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October 9, 2006

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

To Whom It May Concern:

We appreciate the opportunity to comment on the Federal Register / Vol. 71, No. 163 dated August 23, 2006 regarding proposed changes to the Hospital Outpatient Prospective Payment System utilizing ambulatory payment classifications (APCs) and to the Ambulatory Surgical Center (ASC) Covered Procedures List for 2007; ASC Payment System and CY 2008 Payment Rates.

The following comments are offered for your consideration:

Screening Bone Mass Measurements

We agree with CMS that bone mineral density remains the best predictor of fracture risk with the most accepted method being Dual Energy X-ray Absorptiometry (DXA) for a bone density study. We also agree with CMS revising the definition of Bone Mass Measurement (BMM) to remove coverage for use of single photon absorptiometry (SPA) which is not as accurate in measuring bone medical density.

CMS states the current guidelines for coverage of BMM allows for more frequent follow-up BMM when medically necessary to include;

- Monitoring beneficiaries on long term glucocorticoid steroid therapy for 3 months
- Allowing for a confirmatory baseline BMM either central or peripheral to permit monitoring of beneficiaries in the future, if the initial test was performed with a technique that is different from the proposed monitoring method.

With regards to revising the current conditions of coverage for an individual being monitored to assess the response to an FDA approved osteoporosis drug therapy, the individual would be required to meet the present conditions of coverage and the monitoring would have to be performed by the use of DXA at the axial site. CMS also states that for individuals who qualify for a BMM and who receive a confirmatory baseline BMM to permit monitoring in the future, Medicare may cover a medically necessary BMM if the present condition of coverage is met and the BMM is performed by DXA at the axial site if the initial assessment was not performed by this system.

With regards to the central vs. peripheral systems, it is our standard practice to use the central system whenever possible; however our concern is CMS limitation of DXA at the axial site.

For patients who have undergone surgery at either the lumbar spine or femoral neck site, we would add a BMM at the appendicular skeleton, wrist site. For patients having undergone surgery at the hip or spine location, we would add a BMM to the forearm site. Also, the table weight limitation for a BMM is 300 lbs, and there are few patients that cannot be measured at the lumbar spine or hip, but only at the wrist. We encourage CMS to allow greater flexibility to sites for measurement when medically necessary.

Blood and Blood Products

We agree with the CMS statement that allowing each blood product to be assigned its own APC provides more appropriate payments based on individual median costs. In the 2007 proposed rule CMS stated they would use the simulated median costs calculated using 2005 hospital claims data to convert charges to costs. Although this data should accurately reflect the costs of providing blood and blood products, this does not prove to be the case. Program Transmittal 496 published for coding blood and blood products was not published until July 2005; therefore, six months of CY 2005 data may not be accurate.

Based on a review of our institution's blood product costs, the payment rate for several products is still significantly below the actual acquisition costs for the blood. For example, P9016 RBC Leukocyte Reduced (Processing and Storage) costs the institution more than $250.00 per unit but has an anticipated reimbursement rate of $176.89. We realize this is a substantial increase from last year's payment rate of $163.33; however, we are still concerned about Medicare's low payment rates compared to actual costs. Costs to blood centers will continue to increase and the Medicare payment rates will remain inadequate to cover the costs. To more accurately reflect a hospital's cost to charge ratios by using claims data after Program Transmittal 496 for coding blood and blood products was published, we recommend CMS to set the payment rates at the higher of the simulated median costs using claims data for the second half of CY 2005.

APC 195 and 202

Magnetic Resonance Imaging Guided Focused Ultrasound Ablation of Fibroids (Leiomyomata)

We recommend that CMS consider moving CPT codes 0071T and 0072T from APC 195 and 202 to APC 127, which has a more appropriate clinical and resource cost assignment and a payment of $7, 808.00. In addition, the only CPT code associated with APC 127 is G0243.

Currently, magnetic resonance imaging guided focused ultrasound ablation of fibroids (leiomyomata) CPT codes (0071T and 0072T) are currently assigned to APCs 195 and 202 with national unadjusted payment rates of $1,595 and $2,454, respectively. The other procedures in the current APC assignments are less resource intensive procedures for the hospital to offer, making the APC assignments for CPT 0071T and 0072T inappropriate. The time and resources associated with MR guided focused ultrasound, including about three to five hours of continuous MRI usage, are much greater and should be assigned to an APC with appropriate clinical and resources. Some hospitals' charges for the MR guided focused ultrasound procedure range from $18,000 to $24,000. Therefore, the rates for APC 195 and 202 would not appear to be reflective of the resources utilized.

Visits

We appreciate CMS' consideration that CPT descriptions for E/M codes do not describe the hospital visit resources. To compensate for this, hospitals have created their own guidelines to group resources into the levels of services generally described by the CPT codes. Requiring additional coding changes is an administrative burden for hospitals. There will be additional education for coding staff to report the new codes and billing systems will have to be changed to report the codes. In addition, hospitals will have to review their existing guidelines to assure that the new HCPCS codes descriptions meet the current guidelines and coding assignments. It does not appear that CMS will acquire any new or improved data from the coding change that the current CPT coding levels provide.

We believe that this proposal conflicts with the Administrative Simplification Act in the respect that it will require realignment of charge structures, retraining and education of staff for coding and charge processing. We recommend postponing the implementation until the national guidelines for new hospital visits have been finalized.

OPPS: Drug Administration

In 2006, CMS adopted 20 of the 33 CPT codes for drug administration and created HCPCS "C-codes" for the CPT Coding not implemented. We encourage CMS to complete the adoption of all 33 CPT codes for drug administration in 2007. The implementation of HCPCS C-codes has been problematic for hospital coding staffs. Since many commercial payers do not recognize the C-codes, hospitals had to implement all 33 CPT codes for drug administration in 2006. The result has been the reporting of two sets of codes for the same services depending on the payer. Since the hospital industry has had a year to learn the CPT coding, we recommend CMS remove the C-codes and adopt the remaining CPT codes for reporting drug administration services.

Section 5103

When Congress enacted the Medicare Modernization Act of 2003 it mandated that CMS undertake a complete review and revision of the way Medicare pays for ambulatory surgery centers. In 2005, Congress stipulated that the Medicare payment to an ASC would not be more than the facility fee payment to a hospital outpatient department for the same service. CMS is proposing the facility fee payments to ASCs be set at 62% of what Medicare currently pays to hospital outpatient departments. Currently, the ASC facility fee for GI procedures falls into the range of 88% to 92% of what CMS pays to the hospital outpatient department for the same procedure. The GI level is the highest ratio among all specialties. GI ASCs would be the most significantly impacted providers if this proposal were adopted.

We believe that if the rule were implemented as written, it would result in (1) the closing of many GI ASCs, (2) reduction in access for Medicare beneficiaries, (3) reduced levels of colorectal cancer screening, and (4) higher total costs to the Medicare program.

We recommend the CMS to evaluate a more equitable solution in order to reach budget neutrality goals.

Thank you for the opportunity to comment. We sincerely appreciate your consideration of these comments. Please contact either Brad Berg (507) 266-3281 or me at (507) 284-4627 if you have any questions.

Very truly yours,

Ronald Grousky
Director, Medicare Strategy Unit
Mayo Clinic

cc: B. Berg

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October 10, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
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Department of Health and Human Services
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200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1506-P

RE: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update Program – HCAHPS® Survey, SCIP, and Mortality; Proposed Rule

Dear Dr. McClellan:

On behalf of the leading not-for-profit hospitals and health systems allied in Premier, I appreciate this opportunity to submit comments, with two exceptions, on the above notice of proposed rulemaking (NPRM), which was published in the *Federal Register* (Vol. 71, No. 163, pages 49506-49977) on August 23, 2006. Today, through separate correspondence, we also are submitting our comments on the NPRM for the Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update (Section XXIII – File code CMS-4125-P). In addition, we will submit our comments on the NPRM for the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates in subsequent correspondence.

Premier is a strategic alliance of approximately 200 independent, not-for-profit health systems that operate or are affiliated with more than 1,400 hospitals and healthcare sites nationwide. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the effective operation of the outpatient and inpatient prospective payment systems, as we strive to provide optimal patient care.

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1. **Premier opposes the Average Sales Price (ASP) based payment change from ASP + 6 percent to ASP + 5 percent for 2007, which would be used for payment for Specified Covered Outpatient Drugs (SCODs). The Centers for Medicare and Medicaid Services (CMS) must ensure that no drugs are reimbursed below their acquisition cost.**

We continue to be concerned about the reimbursement levels proposed for drugs. We do not believe that ASP+5 percent are sufficient to cover both the drug acquisition and pharmacy handling costs. We note that the 2006 reimbursement rates cut drug payments to hospital outpatient departments by more than $200 million for 115 commonly used cancer drugs and the proposed rule would deepen these cuts by moving to reimbursement set at ASP+5 percent. These cumulative reductions are placing an unfair burden on our hospitals and could create barriers to access for important pharmaceutical therapies. We disagree with CMS' conclusion that prices based on the ASP reimbursement methodology accurately reflect hospital average acquisition costs, as required under Section 1833(t)(14)(A)(iii)(I) of the Social Security Act (SSA). The ASP methodology fails to account for the unique reimbursement issues faced by hospital outpatient departments. We urge CMS to collect data on actual hospital drug acquisition costs, including how those costs might vary by size or location of hospital.

To the extent that CMS retains an ASP-based approach, we urge CMS to make these changes:

- continue to set the payment rate at ASP+6 percent and abandon the proposal to pay at ASP+5 percent;
- adjust the ASP methodology to more appropriately account for hospital acquisition costs by establishing a hospital "class-of-trade" ASP;
- adjust the ASP methodology by placing a limit on the percentage change that can occur for an Ambulatory Payment Classification (APC) for prescription drugs and biologicals from one year to another;
- adjust the ASP reimbursement level more frequently for the prescription drugs and biologicals that are paid separately under the hospital outpatient prospective payment system (OPPS) system; and
- adjust the reimbursement levels for prescription drugs and biologicals with the most significant inadequacies in reimbursement

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such as intravenous immune globuline (IVIG) to more accurately reflect hospital acquisition costs, and support an initiative to promote channel integrity for drugs and biologicals in short supply.

Premier supports continuing the payment for new drugs, biologicals and radiopharmaceuticals at a rate equal to 95 percent of average wholesale price (AWP) prior to assignment of a HCPCS code.

