

# PAIN CARE COALITION

*A National Coalition for Responsible Pain Care*

American Academy of Pain Medicine • American Headache Society • American Pain Society  
American Society of Anesthesiologists

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**By Delivery Room 445-G**

Mark McClellan, M.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, D.C. 20201

Attn: CMS-1501-P

Dear Dr. McClellan:

I am pleased to submit these comments on behalf of the Pain Care Coalition in connection with the agency's proposed hospital outpatient rule for FY 2006. The constituent members of the Pain Care Coalition represent practitioners, researchers and educators dedicated to advancing responsible pain care polices at the federal level which insure patient access to appropriate diagnosis and treatment for acute and chronic pain.

Pain is a tremendous public health problem in this country. It imposes an enormous toll of human suffering on patients and their families. It is well documented that pain is often under treated across demographic groups and care settings. It is a leading cause of lost productivity in the work place and often leads to partial or total disability. It accompanies a wide array of diseases and conditions that are heavily represented in the Medicare population, including arthritis, diabetes, and cancer. For other Medicare beneficiaries, pain is the disease or condition as is the case with migraine or chronic back pain. Given the prevalence of pain in the beneficiary population, it is critically important that Medicare coverage and reimbursement policies insure appropriate access to the wide range of diagnostic and therapeutic modalities now available in different care settings to alleviate suffering and improve health and disability outcomes for acute and chronic pain patients.

One policy area of tremendous consequence to pain patients and those who serve them is the area of new technologies. As new devices are proven safe and effective for the treatment of pain, their dissemination through care settings and ultimately their availability to patients depends on fair treatment in the agency's various payment systems. The comments below focus on certain technology issues in the hospital outpatient rule. Similar considerations should apply under the inpatient PPS system and in ambulatory surgery centers where these same technologies are utilized.

September 16, 2005

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**BY HAND DELIVERY**

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

**RE: CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)**

Dear Administrator McClellan:

On behalf of a diverse group of organizations committed to assuring Medicare beneficiary access to lifesaving intravenous immune globulin (IVIG) therapies, we appreciate this opportunity to comment on the proposed rule concerning the 2006 Hospital Outpatient Prospective Payment System ("HOPPS") rates that were published in the Federal Register on July 25, 2005 (the "Proposed Rule").<sup>1</sup> As a group of patient and provider organizations and industry participants, we are deeply committed to the health and safety of the Medicare beneficiaries who rely upon access to IVIG. IVIG is a lifesaving plasma-derived treatment that strengthens immune systems in primary immune deficient patients. In addition, individual United States licensed IVIG products are labeled for the treatment of Kawasaki's disease, chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial infections, bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults, and idiopathic thrombocytopenic purpura.

Overall the IVIG community understands and supports the Administration's efforts to control Medicare expenditures given budgetary constraints. However, for IVIG, the significant reimbursement rate reduction is likely to dramatically reduce beneficiary access to this critical therapy. The proposed rates reflect a 51% reduction in the payment rate for lyophilized and a 30% decrease for liquid IVIG. The reduced rate is likely to adversely affect patients who depend upon this therapy.

On September 7, 2005 a diverse group representing various sectors of the IVIG community came together in Washington, D.C. for an unprecedented meeting. This group includes representatives from patient advocacy organizations, including the

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

Immune Deficiency Foundation (IDF), the Jeffrey Modell Foundation (JMF), the Neuropathy Association (TNA); the medical community, including the American Academy of Allergy, Asthma and Immunology (AAAAI); health care group purchasing organizations, including Amerinet; distributors of IVIG represented by ASD Healthcare, Cardinal Health, FFF Enterprises, and the Specialty Pharma Distributors Association; manufacturers of IVIG represented by the Plasma Protein Therapeutics Association and its member companies. The group represents over 80% of patients using IVIG, the manufacturers of over 80% of the Plasma Therapies for the United States and more than 60% worldwide, over 3,800 of our nation's hospitals, and the distributors of in excess of 80% of IVIG in the United States. Each representative attending the meeting expressed a desire to work with the Centers for Medicare & Medicaid Services (CMS) and Congress to assure that reimbursement in the HOPPS setting in 2006 is adequate to sustain beneficiary access to IVIG. The comments below represent the views of these groups.

### **Current IVIG Access Limited in 2005 As a Result of Physician Office Reimbursement Reductions**

Since January 1, 2005 patient organizations (see organization descriptions in Attachment A) have received numerous calls from patients, physicians, home health care companies and sites of care concerning treatment problems related to Medicare reimbursement for IVIG treatment. In order to obtain a fair and unbiased assessment of the current impact of changes in Medicare reimbursement since January 2005 on patients with primary immune deficiency diseases who are being treated with IVIG and who are Medicare patients, IDF conducted an independent survey of a sample of this population.

The study identified a subset of patients from two national surveys and ongoing web survey of new patients who reported Medicare coverage. 202 patients with primary immune deficiency diseases, who were currently on Medicare and IVIG users, were interviewed about their treatment experiences in the past 12 months. The survey finds that nearly two out of five (39%) PID patients on Medicare being treated with IVIG have experienced a wide variety of IVIG treatment problems -- most commonly changed locations for infusions (12%) and postponed infusions (16%), but also increased intervals between infusions (11%), lower dosage (6%), switched to less preferred product (7%) and/or less tolerated product (4%). 3% reported having had to stop infusions. Of the 12% who changed site of infusion, 51% reported receiving their infusions in a doctor's office a year ago, as opposed to 9% now. At the same time, 17% reported receiving infusions in a Hospital outpatient setting, and 49% do so now.

According to the survey, the health of 40% of patients experiencing problems getting IVIG in the past 12 months and 15% of all PID Medicare patients on IVIG has been negatively affected. The survey provides verbatim reports from patients experiencing these problems on the role of the new reimbursement standards in these problems and the nature of the adverse health effects they have suffered as a result.

Patient confidence in whether they are currently getting optimal treatment is adversely affected by problems obtaining IVIG. These access issues also dramatically affect patient's confidence in the ability to get appropriate treatment in the future. Less than half (47%) of those who have experienced problems in getting their IVIG treatment in the past 12 months rate the job that the US health care system is doing in getting proper treatment for them as excellent, very good or even adequate.

The experience of Medicare patients at the time this survey was conducted (primarily in May-July 2005) may have been muted by the efforts of many physicians, home health care companies and hospitals to help patients cope with the initial impact of the reimbursement rules. IDF is now receiving more calls about home health care companies and physician offices that had tried to maintain treatment of their Medicare patients since January and are now transitioning them to the hospital setting.

The patient survey information is consistent with the concurrent national survey of 287 physicians with patients using IVIG, totaling 4189 patients with a primary immune deficiency disease, and 935 patients with other disorders. The physician survey found that 31% of those who treat PID patients with IVIG reported patients experiencing significant problems related to reimbursement of IVIG. Of this group, 43% reported adverse health effects on patients as a result of reimbursement. The impact on patients included: 21% switched to a different site of care, 22% postponed infusions, 13% switched brands, and 8% had the interval between infusions increased.

Prior to the implementation of the Medicare Modernization Act (MMA), according to IDF's surveys, 30% of primary immune deficient patients relied on hospital outpatient facilities to receive their IVIG. Since the implementation of the MMA, that number has reportedly increased due at least in part to the fact that health care providers reimbursed under Medicare Part B have had difficulty purchasing IVIG at Medicare's reimbursable rates. We are concerned that under the proposed rule, hospitals (not necessarily nonprofit facilities) will be subject to a similar reimbursement formula, which will put them in the position of administering IVIG at a loss, and will likely adversely affect access to care for all beneficiaries in need of this life-saving product. CMS must prevent the elimination, or even restriction, of access to this important site of care. Each individual needs to have maximum access to the specific formulation which best meets their unique needs and that does not pose serious and potentially life threatening complications.

## **RECOMMENDATIONS**

It is our belief that CMS has the authority and flexibility to address the existing reimbursement problems that will arise if the proposed HOPPS rates are implemented, as we are currently witnessing under Medicare Part B. Specifically, CMS has worked with the dialysis community in order to assure that reimbursement does not deter patient access and care. We request that CMS use this same flexibility so that those Medicare beneficiaries reliant on IVIG are not endangered by a further deterioration in their access to this life sustaining therapy.

For reasons discussed in detail below, the group recommends that CMS take the following actions, with the recommendations listed in order of priority:

1. Establish an add-on payment to the proposed rate for IVIG that captures the true acquisition, direct and indirect handling costs associated with IVIG.
2. In the absence of an add-on, CMS should rely upon precedent from the 2003 HOPPS rulemaking process and apply a 15% dampening provision to the HOPPS IVIG payment methodology for determining the 2006 payment rate.
3. Enhance the representativeness of the payment rate for each IVIG product by establishing unique HCPCS codes for each product.
4. Properly classify IVIG as a biologic response modifier (BRM) and reimburse its administration in a high complexity category.
5. ASP calculation should not include prompt pay discounts.

#### **I. Provide an Add-on Payment**

The present reimbursement environment under Medicare Part B has led to a situation where in certain cases health care providers can no longer purchase IVIG because the cost of the therapy is exceeding its reimbursement. This has resulted in patients being shifted to the hospital outpatient site of service for treatment. With Medicare now proposing to implement the same model for the outpatient site of service, plus an additional 2% of ASP for hospital pharmacy overhead, we are concerned that a similar situation may develop in hospital outpatient care thus leaving those reliant on IVIG without recourse. As you are aware, the June 2005 Medicare Physician Advisory Commission (MedPAC) report found that in the hospital outpatient system, hospital overhead is estimated to be 25-33% of ASP, as this site typically requires greater pharmacy preparation time than do those provided to inpatients. Further, CMS' own Ambulatory Payment Code Advisory Committee recommended that CMS reconsider the 2% add-on for pharmacy overhead costs in addition to reviewing industry data regarding such costs. We request that you take this into account, specifically as it relates to IVIG, when formulating the final OPSS rule.

We also urge CMS, in finalizing the 2006 OPSS rates, to take steps to ensure that hospitals are paid sufficiently for IVIG so that it remains a viable setting for the provision of IVIG. CMS could do this by establishing an add-on payment to the rate for IVIG that captures the acquisition, direct and indirect handling costs associated with IVIG that are above and beyond the rate CMS otherwise determines for the product and pharmacy overhead.

We recognize that the issue of reimbursement for IVIG in all settings has been a complex one. As a result, PPTA has commissioned a study with the Lewin Group to

help clarify the marketplace so that the agency can set appropriate payment policies that will preserve patient access to IVIG in all settings. This study, however, is a significant undertaking, and one that will take some time. PPTA will provide results from the study to CMS upon completion of the project for future ratesetting. In the interim, we urge CMS to adopt an interim measure to ensure that hospitals are adequately reimbursed for IVIG and we offer the preliminary findings of a pilot study from the Lewin Group as the basis for an interim add-on payment to the ASP+6%+2% payment rate.

- The current physician payment rate is not adequate to ensure patient access to IVIG services in physician practices. The last line of defense for many Medicare IVIG patients at this time is the hospital outpatient setting, and hospitals are struggling to ensure they can meet that demand at current payment rates.
- The January 1, 2005 change in Part B reimbursement has resulted in a migration of IVIG patients from physician offices to hospitals.
- Some respondents noted that the change in payment methodology for Part B drugs seems not only to have resulted in physicians transferring their patients to other settings, but, in some instances, keeping their IVIG allocation for use with the non-Medicare patient population.

Appendix A indicates that the cost of goods already exceeds the ASP for the median estimate. This is not sustainable.

## **II. Implement a Dampening Provision in the Absence of an Add-On**

Alternatively, CMS could apply a modified version of the "dampening provision" proposed in the 2003 rulemaking process as many products lost their pass-through status and were paid under the median cost methodology to lessen the impact of dramatic reductions in payment rates for IVIG. CMS stated that the dampening option "mitigate[s] the potential for underpayment" in cases where "costs show significant fluctuations."<sup>2</sup>

Like 2003, the shift in payment methodology proposed for 2006 would drastically reduce the payment rate for IVIG. For example, at present the payment rate for IVIG in the hospital outpatient setting is \$80.68. The proposed 2006 OPSS payment rate for liquid IVIG is \$56.71 and \$39.46 for lyophilized. Even accounting for the 2% of ASP for pharmacy overhead costs, the proposed rates represent reductions of 30% and 51% respectively. It is unreasonable to expect hospital outpatient clinics to be able to adjust to such a drastic reduction in payment without significant consequences. These consequences are most likely to take the form of clinics deciding not to acquire, stock and administer IVIG therapy. This will be tantamount to denying access to care for the patients who rely on IVIG and may well lead to adverse health consequences among this vulnerable population.

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<sup>2</sup> 68 Fed. Reg. 4798, 48003 (Aug. 12, 2003).

Consequently, we recommend that CMS adopt a dampening provision that will limit the reduction in payment rate for IVIG to 15% during the first year of the new payment methodology. A maximum 15% payment reduction, as set by the 2003 precedent in HOPPS rulemaking, for IVIG will force cost efficiencies among hospital outpatient clinics but will not likely lead to a compromise in patient care. This could be achieved by setting the add-on payment at a level equal to the dollar amount necessary to achieve a payment reduction of no more than 15%. In this way CMS can keep payment rates more in line with actual hospital acquisition costs and continue to use the market-based ASP as a reimbursement benchmark in a manner that will optimize patient care and healthcare costs.

### III. Classify IVIG as A Biologic Response Modifier (BRM)

IVIG has been proven to modify the course of several diseases for which there are no other viable therapeutic options. Unfortunately, however, administering IVIG to these patients is a complex undertaking, taking between three to eight hours, and requiring careful monitoring by a trained infusion nurse. In part this relates to the role that IVIG serves as a **biological response modifier (BRM)** in these diseases. A BRM is defined by the National Library of Medicine as: “a treatment intended to stimulate or restore the ability of the immune system to fight infection and disease”. **IVIG is a BRM because it enhances the defective components of immunity to fight and protect against infection and complications of infection.**

As is commonplace with BRM therapy adverse events occur frequently [when administering IVIG therapy], and the risk of severe reactions is real. Because the administration of IVIG is complex, like other BRMs, the process of administering the product should be reimbursed using higher complexity codes. This will allow for the effective and safe administration of IVIG to patients dependent upon this life-saving therapy.

In primary immune deficiencies and in other indications, IVIG modifies aberrant immune response to protect, maintain and restore normal physiology to prevent disease. As is commonplace with BRM therapy reactions occur. For example the FDA licensing studies of IVIG for patients with PI occurrences of reactions (please see package inserts for more information.) The proper diagnosis of reactions in the context of IVIG infusions requires expert supervision and skilled intervention. This is necessary to minimize the impact of the reaction to the patient receiving treatment and in some cases can be life-saving.

Vigilance needs to be maintained for detecting and managing infusions irrespective of an individual patient's personal experience with IVIG. Special precautions include careful monitoring of the entire infusion process which can be as short as three to four hours, but as long as eight hours. Expert nursing care by registered nurses skilled in the administration and risks of IVIG is essential. Nurse to patient ratios of 1:1 and never less than 1:2 are essential to allow frequent clinical assessment (including neurological checks), measurement of vital signs every 15 minutes (including temperature, respirations, heart rate and blood pressure) and comprehensive documentation.

