Sincerely,

Becky Banta, RN, Nursing Director

Patty Espeseth, MFT, Program Director

Cryo

105  
Neygster  
Kane  
Snow  
Hart  
Bazell

September 10, 2005

Mark B. McClellan, M.D.  
Administrator  
Center for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
P.O. Box 8016  
Baltimore, MD 21244-8018

Dear Dr. McClellan:

I have been informed that your proposed hospital outpatient payment rates for the prostate cryosurgery procedures for 2006 will not cover hospital costs. This would likely mean that fewer hospitals would offer this procedure. This would be unfortunate.

I had the cryosurgery procedure done a few months ago and it went very well. It was outpatient, it was minimally invasive, there were few side effects, and I was fully recovered in a few weeks. I would hope that this procedure would be available to more men rather than fewer. My doctor said that the cryosurgery procedure is more cost effective than regular prostate surgery.

Respectfully,

  
Milton J. Harder  
R.R. 1, Box 66  
Deer Creek, Oklahoma 74636



APC/Gen  
APC/D-D  
APC weights  
Pymt/Devices

106

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September 15, 2005

Mark McClellan, MD, PhD, Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
Room 445-G, HHH Bldg  
200 Independence Ave., SW  
Washington, DC 20201

Burley  
Heygster  
Levi  
Kane  
Sallow  
Hart  
Bazell

**Re: Hospital Outpatient Prospective Payment System  
Proposed Rule (CMS-1501-P)  
Update for Calendar Year 2006**

Dear Dr. McClellan:

St. Jude Medical, Inc. appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the hospital outpatient prospective payment system (OPPS) and calendar year 2006 payment rates (CMS-1510-P, *Federal Register*, Vol. 70, No. 141, Monday, July 25, 2005, p.42674). St. Jude Medical is dedicated to the design, manufacture, and distribution of cardiovascular medical devices of the highest quality. These devices offer physicians, patients, and payers unmatched clinical performance and demonstrated economic value. The Company's product portfolio includes pacemakers, implantable cardioverter defibrillators (ICDs), catheters and heart valves.

St. Jude Medical appreciates the considerable effort you and your staff have put into the development of the OPPS. We also appreciate your release of the 2004 outpatient hospital claims database and your willingness to work with industry to preserve beneficiaries' access to the full range of treatment options in the outpatient setting.

St. Jude Medical is committed to a system that ensures that relative weights and payment rates under OPPS include sufficient resources to account for the costs of the medical technologies associated with hospital outpatient procedures and to assure Medicare beneficiaries have access to these technologies in the outpatient setting.

We support the comments submitted by the Advanced Medical Technology Association (AdvaMed) and will limit our comments to the following:

- Device-Dependent APCs
- APCs 107 and 108
- APC Panel Recommendations Pertaining to APC 107 and APC 108
- Mandatory Reporting of C-Codes
- External Data
- Charge Compression

### Device-Dependent APCs

Since implementation of the Medicare hospital outpatient prospective payment system, CMS has found that the medians calculated from hospital charge data would result in payments for some device-dependent APCs that would not even compensate the hospital for the cost of the device. While the numerous coding and data problems associated with the outpatient system have shown some improvement, the fundamental problems still exist. Yet, for CY 2006, CMS is proposing to base the OPSS device-dependent APC medians on CY 2004 claims, the most current available. However, since the use of unadjusted claims medians based solely on hospital claims data – which have proven unreliable for rate setting – would result in dramatic decreases in payment (50 percent or more in some cases) for some device-dependent APCs, CMS has proposed a floor based on 85 percent of the CY 2005 payment median.

Many of the device-dependent APCs subject to the CY 2006 floor have already been reduced substantially over the past few years, including a 5 percent reduction in CY 2005. Additionally, a number of these device-dependent APCs have been underpaid from the start of OPSS.

We believe that a 15 percent reduction in payment from the 2005 OPSS to the CY 2006 OPSS may be problematic for hospitals that provide services contained in these APCs. We are concerned that providers will not be able to accommodate these reductions without needing to eliminate services that Medicare beneficiaries need.

**St. Jude Medical urges CMS set a floor on the 2006 device-related APC rates at no less than 100 percent of the 2005 rates plus the market basket update. While this will not alleviate the underpayment for many device-dependent procedures, it will provide a greater level of stability for hospitals that provide these procedures.**

### APC 107 and APC 108

While the preliminary claims data for CY 2006 indicated improvement over previous years, the data indicated drastic reductions for APC 107 (Insertion of ICD Pulse Generator) and APC 108 (Insertion of ICD System) from the CY 2005 rates, which were undervalued to begin with.

St. Jude Medical, Medtronic and Guidant Corporation provided actual hospital acquisition cost data to CMS in May 2005, in time for CMS to adjust the medians for CY

2006 (presentation attached). However, CMS rejected the use of external data for CY 2006, as they did for CY 2005.

Instead, CMS proposed rates for CY 2006 -- based on the 85 percent floor -- which were significantly less than the device acquisition costs, and would result in losses of \$4,000 or more per case. (See table below.)

<u>APC 0107</u>	<u>APC 0108</u>
Median device costs: \$18,402 <sup>1</sup> - \$19,029 <sup>2</sup>	Median device costs: \$24,824 <sup>1</sup> - \$27,592 <sup>2</sup>
Procedural costs <sup>3</sup> : + \$1,335	Procedural costs <sup>3</sup> : + \$1,467
Total Cost / Case: \$19,737 - \$20,364	Total Cost / Case: \$26,291 - \$29,059
2006 Proposed Payment: - \$15,431	2006 Proposed Payment: - \$20,721
<b>Total Loss / Case: \$4,306 -4,933</b>	<b>Total Loss / Case: \$5,570 - \$8,338</b>

Hospitals have taken a significant loss on these services for several years. At the September 2005 APC Panel meeting, several providers told the panel that reducing the defibrillator APCs by an additional 15 percent would mean that their hospitals may reduce access or close programs for defibrillator procedures and send patients to other hospitals for these services, severely compromising access. Industry also presented on the coding and data problems associated with these APCs and on the severity of the proposed cuts (presentation attached). All commenters requested that the floor for CY 2006 be set at 100 percent of the 2005 payment plus the market update. The Panel agreed, and recommended that for 2006, CMS base the payment rates for APCs 107 and 108 on their 2005 payment rates plus 3.2 percent.

**St. Jude Medical urges CMS to implement the Panel's recommendation in the final rule for CY 2006. While this adjustment will not alleviate the underpayment for defibrillators procedures, it will provide a greater level of stability for hospitals that provide these procedures.**

#### APC Panel Recommendations Pertaining to APC 107 and APC 108

The APC Panel (February 2005) recommended packaging and bypassing services frequently performed with procedures assigned to APC 107 and APC 108. We believe that the recommendations of the Panel show potential for a more robust set of single bills for use in setting medians for APCs 107 and 108. However, we believe that while increasing the single bills available for rate setting, it does not improve the accuracy of the median costs acquired from the claims data.

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1 IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through December 31, 2004.

2 Goodroe Healthcare Solutions, CathSource™ database for January 1, 2004 through December 31, 2004.

3 Determined from Device Related Percentages of APC Costs for 2005.  
Source: <http://www.cms.hhs.gov/providers/hopps/2005fc/1427fc.asp>

Therefore, while we believe that the proposal has merit, we do not believe it would be appropriate to apply the multiple procedure claims methodology for these APCs for the CY 2006 OPSS.

**For CY 2006, we recommend that CMS base payment rates for APC 107 and APC 108 on their 2005 payment rates plus the market basket update. Once CMS has addressed the coding and data problems associated with the outpatient system, including charge compression, implementing this multiple procedure claim strategy should result in more single bills available for setting the median costs for these APCs and yield more appropriate median costs.**

#### Mandatory Reporting of C-Codes

St. Jude Medical continues to support the mandatory reporting of C-codes and the use of device code edits. We believe that requiring hospitals to report applicable C-codes and charges for all devices that are used to perform procedures where such codes exist will increase the accuracy of the claim data used to set OPSS payment rates. However, while we support mandatory reporting of all device category C-codes, we recognize that there may be some procedure codes for which edits should not be established. For example, certain procedure codes may or may not involve the use of a device. In those instances when a provider submits a claim for a procedure that did not involve a device, it clearly would be inappropriate to have an edit in place that would send the claim back to the provider for inclusion of a device category C-code.