1. **CMS must ensure that its outpatient payment rates account for pharmacy handling and overhead costs as documented in the 2005 Medicare Payment Advisory Commission (MedPAC) study. Premier recommends that CMS establish a flat $10 add-on payment for every billed drug to cover pharmacy handling and overhead costs.**

In the 2007 proposed rule, CMS inappropriately uses 2005 OPPS claims data to conclude that a payment rate set at ASP+5 percent is adequate to cover both drug acquisition and pharmacy overhead costs. This is surprising because Premier and many other commenters have consistently raised numerous problems with using OPPS claims data to determine drug costs. In its 2003 report, the General Accountability Office (GAO) found that these claims data do not provide a reliable basis for setting drug payment rates. As a result, other methodologies have been employed to set OPPS drug rates, such as the payment floors established by the Medicare Modernization Act (MMA) and the hospital acquisition cost survey conducted by GAO.

In addition, by definition surveys designed to capture drug acquisition costs, whether the GAO survey or the quarterly reports of manufacturer sales data, do not include pharmacy handling costs. In its 2005 report to Congress, MedPAC confirmed this and found that pharmacy overhead costs add as much as 20 to30 percent to hospitals' total pharmacy costs. MedPAC recommended additional payments to recognize drug handling costs and CMS included an additional payment of two percentage points in the proposed OPPS rule for 2006. Unfortunately, CMS dropped this additional payment in the final 2006 rule.

Premier is very concerned that CMS is inappropriately using one of MedPAC's findings on pharmacy overhead costs. MedPAC stated that hospitals' billed charges for drugs and their revenue received on billed drugs generally cover both hospitals' drug acquisition and pharmacy overhead costs. CMS calculates (really, *estimates*) that costs derived from 2005 billed charges are approximately equal, on average, to ASP+5 percent. Then CMS

inappropriately concludes that ASP+5 percent is an adequate level to cover both sources of cost, citing that costs are derived from billed charges and MedPAC has asserted that charges are set to cover drug and overhead costs. We believe that this is fallacious and circular reasoning, however, because it ignores the documented reliability problems with OPPS claims data.

Finally, physician offices are paid at an appropriate level, ASP+6 percent, for drug acquisition costs and have handling and overhead costs recognized in their practice expense payments. Hospitals do not currently have a comparable payment for drug handling and overhead costs. Therefore, Premier recommends that CMS establish a flat $10 add-on payment for every billed drug to cover pharmacy handling and overhead costs. This level of payment would amount to less than 10 percent of Medicare's payments for the drugs even though the findings in MedPAC's 2005 study would support additional payments of 20 percent or more.

2. **Premier supports the special packaging rule for certain anti-emetics, exempting them from the packaging rule, but we are concerned with the policy to package lower cost drugs. We urge CMS to eliminate the packaging policy and to make a separate payment for all billed drugs similar to the reimbursement for drugs when furnished in a physician's office.**

It is clear after several years of packaging drugs as part of a procedure code that this policy does not adequately reimburse hospitals for their drug costs. Importantly, the policy also does not encourage efficiency because hospitals are not paid separately for the lower cost drugs and thus are given a financial incentive to use a higher cost drug that *is* paid separately. If both high cost and low cost drugs were paid separately, hospitals would be encouraged to use the lowest cost clinically appropriate drug. Thus, both for efficiency and for equity with reimbursement in physicians' offices, CMS should abandon its packaging policy and separately reimburse all drugs used in the hospital outpatient department.

3. **Premier recommends that in 2007, CMS implement the full set of Current Procedural Terminology (CPT) drug administration codes and eliminate the six Healthcare Common Procedure Coding System (HCPCS) C codes created to parallel the 13 drug administration codes that were not implemented in 2006.**

This policy change would eliminate the burden of having to apply and

maintain two sets of codes for essentially the same services. In addition, in 2005 and 2006, CMS provided special instructions to hospitals for the use of modifier 59 in order to ensure proper OPPS payments, consistent with their claims processing logic. Since CMS does not expect any changes to coding structure for 2007 and because the agency has updated service-specific claims data from 2005, CMS no longer needs specific drug administration instructions regarding modifier 59. Therefore, Premier supports CMS' proposal that hospitals apply modifier 59 to drug administration services using the same correct coding principles that they generally use for other OPPS services.

4. **Premier supports CMS' proposal to create six new drug administration APC levels which will provide more accurate payment for complex and lengthy drug administration services.**

Previously, payment for additional hours of infusion has been packaged due to the inability to use claims data to distinguish costs associated with infusions of different duration. However, in 2005, codes used in the outpatient department distinguished between the first hour of infusion and additional hours of infusion. Using newly available 2005 claims data, CMS proposes to assign CPT/HCPCS codes to six new drug administration level APCs, with payment rates based on the median costs from this 2005 claims data. Premier strongly supports this proposal.

5. **Premier recommends that CMS make payment for a second or subsequent intravenous (IV) push of the same drug by instituting a modifier, developing a new HCPCS code for the procedure, or implementing another methodology in 2007 so that an appropriate payment is made for this service.**

As part of the implementation of new drug administration codes in 2006, CMS decided to no longer allow for the reporting of separate IV pushes of the same drug. This coding instruction created a situation in which no payment is made for packaged drugs that are given as separate IV pushes. One good example is pain management where a patient may require multiple IV pushes of morphine, but only one drug administration code could be reported. Because morphine is a packaged drug, not only would the administration services involved in the subsequent IV pushes of morphine not be reimbursed, the drug itself would not be paid. We do not believe CMS' intent was to discontinue payment for this drug when it is medically necessary. Therefore, we recommend that CMS institute an appropriate

procedure for making payment for a second or subsequent IV push of the same drug.

6. **Premier makes these additional recommendations concerning payment for drugs, biologicals and radiopharmaceuticals in 2007.**

   - **We support the continued payment for the furnishing fee for blood clotting factors in 2007, which will be updated based on Consumer Price Index, but we oppose reducing the payment for blood clotting factors from ASP + 6 percent to ASP + 5 percent.**

   - **We support a process that updates the ASP in a more timely fashion, after the quarterly submission from a pharmaceutical company. The current two quarter delay needs to be improved on.**

   - **We urge CMS to extend the current CY 2006 cost-based policy for radiopharmaceutical agents for one additional year, i.e., through CY 2007.** While we recognize that the CY 2006 payment policy was intended to be only a temporary policy, we strongly believe that it must be continued for one additional year to preserve access to these crucial therapies. One sub-option that CMS could consider would be to apply the cost-based policy only to radio-immunotherapy and to proceed to set CY 2007 rates for other radio-pharmaceuticals using 2005 median costs, as set out in the proposed rule. We believe that such a policy would apply only BEXXAR® and Zevalin.

   - **Premier recommends that CMS create a new code for billing the radio-pharmacy compounding service.** A distinct code for compounding products such as Bexxar is needed to reflect the reasonable and necessary separate costs associated with the safe and effective preparation of the products for administration to patients. For 2007, the payment rate should be set between $2,000 and $3,000. We note that this policy would enable CMS to set fixed payment rates for the acquisition and handling for separately payable radio-pharmaceuticals, rather than paying each hospital differently for each claim based on the claim's charges and

the hospital's overall cost-to-charge ratioas in 2006.

- **Premier recommends that CMS establish unique HCPCS codes for each brand of IVIG so that the ASP for each IVIG product is based on information submitted for each brand and therefore representative of each product's unique chemical formulation.** Patient access to IVIG can be affected due to the barrier that the current reimbursement level for brands of lyophilized IVIG presents for both Medicare beneficiaries and private pay patients. Access to all IVIG therapies in all patient care settings is enhanced by establishing an adequate and stable reimbursement mechanism. Such a policy also would be consistent with the statutory requirement that hospital outpatient payment rates reflect acquisition costs.

We urge CMS to ensure that its payment methodology establish rates that are appropriate to address the various brands of IVIG products. Each brand has specific formulation differences which impacts the patient's tolerability of the treatment as well as the physician choice in prescribing a specific brand to meet the patient's clinical parameters. Patient safety is also a strong consideration for keeping patients on the brand of IVIG that results the lowest level of side effects. The side effects of IVIG are highly individualized. If a patient needed to switch brands of IVIG due to reimbursement levels of a certain brand, patient safety could be compromised. The potential of adverse drug events is magnified by a switch in brand of IVIG infused.

Currently there are two J codes; J1566 for IVIG lyophilized 500mg and J1567 IVIG liquid 500mg. We propose that the J codes be expanded from these two J codes to eight (8) J codes. Each new J code would correspond with one of the following brands that are available in the United States market: Polygam® SD, Panglobulin® NF, Iveegam® EN, Gammagard® S.D., Gammagard Liquid, Gamunex®, Flebogamma®, Octagam®, and Carimune™ NF.

- **Premier urges CMS to acknowledge that IVIG is a biologic response modifier for purposes of reimbursement of both the IVIG product and its administration.** Since IVIG is a blood product, it should be reimbursed using the methodologies in effect on October 1, 2003, as required by the MMA. For IVIG, this means that reimbursement should

be based on 95 percent of AWP or reasonable costs. We believe that patients that require IVIG treatment are treated most cost effectively in the physician office or the hospital outpatient setting where highly trained healthcare professionals administer the IVIG in a manner to decrease potential side effects. Patients are also less exposed to less virulent forms of bacteria than they would be in an inpatient hospital setting.

We also note that IVIG is not the same as a pharmaceutical, but rather is a complex infusion requiring specially trained healthcare providers. IVIG infusions may result in a number of adverse drug reactions that are described in the various IVIG prescribing information inserts. The reimbursement rates for IVIG infusions should reflect the true acquisition costs, and the direct and indirect handling costs associated with the supplies and nursing time required to infuse complex IVIG infusions.

According to the 2006 Current Procedural Terminology Professional Edition, page 400, C8954 (which is for chemotherapy administration, intravenous, infusion technique, up to one hour) includes "substances such as monoclonal antibody agents, and other biologic response modifiers." CMS acknowledges that "IVIG is a complicated biological product that is purified from human plasma obtained from human plasma donors." 70 Fed. Reg. at 68648. Based on the definition of IVIG as a biologic response modifier that is supported by the National Library of Medicine and the National Cancer Institute, **CMS should specify that the administration of IVIG for the first hour should be billed under C8954 and for subsequent hours of infusion should be billed under C8955.**

7. **Premier continues to be extremely concerned about the year-to-year volatility of the APC weights and we urge CMS to take appropriate steps to ensure stability in APC weights.**

One approach, for example, would be to adjust the medians derived from claims data to limit the amount of change that occurs from year-to-year. A stability policy should adjust the medians from claims data to ensure that no APC's median falls more than 5 percent compared to the medians used for payment in 2006.