Physician and nurse assessment of a patient to determine suitability for the infusion is also necessary as certain co-morbidities of the primary diagnoses can preclude, or alter the administration of IVIG. The immediate availability of the physician to evaluate the patient at any point during the infusion for assessment of potential complications is also critical. Finally, preparedness for a number of interventions to manage common infusion-related complications, including adjustment of the infusion rate, supplementation with physiological fluids, and provision of analgesics, non-steroidal anti-inflammatories, bronchodilators, antihistamines, steroidal anti-inflammatories, or occasionally systemic sympathomimetics is also required. Clearly, the safe and effective prescription and administration of IVIG requires a highly skilled and coordinated effort from both nurse and physician.

#### **IV. Establish Unique HCPCS Codes for Each Brand of IVIG**

To the extent that CMS finalizes its proposal to pay for all separately payable drugs under OPDS based on ASP information, we believe that CMS could enhance the representativeness of the payment rate for each IVIG product by establishing unique HCPCS codes for each product. That would allow CMS to determine an ASP for each product based on its own ASP information, yielding rates that are pertinent to each product and thus may enhance access to IVIG products.

Unfortunately, there has been an assumption among many policymakers that all eight licensed IVIG products in the United States are exactly the same and the manufacturers' processes have no significant impact on patient care. It is absolutely critical that they understand that IVIG therapies are not interchangeable. Therapies differ in terms of donor pools, manufacturing and final formulation. Indeed, a number of these differences can, and do, affect individuals' tolerability, risk of adverse events, infusion rate, and potential efficacy.

Although this class of therapeutics may be equivalent in some aspect, the U.S. Food and Drug Administration (FDA) recognizes each IVIG brand as unique, and actually makes each drug go through individual clinical trial protocol to receive licensure, even if it is from the same manufacturer. This is because of the differences in basic fractionation and the addition of various modifications for further purification, stabilization and virus inactivation/removal that have yielded products clearly different from one to the other. In addition, there are well-established differences in chemical structure, antibody content, subclass distribution and electrophoretic profile. Clearly, the composition of the final product differs widely.

IVIG therapy is prepared from plasma pooled from thousands of donors. Most production processes begin with sequential precipitation and fractionation with ethanol to isolate IgG from other plasma proteins. The IgG concentrates from initial fractionation are subjected to additional processing to produce material suitable for intravenous administration. This is where major differences exist among products and where biologic function is most susceptible to alteration.

The major differences, which leads to the product characteristics is as follows:

- **Liquid vs. Lyophilized**

The manufacturing process impacts whether the final product is in liquid or lyophilized (freeze-dried powder) form. Liquid preparations are potentially easier to use and may be associated with fewer adverse events. In ready-to-use form, the liquid preparations shorten preparation time and delays for patients. However, lyophilized preparations may have a longer shelf life without the need of refrigeration and are often less costly.

- **Product Concentration**

The manufacturing process also affects product concentration. Products that can be given at higher concentrations decrease volume load, an important aspect in certain patient populations. Concentrating certain products by reconstitution in a smaller volume will increase the osmolality of the final solution and may contribute to significant adverse events such as renal complications or thromboembolic episodes. However, patients that can tolerate rapid infusions can receive higher concentrations of IgG, which would result in shorter infusion times.

- **Product Composition**

The variety of manufacturing processes, as well as starting materials, leads to differences among preparations that may be clinically important. Choosing the preparation of IVIG must take into account specific differences that can significantly impact the outcome in recipients.

- **Fluid Volumes**

The ability to deliver higher amounts of IgG in lower volumes has a major impact on recipients who may be intolerant of large fluid volumes, such as infants or patients with congestive heart failure or renal insufficiency.

- **Sugar Content**

Various sugars, such as: sorbitol, glucose, and sucrose have been added to some preparations as a stabilizer and preservative in order to prevent aggregate formation. Some products contain no sugar. A major concern associated with sugar content is the incidence of significant adverse events, particularly acute renal failure or insufficiency. Although rare, the CDC reported that 90% of the IVIG-associated renal adverse events in the United States occurred with sucrose-containing IVIG preparations.

- **Sodium Content**

In IVIG solutions, the major contributors to osmolality include sodium, sugars, and other excipient proteins. Solutions of IVIG range from physiologic osmolality to solutions that far exceed these levels. Some sugar-stabilized products have higher osmolalities than other sugar stabilized and sugar-free preparations. In

reconstituting lyophilized preparations, careful attention to osmolality is required as adverse events may occur with solutions exceeding the physiologic range. With some lyophilized preparations, reconstitution to higher concentrated solutions results in hyperosmolar solutions.

- **pH**  
The pH optimum for IVIG to prevent aggregation is 4.0-4.5. As a consequence, for preparations at higher pH, agents are added to maintain stability and prevent aggregation. There are various reports that low pH may be associated with phlebitis.
- **IgA Content**  
Patients with selective IgA deficiency and the ability to produce antibodies may be at risk for developing IgE or IgG anti-IgA antibodies resulting in reactions, possibly anaphylaxis.
- **Antibody Titers**  
There are marked differences in the levels of some antibodies among correctly licensed products, which could significantly determine efficacy of intervention with IVIG.

Patient experiences validate these differences. The IDF Treatment Experiences and Preferences of Patients with Primary Immune Deficiency Diseases survey of 2002 showed that patient reaction to IVIG demonstrates that this therapy is not a commodity. The majority of IVIG users surveyed thought there is either a lot (24%) or some (31%) difference between IVIG products in their tolerability. There was also a wide sense that some products may be more effective for specific individuals than others. Given the evidence highlighted above, it is clear that access to the complete range of products is necessary to ensure the physician's ability to provide optimal care.

## **V. Revise Aspects of the ASP Calculation**

Currently, the ASP calculation includes both "prompt pay" and "cash discounts" that manufacturers offer to distributors of IVIG. The current ASP + 6% reimbursement in the Part B physician's office setting does not adequately cover the actual costs of acquiring and safely administering IVIG across all classes of trade. The inclusion of prompt pay discounts in the formula for calculation of ASP could have the unintended consequence of reducing the actual manufacturer's average selling price of IVIG and we therefore request that CMS consider this issue when formulating the Final Rule.

## **CONCLUSION**

The group of organizations represented below appreciates the opportunity to comment on the HOPPS Rule. We are deeply concerned about the impact the rule could have on the lives of patients who rely upon access to IVIG. We do not believe that the drastic drop in the proposed reimbursement rates for this life sustaining therapy that is often the

only available treatment for beneficiaries is sound policy. We urge CMS to consider implementing an add-on for IVIG or, at a minimum, to apply a dampening mechanism that would mitigate reimbursement reductions to no greater than 15% of current rates.

The undersigned organizations look forward to working with CMS and the Administrator toward that goal. Attached is a letter from Congressman Jerry Weller (R-IL) who eloquently expresses his concern for beneficiary access to IVIG in a September 14, 2005 letter to Administrator McClellan. We hope you will also consider the Congressman's viewpoints in your rulemaking process. Please contact Julie Birkofer at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

GBS/CIDP Foundation International  
Immune Deficiency Foundation (IDF)  
Jeffrey Modell Foundation (JMF)  
The Neuropathy Association (TNA)  
Amerinet  
American Academy of Allergy, Asthma and Immunology (AAAAI)  
ASD Healthcare, AmerisourceBergen Specialty Group  
Baxter BioScience  
Cardinal Health  
FFF Enterprises, Inc.  
Grifols USA Inc.  
Octapharma USA  
The Plasma Protein Therapeutics Association  
Talecris Biotherapeutics  
ZLB Behring

### **Medicare Part B Rates Lead to Patient Access Problems**

Patient access to care is essential as IVIG is life saving, as well as life sustaining. Earlier this year, CMS implemented the new average sales price (ASP) payment methodology (ASP + 6 percent) under Medicare Part B. This revision in the payment methodology has not been adequate for health care providers under Medicare Part B to continue to purchase and administer IVIG in physicians' offices, infusion suites, and homecare settings.

TNA and IDF have seen the invoices from the physicians' offices showing that cost for IVIG exceeds the reimbursement payment from CMS. This has caused hundreds of patients to be moved out of their optimal site of care to a new site of care, the hospital, when available. Additionally, due to the shift in patients to new sites of care, the hospitals have been overburdened by the increase in demand for IVIG, which has not been easily accessible. Therefore, patients are facing a reduction in product or in frequency of infusions and higher exposure to infections, which has led to an increase in adverse health impacts of up to forty percent of these patients.

TNA and IDF support comparable reimbursement in all sites of care, as long as it is adequate. The goal should be to ensure that patients have access to all brands of IVIG in all sites of care. Currently, most sites of care under Medicare Part B have been eliminated and we are concerned that if the reimbursement for the hospitals mirrors the reimbursement under Medicare Part B, primary immune deficiency patients will have no place to receive their lifesaving therapy. We wish to work closely with CMS to avert a regretful and avoidable outcome such as hospitals discontinuing service to primary immune deficiency patients requiring IVIG.

Additionally, a letter was sent to Secretary Leavitt on September 6, 2005 by over thirty Members of Congress requesting that the Secretary act upon the recommendations made by the HHS Advisory Committee on Blood Safety and Availability (ACBSA) on May 16, 2005 to declare a public health emergency to enable CMS to apply alternative mechanisms for determination of the reimbursement schedule of IVIG products. ACBSA recognized the "worsening crisis" of IVIG access and how the crisis places "patients' lives at risk." We ask that you work with the Secretary to help increase access to IVIG in all sites of care.

## ATTACHMENT A

The American Academy of Allergy, Asthma & Immunology (AAAAI) is the largest professional medical specialty organization in the United States representing allergists and clinical immunologists. It has approximately 6,200 members in the United States and approximately 600 in 60 other countries. The AAAAI is the main clinical professional organization representing physicians caring for patients with PI. The AAAAI was established in 1943. Its mission is the advancement of the knowledge and practice of allergy, asthma and immunology for optimal patient care.

The Immune Deficiency Foundation (IDF), founded in 1980, is the national nonprofit patient organization dedicated to improving the understanding and treatment of the primary immune deficiency diseases through research, education and advocacy. IDF has more than 17,000 individuals on its data base, with over 10,000 known patients with specific diagnoses, and more than 3,000 physicians who treat patients with primary immune deficiency diseases. IDF provides a number of services to individuals and families, including educational materials, newsletters, and local and national meetings. Its patient advocacy program handles inquiries on treatment, health insurance and diagnosis, and provides a support network of 100 patient volunteers in 35 states. The IDF Consulting Immunologist Program and Visiting Professor Program, as well as medical meetings and materials, help increase education and awareness about the primary immune deficiency diseases. IDF administers the NIH funded US Immunodeficiency Network, a research consortium for the primary immune deficiency diseases. IDF has a well established advocacy program and network, dealing with issues of blood safety and product availability and reimbursement, access to quality health care, and research support. For more information, please visit the website at [www.primaryimmune.org](http://www.primaryimmune.org).

The Jeffrey Modell Foundation (JMF) was established in 1986 in memory of Jeffrey Modell who died at the age of 15 of a Primary Immunodeficiency (PI) Disease. The JMF is an international non-profit organization dedicated to basic and clinical research, physician education, patient support, public awareness and advocacy. There are 23 Jeffrey Modell Diagnostic and Research Centers worldwide and 118 Academic Medical Centers linked in the global JMF Referral Network. There are an estimated 25,000 patients diagnosed or treated at these Centers for PI. Outreach to primary care physicians, pediatricians and sub-specialists in collaboration with NIAID and NICHD at the National Institutes of Health (NIH) have reached more than 200,000 physicians. The Physician Education and Public Awareness Campaign currently generates over 600,000 website hits monthly ([www.info4pi.org](http://www.info4pi.org)) and an average of 500 hotline calls each month (866-INFO-4-PI).

The Neuropathy Association is a non-profit, patient-oriented organization devoted exclusively to all types of neuropathy. It has a membership of 91,400 dues-payers and contributors and has 258 support groups throughout North America and in several European countries. The Association is the

largest and most influential advocacy organization dealing with peripheral neuropathy, which affects upwards of 20 million Americans. Founded in 1995, The Neuropathy Association's mission is to increase public awareness of the nature and extent of neuropathy, facilitate information exchanges about the disease, advocate the need for early intervention and support research into the causes and treatment of neuropathies. Its outreach efforts include its comprehensive website, [www.neuropathy.org](http://www.neuropathy.org), Neuropathy News, its membership newsletter published three times a year, and Momentum, its newest annual publication aimed at neurologists and major supporters. In addition, during 2005 - their ten year anniversary -- the Association opened five "Neuropathy Centers" at major medical universities across the nation. The goal of these centers is to better inform medical professionals, policymakers and the general public about neuropathy by providing resources for education, advocacy and assistance.

The GBS/CIDP Foundation International is a non-profit, 501(c)(3), founded in 1985 and is an organization pledged to providing education and support to patients and their families struck down by Guillain-Barré syndrome (GBS) or chronic inflammatory demyelinating polyneuropathy (CIDP). The organization's research program provides grants to researchers worldwide to find causes and improved treatment options. The GBS/CIDP represents more than 14,000 patients, their families, and over 5,000 physicians and other healthcare providers involved in the care and treatment of our patients.

The Plasma Protein Therapeutics Association (PPTA) is the association that represents the commercial producers of Plasma Therapies. These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80% of the Plasma Therapies for the United States market and more than 60% worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulins ("IVIG") used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

## **PEOPLE WHO RELY ON IVIG**

### **Primary Immune Deficiency**

Primary immune deficiency diseases (PIDD) are disorders in which part of the body's immune system is missing or does not function properly. The World Health Organization recognizes over 130 primary immune deficiency diseases. Many of these disorders are caused by intrinsic or genetic defects in the immune system, which require chronic replacement therapy consisting of intravenous immune globulin infusions to protect individuals from frequent life-threatening infections and debilitating illnesses. IDF has conducted numerous patient and physician national surveys that have produced the only quantitative data available on the incidence of these diseases, as well as the health status of individuals with the diseases, treatment experiences using intravenous

immunoglobulin replacement, and the identification of problems in access to treatments. These surveys have previously estimated over 50,000 patients diagnosed with a primary immune deficiency disease in the U.S. Recent national population surveys estimate that there are actually between 100,000 and 200,000 diagnosed patients in the U.S. Most primary immune deficiency patients do not have an alternative therapeutic option. Therefore survival depends on access to IVIG. For virtually all confirmed antibody deficiencies life long immune globulin replacement is required.

## **Neuropathy**

Two types of neuropathy that can be effectively treated with IVIG are CIDP (*Chronic Inflammatory Demyelinating Polyneuropathy*) and Guillain-Barre Syndrome or AIDP (*Acute Inflammatory Demyelinating Polyneuropathy*). GBS prevalence is estimated at 1.5 to 3.5 per 100,000 population (US) and is treated almost exclusively in the hospital setting.

CIDP prevalence is estimated at 1.9 to 7.7 per 100,000 individuals with GBS. Approximately 50,000 Americans have been diagnosed with CIDP and 20% of these, or 10,000, are treated with IVIG at any one time. Though not definitive at this time, studies suggest that CIDP constitutes approximately 5% of all neuropathies seen in academic centers. CIDP is underrepresented for several reasons, including under-reporting, uncertainty in making the diagnosis and the variants of the disease that have immune or inflammatory aspects and electrophysiological and/or pathologic evidence of demyelinating in common. CIDP is a life-long disease and requires on-going treatment. CIDP is treated in the hospital, hospital out-patient clinic, physician's office, or in the home setting.

Although some neuropathy patients do not respond to IVIG, its efficacy in modifying disease has been demonstrated in placebo controlled trials. Of the 25-27 million grams of IVIG sold annually in the United States, approximately 25% is used to treat patients with neuropathy.