Because edits may not be appropriate in all instances, CMS must make it clear to providers that the absence of an edit does not relieve them of their responsibility to report the appropriate device category C-code whenever a procedure is performed that involves the use of a device described by one of the device category C-codes.

**We believe the mandatory reporting of device codes, combined with the editing of claims for the presence of device codes, where appropriate, would result in claims data that more fully reflect the relative costs of device-dependent procedures. We do not believe, however, that required device coding in CY 2005 will eliminate the need for adjustments to median costs for some APCs in CY 2007.**

#### Charge Compression

We believe that the cost estimates for many higher cost devices have been understated by CMS's cost calculation methodology to the extent that they are significantly below the hospital's actual acquisition costs. Generally, CMS multiplies charges by hospital-specific cost-to-charge ratios (CCRs) to calculate hospitals' costs for all services in a single revenue center, which decreases the charges by a constant factor. This methodology is based on the assumption that each hospital marks up its costs by a uniform percentage within each department to set each service's charge. However, within a revenue center, some hospitals mark-up inexpensive products more than they do

expensive products. However, CMS's methodology does not recognize hospitals' variability in setting charges. If CMS uses a single CCR to estimate costs, the approach will generally lead to an underestimate of hospitals' costs for higher cost items – a phenomenon known as “charge compression.”

In 2003, AdvaMed conducted a study of CMS's cost-calculating methodology applying cost-to-charge ratios to charges submitted on hospital claims. The study determined that for many devices the CMS cost calculation was significantly below the hospital's actual acquisition costs, as a result of hospitals applying a lower mark-up to devices, especially high-cost devices, than to other services within the cost center. As a result, the costs of these devices were understated in the median costs, undermining the base APC rates for many APCs associated with higher cost devices, such as implantable ICDs, pacemakers, and neurostimulators. MedPAC's 2003 survey of hospital charge-setting practices confirmed that hospitals often use smaller mark-ups for more expensive items. Other researchers have found similar results (GAO 2004).

The table<sup>4</sup> below illustrates the variation in mark-up in charges for certain implantable devices in a single revenue center. The mark-up for ICD pulse generators is 79 percent lower than for other less costly devices, leading to charge compression.

Device Type (from least to highest cost)	No. of Hospitals	Percentage Mark-Up (Mean)
Pacemaker Lead	111	266
ICD Lead	69	221
Pacemaker Pulse Generator	111	221
ICD Pulse Generator	60	142

To the extent that hospitals' mark-up practices for high cost devices are systematically out of line with the hospitals' mark-up practices for other items and services, the payment levels for APCs corresponding to these devices are likely to be underweighted and underpaid. The effect on the APC may be especially pronounced when the charge for the device accounts for a high percentage of the total charges associated with an APC, as it would for many implantable devices with high unit costs.

**Until appropriate changes are made to the methodology for calculating device costs, St. Jude Medical recommends the use of external data to validate and, where needed, supplement the device component in the median costs, particularly for high-cost devices. Further, we encourage CMS to seek a longer-term solution.**

<sup>4</sup> Premier Healthcare Informatics, Perspective Comparative Database for January 1 through December 31, 2004.

### Utilizing External Data

The APC Panel (February 2005) recommended that "...CMS proceed with caution in using existing data on devices submitted with C codes to set reimbursement rates and that CMS consider using external data in setting rates, especially for those devices with particularly high costs". Yet, CMS stated in the CY 2006 proposed rule that the agency fully expects to use the unadjusted median costs for device-dependent APCs as the basis of their payment weights for the CY 2007 OPPTS because device coding is required for CY 2005. Consequently, CMS believes that all CY 2005 claims should reflect the costs of devices used to provide services. While we believe that the mandatory device coding will result in medians that more accurately reflect the costs of providing device-related procedures, the use of correctly coded claims will not address the effect of charge compression (discussed above) on high cost devices or the reliance on single procedure claims.

The table below shows a historical comparison of median costs (single procedure claims, C-code code claims only, and external data) for APC 0108 (ICD System Implant) for CY 2003 through CY 2006. Even using only claims containing device codes to set the medians in CY 2003 and CY 2004, the medians were substantially less than the median acquisition cost of the ICD.

Calendar Year	APC Median Cost Single Procedure Claims	APC Median Cost C-Code Claims Only	Median External Acquisition Cost Data Device Only <sup>8</sup>
2003	\$12,101.97 <sup>5</sup> (January 1, 2001-July 1, 2001) 40% less than C-coded claims 48% less than external device acquisition costs	\$20,205.56 <sup>6</sup> (April 1, 2001-March 31, 2002)	\$23,120 <sup>7</sup> (January 1, 2001-December 31, 2001) *Represents mean cost – median unavailable
2004	\$11,821.34 <sup>6</sup> (April 1, 2002-December 31, 2002) 55% less than C-coded claims 58% less than external device acquisition costs 60% less than external device acquisition & proc. costs <sup>5</sup>	\$26,092.91 <sup>6</sup> (April 1, 2002-December 31, 2002)	\$28,313 (January 1, 2002-December 31, 2002)
2005	\$11,854.81 <sup>6</sup> (January – September 2003) 53% less than external device acquisition costs 55% less than external device acquisition & proc. costs <sup>6</sup>	Not Available	\$25,198 (January 1, 2003-December 31, 2003)
2006	\$17,157.41 <sup>7</sup> 31% less than external device acquisition costs	Not Available	\$24,824 (January 1, 2004-December 31, 2004)

5 CMS Proposed Rule: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System Year 2003 Payment Rates; Median Costs for Hospital Outpatient Services, August 9, 2002

6 CMS Data Presented to APC Advisory Panel, February 2004

7 Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule. Federal Register July 25, 2005, page 42715

8 IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases

**Until charge compression and other data issues are addressed, we do not believe that the median cost data will result in rates that uniformly reflect hospitals' cost of providing outpatient services. For 2007, we encourage CMS to use external data to adjust medians for the device dependent APCs when it appears that the adjustment is needed to ensure access to care.**

In closing, St. Jude Medical appreciates this opportunity to comment on the important issues raised in the proposed rule and looks forward to working with you to ensure that Medicare patients have access to new and critical medical devices – both therapies that exist today as well as those on the horizon. We sincerely hope that CMS will give thoughtful consideration to our comments and will incorporate our suggestions, as well as those of AdvaMed, in the final rule. Thank you for your attention to this very important matter.

Sincerely,

A handwritten signature in black ink that reads "Susan Walker". The signature is written in a cursive, flowing style.

Director, Reimbursement

Attachments

# Meeting of the Advisory Panel on Ambulatory Payment Classification Groups



Insertion ICD Pulse Generator & Insertion of ICD  
System // APCs 0107 & 0108

August 17 - 19, 2005

Presented by

Bob Thompson, M.S., M.A.

Director, Reimbursement, Economics & Health Policy  
Medtronic, Inc.

On behalf of Medtronic, St. Jude Medical and Guidant



## Financial Disclosure

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- I am an employee and stockholder of Medtronic, Inc.
- Medtronic is one of three companies that creates the products that are the subject of this presentation.