Premier's analysis of the proposed rule indicates that many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with

payments much lower or higher in 2007 than in 2006. These changes make it extremely difficult for hospitals to plan and budget from year to year. We would expect that four years after the start of the OPPS, the payment rates and associated payment-to-cost ratios would be much more stable.

Comparing APC rate changes in the CY 2006 (final rule) and the proposed CY 2007 rule (see below table) reveals that in most instances the APC weight volatility will likely significantly increase – see the percent change column, which shows the greater volatility. This signal of increasing instability among APC weights creates unnecessary challenges to a hospital's ability to adequately plan and budget, even for the short term, let alone for the long term.

APC Weight Volatility	**CY 2006 Final Rule**	**CY 2007 Proposed Rule**	**Percent Change**
DECREASE:			
Total	219	277	+26.5%
10% or more	59	59	0.0%
20% or more	12	27	+125%
INCREASE:			
Total	148	360	+143.2%
10% or more	41	109	+165.6%
30% or more	17	26	+52.9%

8. **Premier strongly recommends that CMS adjust the median costs of device-dependent APCs, for which comparisons with prior years are valid, to the higher of the CY 2007 unadjusted APC median or 95 percent of the adjusted median on which the payment was based for the CY 2006 OPPS. CMS also should undertake urgent research to develop an adjustment for charge compression to use in setting the 2008 rates.**

CMS proposes to base the payment rates for device-dependent APCs in CY 2007 solely on median costs calculated using claims with appropriate device codes and which have no token charges for devices reported on the claim. The agency does not propose any adjustment of these median costs as in years past to moderate the decreases in medians from CY 2006 to CY 2007; thus, there will be no payment floors or use of external data in CY 2007. While Premier recognizes that CMS wants to move to a system that

bases rates on claims data without payment floors, we believe that CMS' first responsibility is to create appropriate payment rates that recognize the costs incurred by hospitals in providing the service. In the case of major implantable devices, the claims data and CMS methodologies simply are not adequate at the present time. A comparison of the final CY 2006 payment rate to the proposed CY 2007 payment for device-depending APC reveals that payment would decrease for 11 APCs, including six which would decrease by more than 10 percent. Without any hold harmless floor, their reduction would range from 22 to 12.8 percent.

We note that in the final inpatient regulation, CMS acknowledged evidence concerning the effect of charge compression on its rate-setting methodology. The same phenomenon of compressed charges for expensive devices occurs in the outpatient claims data and leads to inadequate rates when relying solely on unadjusted claims data. Therefore, Premier recommends that CMS provide a 95 percent payment floor in 2007 and undertake research to support an adjustment for charge compression in 2008. We are recommending a floor of 95 percent rather than 90 percent because payment rates for these device-dependent APCs already have been reduced 15 percent since 2004 (5 percent in 2005 and 10 percent in 2006).

As an alternative to adopting a payment floor, Premier would support the use of external data to address limitations in hospital claims data.

9. **Premier recommends that when CMS assigns a new service to a new technology APC, the service should remain a new technology APC for at least two years until sufficient claims data are collected.**

CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. CMS generally retains a service within a new technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, however, CMS proposes to assign some services that have been paid under the new technology APCs for less than two years to clinically appropriate APCs. For example, positron emission tomography (PET)/computed tomography (CT) scans, which had been assigned to new technology APC 1514 in 2005, is scheduled to move to a clinical APC in 2007. Some hospitals that adopt these new technologies may be unable to quickly change their charge masters, including changing codes and setting charges that reflect actual costs of the new service. Additionally, the data that CMS obtains in the first

year or two of adoption of these technologies may not appropriately reflect the use and cost of these services because diffusion of new technologies can be slow, and waiting additional years for more hospitals to adopt and use new technology is important. Therefore, we recommend that when CMS assigns a new service to a new technology APC, the service should remain a new technology APC for at least two years until sufficient claims data are collected.

10. **Premier generally supports the proposed policies for devices replaced without cost or with credit to the hospital, but we believe that modifications are necessary to the proposed policy.**

CMS proposes to reduce the APC payment and beneficiary co-payment for selected APCs when an implanted device is replaced without cost to the hospital or with full credit for the removed device. This is in response to device recalls and field actions involving the failure of implantable devices for which manufacturers offer to replace devices without cost to the hospital or to offer credit for the device being replaced if the patient requires a more expensive one. CMS proposes to calculate the reduction to the APC payment rate using the same method it uses to calculate the pass-through rate for implanted pass-through devices. The adjustment would be implemented through the use of an appropriate modifier specific to a device that has been replaced.

Neither the Medicare program nor Medicare beneficiaries should be required to pay hospitals for devices that were provided to the hospital at no cost. In addition, while there are additional burdens on hospitals associated with imposing this new policy, hospitals have been required since January 1 to use the FB modifier with the HCPCS code for a device that was furnished to the hospital without cost. Therefore, this is not an entirely new type of policy for hospitals. **Premier believes, however, that CMS needs to clarify whether and how this FB modifier would be used once the new policy goes into effect.**

Further, as CMS acknowledges in the proposed rule, the FB modifier may not be used appropriately if the replacement device is an upgrade from the device that is being removed from the patient. In any given recall, 10 to20 percent of replaced devices could result in upgrades – the physician opts to use a higher functioning device over the one being replaced in order to meet the patient's current clinical needs – needs that may have changed since implantation of the original device. In these cases, the manufacturer would

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hold the hospital responsible for paying the price difference between the upgraded device to be implanted and the replaced device that is being removed. This price difference may be significant. For instance, in the case of implantable cardiac defibrillators, the hospital payment for the difference between the upgraded and replaced device could range between $1,000 and $7,000.

Premier recommends that CMS revise its proposal to account for the additional cost that the hospital would bear in the event of a device upgrade. This could be accomplished through the use of a second modifier or another approach to identify when the replacement procedure involves an upgraded device. The APC offset for an upgraded device replacement should be set at a lower percentage than the APC offset made for an "even" device replacement.

12. Small Rural Hospitals under OPPS

Premier is concerned about patient access to small rural hospitals with the phase-out of the transitional corridor hold harmless payments. Children's and cancer hospitals have permanent hold harmless provisions under OPPS and we believe small rural sole community hospitals should too.

In closing, we thank you for the opportunity to review and comment on the proposed hospital outpatient prospective payment rule for CY 2007.

Sincerely,

Margaret Reagan
Corporate Vice President
Premier, Inc.

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October 10, 2006

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REF: CMS-4125-P

RE: Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare Administrative Contractors; and Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual payment Update Program – HCAHPS® Survey, SCIP, and Mortality; Proposed Rule

Dear Dr. McClellan:

Premier is pleased to submit the following comments on the "Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update - HCAHPS® Survey, SCIP and Mortality" -- Section XXIII of the above noted notice of proposed rulemaking (NPRM) which was published in the *Federal Register* (Vol. 71, No. 163, pages 49506-49977) on August 23, 2006. Today, through separate correspondence, we are submitting our comments for the non-hospital quality reporting proposals in the above NPRM. In addition, we will submit our comments on the NPRM for the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates in subsequent correspondence.

HEALTH INFORMATION TECHNOLOGY

In the proposed rule, CMS repeats questions posed in the proposed inpatient prospective payment system (IPPS) rule regarding:

- its statutory authority to encourage adoption and use of information technology (IT);

- the appropriate role of IT in any value-based purchasing program; and

- the desirability of including use of certified health IT in hospital conditions of participation.

Premier recognizes that health IT is an important tool for improving the safety and quality of healthcare, and our members are committed to the goal of automating the measurement process into electronic medical records (EMR) by adopting IT as part of their quality improvement strategies. At the same time, however, we would like to emphasize that the Premier Hospital Quality Incentive Demonstration (HQID) project is being implemented without the use of EMR. **Premier strongly believes that it is more important to fix ineffective processes than to implement technology that supports retention of broken process systems.** Any lack of automation across the sector is no excuse for delaying quality process improvement.

Regarding IT investments, our members view IT as a public good that requires a shared investment between the providers and purchasers of care. As summarized in the final IPPS rule, most commenters, including Premier, noted that health IT is a costly tool, requiring both upfront and ongoing spending. While providers bear the burden of those costs, the financial benefits of having IT systems often flow to the payers and purchasers of care, including Medicare. Thus, Premier believes that the payers and purchasers of care should share in its costs. An add-on payment to Medicare is one possible mechanism for doing so, with **any federal funding for physician or hospital information technology coming from "new money/funds."**

Finally, in the FY 2007 final inpatient PPS rule, CMS stated that it would not make use of certified, interoperable health IT a condition of participation in Medicare, but might revisit the issue in future rulemaking. **Premier opposes implementation of HIT through mandates such as the Medicare conditions of payment for hospitals.** The conditions of participation address the basic, essential infrastructure needed to ensure patient safety. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its

understanding of how to implement these systems correctly. In addition, current commercial health IT applications do not always meet hospitals' needs, and certification efforts are in their infancy. As noted in a recent report by the Agency for Healthcare Research and Quality (AHRQ), the evidence on health IT does not yet support this level of requirement. Imposing it would amount to an unfunded mandate.[1]

HOSPITAL QUALITY

CMS Proposal

CMS proposes to implement an outpatient prospective payment system (OPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program effective for payments beginning on January 1, 2007. As an initial step, CMS proposes to link the CY 2007 OPPS payment update to hospital reporting of quality measures in effect under the existing IPPS RHQDAPU program. For CY 2007, hospitals would only receive the full update to the conversion factor used to determine CY 2007 OPPS payments if they meet the IPPS RHQDAPU requirements for FY 2007. Hospitals that do not meet the IPPS RHQDAPU requirements for FY 2007 would receive an update to the CY 2007 OPPS conversion factor that is reduced by 2.0 percentage points (i.e., 1.4 percent instead of the full 3.4 percent update). A reduction applied in one year would not affect a hospital's OPPS update in a subsequent year.

