

# LOUISIANA WHOLESALE DRUG CO., INC.

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OCT -6 2006

Oct. 5, 2006

The Honorable Mark McClellan, M.D., Ph.D.  
Office of the Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-1321-P  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: CMS-1321-P (ASP Issues)

Dear Dr. McClellan:

On behalf of Louisiana Wholesale Drug Co. Inc., I would like to take this opportunity to provide our comments on the Proposed Rule CMS-1321-P, "*Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B*" (the "Proposed Rule"). This rule was published in the *Federal Register* on August 22, 2006.<sup>1</sup>

Louisiana Wholesale Drug is a full line Drug Wholesale with a customer base that includes approximately 250 retail pharmacies in the state of Louisiana with current sales of \$300 million.

Louisiana Wholesale Drug is a member of the Healthcare Distribution Management Association ("HDMA"). As part of our membership activities, we have reviewed the HDMA written comment letter to the Centers for Medicare and Medicaid Services (CMS), on the proposed rule referenced above. Louisiana Wholesale Drug fully endorses the HDMA comments, and is, by submission of this letter, incorporating the HDMA comments by reference into our written comments for the record.

While we fully agree with all of the points raised in the HDMA letter, we wish to place special emphasis on two items addressed in the HDMA comment letter regarding Average Sales Price (ASP) Issues. First, Louisiana Wholesale Drug especially encourages CMS to reconsider its opinion that prompt pay discounts should continue as a type of price concession that manufacturers must include in their ASP calculation. We urge CMS to reverse its position, and inform manufacturers that customary prompt pay discounts should not be applied to wholesalers when they calculate ASP. We believe that manufacturers could continue to deduct any prompt

<sup>1</sup> 71 *Fed. Reg.* 48980 (Aug. 22, 2006).

pay discounts extended directly to end customers on sales that do not go through a wholesaler, but those that are not passed along to the customer are not appropriately included in the ASP. This revision is consistent with recent congressional directives that prompt pay discounts should be excluded from the Average Manufacturer's Price (AMP) calculation.

Secondly, Louisiana Wholesale Drug strongly endorses CMS' proposal to codify the definition of bona fide services, to treat fees paid to wholesalers the same as fees paid to third party logistics providers, and not to deduct those bona fide service fees when ASP is determined.

Thank you for this opportunity to provide our comments on Proposed Rule CMS-1321-P, and to endorse the comments of the HDMA as written. We hope these comments are constructive in your deliberation of developing an Average Sales Price calculation that represents an equitable and reasonable approach to reimbursement for the products that we distribute.

Sincerely,

A handwritten signature in black ink that reads "Gayle R. White". The signature is written in a cursive style with a prominent initial 'G'.

Gayle R. White

President  
Louisiana Wholesale Drug Co., Inc.



October 9, 2006

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1506-P, or CMS-4125-P  
P.O. Box 8011, Baltimore, MD 21244-1850.

Topic Reference: FY 2008 IPPS RHQDAPU  
Public Comment

GlaxoSmithKline (GSK) appreciates this opportunity to comment on the addition of the proposed quality measures for hospital reporting of quality data for the FY 2008 IPPS annual payment update, as referenced in the CY 2007 Medicare Hospital Outpatient Prospective Payment System Proposed Rule, published in the Federal Register on August 23, 2006 (Volume 71, No. 163, page 49506).

We believe that the proposed rule will help improve quality of care and patient outcomes. Thank you for considering the following GSK comments on the proposed rule:

1. GSK supports the proposed addition of quality measures for hospital reporting of quality data.
2. GSK strongly recommends that CMS encourage the updating of the quality measures as soon as possible and on a regular basis. Part of the updating process should include consideration of additional hospital quality measures.

#### Rationale

An explicit process for scheduled and non-scheduled updates is needed in order to adequately address quality and patient needs. It is important to update these measures frequently as professional consensus evolves regarding appropriate diagnosis and treatment (nationally recognized clinical practice guidelines), and as new clinical research and interventions become available. The following is an example of why updates need to be made to the proposed VTE quality measures.

Although fondaparinux sodium (Arixtra®) is approved by the US Food and Drug Administration for VTE prophylaxis in patients undergoing abdominal surgery who are at risk for thromboembolic complications, fondaparinux had not been incorporated into the abdominal surgery section of the most recent ACCP Guidelines (Geerts 2004) at the time the SCIP developed the VTE measures. It is

expected that the next version of the ACCP Guidelines (2007) will include fondaparinux for the approved indications (i.e., abdominal surgery at risk for thromboembolic complications, general surgery with moderate to high risk, gynecologic surgery and urologic surgery).

Because of time lags between FDA approval, completion of studies and practice guideline revisions, appropriate therapies may not be addressed in practice guidelines and related quality measures. If the measures are not updated in a timely manor, implementing the proposed quality measures result may be a disincentive for hospitals to use this and other appropriate therapies. Instead, hospitals should be recognized for using any of the appropriate therapies, such as fondaparinux, as part of their VTE prophylaxis protocol.

In addition to updates, the process of reviewing measurement sets should include consideration of new measures. In the future, GSK suggests consideration be given to adding a measure of "Post Operative Ileus (POI) following Major Abdominal Surgery. Post Operative Ileus (POI) is the most common cause of, and a significant risk factor for, delaying discharge and extending length of hospital stay after abdominal surgery (Collins 1999). The complications of ileus include substantial morbidity increased risk of (Holte 2000, Woods 2000, Holte 2002). POI also increases the risk of other post operative complications such as deep vein thrombosis, pulmonary embolism, bacterial translocation and sepsis and nosocomial infections (Person 2006). "The duration of POI is the most important factor in determining the length of hospitalization [after bowel resection]." (Person 2006).

To help hospitals and clinicians provide higher quality care to surgical patients, we encourage CMS to advocate for the immediate and frequent updating of the proposed measures. We applaud the emphasis CMS is placing on the importance of quality measurements and support the proposed rule.

Sincerely

Deborah L. Fritz, PhD, MPH  
Director

Attachment: References

## References

Geerts WH, Pineo GF, Heit JA et al. Prevention of venous thromboembolism. The seventh ACCP conference on antithrombotic and thrombolytic therapy. Chest 2004; 126:338S-400S.

Collins TC, Daley J, Henderson WH, Khuri SF. Risk factors for prolonged length of stay after major elective surgery. Ann Surg 1999;230(2):251-9.

Delaney CP, Fazio VW, Senagore AJ, Robinson B, Halverson AL, and Remzi FH. 'Fast Track' postoperative management protocol for patients with high comorbidity undergoing complex abdominal and pelvic colorectal surgery. Br J Surg 2001;88, 1-8.

Holte K, Kehlet H. Postoperative ileus: a preventable event [review]. Br J of Surg 2000; 87:1480-93.

Woods MS. Postoperative ileus: dogma versus data from bench to bedside. Perspect Colon Rectal Surg 2000;12:57-76.

Holte K, Kehlet H. Postoperative ileus: progress towards effective management. Drugs 2002;62:2603-15.

Person B, Wexner SD. The management of postoperative ileus. Curr Probl Surg 2006; 43:12-65.

## PROTON THERAPY CONSORTIA

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

775 521 10 02

September 26, 2006

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

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

Dear Dr. McClellan:

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

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

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

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

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

### **Freestanding Proton Therapy Centers**

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

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

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

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

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

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

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

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

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

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

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

### **Practice Expense Relative Unit Value**

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

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### **Proton Therapy Consortia**

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

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

#### **Centers in Operations and Treating Patients:**

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

#### **Centers Currently Under Development:**

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

### **Conclusion**

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

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

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

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



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• Hampton University Proton Therapy Institute • Northern Illinois University*


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

Sincerely,



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



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

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### Appendix 1

#### UNDERSTANDING PROTON BEAM THERAPY

##### Principles of Radiation Oncology

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

##### Increased Effectiveness and Utilization

Physicians have looked for ways to use radiation to treat cancer since the discovery of x-rays by Wilhelm Roentgen and radioactivity by Marie and Pierre Curie 100 years ago. Advances in technology and a better understanding of its effects on the body have made radiation therapy an important part of cancer treatment.

The first proposal for the medical use of protons was made in 1946 in a paper by physicist, Robert Wilson, Ph.D. By 1954, proton beams from a high-energy physics research accelerator were first used to treat humans.

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

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

##### Objectives of Radiation Therapy

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

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

##### Conventional Radiation Therapy Constraints

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

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

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

### **Rationale for Proton Beam Therapy**

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

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### Appendix 2

#### MAJOR COMPONENTS OF A PROTON BEAM THERAPY SYSTEM

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

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

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

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

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

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

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

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

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

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



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October 4, 2006

Honorable Mark B. McClellan, M.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8010  
Baltimore, MD 21244-8018

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

Dear Dr. McClellan:

We are writing to you on a matter of great importance to the proton therapy community. More than 40,000 cancer patients have been treated with proton therapy in many institutions in the United States and across the world. Proton beam therapy, due to its recognized and desired biological effect on malignant tissue, has the clinical advantage of being significantly more precise in delivery. Positive clinical results at these facilities have stimulated worldwide interest in the clinical applications of proton therapy and consequently two additional facilities opened in the United States this calendar year.

**STATEMENT OF SUPPORT FOR THE PROPOSED CALENDAR 2007 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT RATES FOR PROTON THERAPY.**

We fully support the Proposed Calendar Year 2007 (CY'07) Hospital Outpatient Prospective Payment System (OPPS) Payment Rates for proton beam therapy, which is as follows:

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

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

As you know, the National Payment rates for proton therapy are determined based upon submitted claims and cost data received by CMS from centers delivering proton therapy in the United States. Rate setting is a challenging and difficult task. We appreciate the diligence with which you have set the CY'07 proposed payment rates for proton therapy.

**STATEMENTS OF CONCERN REGARDING FREESTANDING FACILITIES**

For freestanding proton therapy centers the CMS has given its contracted Carriers significant latitude but limited guidance from which to determine payment rates for proton therapy.

We remain concerned with the manner in which contracted Carriers of the Centers have managed freestanding Proton Therapy Centers for Medicare and Medicaid Services in the State of Texas, Florida and Indiana. The existing or proposed proton therapy payment rates by State are as follows:

**Comparison of Freestanding Centers' Proton Therapy Rates by State**

	Indiana – Current	Florida – Proposed 9/11/06	Texas – 9/1/06
77520	—	\$750.63	\$652.75
77522	\$516.36	\$776.90	\$653.90
77523	\$782.43	\$806.93	\$783.79
77525	\$782.43	\$900.76	\$954.41

As each State has its own CMS contracted Carrier, variations in existing CY'06 and proposed CY'07 proton therapy coverage and payment rates are occurring and are significant by comparison to CMS's National Payment Policy for protons as expressed in the OPPS rules.