## HCPCCS Codes & APCs Affected

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**APC 0107**

- G0297: Insertion of single chamber pacing cardioverter defibrillator pulse generator
- G0298: Insertion of dual chamber pacing cardioverter defibrillator pulse generator

**APC 0108**

- G0299: Insertion or repositioning of electrode lead for single chamber pacing cardioverter defibrillator and insertion of pulse generator
- G0300: Insertion or repositioning of electrode lead(s) for dual chamber pacing cardioverter defibrillator and insertion of pulse generator

## Clinical Description of the Service

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### Implantation of the Implantable Cardioverter Defibrillator Pulse Generator Only

- Implantation of the implantable cardioverter defibrillator (ICD) is normally performed as part of an ICD replacement procedure. The overall procedure involves two APCs (0105 and 0107)
- An incision is made, the leads are disconnected from the existing ICD and the device is removed (APC 0105)
- The leads are connected to the new ICD and the device and lead functions are tested. The new ICD is then inserted, the incision is closed, and the device therapies are programmed (APC 0107)

## Clinical Description of the Service

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### Implantation of the Implantable Cardioverter Defibrillator System

- Implantation involves the surgical placement of the ICD pulse generator and the placement of pacing or defibrillation lead(s) in the right atrium and/or right ventricle (APC 0108)
- The leads are connected to the ICD and the device and lead functions are tested. The ICD is then inserted, the incision is closed, and the device therapies are programmed (APC 0108)

## Proposed Payment Rates Result in Significant Hospital Losses

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### APC 0107

Insertion of Cardioverter Defibrillator  
Pulse Generator Only

Proposed Rate: \$15,431

### APC 0108

Insertion of Cardioverter Defibrillator  
System

Proposed Rate: \$20,721

- Prior to the publication of the 2006 proposed rule, industry representatives met with CMS and presented third-party device acquisition cost data
- 2006 proposed payment rates clearly show that CMS did not incorporate the data provided, as the rates are significantly less than device acquisition costs and represent a 14.5% reduction over last year and a 16.8% reduction over the last two years
- Hospital losses for APCs 0107 and 0108 may jeopardize patient access to life-saving devices in the outpatient setting and encourage hospitals to move procedures to a setting that is less cost-effective

# Proposed Rates Result in Losses of \$4000 or More Per Case

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## APC 0107

Median device costs: \$18,402<sup>1</sup> - \$19,029<sup>2</sup>  
Procedural costs<sup>3</sup>: + \$1,335  
Total Cost / Case: \$19,737 - \$20,364  
2006 Proposed Payment: - \$15,431  
**Total Loss / Case: \$4,306 - \$4,933**

## APC 0108

Median device costs: \$24,824<sup>1</sup> - \$27,592<sup>2</sup>  
Procedural costs<sup>3</sup>: + \$1,467  
Total Cost / Case: \$26,291 - \$29,059  
2006 Proposed Payment: - \$20,721  
**Total Loss / Case: \$5,570 - \$8,338**

<sup>1</sup> IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through December 31, 2004.  
<sup>2</sup> Goodroe Healthcare Solutions, CathSource™ database for January 1, 2004 through December 31, 2004.  
<sup>3</sup> Determined from Device Related Percentages of APC Costs for 2005. Source:

# Hospital Claims Data Issues

- CY 2004 claims data continue to inadequately represent device acquisition costs due to issues with coding accuracy and charge compression
- This has been a recurring problem since the inception of OPPS
- Requiring C-codes may improve the median costs for 2007, but charge compression will still remain an issue for high cost devices

## APC 0108: ICD System (Pulse Generator & Electrodes)

	APC Median Cost Single Procedure Claims	APC Median Cost C-Code Claims Only	Median External Acquisition Cost Data Device Only <sup>4</sup>
2003	<b>\$12,101.97<sup>1</sup></b> <i>(January 1, 2001-July 1, 2001)</i> 40% less than C-coded claims	<b>\$20,205.56<sup>2</sup></b> <i>(April 1, 2001-March 31, 2002)</i>	<b>\$23,120<sup>*</sup></b> <i>(January 1, 2001-December 31, 2001)</i> *Represents mean cost – median unavailable
2004	<b>\$11,821.34<sup>2</sup></b> <i>(April 1, 2002-December 31, 2002)</i> 55% less than C-coded claims 58% less than external device acquisition costs	<b>\$26,092.91<sup>2</sup></b> <i>(April 1, 2002-December 31, 2002)</i>	<b>\$28,313</b> <i>(January 1, 2002-December 31, 2002)</i>
2005	<b>\$11,854.81<sup>2</sup></b> <i>(January – September 2003)</i> 53% less than external device acquisition costs	Not Available	<b>\$25,198</b> <i>(January 1, 2003-December 31, 2003)</i>
2006	<b>\$18,165.78<sup>3</sup></b> <i>(January 1, 2004– December 31, 2004)</i> 27% less than external device acquisition costs	Not Available	<b>\$24,824</b> <i>(January 1, 2004-December 31, 2004)</i>

- 1 CMS Proposed Rule: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System Year 2003 Payment Rates; Median Costs for Hospital Outpatient Services, August 9, 2002
- 2 CMS Data Presented to APC Advisory Panel, February 2004
- 3 Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule. Federal Register July 25, 2005, page 42715
- 4 IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases

# Issues with Charge Compression

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- When determining costs, CMS assumes that hospitals mark up the cost of each service within a specific department by the same percentage
- However, as the GAO, MedPAC, and CMS have acknowledged, in practice, hospitals apply a lower mark-up to high-cost devices causing a systematic under representation of true costs or “charge compression”

Mark-Up Percentages by Device Type<sup>1</sup>

Device Type	Sample Size	Percentage Mark-Up (Mean)
Pacemaker Lead	70	237
ICD Lead	41	242
Pacemaker Pulse Generator	30	234
ICD Pulse Generator	26	138

<sup>1</sup> Premier Healthcare Informatics, Perspective Comparative Database for January 1 through June 30, 2003.


 Mark-up is 100% lower for ICDs than other devices

## Recommendations

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- We request that the APC Advisory Panel recommend the following to CMS:
  - 2006
    - Base the final payment rates for APC 0107 and 0108 using 2005 payment rates plus the OPPS hospital update (3.2%)
  - 2007 and beyond
    - Address charge compression issues
    - Consider external data when necessary to establish payment rates until claims data are adequate and can be used in rate-setting

# Device Acquisition Cost Data for APCs 0107 and 0108

**Calendar Year 2004 Data  
Hospital Acquisition Costs For ICD and CRT-D Devices  
[Median, Mean, (N)]**

Technology	APC	2006 Proposed APC Payment	CMS 2006 Proposed Unadjusted APC Median Cost <sup>1</sup>	Goodroe <sup>2</sup> Device Acquisition Costs	IMS Health <sup>3</sup> Device Acquisition Costs	Premier <sup>4</sup> Device Acquisition Costs
ICD pulse generator only (Includes CRT-D)	0107	\$15,430.93	\$15,166.64	\$19,029 \$19,409 (296)	\$18,402 \$19,600 (108,936) <sup>5</sup>	Data not yet available
ICD system (pulse generator and electrodes, includes CRT-D)	0108	\$20,720.68	\$18,165.78	\$27,592 \$27,734 (368)	\$24,824 \$26,213 (108,936) <sup>5</sup>	Data not yet available

<sup>1</sup> Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule. Federal Register July 25, 2005, page 42715  
<sup>2</sup> Goodroe Healthcare Solutions, CathSource™ database for January 1, 2004 through December 31, 2004.  
<sup>3</sup> IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through December 31, 2004  
<sup>4</sup> Premier Healthcare Informatics, Perspective Comparative Database  
<sup>5</sup> IMS Health, Hospital Supply Index device mix is 27.3% single chamber, 44.2% dual chamber, and 28.5% CRT-D

Calendar Year 2004 Data  
Hospital Acquisition Costs For Pacemaker, CRT-P, ICD, and CRT-D Devices  
[Median, Mean, (N)]

Technology	APC	2005 Total APC Payment <sup>1</sup>	CMS 2005 Device Related Portion of APC <sup>2</sup> (APC % attributed to device)	Goodroe <sup>3</sup>	IMS Health <sup>4</sup>	Premier <sup>5</sup>
Single chamber pacemaker system (pulse generator and electrodes)	0089	\$6,244.35	\$4,896.19 (78.41%)	<u>\$5,394</u> \$5,604 (92)	<u>\$4,959</u> \$5,030 (34,945)	<u>\$5,854</u> \$6,047 (13,198) <sup>8</sup>
Single chamber pacemaker pulse generator only	0090	\$5,159.42	\$4,093.48 (79.34%)	<u>\$4,900</u> \$4,904 (97)	<u>\$4,269</u> \$4,329 (34,945)	<u>\$4,497</u> \$4,499 (13,198) <sup>8</sup>
Pacemaker system (dual chamber and CRT-P)	0655	\$7,701.05	\$6,280.21 (81.55%)	<u>\$7,134</u> \$7,217 (470)	<u>\$6,649</u> \$6,988 (141,535) <sup>7</sup>	NA
Pacemaker generator only (dual chamber and CRT-P)	0654	\$6,004.90	\$4,868.17 (81.07%)	<u>\$5,635</u> \$5,587 (548)	<u>\$5,149</u> \$5,482 (141,535) <sup>7</sup>	NA
Pacemaker leads only	0106	\$3,142.27	\$1,918.36 (61.05%)	<u>\$723</u> \$734 (1,319)	<u>\$690</u> \$702 (268,122)	<u>\$753</u> \$859 (24,198) <sup>9</sup>
ICD system (pulse generator and electrodes, includes CRT-D)	0108	\$24,121.71	\$22,655.11 (93.92%)	<u>\$27,592</u> \$27,734 (368)	<u>\$24,824</u> \$26,213 (108,936) <sup>6</sup>	<u>\$25,763</u> \$26,431 (7,120)
ICD pulse generator only (includes CRT-D)	0107	\$17,963.71	\$16,629.01 (92.57%)	<u>\$19,029</u> \$19,409 (296)	<u>\$18,402</u> \$19,600 (108,936) <sup>6</sup>	<u>\$20,819</u> \$21,522 (7,120)
ICD leads only	0106	\$3,142.27	\$1,918.36 (61.05%)	<u>\$5,855</u> \$5,494 (374)	<u>\$5,162</u> \$5,454 (50,895)	<u>\$4,397</u> \$4,499 (7,239)
Resynchronization (left ventricular) lead only	1525	\$3,750.00	N/A	<u>\$2,487</u> \$2,672 (119)	<u>\$2,664</u> \$2,279 (31,891)	NA