Medicare's pursuit of this concept involves the collection and submission of performance data and the public reporting of comparative information about hospital performance. CMS believes this will provide strong incentives to encourage hospital accountability in general and quality improvement in particular.

The RHQDAPU program, first implemented in FY 2005, requires hospitals to submit certain quality data in order to receive a full annual payment rate update. The current program uses 10 quality measures; however, the program expanded in FY 2007 (October 1, 2006) is to include 21 quality measures. In linking OPPS payment to the IPPS quality measures, CMS

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

argues that the 21 specific IPPS quality measures in use for FY 2007 reasonably reflect the quality of care provided by hospital outpatient departments.

CMS also discusses the applicability to OPPS of the additional IPPS quality measures proposed for FY 2008. These measures involve a patient survey, additional surgical care measures, and mortality within 30 days of hospital admission. Again, in each case, CMS concludes these measures reasonably reflect care in hospital outpatient departments and indicates its intention to adopt the full set of proposed FY 2008 IPPS quality measures to the CY 2008 OPPS RHQDAPU program. The proposal will be formalized next year in the proposed rule for CY 2008 OPPS payment.

Linking IPPS quality measures to the OPPS is planned as an interim step. CMS intends to begin work, in collaboration with stakeholders, on a set of quality and cost of care measures specific to hospital outpatient departments for implementation at the earliest possible date. Reporting of a more fully developed, outpatient-specific set of quality and cost of care measures may be used for purposes of determining the update as early as CY 2009 following development and announcement of the measures; consideration of comments from the hospital community, patient advocates, and other stakeholders; establishment of the requisite mechanisms for reporting; and initiation of actual reporting of the measures by hospitals.

Premier Comments

Premier strongly supports the goal of promoting higher quality healthcare services. Accordingly, we also support the appropriate application of "value-base purchasing" as a viable strategy to this end. We applaud CMS for adding these well-designed measures representing aspects of care that are important to patients and provide insights into the safety, efficiency, effectiveness and patient-centeredness of care.

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

PREMIER

Premier is concerned about the use on the IPPS quality measures as proxy measures for hospital outpatient services. Although we agree with CMS that there is some correlation between outpatient care and inpatient care for the specific diagnoses, these conditions are not predominantly important in measuring, or indicative of, the overall quality of outpatient care. Our experience in the HQID project has demonstrated that even within the inpatient care environment hospitals may provide high quality care in one or two areas but may not achieve similar levels of quality in other clinical areas. Effective quality measurement programs assess whether the individual received the right care at the right time and in the right place. While there may be some steps in caring for outpatients that are similar to those for patients requiring inpatient admission for heart failure and pneumonia, the patient requiring treatment in an inpatient setting is clinically more complex. The diagnostic requirements, care management and practice guidelines should be different than for a patient who can be evaluated, treated as an outpatient and released to home. Linking the reporting of inpatient quality measures to outpatient payment could result in misinterpretations of the quality of care in the outpatient setting and creates a disconnect between the location of care and payment system.

We support CMS efforts to identify appropriate and relevant quality measures specific to outpatient services. In the interim it would not be prudent for CMS to link inpatient quality measures and outpatient hospital payments.

In closing, thank you for the opportunity to review and comment on the proposed Reporting Hospital Quality Data for FY 2008 Inpatient Prospective Payment System Annual Payment Update hospital outpatient PPS rule for CY 2007.

Sincerely,

Margaret Reagan

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Corporate Vice President
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ZLB Behring

October 10, 2006

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

ATTN: (CMS-1506-P; CMS 4125-P) Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2007 Payment Rates

Dear Dr. McClellan:

ZLB Behring is a leading researcher and manufacturer of life-saving biotherapeutics including intravenous immune globulin (IVIG), which is used in treating conditions such as immune deficiencies; blood clotting factors to treat bleeding disorders, including hemophilia and von Willebrand disease; and alpha$_1$-proteinase inhibitor, used to treat alpha$_1$-antitrypsin deficiency, which is commonly referred to as genetic emphysema. These therapies are created by pooling and manufacturing donated human blood plasma into lifesaving therapies or through the development of recombinant DNA technology.

Thank you for allowing ZLB Behring the opportunity to comment on the proposed rule regarding the 2007 changes to the Medicare Hospital Outpatient Prospective Payment System (HOPPS). Our comments will be focused on the section of the proposed rule entitled "Non Pass-Through Drugs, Biologics and Radiopharmaceuticals" and will center on IVIG. ZLB Behring's concern is that the proposed rule could further exacerbate current patient access difficulties. In fact, some of the provisions suggested in this rule would be contrary to the positive provisions CMS enacted in 2006 in an attempt to address IVIG reimbursement concerns. ZLB Behring requests that CMS consider several changes for the final rule.

Our main points regarding the proposed rule are as follows:

- The determination of Average Sales Price (ASP) plus 5% to be the average acquisition cost for covered therapies, including IVIG, creates a discrepancy between reimbursement in the Part B physician office setting and the HOPPS outpatient setting; potentially creating further patient dislocation as site of service shifts could once again occur. ASP plus 6 percent was not sufficient to assure access to therapies; moving to 5 percent is a move in the wrong direction.

- The reimbursement formula proposed fails to solve the current problem; providers cannot purchase IVIG under current reimbursement rates. Consideration of a payment rate adjustment (similar to that which applies to blood clotting factor) and the establishment of Healthcare Common Procedure Code System (HCPCS) codes for each individual brand of IVIG would substantially improve the reimbursement environment and would allow the provider to more fully recoup the costs of the therapy.

- ZLB Behring applauds CMS for creating a payment code for extended intravenous infusion. Infusions of IVIG typically last for several hours, thus reimbursement for those additional hours is warranted. Moreover, the creation of additional hourly reimbursement, as currently exist under the Part B physician fee schedule, removes a variation in administrative reimbursement between the two sites of service.

- Elimination of the $75 pre-administration code for IVIG (G 0332) is troubling. This code was of help in addressing the shortfall of administrative reimbursement for IVIG. By replacing the pre-administration rate with an hourly infusion rate, the problem of IVIG access is not comprehensively addressed. The pre-administration code should be kept. CMS should also consider classifying IVIG as a biologic response modifier, or reimburse for its administration at a payment rate similar to the BRM applied, so that the complexity of IVIG administration is recognized and properly reimbursed.

NON PASS-THROUGH DRUGS; BIOLOGICALS AND RADIOPHARMACEUTICALS

Ensuring Adequate Payment Rates for Plasma Therapies

Acquisition Price = Average Sales Price (ASP) Plus 5%

ZLB Behring is troubled with the proposal that equates average acquisition price with ASP plus 5%. The Medicare Payment Advisory Commission's recommendation has been to streamline payment mechanisms over separate sites of service in order to reduce confusion and to make reimbursement more straightforward. However this proposed rule creates a separate formula for HOPPS that reimburses at ASP plus 5% and Medicare Part B, which by statute reimburses at ASP plus 6%, while the evidence indicates ASP plus 6% is not adequate. ZLB Behring believes the payment rate formula proposal for HOPPS will only create more complexity in the Medicare reimbursement system while unnecessarily confusing providers and Medicare beneficiaries.

In 2005, it was documented by the Immune Deficiency Foundation that the discrepancy in reimbursement between Medicare Part B (which implemented ASP plus 6%) and HOPPS (83% of AWP) led to a patient shift in site of service, which caused major problems with patients not being able to obtain therapies in their former point of service and the distribution chain taking time to adjust to that shift. With the HOPPS implementation of ASP plus 6% beginning on January 1, 2006, another patient shift occurred. The HOPPS proposed formula for 2007 will only further this trend, as the variation in reimbursement based on site of service will lead to continuing patient dislocation.

In determining that average acquisition cost equaled ASP plus 5%, CMS used hospital outpatient claims data to determine mean and median prices for the nearly 500 Medicare covered therapies. However, the Ambulatory Payment Classification (APC) Advisory Panel has spent significant amounts of time and discussion regarding the questionable quality of the data during many of its meetings. Panel members working in hospitals have acknowledged this to be the case and created a Data Subcommittee to look into ways of improving the data. Moreover, claims data from the 340 B program are also incorporated into CMS' determination of average acquisition cost even though such sales are excluded from the calculation of ASP.

For IVIG, the reliance on nearly 500 Medicare covered therapies to determine a payment rate in the HOPPS site of service is flawed. This is contrary to positive CMS efforts to help address concerns about patient access to IVIG such as the Q3 2006 payment rate in which CMS stated the following:

> *We note the concerns of some advocacy groups and providers about patients' access to intravenous immune globulin services (IVIG, HCPCS codes J1566 and J1567), and concerns that there may be problems with the adequacy of Medicare payment amounts and the supply of IVIG. CMS and other agencies within the Department of Health and Human Services are continuing to work with manufacturers, providers, patient groups, and stakeholders to better 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. For the third quarter of 2006, the Medicare payment amount is increasing 11.9 percent for lyophilized IVIG (powdered form) and 3.5 percent for liquid IVIG. We view these payment increases for IVIG as an important development, and continue to monitor IVIG marketplace developments and beneficiary access to care closely.*

ZLB Behring believes that CMS needs to take a different approach to addressing IVIG access and payment concerns. Instead of treating IVIG in the same manner as all other Medicare covered therapies, we request that CMS consider the following measures, applicable to both Part B and HOPPS payment systems.

Brand-specific Reimbursement - Plasma therapeutics have several brands within a HCPCS code, although each brand has unique features that connect with different patient profiles. Access to all brands is essential so that individual patients may be treated properly. The weighted average calculation of multiple brands within the HCPCS code has resulted in the reimbursement level being too low for providers to purchase some of the brands within the class of therapy. This has in part contributed to the current IVIG patient access situation. Part of the remedy would be to have brand-specific (NDC based) reimbursement based on the statutory reimbursement rate, rather than a volume-weighted average calculated from multiple brands comprised within a single HCPCS code.

IVIG is unique in that it is one of very few biologics, almost all of which are blood plasma therapies, that have multiple brands within a HCPCS code. Bundling these products together can distort provider selection of therapies by arbitrarily having some therapies below or above the calculated volume weighted ASP. We urge CMS to exercise its authority to create new HCPCS codes for each individual product.