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

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

It should be noted that due to the capital cost of proton therapy, both freestanding and HOPD centers have similar costs for patient treatments. The cost of treatment per fraction is consistent, if not higher, in both hospital based and freestanding facilities than the current 2006 APC payment rate. Given the great similarity of capital investment and operating costs of proton beam therapy centers, whether hospital-based or freestanding, this is an appropriate recommendation for CMS given the number of operating centers and patient demand for this valuable therapy.

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

#### CONCLUSIONS

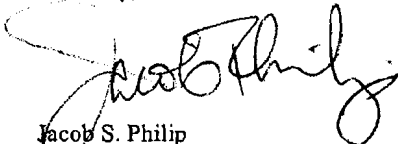
In conclusion, proton beam therapy has a recognized and desirable radiobiological effect on malignant tissue with the clinical advantage of being significantly more precise in the delivery, resulting in better health outcomes and fewer or less significant adverse side effects than other forms of radiation therapy.

We agree with CMS's proposed CY'07 payment rule for proton beam therapy for Hospital Outpatient Departments.

Also, we strongly urge CMS to direct its Carriers on matters concerning proton therapy medical coverage and payment so that Carrier determinations regarding proton therapy payment rates are made in a consistent manner with those in effect for Hospital Outpatient Departments.

CMS thoroughly analyzes proton beam therapy claims and cost data in establishing payment rates for Hospital Outpatient Departments. CMS contracted Carriers should take advantage of vast work already performed on the part of the CMS when determining payment rates.

Sincerely,



Jacob S. Philip  
 Director, Radiation Oncology Business Unit  
 IMPAC Medical Systems, Inc.  
 An Elekta Company

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# The National Association for Proton Therapy

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August 18, 2005

Honorable Mark B. McClellan, M.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Room 314G  
Washington, D.C. 20201

**Re: CMS-1501-P –Proton Beam Therapy**

Dear Dr. McClellan:

The National Association for Proton Therapy (NAPT), founded in 1990, completely supports the classification and payment rates for simple, intermediate, and complex proton therapies as proposed in the CMS CY 2006 OPPS rule and strongly recommends that CMS make the proposed rule **final for CY 2006**.

This action will ensure that the nation's proton centers will continue to have the capability to provide cancer patients with this proven non-invasive radiation treatment. It will also ensure the sustainability and future growth of proton treatment at premier regional cancer centers currently in development and scheduled to open in 2006.

As you know, proton beam therapy is in an early stage of clinical adoption. The new proposed ruling will enhance the possibility of establishing more proton therapy facilities, and/or allow for expansion of current proton centers in order to keep pace with the clinical demand by thousands of cancer patients across the country.

We appreciate the complexities of the hospital payment system and the challenges faced by CMS in developing the proposed rule. We are aware that CMS OPPS works closely with the hospital providers of proton therapy in order to understand and analyze data for payment classification purposes. That is reflected in the CY 2006 proposed rule that ensures the economic viability of both existing proton facilities and those in various stages of construction and development.

We are excited about the future of proton therapy for improving patient outcomes and quality-of-life. As Dr. James Cox, chairman of radiation oncology at the M.D. Anderson Cancer Center, said: *"Oncologists have long known that substituting proton beam radiation for X-rays now used to treat cancer patients would do less harm to normal tissues and organs and more damage to malignant growths. That means more cures."*



On behalf of the proton therapy industry, as well as the many thousands of cancer patients in the U.S. who seek proton radiation treatment, we thank you and your very capable CMS staff for the government's role in providing support for this leading-edge cancer therapy.

In conclusion, we agree with CMS's CY 2006 proposed payment rule for proton therapy and strongly support it being included in the final rule.

Thank you for your attention to this important matter. If you have any questions, I can be reached at 301-587-6100 or via email: [lenarzt@proton-therapy.org](mailto:lenarzt@proton-therapy.org).

Sincerely yours,



Leonard J. Arzt  
Executive Director  
NAPT

[lenarzt@proton-therapy.org](mailto:lenarzt@proton-therapy.org)

October 10, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20001

**Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B - CMS-1321-P**

Dear Administrator McClellan:

On behalf of our organizations and the hundreds of thousands of nurses we represent, we are writing to respectfully request that you and your staff work this year to modify the Medicare payment database so it can capture nurse practitioner specialty-specific data beginning in 2007. Taking this important action will help ensure that the nation's nurse practitioners can participate in future Centers for Medicare and Medicaid Services (CMS) demonstration and pay-for-performance/value-based purchasing programs.

As you know, nurse practitioners are registered nurses who are prepared - through advanced education and clinical training - to provide a wide range of preventive and acute health care services to individuals of all ages. Studies consistently have found that nurse practitioners provide high quality, cost-effective care. Moreover, nurse practitioners often are sole providers of care in underserved and rural communities. With the nation facing the dual challenges of a growing physician shortage and the aging of the Baby Boom generation, nurse practitioners will play an even more important role in providing quality care to Medicare beneficiaries in the years to come.

It is our understanding that the Medicare database currently does not permit the collection of nurse practitioner specialty-specific data. This current limitation unfairly excludes nurse practitioners from participating in certain demonstration projects and will preclude your agency from being able to evaluate nurse practitioners with respect to any pay-for-performance/value-based purchasing programs. We understand that since the Medicare payment database currently captures physician specialty-specific data that the inclusion of nurse practitioner specialty-specific data is feasible. We feel strongly that it is essential to address this differential in data collection and believe that

October 10, 2006

**VIA HAND DELIVERY**

Mark B. McClellan, M.D., PhD, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20021

Re: *CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B*

Dear Dr. McClellan:

EmCare, Inc. ("EmCare") is one of the nation's leading emergency medicine physician practice management organizations. Through its emergency medicine physicians, EmCare provides emergency care in over 340 hospitals in 39 states. These hospitals range from large urban hospitals with high volume emergency departments to smaller community hospitals with lower patient volumes, all of which depend on EmCare's physicians to deliver high quality care. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule regarding *Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Other Changes to Payment Under Part B*, which was published in the Federal Register on August 22, 2006 (the "Proposed Rule"). (71 Fed. Reg. 48982.)

**I. BACKGROUND**

Of primary concern to EmCare is the Proposed Rule's negative payment update of 5.1 percent for the 2007 Physician Fee Schedule ("Fee Schedule"). We strongly believe that this payment cut will have a detrimental impact on beneficiary access to care. The negative payment update is further compounded by the 2006 Fee Schedule payment freeze and minimal Fee Schedule payment updates or reductions since 2002. The Fee Schedule payments over the past five years have failed to keep even with annual inflation costs measured by the Medical Economic Index ("MEI"), which the Proposed Rule would reduce for 2007.

As in past years, the Fee Schedule payment cut will have a negative impact on emergency department physicians who assume a disproportionate share of the costs associated with furnishing uncompensated care. Emergency department physicians must treat all patients 24 hours a day, seven days a week, regardless of a patient's ability to pay. Thus, the 2007 Fee Schedule payment cut further limits access to care for beneficiaries who depend on care received through hospital emergency departments. According to the Centers for Disease Control and

percent reduction in the update to a lower MEI, which was based on the use of a new measure of productivity by the Bureau of Labor Statistics and lower projections of inflation. Few other details were provided in the Fact Sheet. Notably, CMS did not solicit comments on the MEI changes in the Proposed Rule.

We, therefore, urge CMS to delay any changes in the MEI in the final Fee Schedule rule and to provide for full public comment on this important aspect of the Fee Schedule. We believe that soliciting comments on the MEI changes will better inform CMS as it consider changes to the Fee Schedule for 2007.

### **III. RESOURCE-BASED PRACTICE EXPENSE (PE) RVU PROPOSALS FOR CY 2007**

EmCare urges CMS to recognize or publish services for current procedural terminology ("CPT") codes that remain non-covered by Medicare. The Relative Value Update Committee ("RUC") identified and reviewed 24 CPT codes and CMS accepted the time data for each of these codes as submitted in the June 29, 2006 proposed rule on the *Five-year Review of Work Relative Value Units Under the Physician Fee Schedule and Proposed Changes to the Practice Expense Methodology*. (See 71 Federal Register 37170, 37210-218 (June 29, 2006).) Since many other payers rely on the CPT codes established by Medicare, we strongly support CMS publishing relative values for all services, regardless of Medicare's coverage policies. It is our understanding that CMS can include a table in the final Fee Schedule rule for new and revised CPT codes.

As noted in EmCare's comments on the June 29 proposed rule regarding the RUC recommendations, we are very pleased that CMS agrees with the RUC recommendations for work relative value units for emergency Evaluation and Management services. The codes for emergency department visits and critical care services comprise the vast majority of services provided by emergency physicians, and we strongly encourage CMS to make no changes to the proposed work values in this final rule.

We continue to strongly urge CMS to implement any statutory budget neutrality adjustments through an adjustment to the conversion factor rather than the work values. We are joined by the majority of physician specialties in this recommendation and note that there is long-established CMS precedent for this approach.

Lastly, EmCare reiterates its earlier recommendation that CMS work with the physician community to provide support to the design and implementation of a new multi-specialty practice expense survey. A well-designed survey conducted every few years will ensure that all specialties are reporting common data elements in a timely and equitable manner.

### **IV. REASSIGNMENT AND PHYSICIAN SELF-REFERRAL**

In addition to its comments on the proposed changes to the Fee Schedule, EmCare also submits comments on one of the proposed reassignment changes contained in the Proposed Rule. In this section of the Proposed Rule, CMS proposes to amend the reassignment regulations by

requiring that both independent contractor and employee physician suppliers have “unrestricted access” to claims submitted by an entity. Specifically, CMS proposes to modify 42 C.F.R. § 424.80(d)(2) to read:

The supplier who furnishes the service has unrestricted access to claims submitted by an entity for services provided by that supplier. This paragraph applies irrespective of whether the supplier is an employee or whether the service is provided under a contractual arrangement. If an entity refuses to provide, upon request, the billing information to the supplier performing the service, the entity’s right to receive reassigned benefits may be revoked under § 424.82(c)(3).<sup>2</sup>

(71 Fed. Reg. at 49084.)

In the preamble to the Proposed Rule, CMS states that this proposal was prompted by one inquiry from an emergency physician employee of a medium-sized emergency physician staffing company who alleges that he was denied access to billing records for services furnished. (70 Fed. Reg. 49058.) We note that this is the only complaint CMS has received since January 1, 2005 regarding a physician’s ability to review claims data. CMS also points to the Conference Report of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), which states that the “Conference Committee supports appropriate program integrity efforts for any entities billing the Medicare program, including entities with independent contractors as well as employees.” (*Id.*)

EmCare strongly supports Medicare program integrity safeguards. As EmCare has commented in the past, it believes that appropriate program integrity safeguards should be applied to entities with employed physicians as well as to entities who work with independent contractors. Consequently, we support, consistent with the MMA, CMS’s proposal to extend the right to review claims to a supplier who is either an employee or independent contractor.