1 Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Rates; Final Rule. Federal Register November 15, 2004  
2 Source: CMS website, <http://www.cms.hhs.gov/providers/hopps/2005fc/14271c.asp>  
3 Goodroe Healthcare Solutions, CathSource™ database for January 1, 2004 through December 31, 2004.  
4 IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through December 31, 2004  
5 Premier Healthcare Informatics, Perspective Comparative Database for January 1, 2004 through December 31, 2004  
6 IMS Health, Hospital Supply Index device mix is 27.3% single chamber, 44.2% dual chamber, and 28.5% CRT-D  
7 IMS Health, Hospital Supply Index device mix is 95.5% dual chamber and 4.5% CRT-P  
8 Costs include single chamber, dual chamber, and CRT-P  
9 Costs include left sided leads

Cryo 107  
Roland Dorsey  
37 Lane 250A  
Orland, IN 46776

September 8, 2005

Keygster  
Kane  
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Dr. Mark B. McClellan, M.D., Ph.D, Administrator  
Center for Medicare & Medical Services  
Dept of Health & Human Services  
Attn: CMS-1501-P  
PO Box 8016  
Baltimore, MD 21244-8018

RE: CMS-1501-P: Medicare Program Charges for payment of outpatient payment rates for APC-674: Cryosurgery of the Prostate for 2006

Dear Dr. McClellan,

I am a prostate cancer survivor. It was brought to my attention in the July Federal Register that Medicare is planning to cut the amounts that will pay for the cryocare procedure. I was very unhappy to read this as in 2004 I had enough trouble finding a doctor and a hospital to perform cryosurgery.

After being diagnosed it was many months later and having to travel to Tampa, Florida to find a doctor and hospital who would agree to do this surgery. Thank God, I did as after having a PSA of 11.5 prior to cryosurgery, I now have a 0.04 PSA. I preferred the less invasive surgery and shorter recovery with no chemo and radiation treatment.

Please, on behalf of future prostate patients, I urge Medicare to adjust the proposed payment rate for APC 674 upward to reflect a hospital's actual cost to perform the cryosurgery procedure.

Copies mailed to: Jim Hart, Deputy Director, Center for Medicare Management and Mary Sylek, Vice President, Endocare, Inc.

Sincerely yours,

*Roland Dorsey*  
Roland Dorsey



109  
B-Therapy

**Carl Zeiss Surgical Incorporated**

Levi  
Kane  
Snow  
Hart  
Bazell

September 16, 2005

**VIA FED EX**

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, D.C. 20201

Re: **Brachytherapy (CMS-1501-P)**

Dear Administrator McClellan:

These comments are submitted by Carl Zeiss, Inc., a global leader in visualization technologies. Carl Zeiss remains committed to developing innovative radiation cancer therapies to be used in a wide range of contexts, including the Intrabeam<sup>®</sup> Intra-Operative Radiation Therapy system ("Intrabeam"), which is used in the treatment of early-stage breast cancer.

Carl Zeiss appreciates this opportunity to submit comments regarding the payment under the hospital outpatient prospective payment system (OPPS) for Intrabeam Intra-Operative Therapy, which currently is assigned to APC 0313 and is billed using CPT 77781. Intrabeam treats breast cancer using a unique brachytherapy source that should be paid separately as a brachytherapy device. The current APC assignment for the Intrabeam procedure does not account for the cost of the brachytherapy device, resulting in underpayment for the Intrabeam procedure. This underpayment is hindering the adoption of this important technology, which offers tremendous benefits for the treatment of breast cancer.

**I. BACKGROUND ON BREAST CANCER TREATMENT OPTIONS**

Treatment of breast cancer varies by case and depends upon a range of factors, but generally includes a lumpectomy or mastectomy as well as adjuvant therapy, such as radiation, to decrease the likelihood of recurrence. Radiation can be delivered by one of two methods: external beam radiation or brachytherapy.

External beam radiation involves the use of linear accelerators or cobalt machines to deliver high-energy radiation to the entire affected breast from outside of the body.

External beam radiation typically begins about one month after a lumpectomy and consists of five treatments per week for five to six weeks. Brachytherapy, on the other hand, is internal radiation treatment given by placing radioactive material directly into a tumor or close to the tumor site. Brachytherapy for breast cancer is done in one of three ways: (1) the permanent implantation of radioactive seeds near the cancer site, (2) using numerous plastic catheters with the temporary introduction of high dose radioactive sources into the catheters, or (3) with Intrabeam.

## **II. INTRABEAM PROCEDURE**

Intrabeam delivers radiation directly to the tumor site by a probe that is inserted into the tumor cavity after lumpectomy. Intrabeam therapy targets the specific tumor site and thus minimizes radiation exposure to the whole breast as compared to traditional external beam radiation. Moreover, because the radiation can be delivered as part of a patient's initial surgery, the procedure enables patients to return to their normal routines more quickly and results in significant overall cost savings for beneficiaries.

Currently, the Intrabeam is used in the treatment of breast cancer as either boost replacement or as single-dose radiotherapy. As a boost replacement, Intrabeam radiation therapy is used to treat patients diagnosed with early stage invasive breast cancer (T1-T2, <3 cm tumor size) who are candidates for breast conserving surgery followed by a traditional course of external beam radiotherapy. Intrabeam enables a physician to perform the boost treatment (replacing the conventional four to seven days of treatments) as a single, intra-operative dose immediately after lumpectomy, while the patient is still under anesthesia in the operating room.

As part of the currently ongoing international TARGIT trial, Intrabeam therapy is used as single-dose radiation treatment for post/peri menopausal women who are diagnosed with early invasive breast cancer (T1, <=2 cm tumor size; age >=45) and who are suitable candidates for breast conserving surgery. In the TARGIT trial, the single intra-operative dose of Intrabeam radiation replaces the entire conventional course of 35 or more radiation treatments over six to seven weeks in postmenopausal women or women with a low risk of local recurrence.

As an intra-operative treatment, Intrabeam therapy requires the services of a breast surgeon and a radiation oncologist, as well as the general resources associated with surgical procedures performed in the outpatient setting. The Intrabeam procedure is performed as follows: Immediately following tumor resection in the operating room, the surgeon measures the tumor site and selects a spherical Intrabeam applicator that will fill the tumor cavity. The surgeon then places the appropriate resposable applicator onto the probe of the Intrabeam's miniature x-ray source and inserts the ensemble directly into the tumor cavity, using surgical closure techniques to ensure contact between the breast tissue and the x-ray source. The surgeon also shields the skin and muscle from the x-ray source. The radiation oncologist then determines the prescribed dose of radiation and enters the information into the Intrabeam's control console. The Intrabeam radiation source is activated and delivers a high dose of low level energy (50KeV) radiation directly to the tumor site. The radiation is delivered over a period of time determined by

the size of the tumor cavity, usually ranging from 25 to 45 minutes. After the radiation treatment is complete, the surgeon removes the applicator/radiation ensemble and closes the surgical wound, ending the procedure.