Payment Adjustment –Another access remedy is for IVIG to have an add-on payment or payment adjustment similar to that which applies for another plasma derived therapy, blood clotting factor. We believe that CMS has the ability to institute additional reimbursement measures for specific cases when used in conjunction with the statutory reimbursement formula of ASP plus 6%. To support this request with data, the Plasma Protein Therapeutics Association (PPTA), of which ZLB Behring is a member, contracted with The Lewin Group to survey hospitals regarding their overhead costs specific to IVIG. The Lewin Group determined that during the snapshot in time they examined (October – December 2005) there was a 14.6% shortfall between a provider's purchase price for IVIG and the reimbursement rate. ZLB Behring urges CMS to consider a payment adjustment for IVIG, in the form of an add-on payment based on independent data. We believe this will alleviate the patient access issues being driven by a product reimbursement shortfall. Please find attached a legal opinion from Hogan & Hartson illustrating CMS legal authority in addition to a copy of the Lewin Group analysis on the product reimbursement shortfall.

For blood clotting factor, the additional reimbursement is in the form of a furnishing fee, which CMS has wisely incorporated into the therapy's payment rate. This measure has averted any potential patient access difficulties for people with bleeding disorders. The same principles can and should apply for IVIG. ZLB Behring urges CMS to consider this option so that individuals can obtain their life-saving IVIG on a continual basis.

Payment for Extended Infusions

ZLB Behring commends CMS for implementing reimbursement for the administration of intravenous therapies past the first hour. This was a recommendation of the APC Advisory Panel and will allow for some uniformity as intravenous administration under the Part B Physician Fee Schedule also reimburses for extended hours. Given the length and intensity of IVIG infusions, it is appropriate that the multiple hours required by medical staff to administer the therapy are properly reimbursed under HOPPS. We appreciate and support the proposal of CMS implementing reimbursement past the first hour for intravenous administration beginning in 2007.

Continue the Payment for IVIG Pre-administration Related Services/Classify IVIG as a Biologic Response Modifier

ZLB Behring disagrees with the CMS proposal to discontinue the payment for the pre-administration related services in 2007. Currently, Medicare allows a $75 payment for pre-administration related services under G 0332 to reimburse hospitals for the additional resources that are associated with locating and acquiring adequate IVIG products in addition to preparing for an outpatient hospital infusion of IVIG, monitoring and managing inventory, and rescheduling infusions due to product availability and patient needs and physician determinations on product selection. ZLB Behring believes this payment is still necessary to help ensure that administrative reimbursement remains adequate to help reimburse administration costs.

CMS should also consider classifying IVIG as a biologic response modifier or providing a payment similar to BRM, to reflect the complexity of administering IVIG. Immunologists have testified to CMS and Congress about the level of complexity required to administer IVIG. Classifying IVIG as a biologic response modifier, combined with the extended hours of infusion would help to provide needed reimbursement to cover true administration costs. Without retaining the pre-administration code, or substituting a Biological Response Modifier designation in its place, reimbursement for the physician administration will decrease in 2007, thus continuing and magnifying patient access problems surrounding IVIG. We, of course, urge CMS to consult with the providers who administer IVIG to hear their views on what they require. Not only does the therapy itself need to be reimbursed adequately, so does the reimbursement for its administration.

Conclusion

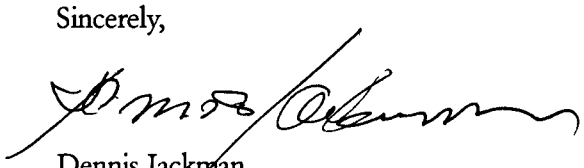
CMS' proposed rule is troubling and will serve to continue the ongoing IVIG patient access dilemma. The pre-administration code implemented in 2006 for IVIG improved patient access. However, the elimination of that code will only cause further access difficulty for patients. While ZLB Behring commends the creation of codes to reimburse for extended hours of infusion, using these extended hours to simply replace the 2006 pre-administration codes is not a remedy to IVIG access difficulty caused by insufficient reimbursement for both the product and its administration.

We ask CMS to implement innovative measures to solve problems surrounding IVIG access. These would include a payment adjustment for IVIG, using the precedent of blood clotting factors as the example, and the creation of HCPCS codes based on the individual brands of IVIG. We believe these two measures, when combined with the extended hours of IVIG infusion and either the continuation of the pre-administration codes or the classification of IVIG as a biologic response modifier will help remedy the patient access situation.

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

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

Sincerely,



Dennis Jackman
Senior Vice President, Public Affairs

Attachments

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MEMORANDUM

March 13, 2006

BY ELECTRONIC MAIL

TO: Julie Birkofer
PPTA

FROM: Stuart M. Langbein

RE: **Questions Related to Intravenous Immune Globulin**

This memorandum responds to questions that you raised relating to Medicare reimbursement for intravenous immune globulin ("IVIG"). Specifically, you have asked whether the Centers for Medicare and Medicaid Services ("CMS") would have the discretion to establish a payment adjustment for IVIG when provided in a hospital outpatient department and in a physician's office. You also asked if any such adjustments could be made without first undertaking a new notice and comment rulemaking process. After a brief background discussion, each of these questions is addressed in turn.

Background

The Plasma Protein Therapeutics Association ("PPTA") and other organizations have been working with CMS to ensure that the Medicare payment rates for IVIG and related services in various settings are sufficient to ensure patient access to the product. Currently, Medicare payments for IVIG and related services are similar in the physician office and hospital outpatient department settings. The product itself is reimbursed at 106 percent of the average sales price ("ASP"), and there is a separate payment made for preadministration-related services (although the amount of this payment differs for physicians and hospitals). Finally, a separate payment is made to reimburse the physician or hospital for the service of administering IVIG, with the

pertinent payment rate set under the physician fee schedule and hospital outpatient prospective payment system ("OPPS"), respectively. 1/

Discussion

I. CMS Has Discretion to Adjust OPPS Payments for IVIG

In considering the ability of CMS to adjust IVIG related payments to hospital outpatient departments, the inquiry begins with the Medicare statutory provisions governing payments for drugs and biologicals (hereinafter, "drugs") under OPPS. The statute provides that, in 2006 and beyond, payment rates for specified covered outpatient drugs, which includes IVIG, shall be equal, subject to a provision on overhead costs,

> "(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or (II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." 2/

The referenced provision on overhead costs allows CMS to "adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account" recommendations made by the Medicare Payment Advisory Commission ("MedPAC"). 3/ In addition to these drug specific provisions, the OPPS statute provides CMS with the authority to establish "adjustments as determined to be necessary to ensure equitable payments" under OPPS. 4/ As detailed below, within the OPPS statute, CMS has considerable discretion to adjust the payment rate for IVIG.

1/ My understanding is that the questions you have raised do not involve changes to the payment for the service of administering IVIG. Thus, such payment will not be considered here. In addition, this memorandum focuses solely on the agency's authority to adjust payment rates for IVIG and does not address the likelihood that CMS would utilize any identified authority.

2/ Social Security Act ("SSA") § 1833(t)(14)(A)(iii).

3/ SSA § 1833(t)(14)(E)(ii).

4/ SSA § 1833(t)(2)(E).

A. Payments for Specified Covered Outpatient Drugs

The OPPS statute, quoted above, offers two mechanisms for determining OPPS payment rates for specified covered outpatient drugs such as IVIG in 2006. Each mechanism contains authority for CMS to adjust payment for IVIG. In setting the 2006 OPPS payment rates for specified covered outpatient drugs, CMS opted to use the ASP plus six percent methodology under SSA § 1847A. This methodology is referenced in SSA § 1833(t)(14)(A)(iii)(II), quoted above, and this provision allows for payment rates to be "adjusted by the Secretary as necessary." Because the language of the statute uses the singular term "drug," any such adjustment could be made on a product-specific basis, provided it was found "necessary." Thus, for example, CMS could find that, based on information provided to the agency, it is necessary for CMS to adjust upward the ASP plus six percent rate for IVIG to ensure patient access to IVIG in the outpatient setting. 5/

The other statutory mechanism for paying for drugs in 2006 under OPPS, SSA § 1833(t)(14)(A)(iii)(I), also provides CMS with authority to change the payment rate for a specified covered outpatient drug such as IVIG. Under this provision, payment is to be set at the average acquisition cost of a drug. The agency could determine that it had not accurately captured the average acquisition cost when establishing the payment rate for such a drug. Such a determination might be the result of additional information that had come to the agency's attention regarding a product. Accordingly, if the agency concluded that the payment rates for IVIG did not reflect average acquisition cost for the product, it could make an adjustment to achieve such a result.

B. Overhead Cost Adjustment

The OPPS statute vests discretion in CMS to adjust payments for drugs to take into account MedPAC recommendations on overhead costs. 6/ As CMS has noted, MedPAC recommended that the agency establish separate payments to reflect such costs. 7/ Thus, CMS could exercise this discretion and adjust payments for IVIG to take into account hospital overhead costs related to the product, as there is nothing in the statutory language that prevents the agency from making a payment adjustment for a single specified covered outpatient drug

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5/ While the statute grants CMS the authority to adjust the payment rates for specified covered outpatient drugs in 2006, it cannot exercise this discretion arbitrarily and capriciously. *See* Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 414 (1971). With regard to IVIG, CMS has already been convinced of the need for a specific payment adjustment, as the agency decided to make a separate payment for preadministration-related services under OPPS uniquely for IVIG because of concerns about beneficiary access to the product. 70 Fed. Reg. 68516, 68649 (Nov. 10, 2005). Thus, adjusting the payment rates solely for IVIG would not constitute arbitrary and capricious agency action.

6/ SSA § 1833(t)(14)(E)(ii).

7/ 70 Fed. Reg. at 68658.

such as IVIG. As discussed earlier, there would have to be support for the need for an individualized adjustment to account for the overhead costs incurred by hospitals in connection with IVIG.

C. Equitable Adjustment

Aside from the OPPS statutory provisions specific to drugs, there is a more general statutory provision that can be used as the basis for the authority to adjust the OPPS payment for IVIG. As noted earlier, SSA § 1833(t)(2)(E) allows CMS to make adjustments to ensure equitable payments under OPPS. As a result, CMS could determine that an adjustment is needed to ensure equitable payments for IVIG under OPPS. 8/

II. CMS Has Discretion to Adjust Payments to Physicians for IVIG

Physicians are reimbursed for the IVIG that they provide to Medicare beneficiaries at the pertinent ASP plus six percent payment rate under SSA § 1847A. Under this statute, CMS determines the ASP plus six percent payment rate for drugs and biologicals on a Healthcare Common Procedure Coding System ("HCPCS") code basis. Much of the specifics of this payment methodology are set forth in the Medicare statute, giving CMS less discretion to adjust the payment for IVIG than the agency has under the OPPS statute. Nonetheless, the agency has options available to it to alter the payments to physicians for IVIG.