However, with regard to the standard of “unrestricted access to claims submitted,” we noted in earlier comments submitted to CMS that it is not clear how physician access to claims submitted data will correspond with improved program integrity. We continue to believe there may be more practical approaches to ensure that all Medicare program requirements are met where an entity submits bills to the Medicare program for services furnished by physicians and other suppliers. EmCare supports physician involvement in compliance programs that are structured to address risk areas particular to their operations.

EmCare is also concerned that providing “unrestricted access to claims submitted” is not a clear requirement that billing entities may have difficulty meeting. Under the HIPAA-mandated American National Standards Institute formatted 837-P electronic Medicare claims, the “claims submitted” are fields of electronic data that require the detailed implementation guide from the appropriate Medicare contractor to decipher the data fields. Provider and

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<sup>2</sup> The Proposed Rule would also revise the title of this subsection to correspond to this modification.

Mark B. McClellan, M.D., Ph.D

October 10, 2006

Page 5

contractor systems are large mainframe computers that do not interface easily with the personal computers likely to be used by an individual physician supplier. These implementation guides may also vary significantly from contractor to contractor.

As noted above, EmCare does not believe that regulating unrestricted access to all submitted claims is the best means to ensure Medicare program integrity. However, we support applying this program integrity requirement to all entities who submit claims on behalf of physicians and other suppliers who furnish services to Medicare beneficiaries.

EmCare appreciates the opportunity to submit its comments and welcomes the opportunity to discuss them with you and your staff. Should you have any questions about our comments, please do not hesitate to contact me at (303) 495-1214.

Sincerely,

A handwritten signature in black ink that reads "Steven G. Murphy (41)".

Steven G. Murphy, Senior Vice President  
Government and National Services

OCT 10 2006

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October 10, 2006  
Reference No.: FASC06011

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

**Re: CMS-1321-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B)**

Dear Administrator McClellan:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the Federal Register on August 22, 2006 (the "Proposed Rule").<sup>1</sup> As an association deeply committed to the health and safety of the patients it serves, these comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") in the physician office setting.

PPTA is the association that represents the commercial producers of plasma protein 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 protein 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 ("A1PI") used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

PPTA is very concerned that the manner in which physicians and suppliers are reimbursed for the costs they incur related to furnishing IVIG therapies is jeopardizing patient access to IVIG. Because access to these life-saving therapies is essential for all

<sup>1</sup> 71 Fed. Reg. 48982.

patients, including more than 10,000 Medicare beneficiaries who rely upon them, PPTA urges CMS to take a number of steps to improve reimbursement so that it does not continue to impede access to IVIG. Among these steps are the continuation of the current payment for preadministration-related services for IVIG and the creation of separate Healthcare Common Procedure Coding System ("HCPCS") codes for each brand name IVIG therapy. Moreover, the administration of IVIG should be billed under the same codes as other biologic response modifiers; CMS should clearly state this in the final rule. PPTA also requests that CMS reconsider the implementation of a payment adjustment for IVIG within the average sales prices ("ASP") plus 6% formula, similar to the precedent it established through its treatment, at Congress' direction, of blood clotting factor, which is also a plasma derived therapy. Finally, PPTA asks CMS to clarify certain aspects of the agency's ASP policy.

## **DISCUSSION**

### **CONTINUING THE PAYMENT FOR IVIG PREADMINISTRATION-RELATED SERVICES ["ASP Issues"]**

IVIG is the only effective treatment for primary immunodeficiency disease and has also been proven clinically beneficial in the treatment of secondary immune deficiency diseases. In addition, individual United States-licensed IVIG therapies are labeled for the treatment of: a) Kawasaki's disease; b) chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial infections; c) bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults; and d) idiopathic thrombocytopenic purpura. Many individuals afflicted with diseases or conditions treated with IVIG must depend on this life-saving therapy for the duration of their lives. Each individual patient requires maximum access to the specific formulation that not only best meets their unique needs, but also significantly limits the risk of exposure to serious and potentially life threatening complications.

In the recently issued outpatient prospective payment system proposed rule, CMS proposed to discontinue the payment for the preadministration-related services for IVIG. In justifying its decision, CMS merely stated that continuing this payment "would not be necessary in CY 2007 to ensure Medicare beneficiary access to IVIG." 71 Fed. Reg. 49506, 49604 (Aug. 23, 2006). While there is no similar statement in the Proposed Rule, in Addendum B, a status indicator of "D" appears for the code used to bill for the preadministration-related services (G0332), which signifies that the code will be deleted or discontinued. 71 Fed. Reg. at 49235. Thus, the Proposed Rule seems to reflect a similar intention to discontinue the current \$69 payment for preadministration-related services for IVIG. PPTA is quite troubled by the lack of any concrete explanation for this apparent policy change.



As CMS noted in last year's physician fee schedule final rule, this payment ensures that physicians are adequately reimbursed for providing IVIG to their patients. See 70 Fed. Reg. 70116, 70220 (Nov. 21, 2005). PPTA does not understand how CMS concluded that this payment is no longer necessary, when physicians will continue to struggle in providing the proper IVIG therapy to Medicare beneficiaries. Because physicians will continue to incur these costs in 2007, just as they are in 2006, CMS must continue to reimburse physicians for these costs through the \$69 preadministration-related services payment.

Moreover, Department of Health and Human Services Secretary Michael O. Leavitt recently touted the CY 2006 preadministration payment as a manner in which CMS has sought to compensate providers for the additional resources associated with administering IVIG.<sup>2</sup> Secretary Leavitt cited this CMS action in response to a letter<sup>3</sup> authored by Representative Joseph R. Pitts (R-PA) and thirty-four other Members of Congress. Ironically, Secretary Leavitt's response letter to the Pitts letter signatories was dated August 29, 2006 – one week after CMS published the Proposed Rule. Disappointed with the "inadequate" response by Secretary Leavitt, Representative Charles Norwood (R-GA) recently submitted an extension of remarks in the *Congressional Record* requesting that CMS "rethink implementing any reimbursement change that has the potential to harm access and reduce medical outcomes."<sup>4</sup> PPTA agrees with Dr. Norwood's concern and urges CMS to make permanent this payment for preadministration-related services for IVIG administered in the physician office setting.

### **IVIG SHOULD BE TREATED AS A BIOLOGIC RESPONSE MODIFIER FOR PURPOSES OF PAYMENT FOR THE ADMINISTRATION OF IVIG ["ASP Issues"]**

Beginning this year, physicians have billed for drug administration services using a number of Current Procedural Terminology ("CPT") codes that were first effective in 2006. Under these new codes, chemotherapy administration codes apply to parenteral administration of biologic response modifiers, according to the language contained in the CPT book. As a result, any product that is a "biologic response modifier" should be billed under such codes. IVIG is such a therapy and PPTA asks CMS to explicitly clarify that the service of administering IVIG should be billed as such.

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<sup>2</sup> See, e.g., Letter from Michael O. Leavitt, Secretary Dep't of Health and Human Services, to Rep. Ellen O. Tauscher (August 29, 2006). ["Attachment A"]

<sup>3</sup> See Letter from Rep. Joseph R. Pitts et al., to Michael O. Leavitt, Secretary Dep't of Health and Human Services (May 31, 2006) (suggesting CMS consider, *inter alia*, both a payment adjustment and product specific reimbursement for IVIG to address its reimbursement shortfall and improve patient access). ["Attachment B"]

<sup>4</sup> See 152 Cong. Rec. E1937-38 (daily ed. Sept. 29, 2006) (statement from Rep. Charles Norwood). ["Attachment C"]

According to the U.S National Library of Medicine, biologic response modifier therapy is defined by reference to “immunotherapy,” which is defined as “treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases.”<sup>5</sup> IVIG is precisely a treatment that restores the ability of the immune system to fight cancer and other diseases – e.g., Kawasaki’s disease, chronic lymphocytic leukemia, primary immune deficiency disease, and secondary immune deficiency diseases. Thus, IVIG qualifies as a biologic response modifier, and CMS must state clearly in the final rule that physicians should bill for administering the product using the CPT codes applicable to biologic response modifiers.

### **SEPARATE HCPCS CODES FOR IVIG THERAPIES** [“ASP Issues”]

As you know, payments for drugs and biologicals are set based on the ASP methodology. That methodology compiles manufacturer information by HCPCS code and computes an average sales price. IVIG is somewhat uniquely situated in this regard in that it is one of the few sole source biologicals for which there are multiple brand name therapies, but no generic products, in the code. PPTA believes that, in such unique circumstances, the ASP methodology does not generate representative payment rates for the different IVIG therapies. In order to provide more accurate reimbursement, CMS must establish unique HCPCS codes for each brand name IVIG therapy so that the ASP rate for each is based on its own ASP information, as is the case for other biologicals. PPTA believes that this would yield rates that are pertinent to each therapy and thus would enhance access to IVIG therapies.

The following brands of IVIG are now broadly available in the United States market: Polygam® SD, Panglobulin® NF, Gammar® P I.V., Gammagard® S.D., Gamunex®, Flebogamma®, Octagam®, Carimune™ NF, Iveegam® EN, Gammagard® liquid. Establishing separate HCPCS codes for these therapies is appropriate because there are important clinical differences among them, such as:

- Some therapies contain no sugars, which is beneficial for diabetics;
- Some therapies have low osmolality and low volume, which physicians sometimes prefer for patients with congestive heart failure or compromised renal function;
- Some therapies contain sucrose, which can create a higher risk of renal failure;
- Some therapies contain less immunoglobulin A (“IgA”), which is better for patients with IgA deficiencies; and
- Some therapies have a lower pH, which may be preferable for patients with small peripheral vascular access or a tendency toward phlebitis.

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<sup>5</sup> See <http://ghr.nlm.nih.gov/ghr/glossary/immunotherapy>.

Because of these differences, there are clinical reasons why physicians order one IVIG therapy in favor of another. CMS' coding of and payment for these therapies should also recognize these differences, which could be done by establishing separate HCPCS codes for each brand name IVIG therapy. Such a policy change would allow CMS to determine separate and more representative payments for each therapy. Moreover, new immune globulin products with different delivery methods (such as subcutaneous delivered immune globulin) should also be reimbursed by brand with a separate HCPCS code rather than bundling them into a class with other therapies.

### **PAYMENT ADJUSTMENT FOR IVIG ["ASP Issues"]**

In our comments on the 2006 physician fee schedule proposed rule, PPTA advocated for an add-on payment for IVIG that captures the acquisition costs, as well as the direct and indirect handling costs associated with the therapy. Although the agency rejected a number of recommended payment adjustments for IVIG, including an add-on payment, because of its belief that ASP data are reflective of physician acquisition costs for IVIG, it nonetheless determined that Medicare should pay physicians \$69 for each administration of IVIG to compensate them for preadministration services related to IVIG. 70 Fed. Reg. at 68649-50.