**III. INTRABEAM RADIATION SOURCE IS A BRACHYTHERAPY SOURCE AND SHOULD BE PAID SEPARATELY AS A BRACHYTHERAPY SOURCE**

The radiation from Intrabeam is delivered directly into a tumor cavity, and therefore, by definition, it is a form of brachytherapy. The Intrabeam radiation source is a point source that is similar to other brachytherapy sources such as seeds or pellets. Intrabeam emits radiation from a point source in the form of x-rays created by an electron beam striking a thin gold foil target at the probe tip. Essentially, this tiny probe tip functions like traditional brachytherapy sources. This characterization of the Intrabeam radiation source as a brachytherapy source is supported by Dinsmore et al.'s assessment of the Intrabeam radiation source: "this source produces a radiation field similar to that of a localized, low-energy brachytherapy source."<sup>1</sup>

Furthermore, the statutory provision that provides separate payment for devices of brachytherapy includes brachytherapy devices other than seeds. Section 1833(t)(12)(H) of the Act states that "with respect to devices of brachytherapy consisting of seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such services separately from other services . . ." (emphasis added). Such a brachytherapy radioactive source would include the Intrabeam radiation source.

The current APC assignment for Intrabeam (APC 0313, using CPT 77781) does not account for the cost of the Intrabeam brachytherapy radiation source, and therefore the OPPS payment does not adequately cover the resource costs for providing Intrabeam therapy. In the past, the costs of Intrabeam were adequately covered and Intrabeam was included in the same APC (0312) as more conventional brachytherapy procedures. But beginning in 2004, CMS began making separate payments for the brachytherapy seeds and sources used in connection with certain brachytherapy procedures assigned to APC 0312. Because separate payment for seeds and sources was created and these resources were no longer accounted for in APC 0312, the payment decreased from \$2,758.08 in 2003 to \$199.90 in 2004.

Currently, Intrabeam is coded with CPT 77781, which maps to APC 0313 with a payment rate of 790.75. This payment rate does not compare to the estimated \$5,500 per procedure cost of Intrabeam, because it does not account for Intrabeam's unique brachytherapy source. While the total payment that hospitals receive for the conventional brachytherapy services billed using the same (or a similar) code to the code used for Intrabeam has remained relatively constant because of the additional separate payment for the seeds and sources, the payments that hospitals receive for Intrabeam has decreased

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<sup>1</sup> M. Dinsmore, K.J. Harte, A.P. Sliski, D.O. Smith, P.M. Nomikos, M.J. Dalterio, A.J. Boom, W.F. Leonard, P.E. Oettinger, J.C. Yanch, A new miniature x-ray source for interstitial radiosurgery: Device Description. *Med. Phys.* 23, 45-52 (1996).

by approximately \$2,000 from the 2003 payment level, resulting in a payment that is significantly less than the total cost of furnishing Intrabeam.

A solution to this payment anomaly is for CMS to properly recognize the Intrabeam radiation source as a device of brachytherapy and provide a separate payment for Intrabeam's brachytherapy source, as is done with other brachytherapy devices. Accordingly, we ask that CMS designate the radiation source used in the Intrabeam procedure as a brachytherapy device and provide a separate payment for the source. This designation will result in payment for Intrabeam in the OPPS that more adequately reflects the cost of this procedure to hospitals and thus will provide for its greater availability to beneficiaries.

The failure to recognize the Intrabeam radiation source as a brachytherapy device with a separate payment would continue to jeopardize beneficiary access to a potentially revolutionary technology. Hospitals cannot reasonably be expected to offer a procedure for which they stand to lose thousands of dollars each time it is performed. Thus, maintaining the status quo for Intrabeam OPPS payment will likely result in the denial of access to Intrabeam for thousands of women diagnosed with breast cancer in the coming year.

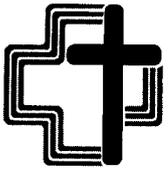
\* \* \*

We appreciate CMS's consideration of this important matter. If you have any questions or would like additional information, please contact me at 419-797-2016.

Sincerely,

A handwritten signature in black ink that reads "Jeff Rospert (JRM)". The signature is written in a cursive style with a large initial "J" and "R".

Jeff Rospert  
Director, National Accounts and Radiotherapy Products



**St Anthony's  
Memorial Hospital**

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d.n.w.

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Images

September 14, 2005

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

Buckley  
Kane  
Singer  
Hart  
Bazell

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program: Changes to the Hospital Outpatient Prospective  
Payment System and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

I am writing on behalf of St. Anthony's Memorial Hospital on an issue of great importance to Medicare beneficiaries with cancer. St. Anthony's Memorial Hospital is one of the leading institutions and research centers for cancer care. Positron emission tomography (PET) technology scans are an integral part of St. Anthony's program to diagnose and manage patients with cancer. We are pleased that the Centers for Medicare and Medicaid Services (CMS) has recently proposed to expand cancer coverage for PET scans. We are concerned, however, that the proposed hospital outpatient payment rate for PET/CT scans is inadequate to cover hospital costs for this new technology.

The PET/CT scanner is the latest advance in oncology imaging which combines two state-of-the-art imaging modalities. PET is a highly sensitive technique that detects the metabolic signal from actively growing cancer cells in the body. The key to PET's effectiveness is that it provides physicians with information about the body's chemistry, cell function, and metabolism that anatomic imaging modalities such as CT and MRI are unable to provide. The PET scan does not provide the exact anatomic location of the signal in the body. CT provides high resolution anatomic information regarding the location, size, and shape of various lesions, however, it cannot differentiate cancerous lesions from normal structures with the same accuracy as PET. The combined PET/CT scanner merges PET and CT images together, thereby more accurately identifying and localizing tumors in the body.

Last year, CMS in the Hospital Outpatient Rule decreased payment rates for PET scans from \$1375 to \$1150. This decrease rate has challenged our ability to provide PET scans to medical beneficiaries. We applaud the CMS decision in the proposed rule to keep stable the payment rate for PET scans, thereby avoiding further constraints on providers' ability to offer this service.

We are concerned, however, about the proposed payment rate for PET/CT. The PET/CT scan is the leading diagnostic imaging tool for managing patients with cancer. The proposed payment rate of \$1250 is well below our cost for these scans. Without adequate reimbursement, beneficiary access to PET/CT will be limited.

I urge you to keep the hospital outpatient payment rates for PET scans stable and to increase the payment rate for PET/CT to represent true costs for hospitals.

Thank you very much for your attention. Please feel free to contact me with more information.

Sincerely,

Robert W. Esker  
Assistant Administrator

RWE:df

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September 14, 2004

The Honorable Mark McClellan, MD  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
ROOM 445-G  
200 Independence Avenue, S.W.  
Washington, DC 20201

**ATTN: FILE CODE CMS-1501-P**

**Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule**

Dear Dr. McClellan:

GE Healthcare (GEHC) appreciates this opportunity to comment on the CMS proposed rule regarding changes to the Medicare hospital outpatient prospective payment system (*Federal Register*, Vol. 70, No. 141, July 25, 2005). Our comments focus on the following topics:

- New Technology APCs;
- Payment discounts for multiple diagnostic imaging procedures;
- Proposed 2006 payment levels for PET/CT procedures; and
- Other APC assignment issues involving CT angiography and proton beam therapy procedures.

GE Healthcare is a \$15 billion unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring, life support systems, disease research, drug discovery and biopharmaceuticals manufacturing technologies. Worldwide, GE Healthcare employs more than 43,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

Our detailed comments follow.

## NEW TECHNOLOGY APCs

New Technology APCs provide a critical mechanism for the timely and appropriate reimbursement of new advances in medical technology and clinical practice. We strongly urge CMS to ensure the transparency, consistency and timeliness of its process for assigning clinical procedures to New Technology APCs and, subsequently, to permanent clinical APCs.

GEHC has two concerns regarding current and proposed policies entailing CMS assignment to New Technology APCs: (1) premature assignment of new procedures to clinical APCs; and (2) the proposed requirement that a coding application be submitted to the American Medical Association (AMA) as a condition for the acceptance of a New Technology APC application for review.