## **Other clinical uses of IVIG**

There are 5 other FDA approved indications for IVIG. These include: 1) prevention of bacterial infection in patients with hypogammaglobulinemia due to B cell chronic lymphocytic leukemia; 2) prevention of coronary artery aneurysms in Kawasaki disease; 3) prevention of infections and graft versus host disease after bone marrow transplantation; 4) reduction of serious bacterial infection in HIV-infected children; and 5) increasing platelet count in idiopathic thrombocytopenic purpura to prevent bleeding. There are also numerous other indications for IVIG many of which have been proven in controlled trials to modify disease. In some of these diseases IVIG represents the only effective therapeutic intervention. The multitude of IVIG uses and evidence supporting these indications has recently been critically reviewed in a Practice Paper of the AAAAI entitled: "Practice paper on the appropriate use of intravenously administered

immunoglobulin (IVIG); and is available on the AAAAI web site -  
[http://www.aaaai.org/media/resources/academy\\_statements/practice\\_papers/](http://www.aaaai.org/media/resources/academy_statements/practice_papers/)

APPENDIX A: IVIG Cost Calculations Based on Hospital Reporting

COSTS PER GRAM (COSTS/Average dose)											vs. 6%	vs. 2%
	Handling	Materials	Pharmacist	Tech	Transp.	Overhead	TOTAL/g	TOTAL/Dose	Cost of Goods (Allocated Price)	Cost of Goods as % over ASP	Handling as % ASP	
<b>POWDER</b>												
LOW	\$ -	\$ 0.06	\$ 0.07	\$ 0.04	\$ 0.01	28%	\$ 0.23	\$ 19.97	\$ 39.80	8.9%	0.6%	
MED	\$ 0.45	\$ 0.08	\$ 0.08	\$ 0.12	\$ 0.03	33%	\$ 1.01	\$ 86.55	\$ 48.38	32.4%	2.8%	
HIGH	\$ 0.70	\$ 0.29	\$ 0.10	\$ 0.53	\$ 0.18	38%	\$ 2.48	\$ 211.83	\$ 50.00	36.8%	6.8%	
<b>LIQUID</b>												
LOW	\$ -	\$ 0.06	\$ 0.07	\$ 0.03	\$ 0.01	28%	\$ 0.22	\$ 10.76	\$ 50.50	-5%	0.4%	
MED	\$ 0.45	\$ 0.08	\$ 0.08	\$ 0.05	\$ 0.03	33%	\$ 0.92	\$ 46.16	\$ 54.50	2.8%	1.7%	
HIGH	\$ 0.70	\$ 0.29	\$ 0.10	\$ 0.22	\$ 0.18	38%	\$ 2.06	\$ 102.86	\$ 58.00	9.4%	3.9%	

ASP Based on CMS Proposed Rule

Non-Lyophilized (liquid)	\$ 53.02	gram	8% of ASP	ASP+8%
Lyophilized (powder)	\$ 36.54	gram	\$ 4.24	\$ 57.26
			\$ 2.92	\$ 39.46

Assumptions

Average dose = 85.36 grams

Overhead is applied to all costs excluding Cost of Good

TOTAL is merely the sum of per gram costs plus overhead

TOTAL/Dose is the total costs times average dose

Overhead costs were not reportable by hospitals in time for this study, therefore an industry range was used

\*\*\*All calculations are based on a limited sample of hospitals and should be considered only as a very broad indicator of the costs present in the IVIG market

**JERRY WELLER**  
11TH DISTRICT, ILLINOIS

DEPUTY MAJORITY WHIP

COMMITTEE ON  
WAYS AND MEANS

SUBCOMMITTEE ON TRADE

SUBCOMMITTEE ON  
SELECT REVENUE MEASURES



UNITED STATES  
HOUSE OF REPRESENTATIVES

HOUSE POLICY COMMITTEE

COMMITTEE ON  
INTERNATIONAL RELATIONS

SUBCOMMITTEE ON  
WESTERN HEMISPHERE  
(VICE CHAIR)

SUBCOMMITTEE ON  
INTERNATIONAL TERRORISM &  
NONPROLIFERATION

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, SW  
Washington, DC 20201

Dear Dr. McClellan:

I would like to raise the issue of Intravenous Immune Globulin (IVIG) and its reimbursement under the Medicare Hospital Outpatient Prospective Payment System. After being informed of patient access difficulties with IVIG under the Average Sales Price (ASP) plus 6% methodology currently utilized under Medicare Part B, I am concerned that Medicare would consider the same methodology without an additional add-on payment for IVIG within the hospital outpatient system.

IVIG is a plasma therapy that is the only effective treatment of primary immune deficiency, a rare and orphan designated condition. It also has been proven clinically beneficial in the treatment of secondary immune deficiency diseases, and certain other rare conditions. As a therapy for rare diseases, patient access is crucial. The present reimbursement environment under Medicare Part B is resulting in certain cases where health care providers can no longer purchase IVIG as the cost of the therapy is exceeding its reimbursement. This has resulted in patients being shifted to the hospital outpatient site of service for treatment. With Medicare now proposing to implement the same model for the outpatient site of service, plus an additional 2% of ASP for hospital pharmacy overhead, I am concerned that a similar situation may develop in hospital outpatient care thus leaving those reliant on IVIG without recourse.

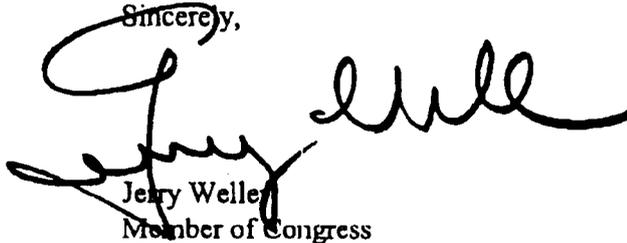
The Medicare Physician Advisory Committee reported that in the hospital outpatient system, hospital overhead is estimated to be 25-33% of ASP, as this site typically requires greater pharmacy preparation time than do those provided to inpatients. Further, CMS' own Ambulatory Payment Code Advisory Committee recommended that CMS reconsider the 2% add-on for pharmacy overhead costs in addition to reviewing industry data regarding such costs. I would request that you take this into account, specifically as it relates to IVIG, when CMS formulates the final rule for the 2006 Medicare Hospital Outpatient Prospective Payment System.

Patient groups, infusion suites, group purchasing organizations, distributors, manufacturers of IVIG and the American Academy of Allergy, Asthma and Immunology have all united in their request that CMS adjust reimbursement for IVIG from what was originally proposed in 2006. Specifically, this coalition has requested that CMS consider an add-on payment or furnishing fee be considered in addition to the proposed reimbursement. This add-on payment will recognize the unique attributes associated with preparing and administering IVIG. As an alternative, CMS may also consider implementing a dampening mechanism as they implemented in 2003 rulemaking. This dampening effect, which required a reduction in reimbursement of no greater than 15%, would serve to blunt the substantial blow that hospital outpatient facilities would incur in 2006. More importantly, this dampening effect would still provide adequate reimbursement for hospital outpatient facilities purchasing IVIG, thus ensuring continued patient access.

I would ask that you consider all options when considering reimbursement for IVIG. Lack of access to this life saving product in the physician's office due to reimbursement has been problematic and the situation will grow worse if the same is allowed to happen in the hospital outpatient setting. Your attention to this situation as CMS prepares its final rule for 2006 will be greatly appreciated.

Thank you for your consideration and I look forward to discussing this matter.

Sincerely,



Jerry Weller  
Member of Congress

APC/Gen Burley  
CCRS Ritter

191

**DUSA**<sup>®</sup>

DUSA PHARMACEUTICALS, INC.®

25 UPTON DRIVE

WILMINGTON MA 01887

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WWW.DUSAPHARMA.COM

September 15, 2005

Dr. Mark McClellan  
Administrator  
Centers for Medicare and Medicaid Services  
Room 445 – G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

RE: CMS – 1501 – P

Dear Dr. McClellan:

On behalf of the hospital outpatient dermatology clinics that use Levulan® Photodynamic Therapy (PDT) to treat Actinic Keratoses Lesions, DUSA Pharmaceuticals appreciates the opportunity to comment on the Proposed Rule for the 2006 Hospital Outpatient Prospective Payment System (HOPPS), (CMS-1501-P).

DUSA Pharmaceuticals' developed, manufactures, and markets the Food and Drug Administration (FDA) approved PDT drug, Levulan® Kerastick®, with the BLU-U® band light source, for the treatment of Actinic Keratoses (AK) of the skin. The sites of service for Levulan® PDT are a physician's private office or a hospital outpatient department. Patients treated by dermatologists in a hospital outpatient department are usually the most severely affected with high numbers of lesions or whole contiguous areas of the face and scalp covered with lesions. Many of these patients are also immunocompromised (e.g. transplant patient, AIDS/HIV, Lupus, etc.).

### **Proposal to Move CPT Code 96567 to APC 0016**

The issue we wish to support is the proposal to move CPT Code 96567, Photodynamic Therapy of the Skin, from APC 0013 paying \$64.85 to APC 0016 with a proposed payment rate for 2006 of \$153.31. We also greatly appreciate the fact that the drug used with this procedure (J 7308) is reimbursed separately and not bundled into the payment for the procedure code. The proposed payment for 2006 of \$153.31 brings hospitals much closer to covering the costs of providing this service after excluding the costs of the drug.

We appreciate that as CMS' median cost data increases both in regard to number of "single" claims used to set the APC assignment, in this instance 96 claims, and in the median cost calculated, in this instance \$196.69, that CMS has proposed to move CPT Code 96567 and assign it to an APC that comes closer to covering the procedure costs.

We commend CMS for proposing that CPT code 96567 be assigned to APC 0016 for CY 2006 and ask that CMS continue to monitor the median costs reported by hospitals for this procedure so that access to Levulan® PDT can be maintained for Medicare beneficiaries.

DUSA Pharmaceuticals appreciates the opportunity to provide comments on this proposed rule. If DUSA can provide CMS with additional information regarding this matter, please do not hesitate to contact me at 1-800-607-2530, ext. 125, or [shulmang@dusapharma.com](mailto:shulmang@dusapharma.com).

Sincerely yours,



D. Geoffrey Shulman, MD, FRCPC  
Chairman and CEO

NPT D-BR  
Payment D BR  
Payment device  
AHMED (4)  
Levi

September 15, 2005

Dr. Mark McClellan  
Administrator  
Centers for Medicare and Medicaid Services  
Room 445 – G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

RE: CMS – 1501 – P

Dear Dr. McClellan:

SenoRx, Inc. appreciates the opportunity to comment on the Proposed Rule for the 2006 Hospital Outpatient Prospective Payment System (HOPPS), (CMS-1501-P). SenoRx is a private company located in Aliso Viejo, California that was founded in 1998 to design, manufacturer and market minimally invasive devices for the diagnosis and treatment of breast cancer. Since its founding, SenoRx has developed multiple, proprietary technology platforms in this area, most notably novel biopsy site marker systems and lesion localization/resection devices.

**RE: "Transitional Pass-through Payments for Devices"**

SenoRx is concerned regarding the Centers for Medicare and Medicaid Services (CMS) decision to move forward with a December 31, 2005 expiration date for device pass-through category C1819 – Tissue Localization Excision Device. SenoRx urges CMS to use its authority to extend this category for another year, supporting the adoption of this device in the diagnosis and treatment of breast cancer.

We are concerned that CMS' median cost data for the procedure CPT codes where a Tissue Localization Excision Device is used do not include the costs attributed to C1819. We believe that the volume of C1819 claims in CMS' OPSS data for 2004 will be such that any increased costs for C1819 will become "averaged" out when CMS uses its current method for determining median costs per CPT code. Therefore, the APC assignment for CPT code 19125 and CPT code 19160 will not reflect the additional costs of these devices.

**CMS' 2004 Median Cost Data for CPT codes 19125 and 19160 Does Not Include Tissue Localization Excision Device Costs:**

In the proposed rule, CMS states that for those device categories where it is discontinuing pass-through payment in CY 2006, it is proposing to package the costs of the devices assigned to in this case C1819 into the costs for the procedures with which the devices were billed in CY 2004, in this case CPT codes 19125 and 19160.

Under this proposal, an analysis of the median costs for CPT codes 19125 and 19160 that have been used to assign them to an appropriate APC over the last three years, should demonstrate



PBT  
NT APC

193

SIR  
APC weights

September 16, 2005

B-Therapy  
IMASIOS  
HERES/DIBIR

Hunter  
Spalter  
Hostetler  
Heggster  
Levi  
Burley  
Ahmed  
Kane  
SARAW  
Hart  
Bazell

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: CMS-1501-P: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates**

Dear Dr. McClellan:

The American Society for Therapeutic Radiology and Oncology (ASTRO)<sup>1</sup> appreciates the opportunity to provide comments on the Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2006 Payment Rates announced in the Federal Register on July 25, 2005. Our comments focus on (1) proposals regarding proton beam therapy; (2) proposal for submission of a CPT application for a new technology service; (3) proposed use of single and multiple procedure claims; (4) stereotactic radiation therapy; (5) proposal to move CPT<sup>®</sup> code 57155 *Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy* from APC 0193 to 0192; (6) the proposed decrease for brachytherapy CPT code 77778 *Interstitial radiation source application; complex*; and (7) multiple diagnostic imaging procedures.

**I. Proton Beam Therapy [70 Fed. Reg. 42707]**

Proton treatment is a precise form of radiation treatment available for certain cancers and other diseases. The precision of the treatment is beneficial to the patient because it minimizes the harm to surrounding healthy tissues and meanwhile allows the patient to resume normal activities with few to no side effects. There are three facilities providing proton therapy at this time (two hospital-based—Loma Linda University Medical Center and Massachusetts General Hospital, and one freestanding facility—Midwest Proton Radiation Institute (MPRI) in Bloomington, Indiana) and approximately five other facilities in the process of starting up their treatment centers. ASTRO supports the classification and payment rates for simple, intermediate and complex proton therapies as proposed (CPT codes 77520, 77522, 77523 and 77525, respectively). The proposed rule not only maintains separation in the complexities of proton therapy, but also because it more accurately provides for the extraordinary capital expense and high operating costs of a proton beam facility.

<sup>1</sup> *The American Society for Therapeutic Radiology and Oncology is the largest radiation oncology society in the world with more than 7,500 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society's mission is to advance the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly evolving socioeconomic healthcare environment. Nearly two-thirds of all cancer patients receive radiation therapy during their illness. Medicare/Medicaid is the predominant source of reimbursement for radiation oncology procedures.*

***Recommendation #1:*** *ASTRO agrees with CMS's proposal to move intermediate and complex proton therapy (CPT<sup>®</sup> codes 77523 and 77525) from New Technology APC 1510 to clinical APC 0667 (Level II Proton Beam Radiation Therapy) based on a median cost of \$934.46 for CY 2006. We also support the proposed payment rates for simple proton therapies (CPT codes 77520 and 77522) to be \$768.13 under APC 0664. Since these proposed payment rates are more reflective of the significant capital demands associated with the high costs of operating and developing a proton therapy center, ASTRO recommends that CMS make the proposed payments final for CY 2006.*

## **II. New Technology APCs [70 Fed. Reg. 42707]**

We understand that CMS is proposing to require that an application for a code for a new technology service be submitted to the AMA CPT Editorial Panel before CMS accepts a New Technology APC application for review. Further, we understand that CMS is requesting that a copy of the submitted CPT application be filed with CMS as part of the application for a New Technology APC assignment under the OPSS, along with CPT Editorial Panel's letter acknowledging or accepting the coding application but that the CPT application does not need to go through the entire CPT process and receive approval from the CPT Editorial Panel upon submission of the New Technology application to CMS. We agree with CMS that in the past, there have been situations when a New Technology APC application is submitted when ambiguity in the coding framework for the new technology has caused problems for hospitals to correctly bill for the services, and that has not always translated well to the coding schema in place for physician reimbursement. In general, ASTRO is in support of new services going through the AMA CPT process to apply for CPT Codes (Category I or Category III). However, we understand that there are certain individual circumstances when it might be necessary to submit an application to the CPT Panel and to CMS at the same time.