PPTA appreciates the recognition by CMS of these additional costs incurred by physicians in providing IVIG to beneficiaries. The prospect of the discontinuation of that payment, as discussed above, however, tempers that sense of appreciation. Even if CMS decides to continue the payment for preadministration-related services for IVIG, reimbursement for the therapy itself is currently insufficient to ensure continued access in the physician office setting. While that payment does reimburse physicians for some of the costs that they incur related to IVIG, other costs would remain uncompensated.

PPTA believes a payment adjustment to the current ASP formula is required to ensure that providers are made whole on the purchase cost of the IVIG therapies so that they receive a fair return on their investments in care. This payment adjustment needs to be reflective of providers' true costs to make IVIG available to their patients in the physician office. Furthermore, the payment adjustment could be based on independent data from the two current IVIG access studies being done by HHS' Office of Inspector General ("OIG") and HHS' Assistant Secretary of Planning and Evaluation.

A payment adjustment precedent to life-saving plasma protein therapies has recently been effectuated by CMS when it implemented, at Congress' direction, a separate payment for blood-clotting factor because of its unique properties and the fragile needs of patients who rely on blood-clotting factors. See Social Security Act ("SSA") § 1842(o)(5)(A) (mandating a separate payment for items and services associated with the furnishing of blood clotting factor). This furnishing fee, which CMS incorporated directly into the payment rate, was \$0.14 per unit in CY 2005, and is

\$0.146 per unit in CY 2006. Since the precedent setting blood-clotting factor furnishing fee was implemented, access to this life-saving plasma protein therapy has not been diminished, making this payment adjustment a successful mechanism in ensuring that the recent payment cuts did not adversely impact access. The same payment cuts, however, have resulted in providers' acquisition cost of IVIG for Medicare beneficiaries exceeding the reimbursement rates from CMS under the current ASP methodology. To this end, IVIG warrants the same acquisition furnishing fee considerations as blood clotting factor because it is similar in that both IVIG and blood clotting factor are plasma protein therapies that have highly unique characteristics that require complex manufacturing, storage, and distribution methods. PPTA has also provided a legal opinion illustrating that CMS does have the authority to incorporate a supplemental payment within the ASP plus 6% methodology.

To ensure Medicare beneficiaries have the best available access to the life-saving IVIG therapies, CMS must provide a payment adjustment to the current ASP reimbursement methodology to enable physicians to cover the costs incurred for acquiring IVIG. The blood-clotting furnishing fee is a precedent-setting provision for plasma protein therapies, one which CMS has the authority to issue for IVIG. Without such a payment adjustment, beneficiaries will continue to be at risk of being unable to obtain the best possible access to care.

**FEES PAID TO GROUP PURCHASING ORGANIZATIONS SHOULD NOT BE INCLUDED IN THE ASP CALCULATION ["ASP Issues"]**

CMS proposes to "clarify" that administrative and other fees paid to group purchasing organizations ("GPOs") would be included in the ASP calculation unless such fees satisfy the definition of a "bona fide service fee." 71 Fed. Reg. at 49001. PPTA strongly recommends that the agency not finalize this proposal, as we believe that administrative and other fees paid to GPOs should not be included in the ASP calculation, regardless of whether they meet the definition of a "bona fide service fee."

Under the statute, ASP is defined as the manufacturer's sales "to all purchasers." SSA § 1847A(c)(1) (emphasis added). As you know, GPOs negotiate contracts with vendor manufacturers on behalf of their members (e.g., physician practices, hospitals, nursing homes), but they typically do not purchase drugs and biologicals. To the best of PPTA's knowledge, GPOs are entities that permit health care providers to band together to create greater purchasing power to facilitate more favorable price negotiations with manufacturers – but do not themselves purchase product. Since GPOs are not purchasers, the fees paid by a manufacturer to a GPO should not be included in the ASP calculation; therefore, CMS should not finalize its proposed "clarification."

**PLASMA PROTEIN THERAPIES SHOULD BE EXCLUDED FROM A WIDELY AVAILABLE MARKET PRICE PAYMENT REVISION ["ASP Issues"]**

Under the ASP statute, if the OIG finds that the ASP for a product exceeds the widely available market price ("WAMP") by a percentage threshold, the OIG informs CMS and the agency then adjusts the ASP rate in the next quarter. SSA § 1847A(d)(3)(C). The OIG is supposed to conduct studies (which can include surveys) to determine the widely available market price. SSA § 1847A(d)(1). In the Proposed Rule, CMS proposes to continue to set the WAMP threshold at 5% and also requests comment on operational issues related to WAMP. 71 Fed. Reg. at 49004.

In response to this request for comments, PPTA suggests that CMS exclude from an ASP payment revision as part of this WAMP process those HCPCS codes which contain only biological products for which there is no generic competition. As explained earlier, in the discussion of IVIG, the ASP methodology does not set representative rates for such products and a further reduction pursuant to the WAMP authority would only exacerbate this precarious situation. Given the statutory direction to consult with the Secretary in the determination of WAMP, SSA § 1847A(d)(1), PPTA believes that the agency has the authority to take this action and that the agency should exercise it to ensure that Medicare beneficiaries' access to these critical therapies is not interrupted by a change resulting from the WAMP process.

**CONCLUSION**

PPTA appreciates the opportunity to comment on the Proposed Rule. We urge CMS to consider carefully these comments, particularly those that suggest mechanisms to improve payments for IVIG. Many beneficiaries depend on this therapy and reimbursement should not impede their access to this necessary treatment. Please contact me at (202) 789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Julie Birkofer  
Executive Director  
PPTA North America

[Attachments]



## Attachment A

THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

AUG 29 2006

The Honorable Ellen Tauscher  
House of Representatives  
Washington, DC 20515

Dear Ms. Tauscher:

Thank you for your letter expressing your concerns about Intravenous Immunoglobulin (IVIG) product supply and payment.

The Department of Health and Human Services, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration are closely monitoring access to and market developments for IVIG care. In addition, the IVIG manufacturers, the Plasma Protein Therapeutics Association, reports that the overall supply of IVIG is adequate and has increased in the past several months.

In accordance with a provision in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare pays for most Part B covered drugs and biologics administered in physicians' offices, based on 106 percent of the average sales price (ASP). Beginning in 2006, Medicare payment for Part B drugs, including IVIG, administered in hospital outpatient departments is also based on 106 percent of the ASP.

The Medicare payment rate, which is updated quarterly, is increasing by 11.9 percent for lyophilized IVIG and 3.5 percent for liquid IVIG in July 2006. We view these payment increases as an important development. The next quarterly update to the Medicare payment rates will occur in October 2006.

In light of the market conditions specific to IVIG, for 2006, CMS established a temporary add-on payment for physicians and hospital outpatient departments that administer IVIG to Medicare beneficiaries. This add-on payment is paid per day of IVIG administration and is for the extra resources expended on locating and obtaining appropriate IVIG products and on scheduling patient infusions during this current period where there may be potential issues in the IVIG market.

A number of components of HHS continue to work together, and to work with manufacturers, providers, patient groups, and stakeholders to understand the present situation and to assess potential actions that will help to ensure an adequate supply of IVIG and patients receiving appropriate and high quality care. To better understand the market for IVIG and evaluate access and reimbursement concerns from patients and physicians, HHS has commissioned an independent, expert study to assess these factors. HHS anticipates using the market analysis gained through this research to inform Departmental decision making related to IVIG in the future. In addition, we are actively exploring options that may be available to us under our legal and administrative authority to address IVIG concerns.

I appreciate your interest in this important issue. I also will provide this response to the cosigners of your letter.

Sincerely,

Michael O. Leavitt

Attachment B

May 31, 2006

The Honorable Michael Leavitt  
Secretary, Department of Health and Human Services  
200 Independence Avenue, SW  
Washington DC 20201

Dear Secretary Leavitt:

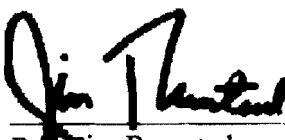
We understand that you have been working with the Centers for Medicare and Medicaid Services to address the shortfalls in the acquisition cost of IVIG and Medicare's reimbursement of this biological therapy in the physician office and hospital outpatient settings. This important patient access issue is also of great concern to us, and we **wanted** to take this opportunity to convey our commitment to working with the IVIG community to assure that this access issue is remedied through implementation of an immediate solution.

As you know, IVIG is a life-saving plasma-derived therapy, and, since the implementation of the MMA's new Medicare reimbursement methodologies, beginning in January 2005, patients have been migrating to the hospital outpatient setting because physicians were reimbursed at a rate lower than their purchase price. Beginning in January 2006, a similar occurrence with Medicare reimbursement in the hospital outpatient setting has taken place. We know you share the same desire to see these patients return to the physician office for treatment, and we are of the opinion that in order to achieve this goal, some type of payment adjustment, combined with product specific reimbursement, should be considered, in addition to any other mechanism that you deem necessary to resolve this patient access dilemma.


Thank you for your attention to the IVIG issue, to assuring Medicare beneficiary access to this therapy, and for working together with Congress to rectify the problems patients have reported in receiving care. We appreciate the opportunity to continue this dialogue with you and the IVIG community, and we look forward to the implementation of a permanent and comprehensive solution.

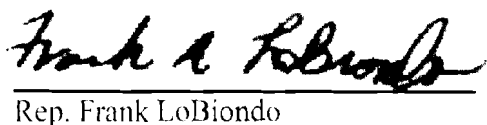
Sincerely,

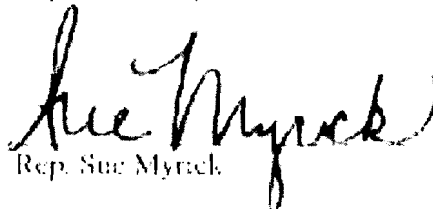
  
Rep. Joseph R. Pitts

  
Rep. Jim Ramstad

  
Rep. John Sullivan

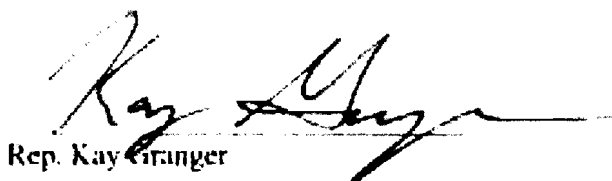
  
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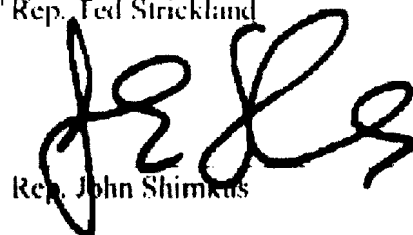
  