### Premature Assignment of New Technology Procedures to a Clinical APC

In certain instances, CMS has taken action to immediately assign new technology related services to a permanent clinical APC once a CPT code has been awarded (CPT Category III or Category I). Before new CPT codes are awarded for these services, they are reported using other existing codes or more general unlisted CPT codes. As a result, by definition, there is insufficient claims data to support appropriate assignment to a permanent clinical APC. Nevertheless, CMS has taken this approach in some cases to prematurely assign services with new CPT codes to permanent APCs. This assignment often occurs with little or no explanation, rationale or opportunity for public comment.

One example of premature assignment involves MR-guided focused ultrasound for the treatment of uterine fibroids. Effective July 1, 2004, the AMA awarded two new CPT Category III codes to report these procedures.<sup>1</sup> In the final regulation setting the HOPPS payment rates for 2005 (*Federal Register* Vol. 69, No.219, November 15, 2004), CMS immediately assigned these codes to APC 193, and proposes the same assignment for 2006. This assignment was determined in the complete absence of claims data. In fact, according to the sole manufacturer of the technology, no hospital claims data were generated for these codes during calendar year 2004 (the year for which data are used to determine the HOPPS proposed rates for 2006).<sup>2</sup>

The CMS Advisory Panel on Ambulatory Payment Classification Groups has expressed concern about the proposed APC assignment of MR-guided focused ultrasound. At its August 2005 public meeting, the panel voted to recommend to CMS that these procedures be removed from APC 193 and that the agency work with providers to assign the codes to an appropriate APC.

**We recommend that CMS consistently assign new technology services to a New Technology APC based on external data provided. Assignment to a permanent clinical APC should not occur until sufficient claims data is available. In addition, we strongly urge CMS to adopt a formalized process for ensuring the appropriate and consistent APC assignment of new technology services.** The process should consider important factors such as opportunity for public input, factors contributing to the appropriate assignment to New Technology APCs in

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<sup>1</sup> CPT 0071T *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue*  
CPT 0072T *Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue*

<sup>2</sup> Insightec comments to the APC Advisory Panel Regarding MR-Guided Focused Ultrasound, page 2.

the absence of claims data, and timely assignment in light of CPT Category I and III scheduled coding updates. Through such a process, patients, providers and manufacturers can be assured of appropriate and timely reimbursement for new technology and clinical practice advances in the hospital outpatient setting.

#### New Technology APC Application Requirements

CMS proposes to require that, before it will accept a New Technology APC application for review, the sponsor must file an application for a code for the service to the AMA CPT Editorial Panel. A copy of the submitted CPT application must accompany the New Technology APC application.

GEHC is concerned that this requirement, if adopted in the final regulation, will result in significant delays in the application process for new technology services – and in the timely and appropriate reimbursement for such services. The CPT code application process can be lengthy and may not coincide with the New Technology APC application process, thereby imposing delays in application filing and CMS decision making. In addition, The AMA Editorial Panel is a private organization whose deliberations and decision making are not open to the public. There is also no medical technology industry representation on the Panel, whereas medical technology companies are frequent sponsors of New Technology APC applications. In essence, the requirement for a CPT code application places demands on medical technology companies to address a process in which they have no ability to participate or control.

For these reasons, **GEHC recommends that CMS withdraw its proposed requirement for a CPT code application to accompany a New Technology APC application.** Failure to take this action could lead to significant delays in the integration and adoption of quality-enhancing technology developments.

#### **PAYMENT DISCOUNTS FOR MULTIPLE DIAGNOSTIC IMAGING PROCEDURES**

In the regulation, CMS proposes to apply a multiple procedure discount to selected diagnostic imaging procedures. Eligible procedures are identified and grouped into 11 “families” of related CPT imaging codes. For these procedures, CMS would make full payment for the procedure with the highest APC payment rate. It would then apply a 50 percent reduction in the payments for second and subsequent imaging procedures in the same family, performed during the same session.

GEHC agrees with CMS that, when selected imaging procedures included in the 11 families are performed during the same session, some of the resource costs may not be incurred twice. Although some level of payment adjustment may be appropriate for these procedures, we have significant concerns about the specifics of the policy recommended by CMS, as well as the lack of rigor in the analytic methods used to support the policy. We strongly recommend that CMS delay implementation of its proposal pending further study.

Although on its surface the CMS proposal appears logical, it fails to recognize a number of unique aspects of diagnostic imaging services that require careful consideration in development of such a policy. These include the following:

- High Capital Costs -- Unlike surgical procedures for which the multiple procedure discount already applies, diagnostic imaging procedures are highly capital intensive. These fixed costs contribute a greater share of total procedure costs and do not vary, regardless of whether a second procedure is performed during the same session.
- Significant Variability in Clinical Labor Activities Associated With Imaging Procedures – In the proposed regulation, CMS assumes that, for the procedures listed in each family, there is no duplication of selected clinical labor activities including the following: retrieving prior exams; preparing the equipment; entering the patient data; positioning the patient; processing the acquired imaging data; and reviewing the study with the interpreting physician. Clearly, there are instances in which certain activities performed for multiple procedures during the same session may not be conducted twice. However, this is *not categorically true* for all procedures listed in the proposed families. For some procedures, all or a portion of the clinical labor activities identified by CMS are, in fact, duplicated for multiple procedures in the same session.

These important considerations have been illustrated in examples provided by the American College of Radiology (ACR) and others.<sup>3</sup> Specifically, the ACR cites examples involving brain MRI and neck MRA (Family 5) for the imaging of beneficiaries with stroke, as well as pelvic ultrasound and transvaginal ultrasound (Family 1). These examples illustrate the complexities associated with the clinical delivery of diagnostic imaging and the resulting challenges in developing an equitable policy involving discounting of multiple diagnostic imaging procedures.

GEHC is very concerned about the rationale and methodology used by CMS to determine the need for the proposed adjustment of certain procedures, as well as the level of adjustment that is appropriate for such procedures. We believe that the wholesale application of a 50% reduction in payment for selected second and subsequent diagnostic imaging procedures is problematic and fails to consider the factors we have discussed above.

**We strongly urge CMS to follow the recommendation of its Advisory Panel on Ambulatory Payment Classification Groups to delay implementation of the multiple procedure discounting policy for one year and to submit the CMS proposal to further study.** Such study should consider the degree to which the cost efficiencies of performing multiple imaging procedures during the same session are already reflected in existing APC payment rates. Failure to take these actions is likely to result in inappropriate and potentially extraordinary decreases in hospital reimbursement, as well as unintended consequences for providers, the Medicare program and its beneficiaries.

## **PET/CT**

**GEHC strongly supports the CMS proposal to retain FDG PET procedures in New Technology APC 1513 with a 2006 proposed payment rate of \$1150.** Adequate payment for these services is essential for ensuring continued patient access to this important technology.

We are concerned about the 2006 proposed payment rate for PET/CT procedures, however. CMS proposes to assign PET/CT procedures to New Technology APC 1514 with a payment rate of \$1250. As we explain below, PET/CT represents an important development in cancer diagnosis, staging, treatment planning, and therapy monitoring. Based on analysis developed on

<sup>3</sup> ACR comments to the Advisory Panel on Ambulatory Payment Classification Groups, August 18, 2005.

offering substantial clinical benefits. We urge CMS to continue to maintain adequate payment levels for this life-saving advance.

We again express our concern regarding the proposed payment levels for CT angiography (CTA) procedures (APC 662). CTA procedures continue to be reimbursed at a lower rate than conventional CT procedures, even though the resource costs of CTA consistently exceed conventional CT.

CTA displays the vasculature in three-dimensional format enabling a wide variety of clinical uses and benefits. The procedure itself consists of a conventional CT scan, combined with sophisticated three-dimensional post processing to render images of arterial and venous vasculature.

Again this year, inaccurate CTA claims data coupled with CMS methodological issues involving application of cost-to-charge ratios for procedures introduced after 2001, have resulted in an APC payment rate for CTA procedures that is below that for CT procedures alone. **We continue to urge CMS to set reimbursement for CTA procedures at a level equal to the CT APC payment (APC 333) plus the post processing APC payment (APC 282).** This may be accomplished by adjusting upward the payment rate for APC 662, or alternatively assigning CTA procedures to an existing APC that more closely reflects the resource costs of performing this service. By making this revision, Medicare beneficiaries can be assured of continued access to this important medical advance that provides an effective and safe alternative to catheter angiography procedures for certain patients.

\*\*\*\*\*

Thank you for providing the opportunity to comment on these important issues. Should you have any questions or wish to discuss our comments further, please contact me at (262) 548-2088.