***Recommendation #2:*** *ASTRO supports the CMS proposal requiring that an application for a code for a new technology service be submitted to the AMA CPT Editorial Panel before CMS accepts a New Technology APC application for review, allowing for those circumstances when a CPT application and a New Technology APC application may need to be submitted at the same time.*

## **III. Proposed Use of Single and Multiple Procedure Claims [70 Fed. Reg. 42681]**

As we have commented to CMS in the past, we are in support of the methodological changes to increase the number of single bills which could be used to calculate the relative weights. These changes include refinement of the policy for determining which HCPCS codes could be bypassed for purposes of creating single bills from multiple bills. In the proposed rule, CMS requested comment on the list of codes that the agency is proposing to bypass for creation of "pseudo" singles for CY 2006. The list of bypassed HCPCS codes added some new HCPCS codes from the 2005 list, including the addition of CPT codes 77295, Set radiation field, and 77402, 77404, 77408 Radiation treatment delivery. We agree with CMS that use of the bypass list allows for more single claims for ratesetting than had the list not been adopted.

***Recommendation #3:*** *ASTRO would like to thank CMS for adopting a bypass list that includes many radiation oncology codes and we support the addition of the new radiation oncology codes for CY 2006.*

## **IV. Stereotactic Radiosurgery [70 Fed. Reg. 42708]**

ASTRO appreciates the continued opportunity to comment on the reimbursement issues surrounding stereotactic radiosurgery (SRS). In past comment letters to CMS, we have recommended the elimination of HCPCS codes G0242 (Cobalt 60-based planning) and G0338 (linac-based planning) and the utilization of existing CPT<sup>®</sup> codes as determined by the process of care. We have repeatedly pointed out that SRS treatment planning is already well described by CPT codes (77295, 3D simulation or 77301 IMRT planning) and that other simulation and physics codes (77300, 77370 and 77315) are currently used by

physicians for their portion of the procedure. ASTRO believes that eliminating the “G” codes for planning would help “clean up” the current coding puzzle and provide more clarity for physicians, and we appreciate your comments that specific data is not required for stereotactic treatment planning.

***Recommendation #4: ASTRO supports the CMS proposal to eliminate G0338 and G0242 for planning and instead the utilization of existing CPT® codes for planning and simulation (77295, 3D simulation or 77301, IMRT planning) and physics (77300, 77370 and 77315) as determined by the process of care.***

At the February 2005 APC Panel Advisory meeting, the Panel discussed the SRS G codes and the Panel recommended to CMS not to change the current G codes for SRS delivery to allow for more time to review the data collected through the use of the G codes. In the proposed rule, we understand that CMS has requested comments based on one APC Panel presenter’s request to combine cobalt planning G0242 and cobalt delivery G0243 together into a single procedure code because the presenter believed that a majority of patients receive cobalt planning and delivery on the same day. While we agree that planning and treatment delivery are performed on the same day for cobalt-SRS, likewise planning and delivery are performed on the same day for linac based-SRS. Therefore, we do not agree with the presenter that cobalt-SRS delivery requires a new APC code that encompasses planning and delivery. Furthermore, having an inconsistent coding scheme for cobalt-SRS versus linac-SRS will cause more confusion and make it more difficult for the person responsible for billing at the hospital.

Since by definition “G” codes are transitional and should eventually either be rolled into permanent CPT codes or deleted, ASTRO would like to let CMS know that we submitted two CPT applications to the AMA CPT Editorial Panel for two technical-only codes to that would roll-over the current G codes for linear accelerator (G0173) and multi-source Cobalt 60 based (G0243) single session SRS delivery. These two new codes will be for the technical component (TC) only of SRS treatment delivery of cerebral lesion(s), complete course in one session—one code for multi-source Cobalt 60 based and one code for linear accelerator based. These codes do not include a physician component (PC) or physician work to them as there are other CPT codes (77432 for the radiation oncologist) available for this aspect. ASTRO will be making recommendations to the AMA at the upcoming September RUC meeting regarding the non-physician work and cost of equipment and supplies for both the linear accelerator and multi-source Cobalt 60 based treatment delivery.

***Recommendation #5: ASTRO urges CMS not to combine cobalt planning G0242 and cobalt delivery G0243 together into a single procedure code. Further, ASTRO supports the CMS proposal to not make any changes to the SRS delivery codes G0173, G0243, G0251, G0339, and G0340.***

#### **V. Brachytherapy Services (CPT® codes 57155 and 77778) [70 Fed. Reg. 42703]**

ASTRO is extremely concerned with the proposed reduction of CPT code 57155 *Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy* from the current payment rate of \$758.17 (APC 0193) to \$254.53 (APC 0192); a decrease of 66.4 percent. We understand that CMS proposed to move this code, as well as 64 other CPT codes that violated the two-times rule, to another APC based on the CMS presentation at the February 2005 APC Panel. We are also concerned about the proposed reduction of CPT code 77778 *Interstitial radiation source application; complex* from the current payment rate of \$1,248.93 to \$717.53; a decrease of 42.5 percent.

As a result of our concern and to understand why the proposals for these codes resulted in such drastic reductions which have the potential of limiting patient access to these important brachytherapy treatments, we conducted a manual review of the multiple claims. Based on this manual replication of the CMS methodology there is evidence that CMS uses multiple claims, grouped by date of service, that have no packaged items as “pseudo” single claims. For CPT® code 77778 and 57155, these claims make up a considerable number of the overall single claims count and have consistently lower cost findings than the

other types of single claims. By using the Pseudo Non-Packaged claims, we would like to emphasize to CMS the following:

- A) Cost findings are not consistent with other types of single claims for the same major procedure;
- B) The median cost for the HCPCS rises when these claims are removed;
- C) The Pseudo single Non-Packaged claims represent a small proportion of overall comparable claims;
- D) The mean and median costs of the packaged items for the comparable claims are not insignificant; and
- E) The overall number of providers is not representative of the number submitting comparable multiple claims.

The single/multiple methodology was then revised to break these claims into pseudo singles by date of service and the resulting frequency counts matched CMS within +/- 1% for 77778 and 57155. Table 1 compares CMS and The Moran Company's (TMC) replication.

Table 1. CMS v. TMC Replication

HCPCS	SI	APC	Pay Rate	CMS Single Count	TMC Single Count	% Diff	CMS Min	TMC Min	CMS Max	TMC Max	CMS Mean	TMC Mean	CMS Median	TMC Median	%Diff.
57155	T	0192	\$256	758	769	1%	\$16	\$16	\$7,756	\$7,769	\$834	\$849	\$303	\$356	18%
77778	S	0651	\$721	342	340	-1%	\$78	\$77	\$7,904	\$7,905	\$1,260	\$1,237	\$733	\$722	-1%

**A) Cost findings are not consistent with other types of single claims for the same major procedure**

In the manual replication, the "single" claims were classified into the following categories:

- (i) Original Single (ORIG)<sup>2</sup>,
- (ii) Pseudo Single by Date of Service (PSEUDO DOS)<sup>3</sup>,
- (iii) Pseudo Single by Bypass (PSEUDO BYPASS)<sup>4</sup>; and
- (iv) Pseudo Single because of No Packaging (PSEUDO NON-PACK).

We reviewed the implication of using "Pseudo" Single Claims because of No Packaging (PSEUDO NON-PACK) on CPT codes 77778 and 57155. We considered these PSEUDO NON-PACK claims as those that have dates of service for all packaged items and once grouped by date of service, result in multiple procedures on the same date of service with NO packaged items. These claims are therefore

<sup>2</sup> **Original Single (ORIG):** These are claims that contain only one unit of one major procedure and therefore, the entire claim is used in rate setting.

<sup>3</sup> **Pseudo Single by Date of Service (PSEUDO DOS):** These are claims that have dates of service for all packaged items and once grouped by date of service, result in only one unit of one major procedure being present on that claim/date match; all the packaged items with the same date of service as the major procedure are used in rate setting.

<sup>4</sup> **Pseudo Single by Bypass (PSEUDO BYPASS):** These are claims that have dates of service for all packaged items and once procedures listed on the bypass list are ignored, result in only one unit of one major procedure being present on that claim/date match; all the packaged items with the same data of service as the major procedure are used in rate setting. The "bypassed" codes are also converted to pseudo singles during this step whereby the line of the bypass code becomes the entire new pseudo claim.

converted into multiple pseudo (line level) single claims. In other words, each line that contains a major procedure becomes a “pseudo” single. We found that a considerable proportion of the single claims for both CPT® code 77778 and 57175 contain these types (PSEUDO NON-PACK) of singles (23% and 80% respectively). For CPT® 57155, these singles make up the majority of the single claims. When we evaluated whether these claims were different in terms of cost findings, we found that these claims also had considerably smaller overall cost findings than the Original Singles, Pseudo Single by Date of Service, and Pseudo Single by Bypass claims.

Our analysis found that there is a large difference between the cost findings for the types of singles. Tables 2 and 3 describe these cost findings. We also found that there are multiple claims that contain a similar distribution of the major procedures that were originally included in the PSEUDO NON-PACK claims. For both CPT codes 77778 and 57155 there are many multiple claims that contain a similar distribution of the major procedures. For the 80 PSEUDO NON-PACK claims for CPT code 77778, the 3 CPT codes that appear most often include: 55859 (33 times), 77920 (30 times), and 76965 (29 times)<sup>5</sup>. For the 621 PSNPk claims for CPT code 57155, the 3 codes that appear most often include: 77290 (358 times), 77784 (258 times), and 77783 (212 times)<sup>6</sup>.

**B) The median cost for the HCPCS rises when the PSEUDO NON-PACK claims are removed**

The median cost of the CPT code 57155 PSEUDO NON-PACK claims is \$211 while the medians for the other types of claims are \$1,141 (ORIG) and \$1,456 (PSEUDO DOS)—an 82% to 86% difference.

Similarly, the median cost of the 77778 PSEUDO NON-PACK claims is \$447 while the medians for the other types of claims are 1,567 (ORIG) and 929 (PSEUDO BYPASS)—a 53% to 71% difference. Tables 2 and 3 summarize these dramatic results.

*Table 2. Descriptive Statistics of Cost Findings for CPT® 57155 by Type of Single Claim*

Type	Single Claim Count	Percent Total Claims	Mean	Min	Max Median	Median	
Pseudo Bypass	60	8%	\$1,720	\$86	\$7,399	\$1,456	-86%
Pseudo Non-Pack	619	80%	\$714	\$16	\$7,769	\$211	
Original	90	12%	\$1,190	\$86	\$7,726	\$1,141	-82%
Sum	769						

*Table 3. Descriptive Statistics of Cost Findings for CPT® 77778 by Type of Single Claim*

Type	Single Claim Count	Percent Total Claims	Mean	Min	Max Median	Median	
Pseudo Bypass	252	74%	\$1,413	\$89	\$6,953	\$929	-52%
Pseudo Non-Pack	77	23%	\$549	\$77	\$2,922	\$447	
Original	11	3%	\$2,005	\$149	\$7,905	\$1,567	-71%

<sup>5</sup> This is the total number of PSEUDO NON-PACK claims before trimming; the previous table reports a count of 77, indicating 3 of these claims are removed in the trimming process.

<sup>6</sup> Similarly, the total number PSEUDO NON-PACK claims before trimming is 621, indicating 2 claims were trimmed during rate setting.

In an effort to estimate the extent to which these PSEUDO NON-PACK claims are affecting the overall median cost for these CPT<sup>®</sup> codes, we removed them from the analysis and re-ran the median methodology. In both cases, the median rises; 265% for 57155 and 29% for 77778. Table 4 summarizes the findings of this simulation.

*Table 4. Change in Median Cost associated with Removing Psuedo Bypass Singles*

HCPCS	Simulated Claim Count	TMC Single Count	Simulated Median	TMC Median	% Change
57155	146	769	\$1,297	\$356	265%
77778	263	340	\$929	\$722	29%

**C) The PSEUDO NON-PACK claims represent a small proportion of overall comparable claims**

Examination of the multiple claims reveals that claims with the similar combinations of these major procedures on the same date of service are prevalent and all have associated packaging. (Note, all of the multiple claims have associated packaging except for those multiple claims that contain more than one unit or those that do not have a date of service for packaged items.) In terms of a proportion of total claims, the PSEUDO NON-PACK claims make up only a minority of the total claims. For CPT code 77778, for instance, the PSEUDO NON-PACK claims represent only 1% of comparable claims; for CPT code 57155, the PSEUDO NON-PACK claims represent about half of comparable claims. In other words, claims that follow this pattern of billed services are often, and in the case of CPT code 57155, are almost always billed with packaged items.

**D) The mean and median costs of the packaged items for the comparable claims are not insignificant**

As expected, the comparable multiple claims have packaged costs associated with the major procedures. While it is true that because there are multiple major procedures on these claims it is not transparent how to apportion these packaged costs to each procedure, it is still important to examine the magnitude of these costs. It is important to note here that again, the “comparable” claims contain a distribution of major procedures congruent to those found on the PSEUDO NON-PACK so that *how* to apportion the packaged cost is not as important as demonstrating that for all these major procedures when performed together, there is more often than not a significant amount of packaged costs attributed to these services. Table 5 describes the costs associated with packaged items on the “comparable” claims for CPT codes 77778 and 57155. The mean and median cost for these packaged items is not insignificant and even if only partly attributable to either CPT codes 77778 or 57155 would be important to the overall cost finding for these claims.

*Table 5. Description of Packaged Costs associated with “Comparable” Multiple Claims*

HCPCS	Single Claim Count	Mean	Median	Min	Max
57155	514	\$3,043	\$2,788	\$271	\$9,372
77778	8637	\$7,859	\$7,125	\$23	\$58,853

**E) The overall number of providers is not representative of the number submitting comparable multiple claims**

The number of providers represented in the PSEUDO NON-PACK claims is not representative of the number of providers submitting similar multiple claims. CMS states in the proposed rule that a particular methodological decision was made based on the fact that the results would have included claims from a small number of providers that were not representative of the total providers submitting similar claims<sup>7</sup>. By comparison, the total number of unique providers submitting “comparable” multiple claims was 783 for CPT<sup>®</sup> code 77778 and 101 for CPT code 57155 while the total number of unique providers submitting PSEUDO NON-PACK claims was 34 and 48 respectively. Moreover, the majority (>60%) of the PSEUDO NON-PACK claims were submitted by 10 or fewer providers.