Rep. Frank LoBiondo

  
Rep. Sue Myrick

  
Rep. Jim Gerlach

  
Rep. Ted Strickland

  
Rep. Kay Granger

  
Rep. John Shimkus

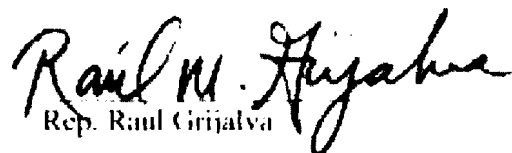
  
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Rep. Ellen Tauscher

  
Rep. Henry Brown

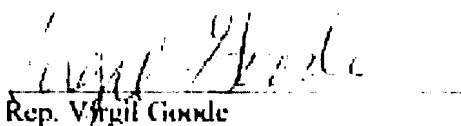
  
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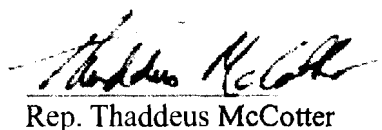
  
Rep. Shelley Moore Capito

  
Rep. Raul Grijalva

  
Rep. Pete Sessions

  
Rep. Michael Fitzpatrick

  
Rep. Virgil Goode

  
Rep. Thaddeus McCotter

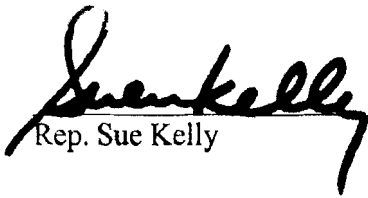


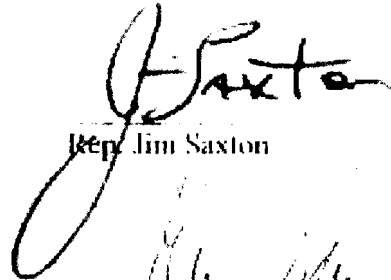
  
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Rep. Michael Burgess

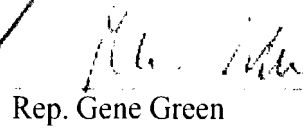
  
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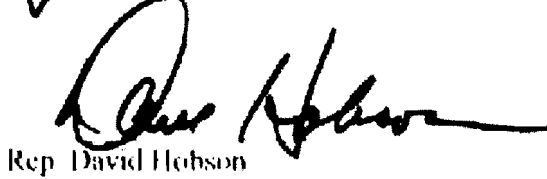
  
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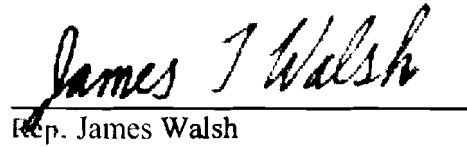
  
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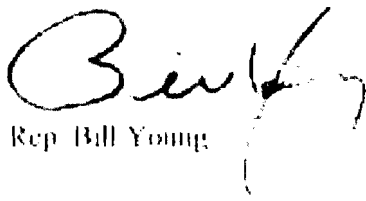
  
Rep. Jim Saxton

  
Rep. Jim Moran

  
Rep. Gene Green

  
Rep. David Hobson

  
Rep. James Walsh

  
Rep. Bill Young

  
Rep. Silvestre Reyes

  
Rep. Charlie Norwood

*Chip Pickering*  
Rep. Chip Pickering

*Wally Herge*  
Rep. Wally Herge

teachers when Ms. Porter took over. She took immediate steps, such as finding music students from the University of Minnesota to teach the band members. And she reached out to the community, and the community responded.

Mr. Speaker, the crescendo of support started with the Brooklyn Center Rotary Club, which saw the problem and marched forward. Under the leadership of "Mr. Brooklyn Center," Phil Cohen, past Rotary President Carrie Engh of Bremer Bank Brooklyn Center and current President Frank Slawson of American Express Financial Planners, the Rotary Club contributed \$10,000.

The Lions Club also made financial contributions and the Brooklyn Center Business Association held a golf tournament to help the band. And the Brooklyn Center Taxpayers Association pitched in, too. The people of Brooklyn Center have really come together to support the band.

Mr. Speaker, Ms. Porter's inspired leadership and the band's hard work resulted in the Grammy Foundation personally delivering the \$15,000 Grammy Enterprise Award to the band at Brooklyn Center High School!

Chris Porter and Chanel Chatham received a well-deserved standing ovation. The tremendous outpouring of affection and support for the band made it all worthwhile!

The story of the Brooklyn Center High School Band even brought tears to the eyes of singer Kelly Clarkson, who was a guest of honor at the event. The story reminded Clarkson of her own high school band, and the story has warmed all of our hearts.

From the trombones to the tubas, the Brooklyn Center High Band is truly playing a joyful tune! There was a lot of hard work that went into this masterpiece.

Thank you, Chris Porter and the wonderful Brooklyn Center High School Band, for bringing so much great music into our lives and the lives of young people. You have all showed us that hard work, creativity, talent and the right instruments can make a beautiful song!

CONFERENCE REPORT ON H.R. 5631,  
DEPARTMENT OF DEFENSE AP-  
PROPRIATIONS ACT, 2007

SPEECH OF

**HON. MARK UDALL**

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, September 26, 2006*

Mr. UDALL of Colorado. Mr. Speaker, I rise in support of this legislation.

The Defense Appropriations bill for fiscal year 2007 funds our military operations in Iraq and Afghanistan, among many other things. It is very similar to the Defense Authorization bill that I supported in the Armed Services Committee and on the House floor.

The bill provides \$447.6 billion in funding, including \$70 billion in emergency funds to support military operations in Iraq and Afghanistan. This grand total represents about 55 percent of the entire Federal discretionary budget. Overall defense spending has risen 40 percent since September 11th and is more than currently being spent by the rest of the world combined.

Appropriating \$70 billion for the so-called bridge fund is realistic and necessary, be-

cause we must support our men and women in uniform, but I also believe the Administration must begin to take responsibility for the full cost of the war in Iraq and consider these costs through the regular appropriations process. There is no "emergency" here—we know that since this bridge fund would take us only halfway through fiscal year 2007, we should be expecting another request before the year is over. With total costs for operations in Iraq and Afghanistan crossing the half trillion dollar point after passage of this bill, the American people deserve greater candor from the Administration about both the predictable costs as well as the anticipated benefits of our undertakings in Iraq and Afghanistan.

Although I don't agree with the "emergency" designation, I'm pleased that the conferees saw fit to increase the bridge fund levels to include \$17.1 billion to replace and refurbish Army equipment. This is the amount General Schoemaker testified that the Army needed in fiscal year 2007 to fully fund its reset program. It's true that even with this funding, the Army will still need tens of billions of dollars over the coming years for equipment rehabilitation and recapitalization—but this is an important start. The bridge fund also includes funding for Marine Corps equipment and body armor as well as \$549 million to cover costs of the enhanced insurance and death gratuity benefits.

I am pleased that the conference report fully funds military pay, benefits, and the pay raise of 2.2 percent for the base force. It also includes language that I advocated for prohibiting funding for permanent U.S. bases in Iraq.

I remain concerned about rising costs of weapons systems that have yet to be fully funded, such as the Future Combat Systems and missile defense program, among others. A recent report from the Department of Defense identified 36 major weapons systems as having significant cost overruns. And yet Congressional Budget Office projections are that we'll need to increase defense budgets by 17 percent per year simply to sustain the current force structure and weapons programs. And this is happening at the same time that operations and maintenance and personnel costs—as well as training and recruiting costs—are rising.

So Mr. Speaker, this conference report is not perfect. It does not solve or attempt to solve some of these looming budget problems. But overall, it deserves to pass and I urge its approval.

CONGRATULATING VINCENT D.  
MURRAY ON RECEIVING THE  
HAROLD W. MCGRAW, JR. PRIZE  
IN EDUCATION

**HON. JOHN LEWIS**

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

*Friday, September 29, 2006*

Mr. LEWIS of Georgia. Mr. Speaker, I rise today to congratulate Vincent D. Murray, who will receive the prestigious Harold W. McGraw, Jr. Prize in Education. Mr. Murray has been the principal of Henry W. Grady High School in Atlanta, Georgia since 1991.

Mr. Murray has been chosen for the prestigious 19th annual award for his leadership in transforming his inner-city public school into a higher achieving institution in which graduation

and college-going rates consistently have risen above the district and state averages.

Sixty-six percent of Grady High students are African American and 44 percent qualify for free or reduced price lunch. When Murray joined Grady High, more than a third of all freshmen were held back and repeated their freshmen year. The student body's passing rate on the Georgia graduation test was below the statewide average.

Mr. Murray has been consistent in his efforts and focused on innovative reform. The result is that today, four out of every five graduates go directly on to college or university, including Ivy League institutions. Average scores on the graduation test, SAT and Advanced Placement exams exceed district, state and national averages. Graduation rates have risen 38 percentage points for African-American students (to 84 percent), 26 points for economically disadvantaged students (to 86 percent) and 25 points for white students (to 97 percent). As a result of Murray's success in transforming Grady High, the U.S. Department of Education recognized him in 2000 with the Department's Title I Distinguished School Award. In 2006, the governor of Georgia named him a High Performance Principal, a top honor in the state.

Mr. Murray has a bachelor of arts degree in history and English from Morehouse College, a master of arts degree in early childhood education from the University of Georgia, and a doctorate in psychology/learning disabilities from Boston University. He has pursued post-doctoral studies at Clark-Atlanta University and Georgia State University.

I salute Mr. Vincent D. Murray for his outstanding contributions to education. He has dedicated himself to improving education in this country and his accomplishments continue to make a difference.

URGING THE CENTERS FOR MEDI-  
CARE AND MEDICAID TO RECON-  
SIDER IVIG REIMBURSEMENT

**HON. CHARLIE NORWOOD**

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

*Friday, September 29, 2006*

Mr. NORWOOD. Mr. Speaker, I would like to bring your attention to a very important issue relating to medical reimbursement by the Centers for Medicare and Medicaid Services (CMS). The Medicare Prescription Drug Improvement Act and Modernization Act of 2003 (MMA) created new reimbursement mechanisms for IVIG therapies. CMS's implementation of the MMA has resulted in reduced access to life-saving therapies for Medicare beneficiaries. CMS potentially closed the door to medical treatment when they issued the CY 2007 proposed rules for the physician fee schedule and the hospital outpatient prospective payment system, which, if implemented, would effectively limit IVIG treatment by not properly reimbursing providers.

IVIG is a vital medical service. It is a plasma-derived therapy tailored to the individual's diseases and treatment options to achieve optimal results. Nearly 10,000 Medicare beneficiaries are afflicted with primary immune deficiency (PID) which only responds to IVIG therapy. For many Americans there is no substitute for IVIG treatment.

OCT 10 2006

October 9, 2006

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

**Re: CMS-1321-P (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B)**

Dear Administrator McClellan:

Stakeholders within the community of patients who rely upon lifesaving plasma derived and recombinant analog therapies and the Plasma Protein Therapeutics Association ("PPTA") appreciate this opportunity to comment on the proposed rule regarding revisions to payment policies under the Medicare physician fee schedule, published in the Federal Register on August 22, 2006 (the "Proposed Rule").<sup>1</sup> We are deeply committed to the health and safety of the patients who rely on plasma therapies and therefore our comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving plasma-based and their recombinant analog therapies ("plasma protein therapies") in the physician office setting.