Sincerely,



Michael S. Becker  
General Manager, Reimbursement



September 14, 2005

Honorable Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, S.W.  
Washington, DC 20201

**File Code: CMS-1501-P**

Dear Dr. McClellan:

On behalf of Elan Corporation, plc ("Elan"), I want to thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Notice of Proposed Rulemaking ("NPRM") regarding changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2006 (the "Proposed Rule").<sup>1</sup> Elan is mindful of the considerable resources that the agency has dedicated to developing this Proposed Rule and appreciates this opportunity to comment. We urge CMS to consider our recommendations relating to several of its proposals and specifically request that CMS consider the following suggestions:

- Specify the drug handling category to which intrathecal drugs will be assigned.
- Clarify certain issues involving the CPT code and ambulatory payment classification group (APC) that relate to the infusion of monoclonal antibodies.
- Clarify that PRIALT<sup>®</sup> (ziconotide **intrathecal infusion**), a drug infused via an implanted delivery pump, will be reimbursed at 95% of its average wholesale price (AWP), in accordance with section 303 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).
- Clarify that PRIALT<sup>®</sup> (C9226) is not an ASP or orphan drug and, thus, is not reimbursed as such.

**BACKGROUND**

Elan is a neuroscience-based biotechnology company that is focused on discovering, developing, manufacturing and marketing advanced therapies to treat neurologic disorders, autoimmune diseases and severe pain. Elan recently received FDA approval for its product, PRIALT<sup>®</sup>, which is indicated for management of severe chronic pain in patients for whom intrathecal (IT) therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjuvant therapies or IT morphine. PRIALT<sup>®</sup> is intended for intrathecal delivery using a programmable implanted variable-rate microinfusion device or an external microinfusion device and catheter. Depending on the site of the service and the drug's method of delivery, PRIALT<sup>®</sup> may be billed as a hospital outpatient service, or as "incident to" a physician service.

<sup>1</sup> 70 Fed. Reg. 42674.

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## COMMENTS TO THE PROPOSED RULE

### A. NonPass-Throughs

Elan applauds CMS's decision to provide reimbursement to cover the handling costs associated with certain separately payable drugs. Elan believes this new policy should be applied to intrathecal drugs, such as PRIALT<sup>®</sup>, and requests that CMS assign PRIALT<sup>®</sup> and other intrathecal drugs to one of the three drug handling categories described in the Proposed Rule. Alternatively, CMS should develop a separate category for intrathecal drugs.

#### 1. **CMS Should Clarify That Hospitals Will Receive Reimbursement For Handling Costs Associated With Separately Payable Intrathecal Drugs**

CMS should clarify whether it will reimburse hospitals for the cost incurred with handling intrathecal drugs. In the Proposed Rule, CMS indicated that it would pay an additional two percent of ASP to cover handling costs associated with separately payable drugs and biologicals.<sup>2</sup> CMS based its decision to provide reimbursement for these drugs' handling costs, in part, on the MedPAC Report referenced in the Proposed Rule. The MedPAC Report, however, does not discuss intrathecal drugs. Accordingly, it remains unclear whether CMS intends to reimburse hospitals for handling costs associated with intrathecal drugs.

Like the drugs discussed in the MedPAC study, PRIALT<sup>®</sup>, and other intrathecal drugs, involve significant handling costs. The University of Utah Pharmacotherapy Outcomes Research Center recently conducted a study (the "Utah Study") that assessed the costs associated with infusion drugs. The Utah Study collected cost data from two medical outpatient infusion centers in Utah and Wisconsin and from two community cancer centers in Virginia and Alabama. The Utah Study concluded that the significant handling costs associated with the infusion of chemotherapy drugs were derived from drug storage, inventory management, waste management, equipment required to handle and administer the drugs, supplies, shipping, drug preparation and insurance management.<sup>3</sup> In summary, the Utah Study calculated that each dose of an infused drug includes a preparation cost of approximately \$36.03.<sup>4</sup>

While the Utah study focused on chemotherapy drugs, the handling costs associated with intrathecal drugs are strikingly similar. Specifically, there are special storage requirements specific to some intrathecal drugs. For example, the temperature of PRIALT<sup>®</sup> must be maintained between two and six degrees.<sup>5</sup> Also, like chemotherapy drugs, many intrathecal drugs must be specifically prepared prior to administration.<sup>6</sup> Finally, similar to chemotherapy drugs, many intrathecal medications require strict adherence to specific rules and procedures for safe administration.<sup>7</sup>

<sup>2</sup> 70 Fed. Reg. 42674, 42730

<sup>3</sup> *Documentation of Pharmacy Cost in the Preparation of Chemotherapy Infusions in Academic and Community-Based Oncology Practices*, University of Utah, Pharmacotherapy Research Center, at p. 4 (attached hereto as "Appendix A").

<sup>4</sup> *Id.* at p. 31.

<sup>5</sup> PRIALT<sup>®</sup> Product Information Sheet at STORAGE (attached hereto as "Appendix B").

<sup>6</sup> See PRIALT<sup>®</sup> Product Information Sheet at DOSAGE AND ADMINISTRATION (requiring that drug is diluted with Sodium Chloride)(Appendix B).

<sup>7</sup> See id. at PRECAUTIONS (warning of risk of meningitis from contamination)(Appendix B).



Based on the foregoing, CMS should ensure that PRIALT<sup>®</sup> and other intrathecal drugs are reimbursed a sum sufficient to cover their handling costs. As the Utah Study plainly illustrates, the handling costs associated with each dosage of such drugs is too expensive for a hospital to absorb. Accordingly, CMS should clarify in its Final Rule, that intrathecal drugs should also be reimbursed a sum sufficient to cover their handling costs.

## **2. Intrathecal Drugs Should Be Assigned To A Drug Handling Category**

In its Proposed Rule, CMS developed three categories in which to capture “varying overhead costs of drugs and biologicals separately payable under OPSS.”<sup>8</sup> CMS developed these categories by condensing the seven categories that MedPAC provided in its Report. While the MedPAC Report focused on specific covered outpatient drugs, none of the medication preparations were for intrathecal administration.<sup>9</sup> The MedAC Report assigned 230 different drugs to seven different categories. Each drug was assigned to a category based upon the resources required to handle the drug. The resources required to handle each drug varied by the specific drug’s level of radioactivity, toxicity, mode of administration and/or the need for special handling. The MedPAC Report assigned drugs to a category based on the resources required to handle properly a particular drug. Drugs in category one required few resources, while drugs in category seven were the most resource intense.<sup>10</sup>

CMS found the MedPAC categories unworkable and created three of its own categories to differentiate the overhead costs associated with the drugs and biologicals.<sup>11</sup> CMS developed these categories by combining the MedPAC categories.

Elan would support the assignment of intrathecal drugs to category three. Proposed category number three is derived from MedPAC category number five, which encompasses “Specialty IV or Agents requiring special handling in order to preserve their therapeutic value or Cytotoxic Agents, oral (chemotherapeutic, teratogenic or toxic) requiring personal protective equipment (PPE).” Similar to the other drugs in MedPAC’s category number five, the administration of intrathecal drugs often requires a disproportionate amount of resources for proper handling. As provided in more detail above under subheading A(1), intrathecal drugs’ handling costs are derived from their shipping, storage, preparation and administration requirements. In the alternative, CMS should create a new category for intrathecal drugs that recognizes the vast resources associated with handling such drugs.

### **B. Pass-Through**

Elan requests that CMS clarify in its Final Rule the methodology under which PRIALT<sup>®</sup> should be paid in the hospital outpatient setting. As provided above, PRIALT<sup>®</sup> is administered through an intrathecal pump. Pursuant to the MMA amendments to the Social Security Act (“SSA”), drugs administered through intrathecal pumps, like PRIALT<sup>®</sup>, are paid at 95% AWP. In this regard the SSA provides:

Except as provided in clause (ii), in the case of infusion drugs furnished through a item of durable medical equipment covered under section

<sup>8</sup> 70 Fed. Reg. 42674, 42729.

<sup>9</sup> Id. at 42728.

<sup>10</sup> Id.

<sup>11</sup> 70 Fed. Reg. 42674, 42729.