***Recommendation #6: ASTRO recommends that CMS, within the scope of the single/multiple methodology, not include these Pseudo Single because of No Packaging (PSEUDO NON-PACK) claims as “pseudo” singles because they inadvertently bias some median cost findings downward. Further, ASTRO strongly recommends that CMS limit this technical change to CPT<sup>®</sup> codes 57155 and 77778.***

## **VI. Multiple Diagnostic Imaging Procedures [70 Fed. Reg. 42748]**

ASTRO is concerned about the CMS proposal to implement the MedPAC recommendation to “reduce the technical component payment for multiple imaging services performed on contiguous body parts.” We understand that specifically, CMS proposes to make full payment for the procedure with the highest APC payment rate and to make a 50% reduction in the OPSS payments for some second and subsequent imaging procedures performed in the same session. ASTRO supports CMS’s position that, when *some* of the procedures identified by CMS are performed in the same session, *some* of the resource costs are not incurred twice. However, we believe that CMS has not taken into consideration the fact that the cost efficiencies of performing multiple imaging procedures in the same session are already captured and accounted for in hospitals’ annual cost reports to CMS and therefore already factored into the APC payment. Since the HOPPS/APC methodology already accounts for the cost efficiencies of multiple procedures in the same session, an additional 50% reduction, as described in this proposed rule, would contradict this methodology and systematically disadvantage hospitals relative to other imaging facilities. It would also result in an unintended, inappropriate and severe financial penalty to hospitals, making it difficult for them to upgrade equipment, hire necessary staff and provide the same hours of outpatient imaging operation, thus decreasing access of necessary care to Medicare beneficiaries.

***Recommendation #7: In agreement with the recommendation of the APC Advisory Panel during the August 2005 meeting, ASTRO recommends that CMS delay for 1 year the proposal to reduce payment for the second and subsequent imaging services when multiple diagnostic imaging procedures are performed in one session so that further data can be gathered regarding the implications for hospitals.***

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<sup>7</sup> CMS states in the latest proposed rule that they chose not to require a device be coded on these claims because “APCs would be set based on very small numbers of claims” and that “the small subset of hospitals are unlikely to be representative of the resource costs of most hospitals that provided the service” \*FR/Vol. 70, No. 141/Monday, July 25, 2005/Proposed Rule, pgs. 42713-14

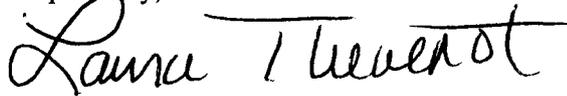
## VII. Conclusion

ASTRO applauds the CMS staff for their efforts to use more current data and to make more information available to the public in the proposed, rather than the final rule. Our recommendations include the following:

- (1) Make final for CY 2006 the proposals for increases in payment for simple, intermediate and complex proton beam therapies;
- (2) Require that an application for a code for a new technology service be submitted to the AMA CPT Editorial Panel before CMS accepts a New Technology APC application for review, allowing for those circumstances when a CPT application and a New Technology APC application may need to be submitted at the same time;
- (3) Make final the bypass list that includes the addition of the new radiation oncology codes for CY 2006;
- (4) Eliminate the G0338 and G0242 for SRS planning and instead utilize existing CPT<sup>®</sup> codes as determined by the process of care;
- (5) Maintain the current SRS delivery HCPCS codes G0173, G0243, G0251, G0339, and G0340;
- (6) Eliminate the use of Pseudo Single because of No Packaging (PSEUDO NON-PACK) claims for those CPT<sup>®</sup> codes 57155 and 77778; and
- (7) Postpone for 1 year the proposal to reduce the second and subsequent diagnostic imaging procedures so that further data and implications can be studied.

The American Society for Therapeutic Radiology and Oncology appreciates the opportunity to offer these comments and looks forward to working with CMS to address these important issues. If you require further information, please contact Trisha Crishock, MSW, Director, Health Policy and Economics Department at (703) 502-1550.

Respectfully,



Laura Thevenot  
ASTRO, Chief Executive Officer

cc: Trisha Crishock, MSW  
Herb Kuhn  
Ken Simon, MD  
Edith Hambrick, MD  
Dana Burley  
Cindy Read

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September 12, 2005

The Honorable Mark B. McClellan, M.D., PhD  
Administrator  
Centers for Medicare and Medicaid Services  
Attention: CMS – 1505 – P  
Post Office Box 8016  
7500 Security Boulevard  
Baltimore, MD 21244-8018

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

File Code: CMS – 1505 – P  
Proposed Payments for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status

Dear Dr. McClellan:

I am a Professor of Surgery as well as the Chair of Research and Assistant Dean of the Dr. William M. Scholl College of Podiatric Medicine at Rosalind Franklin University of Medicine and Science in North Chicago. I also serve as the Director of the Center for Lower Extremity Ambulatory Research [CLEAR] at the Rosalind Franklin University of Medicine and Science.

In these capacities, I see and treat a significant number of chronic wounds. For this reason, and as a concerned clinician-researcher, I am commenting on the Centers for Medicare and Medicaid Services [CMS] Proposed Rule - "Medicare Program; Proposed Changes to the

Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates;  
Proposed Rule.”

Two FDA approved technologies impacted by the proposed rule are Dermagraft and Apligraf - unique living human tissue substitutes used to treat chronic wounds. Over the past five years, these products have improved the quality of life of thousands of Medicare beneficiaries who suffer from chronic leg and foot ulcers. As demonstrated in pivotal trials, many patients would have likely undergone amputations without the benefit of these products. Having extensive experience with many wound healing modalities, the ability to use these proven products provides physicians the ability to treat and close difficult, hard to heal chronic wounds.

Since 2002, both Apligraf and Dermagraft were paid as biologics under the Hospital Outpatient transitional pass through program. Additionally, both products have been paid for as specified covered outpatient drugs in 2004 and 2005 with the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

In the proposed 2006 Medicare Hospital Outpatient Rule, CMS proposed to reimburse specified covered outpatient drugs at average sales price [ASP] plus six percent for the acquisition cost of the drug.

For some reason however, in the proposed rule both Dermagraft and Apligraf were incorrectly identified and the proposed reimbursement was based on 2004 claims data instead of the ASP methodology. Because of the claims data calculation, both products experienced a significant decrease in payment which is unacceptable for purchasing hospitals:

**Medicare Hospital Outpatient**

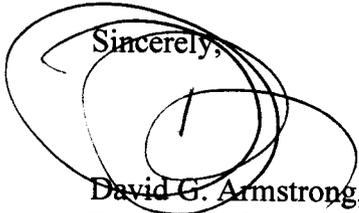
	2005 – Actual	2006 – Proposed
Dermagraft [C 9201]	\$ 529.54	<b>\$ 368.32</b>
Apligraf [C 1305]	\$ 1,130.88	<b>\$ 766.84</b>

Dermagraft and Apligraf have been reimbursed in the hospital outpatient setting as specified covered outpatient drugs since 2004. As such, the ASP payment methodology is appropriate for these and other specified covered outpatient drugs. Without this, Medicare beneficiary access to these advance treatment options in hospital clinics are jeopardized by the payment rates in the 2006 Medicare proposed rule.

I request the proposed 2006 Medicare hospital outpatient reimbursement for Apligraf and Dermagraft be corrected in the final rule, and be reimbursed based on the ASP methodology.

Thank you in advance for your immediate attention to this issue.

Sincerely,



David G. Armstrong, D.P.M., Ph.D.  
Professor of Surgery  
Chair of Research and Assistant Dean  
Dr. William M. Scholl College of Podiatric Medicine at  
Rosalind Franklin University of Medicine and Science  
Director,  
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cc: Mr. Herb Kuhn  
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September 16, 2005

**VIA HAND DELIVERY**

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

**Re: Comments on CMS-1501-P; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 (Payment Rates for High-Energy Extracorporeal Shock Wave Procedures)**

Dear Dr. McClellan:

On behalf of SanuWave, Inc. ("SanuWave"), a leader in the provision of High-Energy Extracorporeal Shock Wave ("ESW") equipment for the treatment of chronic plantar fasciitis and lateral epicondylitis, we write to urge the Centers for Medicare and Medicaid Services ("CMS") to adjust the proposed payment amount for the High-Energy ESW procedures in the hospital outpatient department.<sup>1</sup> In its proposed changes to the Hospital Outpatient Prospective Payment System ("OPPS") for calendar year ("CY") 2006, CMS classified the procedures under new technology ambulatory payment classification ("APC") 1547.<sup>2</sup> The proposed payment rate of \$850 (with an unadjusted minimum co-payment amount of \$170) would leave in place a payment level that does not consider all the costs incurred by hospitals in providing the services. For the reasons more fully explained below, SanuWave submits that the appropriate new technology cost band for the ESW technology is Level XXII (\$2,000-\$2,500), or APC 1559. SanuWave respectfully requests that CMS assign the procedure to the Level XXII cost band for CY 2006.

<sup>1</sup> On August 2, 2005, SanuWave acquired the orthopedic High-Energy ESW assets of HealthTronics, Inc., the prior owner of the OssaTron<sup>®</sup> technology.

<sup>2</sup> 70 Fed. Reg. 42673, 42917 (July 25, 2005).

## **Background**

By way of background, we note that the High-Energy ESW procedures to treat plantar fasciitis and lateral epicondylitis were first placed into a New Technology APC in the November 15, 2004 final rule with comment period.<sup>3</sup> It appears that CMS classified the procedures into APC 1547 based on the misapprehension that the costs and resources involved in performing these surgical procedures are reflected in those used for diagnostic colonoscopy. This is incorrect. In fact, the two procedures require vastly different resources, with different cost considerations. Setting Medicare payment for the High-Energy ESW procedures using cost information for the diagnostic colonoscopy therefore results in a gross underpayment for the technology. Not only does the payment rate jeopardize beneficiary access to needed treatment, it limits patient options to invasive and less effective treatment, with overall higher treatment costs.

In response to the November 15, 2004 final rule with comment period, HealthTronics, Inc, the former owner of the OssaTron<sup>®</sup> High-Energy ESW technology — used in procedures known as Orthotripsy<sup>®</sup> — submitted a comment letter challenging the payment levels set for CY 2005.<sup>4</sup> (A copy of this January 12, 2005 comment letter is attached at Tab A for quick reference.) The comment letter discusses the costs incurred in furnishing High-Energy ESW procedures and distinguishes the resources for these surgical procedures from the resources used in a diagnostic colonoscopy. We have been advised that the January comment letter was not considered in the development of the proposed CY 2006 rule, but would be considered by CMS in its development of the CY 2006 final rule. We ask that the discussion below be considered in tandem with the discussion in the earlier letter.

In brief, SanuWave believes that the Medicare payment level for its High-Energy ESW procedures for plantar fasciitis and lateral epicondylitis should be based on the costs of the ESW technology itself, and not on the costs of other technologies. If, however, CMS chooses to rely on the costs of other procedures to make a payment determination here, the most comparable procedure would be lithotripsy, which also involves the use of High-Energy ESW and similar resources. The established payment level for the lithotripsy procedure — which has been assigned to APC 0169, for which CMS has proposed a CY 2006 OPPS payment rate of \$2,541.27 (with unadjusted minimum co-payment of \$508.25) — offers a reasonable basis for comparison of costs here.

## **Payment for New Technology—Generally**

CMS has established a number of new technology APC codes, using refined cost bands, to provide payment for a temporary period for those new technologies that do not qualify for transitional pass-through payments and for which CMS has little or no data to base assignment to an existing APC.<sup>5</sup> A new procedure is to be classified into a new technology APC *on the basis*

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<sup>3</sup> 69 Fed. Reg. 45682 (Nov. 15, 2004).

<sup>4</sup> See *supra* note 1; see also <http://www.sanuwave.com> (describing the OssaTron<sup>®</sup> technology).

<sup>5</sup> See 66 Fed. Reg. 59856, 59900 (Nov. 30, 2001). New technologies are eventually assigned to an APC with other services and procedures that are comparable clinically and in terms of resource use. This occurs once the agency has collected sufficient claims data to determine into which

of the costs expended by hospitals in furnishing the specific services involved, not on its clinical characteristics.<sup>6</sup> In the OPPS final rule establishing use of new technology APCs, the agency clarified:

In contrast to the other APC groups, the new technology APC groups do not take into account clinical aspects of the services they are to contain, but only their costs.... After we gain information about actual hospital costs incurred to furnish a new technology service, we will move it to a clinically-related APC group with comparable resource costs.... To be considered [for classification in a new technology APC], requests must include the following information: ... Current cost of the item to hospitals (*i.e.*, actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in-kind). In other words, submit the best and latest information available that provides evidence of the hospital's actual cost for a specific item.<sup>7</sup>

SanuWave seeks classification based on the established Medicare rules — such that its new technology procedures are classified based on submitted cost data, and not on resources expended for other procedures.

### **Payment for High-Energy ESW**

The High-Energy ESW procedures for plantar fasciitis and lateral epicondylitis have been assigned to two HCPCS codes when they are furnished in the hospital outpatient department setting — C9720 (High-Energy ESW treatment lateral epicondylitis) and C9721 (High-Energy ESW treatment plantar fasciitis).<sup>8</sup> In both its November 15, 2005 final rule with comment period and in the July 25, 2005 proposed rule, CMS classified the two High-Energy ESW procedures under APC 1547, which has a payment rate of \$850 (with an unadjusted minimum co-payment amount of \$170). This payment level ignores cost data submitted with the new technology

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permanent APC the technology should be assigned. *Id.* at 59897; *see also* 42 U.S.C. § 1395l(t)(2); 42 C.F.R. § 419.31.

<sup>6</sup> 65 Fed. Reg. 18434, 18477 (April 7, 2000).

<sup>7</sup> *Id.* at 18477-78. CMS's current instructions for the Application for New Technology APC Designation further underscore that the costs of the procedure itself are to form the basis for classification into a particular band. The agency requires an applicant to submit, among other things, "[a]n itemized list of the costs incurred by a hospital to furnish the new technology service, including labor, equipment, supplies, overhead, etc." No information regarding costs for other, similarly resource intensive procedures is sought. *See* [http://www.cms.hhs.gov/providers/hopps/newtechapc\\_72605.pdf](http://www.cms.hhs.gov/providers/hopps/newtechapc_72605.pdf).

<sup>8</sup> Effective July 1, 2005, the American Medical Association refined its Category III Codes to distinguish between the High-Energy and Low-Energy ESW procedures. Code 0020T defines ESW for plantar fasciitis and Code 0102T defines High-Energy ESW for lateral epicondylitis. (Other conditions treated using High-Energy ESW are defined under Code 0101T.) Low-Energy ESW procedures are defined by Code 0019T. *See* <http://www.ama-assn.org/ama/pub/category/3885.html>. SanuWave has been informed that a Category I CPT code for the High-Energy plantar fasciitis procedure is expected to become effective on January 1, 2006.

application. The cost data, based on 4,800 procedures performed over an eight-month period using the OssaTron<sup>®</sup>, shows that the cost per procedure can be estimated at \$2,282.19. (The data for both the High-Energy procedures were comparable.) This estimated amount should form the basis of the new technology classification.

***Cost Comparison between High-Energy ESW and Diagnostic Colonoscopy***

Information obtained by the company's predecessor (HealthTronics, Inc.) from CMS staff in 2004, confirms that CMS made its payment decision using estimates of the median cost of furnishing diagnostic colonoscopies. Although CMS had accepted the capital cost expenditures submitted for the estimates for the High-Energy ESW, it has calculated the other resources to be \$478.15, using the median cost of the resources for furnishing diagnostic colonoscopies.<sup>9</sup>

It is unclear as to why this comparison regarding other resources has been drawn, given that it is contrary to both Medicare policies and, most critically, the two procedures are vastly different. The High-Energy ESW procedures using the OssaTron<sup>®</sup> — referred to as Orthotripsy<sup>®</sup> — are non-invasive surgical treatment to heal tissue, whereas the diagnostic colonoscopy is a test to evaluate the presence of abnormal conditions. The chart below (also provided in the January 12 comment letter) offers a side-by-side comparison of the cost and resource inputs needed to perform High-Energy ESW and the calculations performed by CMS to derive costs using diagnostic colonoscopy as a proxy.