While we are concerned that inadequate reimbursement mechanisms may be problematic for access to care for all plasma protein therapies, our comments on the Proposed Rule focus mainly on immunoglobulin therapy, or IVIG. The undersigned are very concerned that patient access to IVIG is being jeopardized by different aspects of the manner in which physicians and suppliers are reimbursed for the costs they incur related to furnishing this product. Further it is important to note that for many patients who receive IVIG there is no alternative treatment available. Given the importance of this product to the beneficiaries that need it, we recommend that CMS consider looking at the possibility of several options to the current reimbursement methodology to improve reimbursement so that it does not impede access to IVIG. We recommend that CMS continue the current payment for preadministration-related services. Other suggestions that CMS may wish to consider include the continuation of the current payment for preadministration-related services and the creation of separate Healthcare

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<sup>1</sup> 71 Fed. Reg. 48982.

Common Procedure Coding System (“HCPCS”) codes for each brand of IVIG product, as well as including a payment adjustment based on recommendations from the two IVIG access studies currently underway.. Moreover, we recommend that CMS consider that the administration of IVIG be billed under the same codes as other biologic response modifiers and CMS should make this clear in the final rule. As far back as January 2005, the HHS Advisory Committee on Blood Safety and Availability (ACBSA) put forth a recommendation to the HHS Secretary stating that, “current reimbursement schedules for plasma derived products and their recombinant analogues for treatment of chronic conditions are not adequate to support optimal care of individual patients.”<sup>2</sup>

### **CONTINUING THE PAYMENT FOR IVIG PREADMINISTRATION-RELATED SERVICES** [“ASP Issues”]

IVIG is the only effective treatment for primary immunodeficiency disease and also has been proven clinically beneficial in the treatment of secondary immune deficiency diseases. In addition, individual United States licensed IVIG products are labeled for the treatment of: a) Kawasaki’s disease; b) chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial infections; c) bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults; and d) idiopathic thrombocytopenic purpura. Many individuals affected by diseases or conditions treated with IVIG depend on this life saving therapy for the rest of their lives. Each individual needs to have maximum access to the specific formulation which best meets their unique needs and does not pose serious and potentially life threatening complications.

In the recently issued outpatient prospective payment system proposed rule, CMS proposed to discontinue the payment for the preadministration-related services for no apparent reason other than the vague statement that it “would not be necessary in CY 2007 to ensure Medicare beneficiary access to IVIG.” 71 Fed. Reg. 49506, 49604 (Aug. 23, 2006). While there is no similar statement in the Proposed Rule, in Addendum B, a status indicator of “D” appears for the code used to bill for the preadministration-related services (G0332), which means that the code will be deleted or discontinued. 71 Fed. Reg. at 49235. Thus, the Proposed Rule seems to reflect a similar intention to discontinue the current \$69 payment for preadministration-related services for IVIG.

As CMS noted in last year’s physician fee schedule final rule, this payment ensures that physicians are adequately reimbursed for providing IVIG to their patients. See 70 Fed. Reg. 70116, 70220 (Nov. 21, 2005). We do not understand how CMS came to the conclusion that this payment is no longer necessary, when physicians will continue to struggle to be able to provide the proper IVIG product to Medicare

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<sup>2</sup>Mark E. Brecher, M.D., “Reimbursement of Plasma Derived Products and Their Recombinant Analogues,” ACBSA, 25 Jan 2005.

beneficiaries. Moreover, we are troubled by the lack of any explanation of this apparent change in the Proposed Rule. Because physicians will continue to incur these costs in 2007, just as they are in 2006, CMS must continue to reimburse physicians for these costs through the \$69 preadministration-related services payment.

Furthermore, Department of Health and Human Services (“HHS”) Secretary Michael Leavitt’s August 29<sup>th</sup>, 2006 letter to Representative Ellen Tauscher<sup>3</sup> (D-CA) states that, “this add-on payment is paid per day of IVIG administration and is for the extra costs resources expended on locating and obtaining appropriate IVIG products and on scheduling patient infusions during this current period where there may be potential issues in the IVIG market.” This additional payment is helpful in reimbursing providers for these extra costs. Despite CMS’ acknowledgement of these additional costs for the administration of IVIG in the August 29<sup>th</sup> letter, the agency ironically proposes to eliminate the payment in their CY 2007 Proposed Rule. This preadministration payment was established to reimburse physicians for actual costs they incur in furnishing IVIG. These costs will not simply disappear in 2007. As such we strongly urge CMS to maintain the preadministration-related services payment.

**IVIG SHOULD BE TREATED AS A BIOLOGIC RESPONSE MODIFIER FOR PURPOSES OF PAYMENT FOR THE ADMINISTRATION OF IVIG [“ASP Issues”]**

Beginning this year, physicians have billed for drug administration services using a number of Current Procedural Terminology (“CPT”) codes that were first effective in 2006. Under these new codes, chemotherapy administration codes apply to parenteral administration of biologic response modifiers, according to the language contained in the CPT book. As a result, any product that is a “biologic response modifier” should be billed under such codes.

IVIG is such a product and we ask CMS to clarify explicitly that the service of administering IVIG should be billed as such. According to the U.S National Library of Medicine, biologic response modifier therapy is defined by reference to “immunotherapy,” which is defined as “treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases.”<sup>4</sup> IVIG is precisely a treatment that restores the ability of the immune system to fight cancer and other diseases – e.g., Kawasaki’s disease, chronic lymphocytic leukemia, primary immune deficiency disease, secondary immune deficiency diseases, and immune thrombocytopenia purpura. Thus, IVIG qualifies as a biologic response modifier, and CMS should consider stating clearly in the final rule that physicians should bill for

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<sup>3</sup> On May 31<sup>st</sup>, 2006 Representative Joe Pitts (R-PA) and thirty four other Members of Congress, including Representative Tauscher (D-CA), wrote Secretary Leavitt urging the agency take action to address the IVIG patient access dilemma by implementing permanent and comprehensive solutions. The response to this letter to Mr. Pitts and the other thirty-four co-signers was delivered on August 29, 2006.

<sup>4</sup> See <http://ghr.nlm.nih.gov/ghr/glossary/immunotherapy>.

administering the product using the CPT codes applicable to biologic response modifiers.

### **SEPARATE HCPCS CODES FOR IVIG PRODUCTS** ["ASP Issues"]

As you know, payments for drugs and biologicals are set based on the ASP methodology. That methodology compiles manufacturer information by HCPCS code and computes an average sales price. IVIG is somewhat uniquely situated in this regard in that it is one of the few sole source biologicals for which there are multiple brand name products, but no generic products, in the code. We believe that, in such unique circumstances, the ASP methodology does not generate representative payment rates for the different IVIG therapies. Rather, CMS should consider establishing unique HCPCS codes for each brand name product so that the ASP rate for each product is based on its own ASP information, as is the case for other biologicals. This would yield rates that are pertinent to each product and thus may enhance access to IVIG products.

The following brands of intravenous immune globulin are now broadly available in the United States market: Polygam® SD, Panglobulin® NF, Gammar® P I.V., Gammagard® S.D., Gamunex®, Flebogamma®, Octagam®, Carimune™ NF, Iveegam® EN, Gammagard® liquid. Establishing separate HCPCS codes for these products is appropriate because there are important clinical differences among them, such as:

- Some products contain no sugars, which is beneficial for diabetics;
- Some products have low osmolality and low volume, which physicians sometimes prefer for patients with congestive heart failure or compromised renal function;
- Some products contain sucrose, which can create a higher risk of renal failure;
- Some products contain less immunoglobulin A ("IgA"), which is better for patients with IgA deficiencies; and
- Some products have a lower pH, which may be preferable for patients with small peripheral vascular access or a tendency toward phlebitis.

Because of these differences, there are clinical reasons why physicians order one IVIG product or another. CMS' coding and payment for these products also should recognize these differences, which could be done by establishing separate HCPCS codes for each product. That, in turn, would allow CMS to determine separate and more representative payments for each product. Moreover, CMS may want to consider reimbursing new immune globulin products with different delivery methods (such as subcutaneous delivered immune globulin) by brand with a separate HCPCS code rather than bundling them into a class with other products.

### **PAYMENT ADJUSTMENT FOR IVIG** ["ASP Issues"]

In comments on the 2006 physician fee schedule proposed rule, PPTA advocated for an add-on payment for IVIG that captures the acquisition, direct and indirect handling costs associated with the product. Although the agency rejected a number of recommended payment adjustments for IVIG, including an add-on payment, because of its belief that ASP data are reflective of physician acquisition costs for IVIG, it nonetheless determined that Medicare should pay physicians \$69 for each administration of IVIG to compensate them for preadministration services related to IVIG. 70 Fed. Reg. at 68649-50.

We appreciated the agency's recognition of these types of costs incurred by physicians in providing IVIG to beneficiaries, although that is tempered by the prospect of the discontinuation of that payment, as discussed above. However, even with a continuation of the payment for preadministration-related services, we are concerned that reimbursement for IVIG may still be inadequate to ensure continued access in the physician office setting. While that payment does reimburse physicians for some of the costs that they incur related to IVIG, other costs would remain uncompensated.

We suggest a payment adjustment to the current ASP formula may be warranted to ensure that providers are made whole on the purchase cost of the IVIG therapies so that they receive a fair return in their investments in care. This payment adjustment needs to be reflective of providers' true costs to make IVIG available to their patients in the physician office. Furthermore, the payment adjustment could be based on independent data from the two current IVIG access studies being done by the Office of Inspector General ("OIG") and HHS' Assistant Secretary of Planning and Evaluation.

A payment adjustment precedent to life-saving plasma protein therapies has recently been effectuated by CMS when it implemented, at Congress' direction, a separate payment for blood-clotting factor because of its unique properties and the fragile needs of patients who rely on blood-clotting factors. See Social Security Act ("SSA") § 1842(o)(5)(A) (mandating a separate payment for items and services associated with the furnishing of blood clotting factor). This furnishing fee was \$0.14 per unit in CY 2005, and is \$0.146 per unit in CY 2006. Since the precedent setting blood-clotting factor furnishing fee was implemented, access to this life-saving plasma protein therapy has not been diminished, making this payment adjustment a successful mechanism in ensuring that the recent payment cuts did not impact access. However, the same payment cuts have resulted in providers' acquisition cost of IVIG for Medicare beneficiaries exceeding the reimbursement rates from CMS under the current ASP methodology. To this end, it would make sense that IVIG warrants the same acquisition furnishing fee considerations as blood clotting factor because it is similar in that both IVIG and blood clotting factor are plasma protein therapies that have highly unique characteristics that require complex manufacturing, storage and distribution methods.