1861(n) on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003.<sup>12</sup>

\* \* \*

Drugs that do not have a published price as of October 1, 2003, will be paid based upon the drug's first published AWP.<sup>13 14</sup>

Despite the above statutory and transmittal language, the Proposed Rule does not indicate how infusion drugs, like PRIALT<sup>®</sup>, are reimbursed in the hospital outpatient setting for 2006. Rather, the Proposed Rule simply states that drugs and biologicals provided in the hospital outpatient setting are reimbursed under the payment methodology utilized in the physician office setting.<sup>15</sup> Most drugs provided in the physician office setting are reimbursed under average sales price methodology.

Elan requests that CMS clarify in its Final Rule that PRIALT<sup>®</sup> is paid at 95% AWP pursuant to section 1842(o)(1)(D) of the SSA. In the absence of such clarification, hospitals may be confused regarding whether PRIALT<sup>®</sup> is reimbursed under average sales price methodology or at 95% AWP.

In addition, Change Request 4035 lists PRIALT<sup>®</sup> (Ziconotide)(C9226) with ASP and single-indication orphan drugs.<sup>16</sup> Elan requests that CMS also clarify in its Final Rule that PRIALT<sup>®</sup> is not an orphan drug.

### C. Drug Administration

We are pleased that CMS has proposed to continue its policy with respect to using CPT codes to bill for drug administration services provided in the hospital outpatient department and believe that this will allow CMS to collect the data necessary to establish more appropriate payment rates for drug administration services in the future. We have discovered that some physician offices are experiencing confusion resulting from new CPT codes and expect that hospitals will experience similar confusion. In order to resolve some of this confusion, we would like to comment on several aspects of the Proposed Rule that involve the CPT code applicable to the infusion of monoclonal antibodies and the APC to which that CPT code is mapped. Specifically, Elan requests that CMS clarify in its Final Rule that the infusion of monoclonal antibodies should be paid under CPT code 96413. Elan also requests that CMS modify APC 0117's title to include the infusion of monoclonal antibodies. Absent such clarifications, providers will face uncertainty regarding how to code properly for the infusion of monoclonal antibodies.

<sup>12</sup> SSA § 1842(o)(1)(D)(i)(emphasis added).

<sup>13</sup> CMS Transmittal 561, Change Request 3846 dated May 13, 2005.

<sup>14</sup> Change Request 3846 also provides that drugs infused through DME are reimbursed at 95% AWP regardless of whether the pump is implanted.

<sup>15</sup> 70 Fed. Reg. 42674, 42731 (drugs with HCPCS codes that do not have pass-through status are paid under the same rate that they would receive in the physician office setting); *Id.* at 42722 (stating that new drugs with HCPCS codes receive a separate payment equivalent to the payment they would receive in the physician office setting).

<sup>16</sup> CMS Transmittal 662, Change Request 4035 dated August 26, 2005.



## 1. The Infusion of Monoclonal Antibodies Should Be Billed Under CPT Code 96413

In its November 15, 2004 Final Rule with Comment Period (“FRCP”) relating to revisions to the Physician Fee Schedule for 2005, CMS announced that the infusion of monoclonal antibodies should be billed under G0359. In this regard, the FRCP provided:

The first hour of infusion of anti-neoplastic agents provided for treatment of noncancer diagnoses or substances such as monoclonal antibody agents and other biologic response modifiers is billed under G0359.<sup>17</sup>

Elan agrees that CMS was correct in assigning the infusion of monoclonal antibodies to G0359 in its November 15, 2004 FRCP. The instant Proposed Rule, however, does not discuss specifically the CPT code applicable to the infusion of monoclonal antibodies. Instead, Table 27 of the Proposed Rules pairs G0359 with CPT code 96410.<sup>18</sup> Since publication of the Proposed Rule, the American Medical Association (“AMA”) published its CPT Codes for 2006. In this publication, the AMA instructed that Chemotherapy Administrative codes 96401-96549 apply to substances such as monoclonal antibody agents. In addition, the AMA instructed that CPT code 96410 “is deleted and that providers should report CPT code 96413 in its place.” Likewise, the CPT code 96415 would be used to report each additional hour, 1 to 8 hours, for the administration of monoclonal antibodies. In order to prevent any confusion, Elan requests that CMS clarify in its Final Rule that the infusion of monoclonal antibodies should be paid under CPT code 96413 and 96415 in accordance with the newly published CPT codes.

## 2. APC 0117’s Title Should Include The Infusion of Monoclonal Antibodies

Similarly, Elan requests that CMS clarify in its Final Rule that APC 0117 includes the first hour of infusion of monoclonal antibodies. On Table 27 of the Proposed Rule, CPT code 96410 is mapped to APC 0117.<sup>19</sup> As provided above, the AMA has instructed that CPT code 96410 is deleted and that CPT code 96413 should be reported in its place. In an effort to prevent confusion among providers and to ensure that CMS’s clarification is memorialized in the Final Rule, Elan requests that CMS map the newly created CPT code 96413 to APC 0117. In addition, Elan urges CMS to modify APC 0117’s title to include the administration of monoclonal antibodies.

Currently, APC 0117’s title states, “Chemotherapy Administration by Infusion Only.”<sup>20</sup> Elan proposes that CMS modify APC 0117’s title to read, “Chemotherapy or Monoclonal Antibody Administration and Other Biologic Response Modifiers; by Infusion Only.” These minor clarifications will help alleviate confusion among providers when billing for the first hour of infusion of monoclonal antibodies.

### CONCLUSION

We appreciate this opportunity to comment on the Proposed Rule and we hope our suggestions will assist CMS in structuring its Final Rule. We urge CMS to consider our comments regarding

<sup>17</sup> 69 Fed. Reg. 66236, 66304. It is noteworthy that this G0359 was only used in the physician office.

<sup>18</sup> 70 Fed. Reg. 42674, 42738.

<sup>19</sup> Id.

<sup>20</sup> 70 Fed. Reg. 42674, 42765.



reimbursement for handling costs associated with intrathecal medications. In the event these drugs' handling costs are not reimbursed, providers may cease offering them due to their inability to absorb their handling costs. In addition, Elan requests that CMS clarify that PRIALT<sup>®</sup> is reimbursed at 95% AWP. Finally, we urge CMS to consider our comments regarding the proper CPT code and APC for the infusion of monoclonal antibodies. Absent some clarification from CMS, the provider community will confront difficulty when billing for these drugs.

Elan is hopeful that CMS responds favorably to its suggestions. If you have any questions, please feel free to contact me at 858-320-7681.

Sincerely,

A handwritten signature in cursive script that reads "Nick Poulos, PhD".

Nick Poulos, PhD  
Vice President, Reimbursement  
Elan Pharmaceuticals

# **APPENDIX A**

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## **Executive Summary:**

The National Patient Advocate Foundation contracted with the Pharmacotherapy Outcomes Research Center at the University of Utah on a research project to assist in the identification of “true cost” associated with the drug-related handling for the preparation and delivery of chemotherapy doses.

The study was conducted within two academic medical outpatient infusion centers (Universities of Utah and Wisconsin) and two community cancer centers (Fairfax, Virginia and Montgomery, Alabama). All “fixed costs” associated with the preparation of chemotherapy doses were collected including drug storage, space, insurance management, inventory and waste management, pharmacy staff payroll, equipment, supplies, information resources and shipping. These costs were annualized and then divided by the number of chemotherapy doses given at each site per year. The total average fixed costs for the preparation of chemotherapy doses across all sites is \$36.03 (range \$32.08 for Virginia and \$67.19 for Utah).

In addition to the “fixed cost” data, a Time-and-Motion study was performed on the top fifteen drugs and regimens used across the four sites to determine what tasks were conducted by pharmacy staff and how much time was spent in the preparation of these agents. Pharmacy staff were observed as to the time spent in each task relative to the total time in an average shift to determine the proportion of total work hours dedicated to the preparation of the selected chemotherapy drugs. Pharmacists were observed to spend the majority of their day (90 % or higher) on tasks directly related to the preparation of these agents.

In addition to the “fixed cost” data, a Time-and-Motion study was performed on the top fifteen drugs and regimens used across the four sites to determine what tasks were conducted by pharmacy staff and how much time was spent in the preparation of these agents. Pharmacy staff was observed as to the time spent in each task relative to the total time in an average shift to determine the proportion of total work hours dedicated to the preparation of the selected chemotherapy drugs.