<b>Costs</b>	<b>OssaTron<sup>®</sup> High-Energy ESW Cost Data</b>	<b>CMS/Diagnostic Colonoscopy Cost Data<sup>10</sup></b>
<b>Capital Costs</b>	<ul style="list-style-type: none"> <li>• \$500,000 - cost of device</li> <li>• \$48,0000 - cost specialized van</li> <li>• 7 year life span of device/van</li> <li>• 20 procedures per month</li> </ul> <p><b>Per Procedure Total: \$326.19</b></p>	<ul style="list-style-type: none"> <li>• \$500,000 - cost of device</li> <li>• \$48,0000 - cost specialized van</li> <li>• 7 year life span of device/van</li> <li>• 20 procedures per month</li> </ul> <p><b>Per Procedure Total: \$281.55<sup>11</sup></b></p>

<sup>9</sup> This amount is in line with the proposed CY 2006 payment rate for diagnostic colonoscopies. The CMS proposed payment rate for diagnostic colonoscopies is \$513.23 (with an unadjusted minimum co-payment amount of \$102.65) under APC code 0143. 70 Fed. Reg. at 42831.

<sup>10</sup> This information was gathered during discussions with CMS after the publication of the November 15, 2004 final rule with comment period.

<sup>11</sup> Discussions with CMS revealed that it accepted the \$548,000 capital costs, device life of 7 years, and estimate of 20 procedures per month, yielding a per procedure cost of \$326.19. The capital costs on this side of the chart therefore include amounts for High-Energy ESW capital equipment (and not diagnostic colonoscopy capital equipment). CMS, however, calculated these per procedure costs at \$281.55, a difference that has not been reconciled.

Costs	OssaTron <sup>®</sup> High-Energy ESW Cost Data	CMS/Diagnostic Colonoscopy Cost Data <sup>10</sup>
<b>Resources</b>	<ul style="list-style-type: none"> <li>• \$400 - surgery room rate</li> <li>• \$342 - ESW technician fee</li> <li>• \$40 - recovery room rate</li> <li>• \$43 - oxygen and supplies</li> <li>• \$75 - IV supplies and solutions</li> <li>• \$85 - cost of electrode</li> <li>• \$15 - other supplies</li> <li>• \$116 - cardiac monitor</li> <li>• \$200 - anesthesia drugs (plus \$203 if general anesthesia is used)</li> <li>• \$207 - service and maintenance</li> <li>• \$6 - malpractice expense</li> <li>• \$25 - liability insurance</li> <li>• \$84 - technician travel/mileage</li> <li>• \$191 - administrative costs</li> <li>• \$20 - miscellaneous expenses</li> </ul> <p><b>Per Procedure Total: \$1,849.00</b></p>	<ul style="list-style-type: none"> <li>• \$478.15 - median cost data; resource cost for diagnostic colonoscopy</li> <li>• \$85 - cost of electrode</li> </ul> <p><b>Per Procedure Total: \$563.15</b></p>
<b>Staff Work</b>	<ul style="list-style-type: none"> <li>• \$25 - nursing, pre-operational</li> <li>• \$32 - nursing, procedure</li> <li>• \$50 - nursing, post-operational</li> </ul> <p><b>Per Procedure Total: \$107.00</b></p>	<p><b>Per Procedure Total: not included</b></p>
<b>TOTAL</b>	<b>\$2,282.19</b>	<b>\$844.70<sup>12</sup></b>

Even a cursory review of the High-Energy ESW procedures and associated costs reveals that, unlike diagnostic colonoscopies, these are surgical procedures, requiring very different resources. The High-Energy ESW procedures employing SanuWave's OssaTron<sup>®</sup> (a Class III device receiving pre-market approvals from the Food and Drug Administration in 2000 and 2003, for chronic plantar fasciitis and chronic lateral epicondylitis, respectively), effect healing through the use of shock waves created by very strong acoustic energy delivered to the affected part of the body. The procedures are performed in a hospital outpatient department or an ambulatory surgical center by physicians trained in the surgical treatment of foot and ankle conditions (for chronic plantar fasciitis) and hand and elbow conditions (for chronic lateral epicondylitis), and certified to use the device for surgery. Because the procedures are painful, anesthesia is administered before the treatment, and requires that an anesthesiologist be present during the procedure. Resources thus include surgical suite expenses, as well as trained nursing staff costs for pre- and post-op care. In addition, anesthesia drug expenses are incurred. A technologist, trained in the use of the High-Energy ESW device and procedure protocol, assists

<sup>12</sup> The total payment amount, including the minimum unadjusted co-payment, is \$1,020.

the physician with management of the device and is present throughout the procedure. Upon completion of the procedure, the patient is placed in a post-operative recovery room and is monitored until she has stabilized and it is determined that there have been no adverse effects from the anesthesia or the procedure.<sup>13</sup>

Unlike the more resource-intensive High-Energy ESW procedures, a diagnostic colonoscopy typically requires neither an anesthesiologist nor a technician during the procedure. A mild sedative or pain medication is used for patient comfort during the examination. The physician will insert a long, flexible, lighted tube into the colon. This colonoscope transmits an image of the inside of the colon, so the physician can view the lining of the colon. The patient remains in a recovery area until the sedative wears off.<sup>14</sup> Because fewer resources are needed, it is logical, therefore, that the CMS data for diagnostic colonoscopies would confirm that the costs for these procedures are much less than the estimates presented for the High-Energy ESW procedures.

### *Cost Comparisons between High-Energy ESW with the OssaTron<sup>®</sup> and Lithotripsy*

As discussed above, SanuWave contends that the established Medicare policy for classifying a new procedure under the new technology cost bands requires the evaluation of costs incurred by hospitals for the procedure at issue. If CMS nonetheless chooses instead to use costs from other procedures as a proxy, then the agency should use cost data for lithotripsy — the procedure that most closely resembles the High-Energy ESW using the OssaTron<sup>®</sup>.

Like High-Energy ESW for treatment of lateral epicondylitis and plantar fasciitis, lithotripsy employs High-Energy ESW, but for the treatment of kidney stones. The shock waves are focused on the kidney stones and break them into tiny pieces, which are passed out of the body naturally during urination. The High-Energy ESW is administered to the patient (who is positioned either in a specially designed surgical tub or, more typically, on top of a surgical table) with an ESW device.<sup>15</sup> Lithotripsy also typically requires the administration of anesthesia and is performed in hospital outpatient departments or ambulatory surgical centers.

SanuWave believes that the lithotripsy procedure using ESW is similar to the Orthotripsy<sup>®</sup> procedures, which target healing in other areas of the body. It is well recognized that the devices used for lithotripsy formed the basis for those procedures in which High-Energy ESW is used to treat musculoskeletal conditions.<sup>16</sup> Based on its experiences with the

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<sup>13</sup> See HealthTronics Surgical Services, Inc.'s "Application for New Technology Ambulatory Payment Classification (APC) Under the Hospital Outpatient Prospective Payment System (OPPS)"; see also Ogden, John A., et al., *Electrohydraulic High-Energy Shock-Wave Treatment for Chronic Fasciitis*, *Journal of Bone and Joint Surgery* 86:2216-2218 (2004).

<sup>14</sup> See <http://digestive.niddk.nih.gov/ddiseases/pubs/colonoscopy/>.

<sup>15</sup> See <http://www.nlm.nih.gov/medlineplus/ency/article/007113.htm#Description> and <http://www.kidney.org/atoz/atozItem.cfm?id=87>.

<sup>16</sup> See, e.g., Ogden, John A., et al., *Shockwave Therapy for Chronic Proximal Plantar Fasciitis: A Meta-Analysis*, *Foot & Ankle International* 23:302 (2002) ("The shockwave devices reviewed in this study have evolved from those currently in widespread clinical use for lithotripsy. . . . The

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technologies, SanuWave believes that the primary difference between the resources needed for lithotripsy and the Orthotripsy<sup>®</sup> procedures is the imaging component used to monitor the location of the kidney stones. This is typically done using fluoroscopy or ultrasound.<sup>17</sup> Therefore, any comparison in cost of resources should deduct the costs of the resources used for the imaging component.

Lithotripsy is assigned to APC 0169, for which CMS has proposed a CY 2006 OPPS payment rate of \$2,541.27 (with unadjusted minimum co-payment of \$508.25). Subtracting the payment amount for fluoroscopy, which has a proposed payment amount of \$81.54,<sup>18</sup> the payment level is remarkably close to what is being requested here under New Technology Level XXII, or APC 1559, for High-Energy ESW treatment for plantar fasciitis and lateral epicondylitis, as would be expected.<sup>19</sup>

Because of the similarities in clinical procedures using High-Energy ESW for kidney stones and for plantar fasciitis and lateral epicondylitis, SanuWave believes that if CMS looks to other procedures as a proxy for determining new technology costs here, then the lithotripsy procedure should be used, rather than the diagnostic colonoscopy.

\* \* \*

Based on the foregoing, SanuWave asks that CMS assign HCPCS codes C9720 and C9721 to New Technology APC Level XXII, for which a CY 2006 rate of \$2,250 per procedure has been proposed. This payment rate much more closely matches the estimated \$2,282.19 per procedure costs of performing the services. At this time, SanuWave would like to renew the offer (previously made by HealthTronics, Inc.) to provide a demonstration of the procedures, so that CMS medical staff can observe first-hand how the treatment is provided and the resources needed.

Thank you for your consideration of these comments. Should you require further information, please do not hesitate to contact me at 202-637-2266.

Very truly yours,



Esther R. Scherb  
of LATHAM & WATKINS LLP

Enclosure

cc: SanuWave, Inc.

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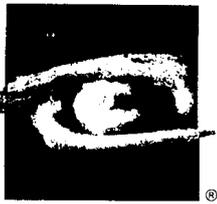
current meta-analysis is directed at an evaluation of the application of extracorporeal shockwaves (orthotripsy) to chronic proximal plantar fasciitis.”)

<sup>17</sup> See *supra* note 15.

<sup>18</sup> Fluoroscopy, CPT code 7600, is paid under APC 0272. 70 Fed. Reg. at 42866.

<sup>19</sup> 70 Fed. Reg. at 42766.

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# AMERICAN ASSOCIATION OF EYE & EAR HOSPITALS

*Payment Rate  
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September 16, 2005

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

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule; (70 Federal Register 42674), July 25, 2005 (CMS-1501-P)

Dear Dr. McClellan:

The American Association of Eye and Ear Hospitals (AAEEH) respectfully submits its comments on the Centers for Medicare & Medicaid Services' (CMS) proposed regulation to make changes to the hospital outpatient prospective payment system and to set the calendar year 2006 payment rates.

The AAEEH is very concerned that the OPPTS continues to be under funded, paying only 87 cents for every dollar of hospital outpatient care. The proposal includes a 3.2 percent market basket update, but the average increase in outpatient payments will increase by only 1.9 percent less than the cost of inflation when congressionally mandated policy changes are made.

Several aspects of the proposed rule could potentially have a detrimental affect on eye and ear specialty hospitals and the patients we serve. Included among these are: the insufficient overall payment rate increase and the inadequate reimbursement rate for cochlear implants. After carefully reviewing the proposed rule, we believe it raises substantive issues and concerns directly affecting eye and ear specialty hospitals that need to be fully addressed prior to implementation.

## **Background**

The AAEEH is comprised of the world's premier centers for specialized eye and ear procedures. Eye and ear specialty hospitals have led the way as providers of high-quality, cost-effective outpatient health care services. The mission of these specialty institutions requires that they maintain leading edge technologies, enabling them to provide highly specialized services not available in general hospitals. AAEEH member facilities serve as models of cost efficiency and high-quality care when surgery and services are rendered by

specialty hospitals on an outpatient basis. Association members are major nation-wide referral centers with a commitment to teaching, research and hands-on patient care of the highest level of quality. These specialty hospitals routinely treat the most severely ill eye and ear patients.

Today, eye and ear specialty hospitals experience large outpatient volumes and are heavily dependent on Medicare outpatient revenues. As such, they are uniquely qualified to comment on certain aspects of the CMS's proposed hospital outpatient prospective payment system update. Clearly, the implications this proposed rule will have on eye and ear specialty hospitals are substantial.

### **Calendar Year 2006 Payment Rates**

The AAEEH accepts the positive developments it has identified in the proposed rule, including a modest increase in overall outpatient prospective payment rates to hospitals of 3.2 percent. Over the past several years, CMS has proposed a payment rate increase to eye and ear specialty hospitals of 10.4 percent (1998), 13.7 percent (2002), 5.2 percent (2003), and 6.6 percent (2004).

However, the proposal will cut calendar year 2006 payments for APC 0245 (Level I Cataract Procedures without IOL Insert) from \$794.15 to \$789.47. Payments for APC 0246 (Cataract Procedures with IOL Insert) will increase from \$1,329.48 to \$1,386.03. The payment rate for APC 0259 (Level VI ENT Procedures) will decrease from \$26,006.75 to \$21,643.31 – less than the CY 2004 rate of \$22,643.98.

A 3.2 percent increase in payment rates does not keep up with medical inflation or the rising costs eye and ear specialty hospitals face every day to deliver patient care. Eye and ear specialty hospitals experience large outpatient volumes and are heavily dependent on Medicare outpatient revenues. They are also the premier teaching settings for surgical residents specializing in ophthalmology and otolaryngology. Because eye and ear hospitals provide cutting edge expertise, they often incur higher costs. Despite these high costs, specialty eye and ear hospitals often have difficulty breaking even financially, leaving many Medicare beneficiaries without first class eye care surgery and services. As a result, there are now only half the number of specialty eye and ear hospitals in the country than there was just a decade ago.

Despite unprecedented pressures, eye and ear specialty hospitals remain the premier teaching settings for surgical residents specializing in ophthalmology and otolaryngology. Teaching institutions are under extreme pressure to maintain their academic programs while taking on Medicare payment cuts and added regulatory oversight. Unless payment rates are maintained at least on par with medical inflation, these specialty institutions will be forced to avoid utilization of the latest technologies and procedural advancements that are improving patient outcomes and that distinguish them from general acute care hospitals.

We urge CMS to maintain its appreciation of the value that eye and ear specialty hospitals provide to Medicare beneficiaries and set the payment rates accordingly.

## **2 Times Rule**

The AAEEH and the eye community are pleased with the agency's recommendation to exempt the Level I posterior segment eye procedures from the 2 Times Rule and to keep these procedures in APC group 0235. The AAEEH is also pleased with the decision to move several other ophthalmology procedures into higher paying APC groups among them: 65265, 65285, 66220, 67025, 67027, 67036, 67038, 67039, and 67121. These changes will ensure that reimbursement for these procedures will remain at a fair level when they are performed in the outpatient department.

Despite these positive changes, however, the AAEEH has reservations about the agency's decision to move ophthalmology codes 92004 and 92014 to the lower paying APC group 0601. These codes are comprehensive eye exam codes. One represents treatment for a new patient while the other represents treatment for an established patient. The procedure for performing these codes in the hospital outpatient setting has not drastically changed in the past year yet CMS is proposing that the payment associated with these two procedures be reduced from APC 602 high level clinic visits to APC 601 mid-level clinic visits. Changing the APC group for these codes would result in a reduction in payment of \$25.10 for each procedure. We urge CMS to reconsider this decision and to allow these codes to remain in APC group 0602.