To ensure Medicare beneficiaries have the best available access to the life-saving IVIG therapies, CMS may want to consider providing a payment adjustment to



the current ASP reimbursement methodology to enable physicians to cover the costs incurred for acquiring IVIG. The blood-clotting furnishing fee is a precedent-setting provision for plasma protein therapies, one which CMS has the authority to issue for IVIG. Without such a payment adjustment, we are concerned that beneficiaries will continue to be at risk of not being able to obtain the best access to care as possible.

### **CONCLUSION**

We appreciate the opportunity to comment on the Proposed Rule. We urge CMS to consider carefully these comments, particularly those that suggest mechanisms to improve payments for IVIG. Many beneficiaries depend on this product and reimbursement should not impede their access to this necessary treatment. Thank you for your attention to this very important matter.

Respectfully submitted,

Alpha-1 Association  
Alpha-1 Foundation  
GBS/CIDP Foundation International  
Hemophilia Association of New Jersey  
Hemophilia Federation of America  
Immune Deficiency Foundation  
Jeffrey Modell Foundation  
National Hemophilia Foundation  
Platelet Disorder Support Association  
Plasma Protein Therapeutics Association

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October 10, 2006

**By Hand Delivery**

Leslie Norwalk, Esq.  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201

Re: CMS-1321-P: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B; ASP Issues

Dear Ms. Norwalk:

ImClone Systems Incorporated ("ImClone") is pleased to submit these comments in response to the discussion of Average Sales Price (ASP) in the Preamble of the proposed rule, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B. We commend the Centers for Medicare and Medicaid Services (CMS) for its continued efforts to implement ASP and to address issues raised by bundled sales arrangements.

ImClone is a biotechnology company dedicated to developing and commercializing novel therapeutic products in the field of oncology. We are committed to providing treatments to meet the needs of cancer patients, and our efforts have resulted in a broad spectrum of innovative product candidates. Consistent with this commitment, ImClone currently manufactures and markets the anti-cancer product Erbitux® (Cetuximab), which is indicated for the treatment of colorectal cancer and a type of locally or regionally advanced head and neck cancer. Erbitux® is also approved to treat patients with a certain type of head and neck cancer whose tumor has returned in the same location or spread to other parts of the body and who have failed platinum-based chemotherapy. It is this type of focus, we believe, that furthers innovation in specialized fields, such as oncology.

In these comments, ImClone focuses on the issues raised by bundled price concessions, and in particular, we discuss:

- a common bundled sales arrangement where price concessions given on products that have no or limited alternatives in the market are conditioned upon the purchase of products that have alternatives, particularly branded alternatives, in the market;

- the effect of bundled price concessions on reimbursement calculations, provider choice, patient access, and industry innovation;
- the methods presently employed by the Federal government to address bundled price concessions; and
- a method to address the specific issues raised by bundled price concessions in the Medicare Part B context.

## **I. A Common Bundled Sales Arrangement**

As evidenced by CMS' many inquiries from pharmaceutical manufacturers and other stakeholders, bundled price concessions are prevalent in the pharmaceutical industry, and as CMS is aware, bundled sales arrangements come in many varieties.

A bundled sales arrangement that is particularly troubling and that currently exists in the market involves a manufacturer that leverages, or bundles, two of its products (Products A and B) with one or more products (Products C and D). In this case, Products A and B have no significant drug alternative or alternatives that are less competitive than the drug alternatives for Products C and D. In other words, the practice involves offering a discount or rebate on products that face no or limited competition but conditions the discount or rebate on the purchase of other products, also manufactured by the seller, that face stiffer competition. If the buyer wants to secure Products A and B, it is forced to purchase a certain percentage, market share, or volume of its needs for Products C and D from the manufacturer, instead of looking to possibly lower cost options or clinically superior options in the market. Such an arrangement is clearly designed to influence purchases of the manufacturer's products that face stiffer competition, which in the absence of the arrangement, will not sell as well.

## **II. Effects of Bundled Sales Arrangements**

Bundled sales arrangements can distort price and result in inaccurate reimbursement calculations, limited provider choice, restricted patient access, and ultimately less industry innovation.

As discussed above, in problematic bundled sales arrangements, manufacturers offer discounts or rebates on products for which there are no or limited market alternatives only if the buyer also buys products that face significant alternatives in the market. If the buyer refuses to buy the additional products, it suffers the consequences of paying a higher price on the products that have no or limited alternatives. As a result, manufacturers engaging in this type of arrangement are able to keep the prices of their products that have alternatives high and still increase the products' sales, even though the products face stiff competition.

Consequently, in these arrangements, the prices of the products that face stiffer competition are artificially inflated. This situation, of course, results in inaccurate reimbursement levels, creating higher ASP reimbursement and lower Medicaid rebates than should apply. Where market prices are artificially inflated, the affected ASP, calculated on the basis of these artificial prices, will necessarily not be reflective of the true market price, as

Congress specifically intended in passing the Medicare Prescription Drug Improvement and Modernization Act of 2003. As we explain below, we recommend that CMS remedy these problems by allocating all of the discount or rebate ostensibly offered on the “stronger” drug to the products which have alternatives in the market, the “weaker” drugs.

It is critically important to emphasize that bundled price concessions also force providers to make decisions based on discount and rebate economics, rather than on a drug’s clinical advantages. At a time when providers, particularly physicians in the Part B context, are faced with very tight operating margins, these decisions are very difficult for providers to confront and may influence how they practice medicine. These same decisions can limit a patient’s access to certain drugs that are clinically superior to the alternatives. To the extent a provider elects not to order a particular drug as a result of a bundled sales arrangement, a patient’s access to that drug is negatively impacted. Accordingly, this is not just an important issue from the perspective of limiting Medicare costs, it is an important quality of care issue as well.

Bundled sales arrangements also discourage innovation in the pharmaceutical industry. The practice of offering bundled price concessions clearly favors those manufacturers that possess a large portfolio of products. Those manufacturers that only market one product, or a small portfolio of products, are placed at a greater disadvantage than they otherwise would be. While a small biotechnology company may market a product that has been shown to have better clinical outcomes than a competitor’s product, if the competitor’s product is included in a bundled sales arrangement, providers will have a financial incentive to purchase the competitor’s product, not because of the stand alone price of that particular product, but because of the collateral impact purchasing the competitor’s product could have on the price of the competitor’s other products. Consequently, if manufacturers are unable to compete in a market for a particular therapy, they will be reluctant to invest their resources in developing products for that therapy.

### **III. Methods Presently Employed to Address Bundled Sales Arrangements**

Presently, the Department of Health and Human Services (“the Department”) employs various methods to address the use of bundled sales arrangements by manufacturers to offer discounts or rebates on their products. CMS requires pharmaceutical manufacturers to account for bundled sales in its Medicaid Drug Rebate Program (MDRP), and the Office of Inspector General (OIG) restricts the application of the discount safe harbor in the case of bundled sales arrangements.

Under the MDRP, the Medicaid Rebate Agreement (MRA) requires manufacturers, in calculating its Average Manufacturer Price (AMP) and Best Price (BP), to allocate the discounts on bundled sales “proportionately to the dollar value of the units of each drug sold under the bundled arrangement.”<sup>1</sup> The MRA even defines a “bundled sale” as “the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which

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<sup>1</sup> Model Medicaid Rebate Agreement (MRA) § I(d).

would have been received had the drug products been purchased separately.”<sup>2</sup> This requirement of the MDRP recognizes the potential bundled sales arrangements have to distort price and is an effort by CMS to secure more accurate prices.

In addition to MDRP’s treatment of bundled sales arrangements, the OIG recognizes the potential for abuse of the Federal health care programs by these arrangements, and thus, in the safe harbor regulations to the Anti-kickback Statute, it restricts the application of the discount safe harbor when arrangements involve bundled sales. According to the applicable regulations, when discounts involve bundled products, the products supplied must be reimbursed by the same Federal health care program using the “same methodology” in order to qualify for protection.<sup>3</sup> Furthermore, in a 1999 final rule, the OIG articulated its concern with bundled price concessions, in that “[t]hese discounts are problematic because they shift costs among reimbursement systems or distort the true costs of all items[, and a]s a result it may be difficult for Federal health care programs to determine proper reimbursement levels.”<sup>4</sup>

These efforts by the Department reveal the Federal government’s appreciation of how bundling can impact price and create improper incentives. They also act as a precedence for addressing bundling, although the methodology under Medicaid is too ill-defined to be adopted in the ASP context. Likewise, the OIG approach would not make sense from a pricing perspective.

#### **IV. A Method to Address the Issues Raised by Bundled Sales Arrangements**

Given the potential negative effects of bundling in certain circumstances, CMS must determine how the arrangements should be accounted for under ASP. Fundamentally, ASP should be reflective of a drug’s true market price. This requires manufacturers to apportion discounts and rebates on bundled sales. For instance, where a manufacturer bundles products for which no significant drug alternative exists with products that face stiffer competition, CMS should require the manufacturer to apportion all of the discounts or rebates ostensibly assigned to the products with no significant drug alternative to the products that face stiffer competition. The only economic reason to tie these products together is to influence purchases of the products that face stiffer competition, and therefore, these products should bear the full load of the discounts or rebates. By proceeding in this fashion, CMS would prevent manufacturers from increasing their market share at the expense of Medicare and other payors.

Significantly, the ASP rule permits CMS to impose such a requirement. The ASP rule states that in calculating ASP, “such price shall include volume discounts,” and the Department may “include in the [ASP calculation] other price concessions . . . that would result in a reduction of the cost to the purchaser.”<sup>5</sup> Since bundled price concessions are ultimately used to influence the purchase of certain products while awarding the discount to other products, such price concessions should be apportioned in a manner representative of their intended effect.

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<sup>2</sup> *Id.* at § I(e).

<sup>3</sup> 42 U.S.C. § 1001.952(h)(5)(ii).

<sup>4</sup> Dep’t of Health and Human Servs., Office of Inspector Gen., Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule, 64 Fed. Reg. 63518, 63530 (Nov. 19, 1999).

<sup>5</sup> 42 U.S.C. 1345ww-3a(c)(3).

**V. Conclusion**

For the many reasons articulated, ImClone strongly urges CMS to promulgate a rule that squarely addresses bundled sales arrangements in the calculation of ASP in a way that promotes accuracy of drug prices. We thank CMS again for the opportunity to comment on this important ASP issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "G. Mayes".

Gregory T. Mayes  
AVP, Associate General Counsel and  
Chief Compliance Officer



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October 5, 2006

The Honorable Mark McClellan, M.D., Ph.D.  
Office of the Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-1321-P  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: CMS-1321-P (ASP Issues)**

Dear Dr. McClellan:

On behalf of FMC Distributors, Inc., I would like to take this opportunity to provide our comments on the Proposed Rule CMS-1321-P, "*Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B*" (the "Proposed Rule"). This rule was published in the *Federal Register* on August 22, 2006.<sup>1</sup>

*FMC Distributors, Inc. services independently owned pharmacies regionally in Puerto Rico and the continental United States. FMC provides a full range of pharmaceutical products including brand, generic and respiratory goods to our clients. FMC is ranked at Number 44 in the TOP 400 BUSINESSES by Caribbean Business, a local business publication in Puerto Rico, with revenues exceeding \$85Million annually.*

FMC Distributors is a member of the Healthcare Distribution Management Association ("HDMA"). As part of our membership activities, we have reviewed the HDMA written comment letter to the Centers for Medicare and Medicaid Services (CMS), on the proposed rule referenced above. FMC Distributors fully endorses the HDMA comments, and is, by submission of this letter, incorporating the HDMA comments by reference into our written comments for the record.