A. Creation of Product Specific HCPCS Codes

As noted, CMS computes the ASP plus six percent payment rates for all drugs payable to physicians under Medicare Part B by HCPCS code. Currently, there are two HCPCS codes for IVIG, J1566 (immune globulin, powder) and J1567 (immune globulin, liquid) that are distinguished based on whether the product is a liquid or a powder. This distinction among IVIG products generates different payment rates for IVIG products. When physicians were first paid for IVIG under the ASP methodology in the first calendar quarter of 2005, this distinction among IVIG products did not exist. The coding change, and thus the payment change, was first effective in the second calendar quarter of 2005. 9/ As a result, changes to HCPCS codes, which are within the agency's authority, can cause changes to the physician office reimbursement rates. Accordingly, CMS could alter the payment rates for IVIG, as it has done before, by revising the HCPCS codes for IVIG. 10/

8/ All of the authorities discussed in Section II below also could be used as a basis for a payment adjustment for hospital outpatient departments.

9/ *See* http://www.cms.hhs.gov/Transmittals/2005Trans/itemdetail.asp?filterType=none&filterByDID=-.

10/ The requirement to treat single source drugs within the same billing and payment cost as of October 1, 2003 as multiple source drugs for purposes of the ASP statute, SSA § 1847A(c)(6)(C)(ii), does not alter the agency's

[Footnote continued]

B. Demonstration Project

The agency also has the authority to alter Medicare payments to physicians for IVIG under the agency's demonstrations authority. Section 402(a)(1) of the Social Security Act Amendments of 1967 ("SSAA") authorizes the Secretary to conduct demonstration projects for various purposes set forth in that statute, including:

> "(A) to determine whether, and if so which, changes in methods of payment or reimbursement [] for health care and services under health programs established by the Social Security Act, including a change to methods based on negotiated rates, would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives without adversely affecting the quality of such services";
> "(B) to determine whether payments for services other than those for which payment may be made under such programs (and which are incidental to services for which payment may be made under such programs) would, in the judgment of the Secretary, result in more economical provision and more effective utilization of services for which payment may be made under such program . . . ."

In exercising this demonstration authority, "the Secretary may waive compliance with the requirements of titles XVIII and XIX of the Social Security Act insofar as such requirements relate to reimbursement or payment on the basis of reasonable cost, or (in the case of physicians) on the basis of reasonable charge, or to reimbursement or payment only for such services or items as may be specified in the experiment . . . ." 11

The agency has exercised this authority on numerous occasions, including some recently that included added Medicare payments to physicians. Effective for calendar year 2005, CMS established a demonstration project under SSAA § 402(a) "to identify and assess certain oncology services in an office-based oncology practice that positively affect outcomes in the Medicare population." 12 Under this demonstration, participating physicians were paid $130 per

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[Footnote continued]

ability to create unique product-specific HCPCS codes for IVIG. Under § 1847A, computing the payment rate for a multiple source drug differs from that for a single source drug in that wholesale acquisition cost ("WAC") is used in computing rates for single source drugs. Thus, creating product-specific HCPCS codes for IVIG but determining payment rates without consideration of WAC in the computations is consistent with SSA § 1847A(c)(6)(C)(ii).

11 SSAA § 402(b).

12 69 Fed. Reg. 66236, 66308 (Nov. 15, 2004).

encounter for submitting certain patient assessment data. 13 For 2006, CMS replaced this demonstration project with another demonstration project under SSAA § 402(a), which involves a payment of $23 for physicians that submit specific codes when certain evaluation and management services are billed. 14 The agency's most recent use of this demonstration authority was the establishment a few weeks ago of a demonstration project to allow "States to be fully reimbursed for their efforts to help ensure that their beneficiaries eligible for Medicare and Medicaid have access to their covered Medicare drugs as they move to their new Medicare Part D drug coverage." 15

CMS could establish a demonstration project that would increase payments to physicians for IVIG consistent with the statutory authority vested in it by SSAA § 402(a). For example, one purpose of such a demonstration could be to determine whether increased payments would result in more economical provision and effective utilization of services paid by Medicare, pursuant to SSAA § 402(a)(1)(B). As has been reported to CMS, there are concerns about continued beneficiary access to IVIG which could lead to greater health complications for beneficiaries that receive IVIG. Accordingly, a demonstration project could test whether the added payment for IVIG would ensure access in a way that would diminish the need for other Medicare expenditures for affected beneficiaries. This assessment also would fall within SSAA § 402(a)(1)(A), which authorizes demonstrations to determine whether a change in payments would increase the efficiency and economy of Medicare services.

C. Inherent Reasonableness

CMS or a Medicare carrier may reduce or increase the payment for an item or service if it determines that the otherwise applicable rate "is not inherently reasonable." 16/ If CMS were to utilize this authority to establish a new national rate, it must publish proposed and final notices before the revised rate could be effective. If a carrier were to utilize this authority, it must inform affected entities, evaluate comments it receives, notify CMS of a final limit it plans to establish, notify affected entities of the final limit, and provide for an effective date that is at least 60 days after affected parties have been notified of the final limit. Regardless of whether pursued by CMS or a carrier, an adjustment could not be made unless the difference between the current and the proposed rate is at least 15%. 17/ Although CMS has yet to exercise this authority since final, revised regulations were issued 2002, the agency nonetheless retains the authority to use this tool.

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13 69 Fed. Reg. at 66308-09.

14. 70 Fed. Reg. 70116, 70272-73 (Nov. 21, 2005).

15 *See* http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1761.

16/ SSA § 1842(b)(8)(A)(i)(I).

17/ 42 C.F.R. § 405.502(g)(1)(ii).

III. CMS Could Adjust Payments for IVIG Without Further Rulemaking

The prior sections of this memorandum address the authority of CMS to adjust the payment rate for IVIG in the hospital outpatient and physician office settings. Were CMS to decide to exercise any such authority, an important question becomes the manner in which CMS could take action. You have asked whether CMS could establish a payment adjustment for IVIG without going through new notice and comment rulemaking. As explained below, CMS would be able to exercise the above areas of authority to make such an adjustment without undertaking a new notice and comment rulemaking process, in all circumstances but one.

Both the OPPS final rule and the physician fee schedule final rule issued setting the 2006 rates for drugs were issued as final rules with comment periods. 18/ In the OPPS rule, as the agency has done with past OPPS final rules, CMS allows for "comments on the payment classification assigned to HCPCS codes identified in Addendum B with the NI comment code and other areas specified through the preamble." 19/ Among the codes that have the NI comment code are those to be used to bill for IVIG. 20/ The physician fee schedule rule did not contain any limitations on the issues for which the agency would accept comments. 21/

A "final rule with comment period" is not specifically recognized by the Administrative Procedure Act ("APA"). The courts likewise have not afforded any special status to final rules with comment. Nonetheless, by designating a payment rate or an issue for comment in a final rule, the agency affords itself the opportunity to respond to comments submitted on such issues without first reissuing a proposed rule on that topic. The purpose of the notice requirement in the APA is to ensure that interested parties are able to communicate information and views about proposed policies to the agency. 22 By specifying that certain aspects of a final rule are subject to comment, the agency can argue that it has provided the notice that an issue is under consideration that the APA requires. As a result, the agency would claim, a subsequent change could be in compliance with the APA.

18/ *See* 70 Fed. Reg. 70116 (Nov. 21, 2005) (physician fee schedule rule); 70 Fed. Reg. at 68516 (OPPS rule).

19/ 70 Fed. Reg. at 68516.

20/ 70 Fed. Reg. at 68899.

21/ *See* 70 Fed. Reg. at 70116.

22 See American Acad. of Pediatrics v. Heckler, 561 F.Supp. 395, 398 (D.D.C. 1983) ("The Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*, was designed to curb bureaucratic actions taken without consultation and notice to persons affected. Broad delegations of rulemaking authority from the Congress were intended to be tempered by assuring a degree of due process for those to be governed by the rule") (citing United States v. Morton Salt Co., 338 U.S. 632, 644 (1950).

If the agency were to revise a policy or payment rate based upon a comment to a final rule with comment, any procedural vulnerability likely would result from a court finding that the revised policy is not a "logical outgrowth" of the rule that afforded notice. 23 Courts set rules aside for insufficient notice when the purposes of notice and comment "have not been adequately served" and "a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule." American Water Works Ass'n v. EPA, 40 F. 3d 1266, 1274 (D.C. Cir. 1994). If CMS were to make a change to the payments for IVIG, whether that change would satisfy the "logical outgrowth" standard would have to be assessed based on a review of the change in comparison to what the agency said in the rule and based on the comments submitted on the subject. Given that PPTA and others submitted comments to CMS on the payment rate for IVIG, an argument can be made that CMS' exercise of most of the above authorities would be a logical outgrowth of the final rule with comment period (and the comments submitted to it). For example, the agency could argue that a payment adjustment was a response to timely submitted comments on the recent final rules indicating that the payment rates for IVIG were insufficient to ensure access to IVIG. As a result, the agency could issue a Federal Register notice explaining and implementing an adjustment to the payment for IVIG under one of the aforementioned authorities (except for inherent reasonableness, as noted below) as soon as practicable.

Indeed, there is ample precedent to support such an approach. In the agency's implementation of the ASP payment methodology the agency issued a final rule with comment period and decided to issue a subsequent final rule that addressed a single issue in response to comments received. After issuing an interim final rule with comment on April 6, 2004 that related to the calculation and submission of ASP data, CMS issued a final rule to respond "to the public comments received on the interim final rule concerning the methodology for estimating price concessions associated with manufacturers' ASP reporting requirements. Other issues and comments will be addressed at a future time." 24 Consistent with the approach taken for this ASP final rule, CMS could issue a final rule addressing only the payment for IVIG.