Some eye and ear specialty surgical providers have evaluated the impact of the reimbursement changes on their slim operating margins and have been forced to make decisions with negative consequences for Medicare beneficiaries. This is especially true with cataract removal -66984- because of low reimbursement. We fear that this is a trend that will grow if the APC rates associated with these procedures continue to be cut. We therefore strongly urge CMS to keep 92004 and 92014 in APC group 0602 for the sake of all of our patients, especially Medicare beneficiaries.

## **Non Pass-Throughs: Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals**

The AAEEH supports CMS's continued use of packaged and separate payment systems, depending on the median per day cost of drugs, in establishing payment for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status. The per day cost for verteporfin, a drug used by ophthalmologists, exceeds \$50 and is typically paid separately. The method proposed by CMS for paying for this drug and others like it allows hospital outpatient departments to procure these drugs at a reasonable price while also ensuring that the Medicare program is only billed for the actual amount of drug used. This system also allows hospital outpatient departments to have an efficient option for packaging and for collecting payments for less costly drugs.

## **Cochlear Implants**

A cochlear implant is an electronic device that restores partial hearing to the deaf. It is surgically implanted in the inner ear and activated by a device worn outside the ear. Unlike a hearing aid, it does not make sound louder or clearer. Instead the device bypasses damaged

parts of the auditory system and directly stimulates the nerve of hearing, allowing individuals who are profoundly hearing impaired to receive sound.

The AAEEH considers cochlear implants appropriate procedures in adults and children unable to benefit from conventional hearing aids with severe sensorineural hearing loss. The AAEEH also considers cochlear implants an appropriate procedure in congenital and acquired deafness in adults and children. Distinct diagnostic and remedial strategies are necessary for each individual to develop optimal auditory discrimination and comprehension. These skills must be systematically trained to optimize speech reception and production and language acquisition using the cochlear implant.

Each year, AAEEH hospitals restore hearing to hundreds of profoundly deaf individuals through cochlear surgery. The benefits of cochlear implants go far beyond helping the individual. Cochlear implants increase employability and performance in mainstream jobs by helping individuals maintain good speaking skills, allowing them to participate in meetings, follow conversations, use the telephone, and to do many of the activities that those with hearing take for granted.

The cost effectiveness of cochlear implantation has been well-documented by a large body of evidence-based literature and accepted by the medical profession and by insurers. If adopted, the proposed level of reimbursement would worsen patient access – especially Medicare beneficiaries - to this highly effective medical technology.

The total cost of a cochlear implant including evaluation, surgery, the device, and rehabilitation is around \$40,000. Under the proposed rule, however, CMS would cut payment rates for cochlear implants (Level VI ENT Procedures/APC 0259) from \$25,307 to \$21,739. The cost of the implant alone is \$21,000. One of our hospitals reports that conservatively speaking personnel and supply costs are approximately \$7,000 per patient. Consequently, the facility must take a significant loss on every cochlear implant patient or must consider whether to provide the service at all, a decision that has already been made by some acute care hospitals, leaving our specialty hospitals the site of last resort.

Clearly the proposed \$21,739 level of reimbursement would have a severe impact on Medicare beneficiary access to cochlear implantation. The AAEEH urges CMS to substitute accurate external device cost data as determined by a recent Lewin Group study and recalculate the relative weight of APC 0259. Alternatively, we request that CMS set the 2006 OPPS payment no lower than 100 percent of the 2005 payment rate plus the inflation and other update factors applied to all APCs.

## **Conclusion**

While it appears that the outpatient prospective payment system is beginning to mature, many outpatient payment rates continue to fluctuate dramatically, with payments much lower in 2005 as compared to 2004. These changes make it extremely difficult for hospitals to appropriately plan and budget from year to year. While the agency proposes a number of policies that would help stabilize these rate changes, we are concerned that many issues remain. Not surprisingly, some institutional providers have evaluated the impact of the

reimbursement changes on their slim operating margins and may be forced to make decisions with negative consequences for Medicare beneficiaries.

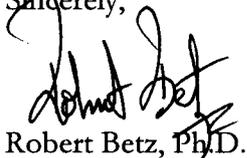
Eye and ear specialty hospitals must have adequate funds to address critical issues they face, such as severe worker shortages, skyrocketing liability premiums, expensive drugs and technologies, aging facilities and expensive regulatory mandates.

The American Association of Eye and Ear Hospitals has consistently argued that Medicare should pay adequate rates for efficiently provided care. In addition, we urge CMS to increase payment rates for cochlear implants to more accurately reflect hospitals' acquisition and implantation costs.

We acknowledge that there are problems with the hospital outpatient payment system methodology that makes it difficult for CMS to accurately track actual device costs. The AAEEH welcomes the opportunity to work with the agency to review the comments and recommendations contained herein, particularly to ensure appropriate payment updates for these vital procedures that restore vision and hearing to hundreds of thousands of Medicare beneficiaries each year.

The AAEEH appreciates the opportunity to comment on this proposed rule. We respectfully request that every consideration be given to the issues we raised while you finalize the regulation and offer to assist you in any way that we can. If you have any questions regarding our comments, please contact me or Cathy Clark Betz, Executive Health Counsel, at (703) 243-8848.

Sincerely,



Robert Betz, Ph.D.  
Executive Director

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PO Box 61501  
King of Prussia, PA 19406-0901  
Tel: 610-878-4583  
www.zlbbehring.com

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R. Hen

**ZLB Behring**

September 15, 2005

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8016  
Baltimore, MD 21244-8018

**ATTN: (CMS-1501-P) Medicare Program; Proposed Changes to the Hospital  
Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates**

Dear Dr. McClellan:

ZLB Behring is a leading researcher and manufacturer of life-saving biotherapeutics including intravenous immune globulin (IVIG), which is used in treating conditions such as immune deficiencies; blood clotting factors to treat bleeding disorders, including hemophilia and von Willebrand disease; and alpha<sub>1</sub>-proteinase inhibitor, used to treat alpha<sub>1</sub>-antitrypsin deficiency, which is commonly referred to as genetic emphysema. These therapies are created by pooling and manufacturing donated human blood plasma into lifesaving therapies or through the development of recombinant DNA technology.

Thank you for allowing ZLB Behring the opportunity to comment on the proposed rule regarding the 2006 changes to the Medicare Hospital Outpatient Prospective Payment System (HOPPS). The focus of our comments will pertain to the section of the document entitled "Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status." Our main points regarding the proposed rule as it relates to plasma protein therapeutics follow:

- Average Sales Price (ASP) is a better basis for hospital reimbursement than the survey data derived from the Government Accountability Office (GAO). However, there are unique problems with the ASP plus 6% model in regard to plasma therapeutics that have seriously impacted patient access in the physician office setting, reimbursed under Medicare Part B, and will likely do so in the outpatient setting if it is applied in the same ways.
- 2% of ASP does not appear adequate in reflecting drug and hospital overhead costs for plasma and recombinant therapies. An additional add-on payment will be necessary for plasma therapies, specifically IVIG, in order to adequately reimburse such therapies.

- The final rule should use the most recent ASP submissions in determining the payment rates to be more reflective of current hospital acquisition costs.

### Non Pass Throughs

#### Acquisition Price = Average Sales Price Plus 6%

CMS correctly notes that the GAO data reflected a less recent time period than the present ASP data, which is updated on a quarterly basis. Moreover, CMS is correct in their assertion that updating GAO mean purchasing prices in future years would have been challenging and problematic. Basing HOPPS reimbursement on quarterly ASP data could be a more accurate, current figure than the GAO data derived from a snapshot in time

ASP can be more reflective of a real market acquisition price if the ancillary and administrative costs are incorporated into this calculation. However, the experience with ASP plus 6% in Medicare Part B for plasma therapeutics has led to widely reported access issues regarding IVIG. To prevent a similar situation from occurring under HOPPS, we recommend the following:

**Brand-specific reimbursement** - Plasma therapeutics have several brands within a HCPCS code, although each brand has unique features that match up with different patient profiles. Access to all brands is essential so that individual patients may be treated properly. The weighted average calculation of multiple brands within the HCPCS code has resulted in the reimbursement level being lower than providers can purchase some of the brands within the class of therapy in Part B thus creating access issues, such as is presently occurring with IVIG. The same situation is inevitable under HOPPS unless addressed. The solution would be to have brand-specific (NDC) reimbursement based on ASP plus an adequate percentage, rather than a volume-weighted average calculated from all brands comprised within a HCPCS code.

**Reduction in the lag time** - The 6-month lag time between the reporting of prices and CMS posting of payment rates for Medicare Part B has exacerbated providers receiving reimbursement that is below their acquisition costs. The HOPPS proposed rule, on which we are commenting, has a 9-month lag in place. The lag should be shortened as much as possible, within administrative capabilities, to perhaps 3 months. Further, the lag should be the same for both HOPPS and Part B. The shorter lag time assures more accurate reflection of market costs and the equity between sites of service would prevent demand shifts due to disparities.

To illustrate this point, the proposed HOPPS rule indicated a significant difference for IVIG, lyophilized, if CMS used the Q1 2005 ASPs (which were available at the time of publication of

the proposed rule and would be equivalent to a 6-month lag) instead of the Q4 2004 figures, which would equal a 9-month lag.

Product and HCPCS Code	Listed Rate in Proposed Rule (ASP plus 8% using Q4 2004 data)	What rate would be if ASP plus 8% were used for Q1 2005 data.
Q 9941, IVIG, lyophilized, 1 gram	\$39.46	\$42.83

With a typical dosage of IVIG being approximately 40 grams and spanning up to 60 grams, the shortfall due to this extended lag period, as compared to the present Part B lag time, which a hospital will incur for IVIG ranges from \$134.80 - \$202.20. This much needed hospital outpatient reimbursement can be rectified if the HOPPS lag time was equal to that of Medicare Part B. Further, for ASP to be truly representative of hospital acquisition costs, the most recent submitted ASPs will need to be utilized.

#### Drug and Hospital Overhead Costs

CMS correctly acknowledges that hospitals incur costs for handling drugs and biologicals. However, ZLB Behring is concerned that 2% of ASP will not adequately represent these overhead costs, specifically as they relate to plasma and recombinant therapies. As the June 2005 MedPAC study concluded, handling costs for drugs and biologicals delivered in the hospital outpatient setting are not insignificant *as they typically require greater pharmacy preparation time than do those provided to inpatients*. MedPAC determined that 25-33% of ASP is an accurate reflection of overhead costs. Further, CMS' own Ambulatory Payment Code Advisory Committee recommended that CMS *reconsider* the 2% add-on for pharmacy overhead costs and to accept and review industry data regarding such costs. CMS should consider this advice as well as other survey data supplied to the agency by reputable sources regarding overhead costs and upwardly adjust the overhead costs in order to be truly reflective of total costs associated with hospital acquisition.

**Add-on Payment** – Significant IVIG access issues have been widely reported under Medicare Part B since implementation of the Medicare Modernization Act and have been largely attributed to some of the changes in the reimbursement methodology. One potential remedy for this situation and the similar situation that will likely develop in HOPPS unless addressed would be for plasma therapeutics, such as IVIG, to have an add-on payment or furnishing fee similar to blood clotting factor in the Part B setting. We believe that CMS has significant latitude under HOPPS to institute a percentage greater than 2% of ASP. To support this request with data, the Plasma Protein Therapeutics Association (PPTA), of which ZLB Behring

is a member, has contracted with The Lewin Group to survey hospitals regarding their overhead costs specific to IVIG. The Lewin Group will prepare a proxy add-on figure (which PPTA will submit to the agency as part of its comments) for CMS to consider based on preliminary survey data, while they proceed with a more comprehensive study of IVIG hospital pharmacy overhead. ZLB Behring urges CMS to consider this proxy add-on figure for IVIG and to incorporate into the final rule for an interim period, until such time that the final study is completed and submitted to CMS for consideration.

Blood clotting factors under Medicare Part B were provided with a \$0.14 furnishing fee for its handling and administration. This fee was determined by CMS after a review of survey data prepared by The Lewin Group. The \$0.14 furnishing fee equates to a greater percentage of ASP than does the 2% designated under HOPPS and illustrates the inadequacy of the proposed fee for hospital overhead when considering plasma derivatives. Using the current, third quarter 2005 listed Part B rates for blood clotting factors in determining what percentage of ASP the furnishing fee represents; a sampling would be as follows:

Product and HCPCS Code	Volume Weighted ASP	ASP plus 6% Q3 2005 published Part B rates	Furnishing Fee	Furnishing Fee as Percentage of ASP
J 7190 – factor VIII	\$0.48	\$0.51	\$0.14	29.2%
J 7192 – recombinant factor VIII	\$0.87	\$0.92	\$0.14	16.1%
J 7193 – factor IX, non recombinant	\$0.70	\$0.74	\$0.14	20.0%
Q 2022 – von Willebrand Factor	\$0.69	\$0.73	\$0.14	20.3%

As blood clotting factors were given special recognition under Medicare Part B, with the creation of a furnishing fee, ZLB Behring requests that CMS also consider an add-on fee for the administering of clotting factor in the HOPPS setting. While the site of service may be different, the issues associated with overhead and administration for blood clotting factors are similar.

## Orphan Drugs

With regard to orphan drugs used solely for orphan conditions, ZLB Behring appreciates the attention that CMS provided specific to J 0256, alpha<sub>1</sub>-proteinase inhibitor. CMS correctly stated that the GAO report did not provide a representative sample of total hospitals purchasing the drug. As such the GAO figures are not appropriate in determining a true hospital acquisition costs. Our comments regarding ASP methodology and remedies, including the add-on payment, also apply for alpha<sub>1</sub>-proteinase inhibitor, as there is similarity of issues and cost factors across immune globulin, clotting factor and A1PI therapy.

## Conclusion

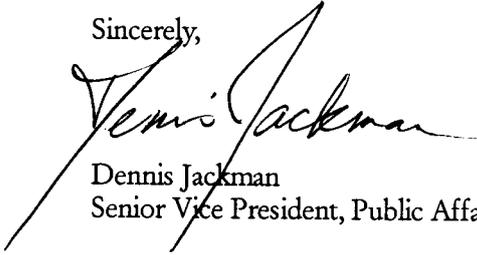
The Medicare Part B rates reportedly have forced many IVIG patients into the HOPPS setting in order to obtain treatment. If the HOPPS payments mirror the Part B payments as currently constructed, the access issues for patients due to reimbursement issues will increase and leave the patient with nowhere to turn. We urge that the reimbursement-caused access problems associated with IVIG under Medicare Part B not be replicated in HOPPS. In order to achieve this, ZLB Behring suggests that add-on payments be implemented for plasma therapies, in a similar fashion as for clotting factor in Medicare Part B. Such a payment, when combined with NDC based reimbursement and the reduction in the lag period for the publishing of payment rates will be of great benefit for patients reliant on IVIG for their quality and sustenance of life.

The remedies suggested for HOPPS should also be applied to Medicare Part B to help correct the access issues due to reimbursement currently in place for the physician office and prevent disparities in points of service. These disparities artificially force the migration of patients from one site of service to another, regardless of what is most appropriate for them.

Finally, as mentioned in previous comments, the plasma therapeutics industry supply chain is not like that of traditional pharmaceuticals. These are expensive products to manufacture, with high cost for starting materials and all of the related costs of manufacturing inherent in producing a biologic. These costs can only be recovered in limited populations of use. Reimbursement policies that limit patient access to these therapies not only endanger patient care now, but also economically threaten the future of manufacturers and providers to viably provide these in the future. Given the critical nature of these therapies, that would be a terrible consequence and is not unlike the loss of vaccine suppliers, and the consequences over time in the United States.