While we fully agree with all of the points raised in the HDMA letter, we wish to place special emphasis on two items addressed in the HDMA comment letter regarding Average Sales Price

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<sup>1</sup> 71 *Fed. Reg.* 48980 (Aug. 22, 2006).

(ASP) Issues. First, FMC Distributors especially encourages CMS to reconsider its opinion that prompt pay discounts should continue as a type of price concession that manufacturers must include in their ASP calculation. We urge CMS to reverse its position, and inform manufacturers that customary prompt pay discounts should not be applied to wholesalers when they calculate ASP. We believe that manufacturers could continue to deduct any prompt pay discounts extended directly to end customers on sales that do not go through a wholesaler, but those that are not passed along to the customer are not appropriately included in the ASP. This revision is consistent with recent congressional directives that prompt pay discounts should be excluded from the Average Manufacturer's Price (AMP) calculation.

Secondly, FMC Distributors strongly endorses CMS' proposal to codify the definition of bona fide services, to treat fees paid to wholesalers the same as fees paid to third party logistics providers, and not to deduct those bona fide service fees when ASP is determined.

Thank you for this opportunity to provide our comments on Proposed Rule CMS-1321-P, and to endorse the comments of the HDMA as written. We hope these comments are constructive in your deliberation of developing an Average Sales Price calculation that represents an equitable and reasonable approach to reimbursement for the products that we distribute.

Sincerely,



Wayne S Thuna

Vice President, Operations  
FMC Distributors, Inc.





October 10, 2006

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

**Re: CMS-1321-P; Comments Regarding the Proposed  
Physician Fee Schedule Rule for Calendar Year 2007**

Dear Dr. McClellan:

Astellas Pharma US, Inc. ("Astellas") appreciates the opportunity to comment on the Medicare physician fee schedule proposed rule for calendar year 2007 published by the Centers for Medicare and Medicaid Services ("CMS").<sup>1</sup> Astellas is among the top 20 global pharmaceutical companies, with North American product lines that focus on the therapeutic areas of immunology, cardiology, dermatology, infectious disease, and urology. Our drugs and biologicals are used to treat Medicare beneficiaries in a variety of settings, including physician offices.

Astellas understands that CMS faces significant challenges in devising payment systems that encourage physician participation, facilitate beneficiary access to appropriate therapies, and ensure the continued fiscal integrity of the Medicare program. Our comments are designed to assist CMS in balancing these goals, as well as to preserve the incentives for therapeutic innovation that have enhanced Medicare beneficiaries' treatment options. The comments below focus on four key issues, and can be briefly summarized as follows:

- (1) Supplying fees for certain Part B drugs, including immunosuppressives.** CMS should carefully evaluate the need for increased supplying fees in 2007, and should adopt a mechanism for annually updating supplying fees to account for routine increases in pharmacies' costs.
- (2) Physician administration fees and appropriate coding.** To help ensure adequate reimbursement for physicians' drug administration services, CMS should instruct its contractors to pay for administration of biological response modifiers using the codes applicable to anti-cancer therapies.

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<sup>1</sup> Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and other Changes to Payment under Part B; Proposed Rule, 71 Fed. Reg. 48982 (Aug. 22, 2006).

**(3) Average Sales Price (ASP) issues.** CMS should issue guidance that improves the accuracy and efficiency of manufacturers' ASP calculations and ensures that the ASP-based payment system for Part B drugs supports continued beneficiary access to these essential therapies. Specifically, CMS should clarify that "bona fide service fees" include fees for data services; that manufacturers need not seek information on their customers' downstream transactions to determine that a fee qualifies as a bona fide service fee; and that fees to non-purchasers are not "discounts" for ASP purposes. Finally, CMS should adopt rules to ensure that comparisons between ASP, AMP and Widely Available Market Price (WAMP) produce reliable data and do not result in unwarranted payment reductions that jeopardize beneficiary access.

\* \* \*

**I. Supplying fees for certain Part B drugs, including immunosuppressive therapies**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") requires CMS to pay a separately billable "supplying fee" to pharmacies for dispensing Part B immunosuppressives and certain other drugs.<sup>2</sup> Currently, pharmacies receive a per-prescription supplying fee of: (1) \$24, for the initial prescription filled for a beneficiary in a 30-day period (or \$50, for the initial prescription of immunosuppressives supplied during the first month after a transplant); and (2) \$16, for additional prescriptions filled for a beneficiary during a 30-day period.<sup>3</sup> CMS has not proposed any changes in these fees for 2007.

Astellas urges CMS to evaluate the adequacy of the existing fees, in light of the costs pharmacies currently incur to perform the range of services necessary to supply these critical medications to Medicare beneficiaries. The proposed rule does not explain the rationale for maintaining the 2006 fee structure, and we believe that a careful review of recent cost information provided by stakeholders is essential to ensure that the supplying fees for 2007 will be sufficient to cover pharmacies' costs and support beneficiary access.

Astellas also is concerned that the regulations set a specific payment amount for these pharmacy services, without a provision for annual fee increases due to ordinary increases in expenses (including labor costs), and will therefore result in deficient Medicare payment for these services over time. Consequently, we request that CMS incorporate a payment adjustment process to ensure that reimbursement to pharmacies for costs incurred in connection with supplying these important therapies remains adequate.

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<sup>2</sup> Social Security Act (SSA) § 1842(o)(6). Specifically, in addition to immunosuppressives, supplying fees also are required for oral anti-cancer chemotherapy drugs and oral anti-emetics. *Id.*

<sup>3</sup> 42 CFR § 414.1001(a), (b).

## **II. Physician administration fees and appropriate coding mechanisms**

Consistent with its commitment to pay physicians adequately for drug administration services, CMS in 2005 adopted the AMA's revisions to the CPT codes for these services a year earlier than the 2006 effective date of the CPT revisions. Specifically, CMS created a set of G codes that, in part, incorporated the CPT panel recommendation to pay for administration of complex biologicals using the codes applicable to anti-cancer therapies.

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

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

## **III. ASP Issues**

Astellas shares CMS' interest in ensuring that the ASP-based payment system for Part B drugs and biologicals supports Medicare beneficiaries' continued access to appropriate new and established therapies, and we appreciate the Agency's ongoing efforts to improve the accuracy and reliability of ASP calculations. CMS recognized that manufacturers and other stakeholders may not have had sufficient experience with an ASP-based system to provide meaningful comment to the April 6, 2004 ASP interim final rule, and has requested additional comment. Astellas appreciates the additional opportunity for comment on the changes CMS proposes to ASP calculation and reporting.

### **1. Bona Fide Service Fees**

For ASP calculation purposes, bona fide service fees that are paid by a manufacturer to an entity (e.g., distributors, GPOs or PBMs) are not considered price concessions. CMS proposes to define bona fide service fees as those fees "paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug."

CMS is seeking comment from stakeholders so that it can potentially provide further guidance on a variety of issues including: (1) the types of services that may qualify as bona fide services (which could vary by drug category); (2) the methodology manufacturers must use to determine the fair market value of a bona fide service; and (3) appropriate methods for determining whether a fee is passed on in whole or in part.

Astellas supports CMS' efforts to establish clear guidelines on these issues that will improve the accuracy and consistency of ASP calculations. Appropriate guidelines are also important to help ensure that manufacturers can contract with purchasers for needed services without risk that the fees for those services would constitute a "discount" for purposes of ASP calculation. We would also urge the agency to minimize the reporting burden and confusion that would accompany divergent guidelines between Medicare and Medicaid treatment of bona fide service fees.

Manufacturers frequently purchase data to guide business decisions and evaluate product lines. Some forms of valuable data contain a greater degree of validity if purchased directly from a distributor, wholesaler, PBM, or GPO. Accordingly, Astellas urges CMS to clarify that data services represent bona fide services.

Moreover, Astellas encourages CMS to specify that an administrative fee to a non-purchasing entity is not a price concession for ASP purposes, since it seems anomalous to identify a reportable "discount" without a purchase transaction. We would welcome clear CMS guidance on this issue.

Astellas would agree that a fee arrangement that provided for a downstream price reduction to purchasers should be treated as a discount for ASP calculation purposes. However, we are concerned that the language in the proposed rule stating that a bona fide service fee cannot be "passed on, in whole or in part, to a client or customer of an entity [receiving the fee]" could be misinterpreted as shifting responsibility to manufacturers for a purchaser's future transactions and business decisions. Manufacturers do not, and should not, have a right to demand confidential business information disclosures from their customers. If a manufacturer contracts for a service it needs, pays the contracted fee for the service, and receives the benefit of that service, the service fee should not be considered a discount for ASP purposes. Consequently, we encourage CMS to clarify that manufacturers can properly treat such fees as bona fide service fees for ASP purposes, without requesting information on the fee recipient's intended use of the fees.

## **2. Widely Available Market Price and AMP Threshold**

Under the MMA, CMS may disregard a product's ASP in setting payment levels if the Office of the Inspector General (OIG) determines that the product's ASP exceeds its WAMP or AMP by a threshold determined by HHS. CMS proposes to continue to utilize 5% as the threshold, but expresses concerns regarding the operational issues associated with substituting a lower payment rate for a drug. Specifically, the Agency seeks comment on the timing and

Dr. Mark B. McClellan  
October 10, 2006  
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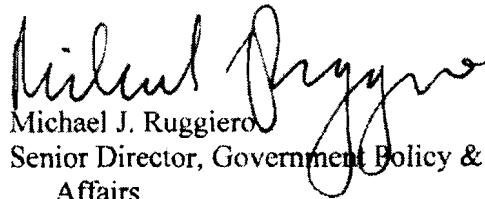
frequency of ASP, AMP, and WAMP comparisons, as well as the effective date and duration of any rate substitution.

Astellas agrees that clear guidelines are needed on the timing of these price comparisons and the duration of any rate substitutions. Given the potential for fluctuations in WAMP, AMP, and ASP within and between quarters, it may be inappropriate to reduce Medicare payment for a product based upon a single quarter of data. We suggest that the data be compared quarterly, but that a determination to substitute a lower payment amount would not be made until the ASP exceeded the WAMP or AMP by the relevant threshold for a CMS-specified number of consecutive quarters. The substituted payment amount would apply until the quarter following the reporting period in which the product's ASP no longer exceeded the WAMP or AMP by the specified threshold.

\* \* \*

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

Sincerely,



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