Another alternative for CMS would be to include a payment adjustment for IVIG in a correction notice. CMS has made numerous changes to payment rates after the issuance of an OPPS final rule in a correction notice published in the Federal Register, which demonstrates that CMS believes it has the authority to make policy changes after the issuance of a final rule. For instance, in 2003, subsequent to the issuance of an OPPS final rule with comment period, CMS issued a correction notice that included a revised payment rate for a product based on information submitted by the manufacturer on the cost of the product. 25

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23 This discussion is not to suggest that the agency must act through notice and comment rulemaking, but assumes that the agency were to take the position to that it must act through such a process.

24 69 Fed. Reg. 55763 (Sept. 19, 2004).

25 68 Fed. Reg. 75442, 75444 (Dec. 31, 2003).

The agency has also made changes affecting payment rates through a Program Transmittal, without the subsequent issuance of a Federal Register notice. When first implementing the transitional OPPS payment rate methodology from the Medicare Modernization Act, the agency treated a number of biologicals as multiple source drugs for purposes of the average wholesale price based ceilings to payment rates in a final rule with comment period. 26 In a transmittal issued on February 27, 2004, 27/ the agency determined that all biologicals should be treated as sole source specified covered outpatient drugs, thus applying different payment rates to these products than had been set forth in the final rule. Similarly, as noted in Section II(A) above, the agency altered the payment rate for IVIG through a Program Transmittal when it announced the establishment of new HCPCS codes for IVIG.

CMS' actions also illustrate that the agency's exercise of its demonstrations authority need not be done through new notice and comment rulemaking. The most recent project involving payments to States in connection with the implementation of Part D was commenced with the release of a CMS Fact Sheet, without rulemaking. Thus, a demonstration on IVIG likewise could be accomplished without rulemaking.

Of all of the identified authorities in Sections I and II for altering payments for IVIG, only the use of inherent reasonableness would require a process akin to rulemaking. A proposal to apply inherent reasonableness to a product nationwide would have to be issued first, followed by a public comment period, followed by a final determination from CMS prior to the application of inherent reasonableness. Practically, this amounts to a new rulemaking process.

Conclusion

For the reasons stated above, there are a variety of authorities that CMS could rely on to make a payment adjustment for IVIG in the physician office and hospital outpatient settings. Almost all of the identified authorities for making such an adjustment could be made without engaging in a new round of rulemaking, whether through the issuance of a final rule, a correction notice, or a Program Transmittal.

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26 69 Fed. Reg. 820, 825 (Jan. 6, 2004).

27/ *See* http://www.cms.hhs.gov/manuals/pm_trans/R112CP.pdf.

Assessing the Cost of IVIG Infusion Services in Physician Offices & Hospital Pharmacy Departments

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Presentation Overview

- Background of IVIG
- Presentation Purpose
- Study Methods
- Providing IVIG Infusion Services
- Comparison of CMS Payments to Reported Costs for IVIG Costs of Goods
- Comparison of Total CMS Payments to Total Reported Costs per Infusion in Physician Offices
- Total Infusion Costs per Month: CMS Payments vs. Physician Office Cost Data
- Study Conclusions

The following presentation is based on report submitted to CMS (report dated 12/27/05), and revisions sent to CMS (Herb Kuhn letter, dated 2/3/06).

Background of IVIG

- IVIG is a complex biological product used to treat numerous chronic disorders (e.g., Chronic Variable Immune Deficiency, Hypogammaglobunemia, and Idiopathic Thrombocytopenic Purpura) and can be provided in various settings.
- Aggregate provider IVIG usage is difficult to estimate and predict due to varying patient needs and diagnoses.
- The IVIG market is complex:
  - Current IVIG market prices differ significantly between contracted and non-contracted purchases
  - As providers cannot easily predict patient need some IVIG products are purchased at higher off-contract rates (contract rates only apply to IVIG product amount contracted for in advance)

Background of IVIG (continued)

- Physicians and hospitals reported that reduced physician Medicare payments beginning in 2004 (a decrease from $4109.20 in 2003 to $2878.28 in 2004*) resulted in a migration of patients from physician offices to the outpatient hospital setting, complicating patient access and IVIG market allocation.

- In 2006 CMS provided a temporary add-on payment for physician offices of $69, and for hospitals of $75 to cover pre-service costs related to "temporary market instability".

*Total infusion cost based on a 5 hour infusion at 50 grams of lyophilized/non-lyophilized IVIG.

Presentation Purpose

- To identify the costs of providing IVIG infusion in physician offices.
- To provide the total and component costs, on average, for providing IVIG infusions in physician offices.
- To compare CMS IVIG physician office infusion payments to costs incurred to provide IVIG infusion therapy.
- To determine the impact of CMS physician payment policies on physicians' willingness to provide IVIG infusions in physician's offices.

Study Methods

- Review past and current Medicare IVIG reimbursement.
- Develop an understanding of the IVIG market as it affects providers.
- Collect distributor and manufacturer pricing.
- Survey 76 physician offices to compare CMS payments to current physician office, cost of goods and physician time costs.
- Survey 30 hospital pharmacy departments to compare CMS payments to current pharmacy department cost of goods, product and handling costs.
- Conduct data analyses and policy interpretation.

Methods: Components of IVIG Infusion Costs for Physicians (revised categories, 2/06)

- Pre-Service
  - Check inventory
  - Locate & procure product
  - Place order
  - Shelving and storing
  - Pre-certification/verification of insurance
  - Telephone patient assessment /confirm appointment
- Clinical Administration
  - Prepare and/or reconstitute IVIG product*
  - History*
  - Vital check*
  - Physical exam*
- Clinical Administration (continued)
  - IV start
  - Pre-medication administration
  - Physician coordination and monitoring
  - Adverse events intervention
  - Discontinue IVIG infusion
  - Immediate post-infusion assessment**
- Post-Service
  - Post-infusion assessment by telephone (w/in 24 hours)

* Tasks shifted from pre-service category
**Tasks shifted from post-service category
Revised categories documented in letter to CMS (Herb Kuhn, 2/3/06)

Providing IVIG Infusion Services

- IVIG infusion services are currently provided by an increasing number of hospitals and physician specialists.
- Treatment varies in amount of product provided over time, as well as speed, concentration and frequency of infusions.
- Special training is required due to the extra complexities of infusing any biological product.
- Physicians, hospital pharmacists and staff expend extra hours obtaining appropriate IVIG products.
- When lack of availability of specific IVIG products require that a patient switch products, additional clinical time is needed for evaluation and monitoring of potential adverse reactions.
- Patients' clinical indications, medical conditions and past reactions to various products determine recommendations for specific products.
- As a result of the above factors, IVIG pre-infusion services are more resource-intensive than other infusions.

Comparison of CMS Payments to Reported Costs for IVIG Costs of Goods

Acquisition costs tend to be above CMS ASPs because these costs include off contract prices with a wide variety of suppliers, and reflect real time prices as opposed to dated prices embodied in CMS ASPs.

	CMS Final Rule CY 2006 ASP + 6%	Acquisition Costs*		Distributor/Manufacturer Price	
		Contract	Total (Contract and Off Contract)	Contract	Total (Contract and Off Contract)
PHYSICANS					
Lyophilized					
Average	$42.57	$44.57	$50.27	$43.50	$47.47
Liquid					
Average	$56.30	$58.36	$62.64	$54.33	$56.86
HOSPITALS					
Lyophilized					
Average	$42.57	$45.54	**	$42.79	$46.98
Liquid					
Average	$56.30	$56.09	**	$56.59	$58.47

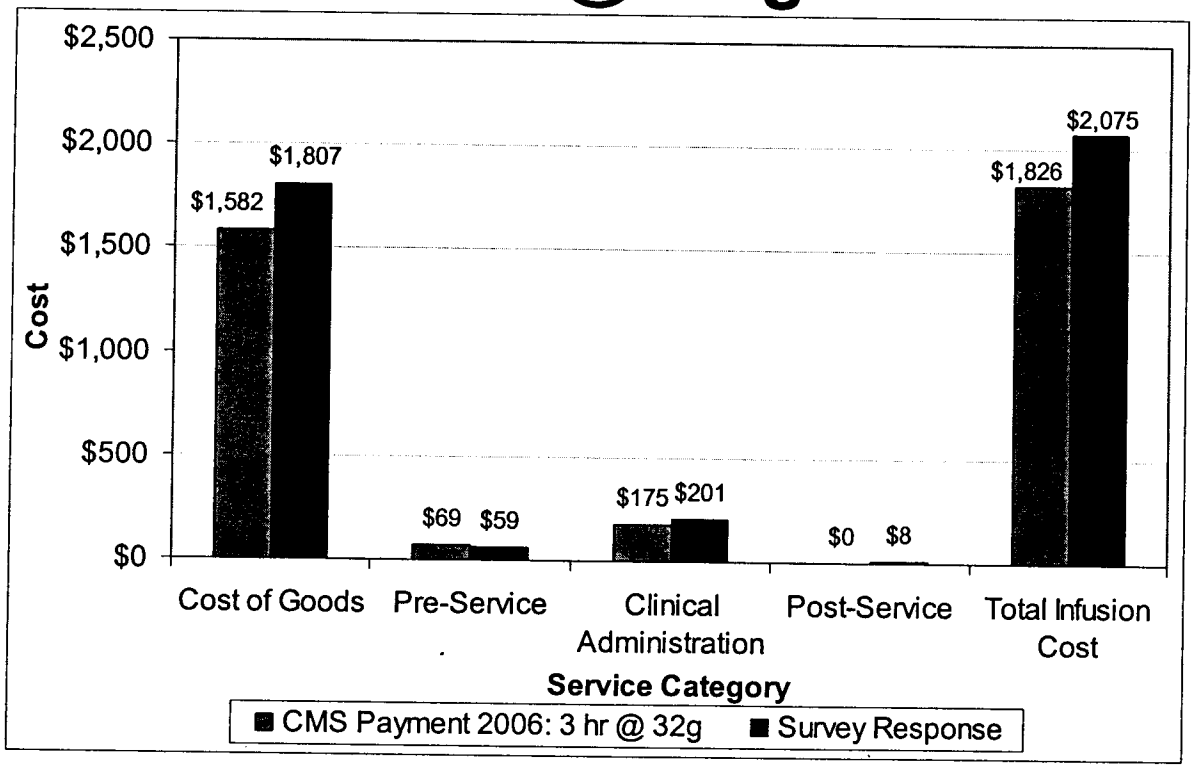
Data reflect reported distributor and manufacturer prices for "direct to physician" or "direct to hospital" sales. Reported distributor prices are estimated to represent over 55% of the physician market, while manufacturer prices include all reported manufacturer sales YTD through Q3 of 2005. All distributor ASPs reflect YTD totals as reported by distributors through November 2005.