Thank you for the opportunity to comment on this proposed rule. Should there be any questions or if we may be of assistance, please feel free to contact either myself or Patrick Collins (610-878-4311). Your consideration of these comments in the formulation of the final rule is greatly appreciated.

Sincerely,

A handwritten signature in black ink that reads "Dennis Jackman". The signature is written in a cursive style with a large, sweeping initial "D".

Dennis Jackman  
Senior Vice President, Public Affairs

VIA OVERNIGHT DELIVERY

September 1, 2005

PHP ASP her

Mark B. McClellan, M.D., Ph.D., Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1501-P  
Mail Stop: C4-26-05  
7500 Security Blvd.  
Baltimore, MD 21244-1850

**RE: CMS-1501-P: Proposed Changes to the Hospital Outpatient PPS**

**NOTE: "PARTIAL HOSPITALIZATION" COMMENTS**

Dear Dr. McClellan,

As an association representing behavioral healthcare provider organizations and professionals, the National Association of Psychiatric Health Systems (NAPHS) appreciates the opportunity to provide comments on the "Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" as published in the July 25, 2005, *Federal Register*.

We are specifically providing comments on proposed partial hospitalization program (PHP) and community mental health issues.

**About NAPHS**

Founded in 1933, NAPHS advocates for behavioral health and represents provider systems that are committed to the delivery of responsive, accountable, and clinically effective prevention, treatment, and care for children, adolescents, adults, and older adults with mental and substance use disorders. Our members are behavioral healthcare provider organizations, including more than 400 specialty hospitals, general hospital psychiatric and addiction treatment units, residential treatment centers, youth services organizations, behavioral group practices, and other providers of care. Our members deliver all levels of care, including partial hospitalization services, outpatient services, residential treatment, and inpatient care.

Partial hospitalization – specifically – has long been a level of care offered by NAPHS members. In our most recent *NAPHS Annual Survey*, more than half of all NAPHS members responding offered partial hospitalization services for their communities.

Throughout the years, these NAPHS members have been a stable group of providers working hard to meet a community need. Patients may use partial hospitalization either as a transition from a hospital program or as an alternative to inpatient care.

**Providers have serious concerns with proposed partial hospitalization changes.**

We are concerned that proposed changes to the outpatient prospective payment system (PPS) could negatively affect the partial hospitalization benefit. Although providers are committed to finding ways to ensure that their patients have access to this essential level of care, partial hospital capacity in the behavioral healthcare system remains a concern. Many partial programs have closed or limited the number of patients they can accept, and fewer partial hospital slots now exist nationwide.

**ISSUES OF CONCERN**

**The current methodology for determining the PHP rate is in flux.**

We appreciate the various approaches CMS considered in the 2006 proposed rule in dealing with the complexities of the historical cost data supplied by hospital and community mental health center (CMHC) providers of the partial hospitalization benefit. We agree that the range of data provided by the CMHCs throughout the last five years (with a median per diem cost ranging from a high of \$1,037 to a low of \$143) has made it difficult to determine actual costs. We are aware of the various strategies CMS has applied in dealing with the CMHC data, including adjusting cost-to-charge ratios, examining the influence of outlier payments, and recognizing the significant drop in the cost per day.

Based on the clinical intensity of the PHP benefit, we do not understand how it could possibly be provided for \$143. This figure raises serious questions about the accuracy of the data reported on CMHC cost reports. By regulation, PHPs are required to provide a program of active treatment which includes at least three individualized treatment sessions per day, in addition to appropriate individual therapy and treatment planning. This level of intensity closely mirrors the care provided in an inpatient treatment setting. Were it not for the existence of partial hospitalization, beneficiaries would be hospitalized.

We noted the various ways CMS proposed to deal with the complexities of determining an updated payment rate (such as following the methodology used for the CY 2005 OPSS update, basing the update on hospital-based PHP data alone, or applying different trimming methodologies to CMHC cost data in an effort to eliminate aberrant data and decrease the instability in CMHC data).

We noted the desire of CMS to lessen the PHP payment reduction for CY 2006, so that you can ensure an adequate payment amount and continuing access to the partial hospitalization benefit for Medicare beneficiaries. CMS proposed a reduction of 15% as a way of doing this. The rationale for this reduction (from \$289 to \$245.65) states that CMS think this will recognize the decrease in the median per diem costs in both the hospital and CMHC data and also reduce the risk of any adverse impact on access to these services that might result from a large single-year rate reduction. CMS further state that you will continue to work with CMHCs to improve their reporting so that payments can be calculated based on better empirical data.

**We believe that a 15% decrease in the per diem rate may negatively impact the availability of partial hospitalization to beneficiaries and is an unacceptable variance in the payment rate.**

The basis of a prospective payment system is to provide stability and predictability in payment in order to encourage efficiency in the delivery of services and to allow providers to budget and plan for the provision of services. A PPS system is not designed to endure significant adjustments every year based on historical costs. Changes of the magnitude of 15% undermine the basis of the system. Providers and payers alike need to be able to rely on a predictable methodology for determining payment that will allow the PHP benefit to be available to Medicare beneficiaries in a stable way. This methodology needs to be predicated on reliable data.

**We respect the thought that has gone into the determination of the proposed reimbursement rate for PHP for 2006, yet we think the methodology does not adequately account for all important variables.**

Selecting the 15% reduction may protect providers from more onerous cuts, but it is in itself not an acceptable solution. The volatility in the CMHC data continues to be inadequately explained.

There are many administrative costs (transportation, food) that are not Medicare-reimbursable. But they are real costs to the provider and need to be considered as payers and providers analyze the fiscal realities of providing the benefit. There are also highly prescriptive administrative and regulatory responsibilities that providers must meet in order to offer the benefit. These, too, contribute significantly to costs. Especially in the new era of Medicare inpatient psychiatric prospective payment, it is very important there be a strong alternative to hospitalization. Partial hospitalization *is* that alternative.

## **RECOMMENDATIONS**

**1. To allow the time and resources necessary to fully develop an adequate payment methodology, we propose that the 2006 PHP payment rate remain the same as the 2005 rate--\$281.33. We would continue to work with CMS and others to study the data and refine the methodology to develop a payment rate that is fair and predictable.**

**2. Strategies that may be considered in the development of PHP rates could include the following:**

- Use inpatient costs per day as the basis for the PHP median cost per diem. CMS could apply to the IPF PPS cost per diem a scaling factor (perhaps 50%) to develop a basis for the PHP median cost per diem. CMS would, in effect, develop a corollary factor between the PHP cost and inpatient psychiatric cost.
- Develop a cost method that uses, as an example, a three-year rolling average of the CMHC PHP cost per diem. This would use an average cost over time rather than a cost that has changed dramatically from year to year.

**3. The successful use of any revised methodology would be dependent on developing a method for improving future CMHC cost report information. We recommend that CMS**

review and revise the various forms and worksheets used by CMHCs to report data. Specifically, CMS should:

- a. **Revise the CMHC cost report form (CMS-2088)** to include a field which allows the CMHC to report its Medicare PHP days. The existing worksheet S-7, Part IV (Statistical Data) could be modified to include this new field. This field would be similar to the CMS- 2552-96 worksheet S-2, Part I field in which outpatient "Observation Bed Days" are reported. This information would then be subject to Medicare fiscal intermediary review and validation as part of the cost report desk review and audit process.
- b. **Revise settlement worksheet D on the CMS-2088** to include new fields that 1) display the Medicare PHP cost per day and 2) separate PHP reimbursement between outlier and non-outlier reimbursement (since the current cost report form commingles both types of reimbursement). This data will provide CMS and the provider with a quick snapshot of the facility's cost and payment per diem data. This new information will help in the Medicare fiscal intermediary's evaluation of the cost report data if any of the cost or payment PHP per diem amounts appear to be aberrant.
- c. **Revise the CMHC Provider Statistical & Reimbursement Report ("PS&R") Report Type: 76P** to include a field which reports actual paid Medicare PHP days. This information can then be used by the provider and fiscal intermediary for the CMHC cost report submission and final settlement.

## CONCLUSION

Thank you for your consideration of our comments. We look forward to continuing to work with CMS and HHS to ensure that partial hospital services remain available for the beneficiaries who require this level of care.

Sincerely,



Mark Covall  
Executive Director

**Docket Management Comment Form****Docket: CMS-1501-P - Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates****Temporary Comment Number: 22328**

<b>Date:</b>	09/12/05
<b>Organization:</b>	National Association of Psychiatric Health Systems
<b>Category:</b>	Health Care Provider/Association
<b>Issue Areas/Comments</b>	
<b>General</b>	
See our comments on PARTIAL HOSPITALIZATION	
<b>Attachments</b>	
CMS-1501-P-T22328-Attach-1.pdf	

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Johnson & Johnson Banker

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BY COURIER

September 16, 2005

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

Attention: *Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates July 25, 2005 Proposed Rule (CMS-1501-P)*

Issue: Proposed reduction in payment rate for APC 112 "Apheresis, Photopheresis, and Plasmapheresis"

Dear Dr. McClellan:

On behalf of Therakos, a member of the Johnson & Johnson family of companies that provides products used in extracorporeal photopheresis, we respectfully offer the following comments on the above captioned proposed rule.

CMS has proposed that hospitals utilizing APC 112 "Apheresis, Photopheresis, and Plasmapheresis" receive a dramatic 25% reduction in 2006 for all procedures included in the APC. We are concerned that CMS' estimates of median cost for CPT codes 36515 and 36516 are inappropriately low, and appear to reflect significant problems in the quality of claims data or their processing. Therefore, there is serious concern that flawed claims data is significantly reducing the median cost for all procedures under APC 112, thus leading to significant and abrupt reduction in the overall payment rate for the hospital in 2006.

We are also concerned that this proposed reduction is excessive and may be very difficult for hospital providers to absorb in a single year. This action has the potential to result in reduced access for Medicare patients to important therapies covered by this APC. In the event that a rate reduction remains necessary, we

offer two options to the agency on how to minimize this reduction for providers utilizing APC 112 in 2006.

As a first option, we ask the agency to consider treating this APC as a “device dependent APC” subject to a floor of 85% of the CY 2005 medians used to set the payment rates in CY 2005. APC 112 includes three HCPCS codes:

- 36522: Extracorporeal photopheresis;
- 36515: Therapeutic apheresis with extracorporeal immunoadsorption and plasma reinfusion; and
- 36516: Therapeutic apheresis with extracorporeal selective adsorption or selective filtration and plasma reinfusion

All three procedures utilize device systems to modify or selectively remove agents from blood and return that blood to the patient. Like the other “Device-dependent APCs” listed in Table 15 of the proposed rule, these device systems are a major cost component of and are integral to the procedure. We believe this device-dependent APC should be afforded the same protection as other device-dependent APCs on Table 15 of the proposed rule. Otherwise, providers will be forced to absorb a very significant reimbursement reduction over a single year period.

As an alternative, CMS could also apply the same policy being applied to “blood and blood products whose 2006 medians would have otherwise experienced a decrease of more than 10 percent in comparison with their CY 2005 payment rates.” (See p. 42741 of July 25, 2005 Proposed Rule) The procedures covered by APC 112 relate to blood processes. Blood is taken from the body, treated, and returned to the body. Accordingly, CMS could consider these processes to be closely related to blood and blood products. Such products have been the subject of special dampening provisions as well as specific data calculations by CMS. We urge CMS to consider applying the same methodology to APC 112 as is being applied to blood and blood products for this year—namely, limit the decrease in medians to 10 percent. CMS could treat this APC in a manner similar to blood and blood products and limit the decrease so that providers would not be forced to absorb the proposed 25% reduction in a single year.

### **Background on Photopheresis**

Within APC 112, HCPCS code 36522—extracorporeal photopheresis--has the largest number of claims based on the 2004 Hospital Outpatient Claims Data Base. Extracorporeal photopheresis is an immunomodulatory therapy for cutaneous T-cell lymphomas (CTCL), a group of skin-invasive, non-Hodgkin lymphomas characterized by a clonal proliferation of malignant T lymphocytes. Early-stage disease is typically confined to the skin as patches or plaques. As the disease progresses, however, patients develop cutaneous tumors or

erythroderma and associated peripheral blood, lymph node, and visceral organ involvement. There is no cure for CTCL since late-stage disease is generally resistant to chemotherapy and radiotherapy. Median survival in these patients is approximately 43 months or 3.5 years from first treatment. Photopheresis, however, has demonstrated the ability to significantly improve the skin manifestations of CTCL. Furthermore, findings of long-term follow-up of patients with advanced CTCL have indicated that photopheresis therapy produces significant improvement in quality of life and may prolong life in comparison with historical controls.

Photopheresis treatment consists of the patient's blood being passed through a device that permits selective exposure of the white blood cells, while they are outside the body (extracorporeal), to ultraviolet A light and the drug methoxsalen. The patient's red blood cells, plasma, and treated white blood cells are then returned to the patient. A major cost component of the procedure is the device system that collects the blood, segregates the leukocytes (white cells), and then photoactivates them using precise levels of ultraviolet energy and drug. This procedure could not be done without the device system. The complete system consists of the instrument that processes the blood, a light assembly, and a procedural kit containing a "fluid logic module"--a microprocessor-controlled and pneumatically driven cassette that is covered by two flexible PVC membranes. Internally, multiple chambers, pathways, and valves rely on pneumatic pressure to establish appropriate fluid pathways, open and close valves, and move fluid to and from the patient, centrifuge, collection bags, and the photoactivation chamber.

### **Summary**

To summarize, we believe that the proposed rate reduction is based on flawed claims data and has the potential to reduce access to an important therapy for Medicare patients. In the event of any rate reduction, we ask CMS to either treat APC 112 as a "device-dependent" APC subject to a floor, or in a manner similar to blood and blood products subject to a floor.

Thank you for your consideration of these comments.

Sincerely,



Susan Reardon  
Director, Federal Affairs  
Johnson & Johnson

Thank you for your prompt attention and correction of this 2006 payment issue.

Best regards,

A handwritten signature in black ink that reads "James E. Seay, M.D." The signature is written in a cursive style with a large initial 'J' and 'S'.

Physician Name: Dr. James Seay

cc: Herb Kuhn  
Director, Center for Medicare Management  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

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James E. Seay, M.D.  
PO Box 2144  
Mobile, AL 36652

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September 14, 2005

Mark B. McClellan, M.D., PhD  
Centers for Medicare and Medicaid Services  
U. S. Department of Health and Human Services  
Attn: CMS - 1505 - P  
P. O. Box 8016  
7500 Security Boulevard  
Baltimore, MD 21244-8018

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

File Code: CMS - 1505 - P  
Proposed Payments for Drugs, Biologicals, and Radiopharmaceuticals Without  
Pass-Through Status

Dear Dr. McClellan:

As a practicing physician treating patients with chronic wounds, I am very  
concerned with the proposed 2006 Medicare Hospital Outpatient payment for  
Dermagraft [C 9201] and  
Apligraf [C 1305].

For this reason, I am submitting comments in response to the Centers for  
Medicare and Medicaid Services [CMS] Proposed Rule - Medicare Program;  
Proposed Changes to the Hospital Outpatient Prospective Payment System and  
Calendar Year 2006 Payment Rates; Proposed Rule.

Apligraf and Dermagraft are distinctive living human tissue substitutes for  
the treatment of chronic wounds. These products have improved the quality  
of life of thousands of diabetics and Medicare beneficiaries who suffer from  
chronic wounds. Many of these patients would have had to undergo  
amputations without the benefits of Dermagraft and Apligraf.