*As reported by survey respondents.

** Hospitals reported paying between $45 and $156 per gram off-contract with widely varying amounts and products, depending on patient need and brand availability.

Comparison of Total CMS Payments to Total Reported Costs per Infusion in Physician Offices

3 hr @ 32 g

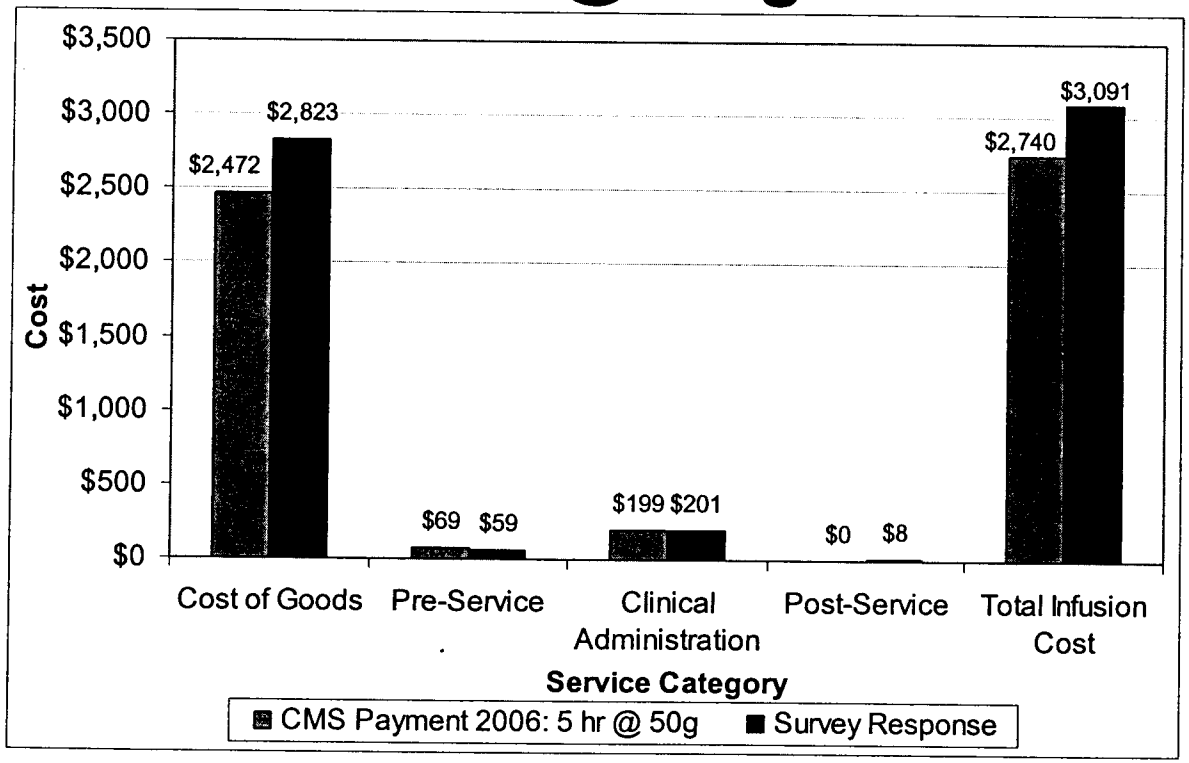


While CMS payments are based on a 3 hour infusion, survey data reflect each practices' reported average infusion costs.

Survey data represent the average of lyophilized and non-lyophilized data for intra-service time ($206.24 - lyophilized; $195.83 - non-lyophilized). Cost of Goods for CMS and Survey data are based on the average for lyophilized and non-lyophilized (CMS: $42.57 - lyophilized and $56.30 non-lyophilized; Survey $50.27 lyophilized and $62.64 non-lyophilized).

Comparison of Total CMS Payments to Total Reported Costs per Infusion in Physician Offices

5 hr @ 50 g

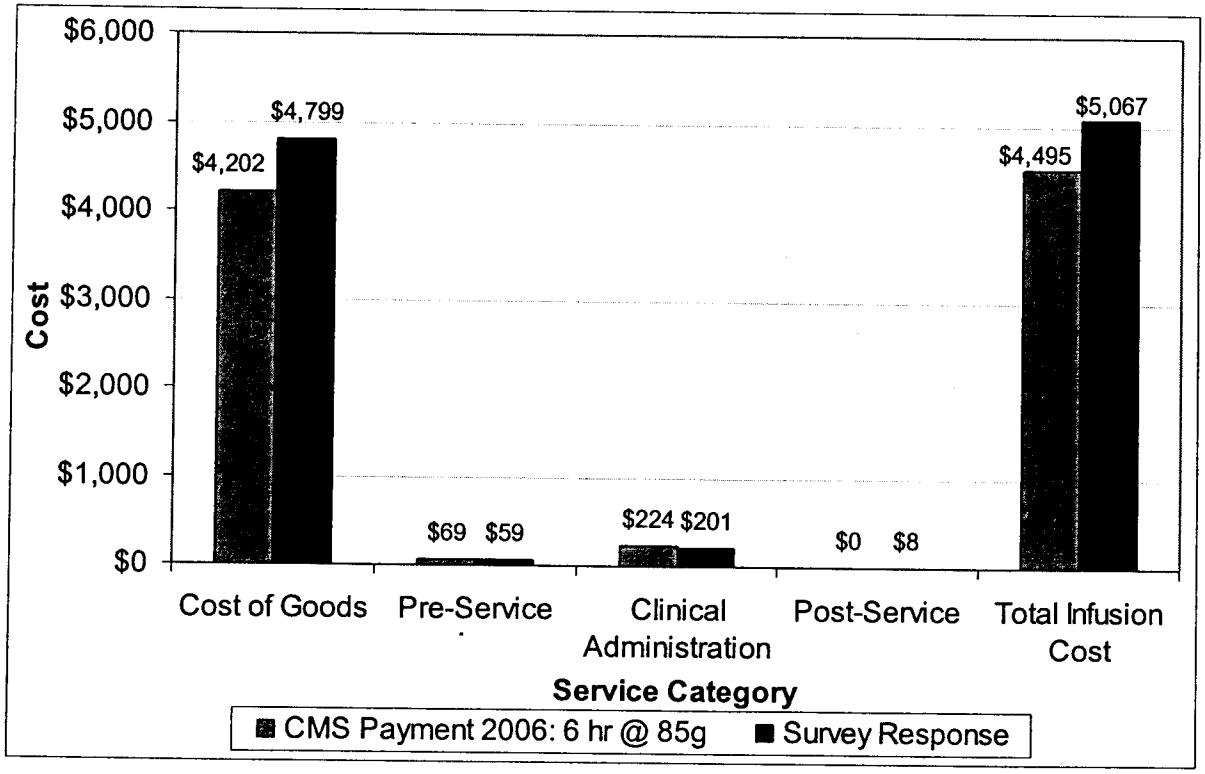


While CMS payments are based on a 5 hour infusion, survey data reflect each practices' reported average infusion costs.

Survey data represent the average of lyophilized and non-lyophilized data for intra-service time ($206.24 - lyophilized; $195.83 - non-lyophilized). Cost of Goods for CMS and Survey data are based on the average for lyophilized and non-lyophilized (CMS: $42.57 - lyophilized and $56.30 non-lyophilized; Survey $50.27 lyophilized and $62.64 non-lyophilized).

Comparison of Total CMS Payments to Total Reported Costs per Infusion in Physician Offices

6 hr @ 85 g



While CMS payments are based on a 6 hour infusion, survey data reflect each practices' reported average infusion costs.

Survey data represent the average of lyophilized and non-lyophilized data for intra-service time ($206.24 - lyophilized; $195.83 - non-lyophilized). Cost of Goods for CMS and Survey data are based on the average for lyophilized and non-lyophilized (CMS: $42.57 - lyophilized and $56.30 non-lyophilized; Survey $50.27 lyophilized and $62.64 non-lyophilized).

More IVIG Physician Services Provided Result in Greater Losses

Total Infusion Cost per Month: CMS vs. Physician Office Cost Data

Physician Offices total estimated non-reimbursed **monthly costs** based on the number of infusions

3 hr @ 32 g			
	6 infusions	10 infusions (median)	25 infusions (average)
Lyophilized	-$1,802.76	-$3,004.60	-$7,511.51
Liquid	-$1,479.24	-$2,465.40	-$6,163.51

5 hr @ 50 g			
	6 infusions	10 infusions (median)	25 infusions (average)
Lyophilized	-$2,339.16	-$3,898.60	-$9,746.51
Liquid	-$1,868.76	-$3,114.60	-$7,786.51

6 hr @ 85 g			
	6 infusions	10 infusions (median)	25 infusions (average)
Lyophilized	-$3,808.56	-$6,347.60	-$15,869.01
Liquid	-$3,052.56	-$5,087.60	-$12,719.01

Study Conclusions

- The majority of costs associated with physician pre-service payments are constant, regardless of market conditions.
- Therefore, study findings suggest that the temporary add-on payments established by CMS accurately reflect pre-service costs and should be made permanent.
- CMS' Final Rule CY 2006 ASPs are below the prices paid by surveyed hospitals and physicians.
  - Providers pay widely varying prices depending on manufacturers, distributors, and suppliers involvement.
  - Survey prices reflect real time supplier prices, as opposed to dated quarterly manufacturer prices embodied in CMS ASPs.
- The more IVIG services physicians provide, the more money they lose, mostly attributable to the difference in ASP payments versus provider costs.

Study Conclusions (continued)

- Physicians and hospitals reported that reduced physician Medicare payments beginning in 2004 resulted in a migration of patients from physician offices to the outpatient hospital setting, complicating patient access and IVIG market allocation.
- It appears that CMS' attempt to correct for perceived overpayments of product in 2004 "overcorrected". This resulted in physicians being paid less than costs incurred for IVIG infusion services, primarily due to inadequate CMS ASPs that do not reflect what providers have to pay for product in the marketplace.
- The combination of product and market complexity and government administered prices is resulting in patient access issues in some markets.