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October 9, 2006

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

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

Dear Administrator McClellan:

Stakeholders within the community of patients who rely upon lifesaving plasma derived and recombinant analog therapies and the Plasma Protein Therapeutics Association ("PPTA") appreciate this opportunity to comment on the proposed rule concerning the 2007 hospital outpatient prospective payment system ("OPPS") rates that were published in the Federal Register on August 23, 2006 ("Proposed Rule").[1] We are deeply committed to the health and safety of the patients we serve, and our comments on the Proposed Rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("plasma protein therapies") in the hospital outpatient setting.

We commend CMS for its proposal to pay separately for additional hours, beyond the first hour, for intravenous infusions and urges CMS to finalize this proposal. At the same time, however, we are very disappointed in the agency's proposal to reduce the payment rates for plasma protein therapies furnished in hospital outpatient departments, and IVIG in particular. We disagree with the agency's rationale for proposing payment at average sales price ("ASP") plus 5%, and are extremely troubled by the differential it would create in payments between the hospital outpatient and physician office settings. This likely will further dislocate Medicare beneficiaries and impede their care by yet again resulting in a shift in site of service to their detriment for beneficiaries receiving plasma protein therapies.

On top of this payment reduction, payment for IVIG would be further reduced by the proposed elimination of the preadministration-related services payment. Again, there is no basis for such action. Furthermore, Department of Health and Human Services ("HHS") Secretary Michael Leavitt's August 29, 2006 letter to Representative

[1] 71 Fed. Reg. 49506.

Ellen Tauscher[2] (D-CA) states that, "this add-on payment is paid per day of IVIG administration and is for the extra costs and resources expended on locating and obtaining appropriate IVIG products and on scheduling patient infusions during this current period where there may be potential issues in the IVIG market." This additional payment is helpful in reimbursing providers for these extra costs. Despite CMS' acknowledgement of these additional costs for the administration of IVIG in the August 29th letter, CMS ironically proposes to eliminate the payment in the Proposed Rule. This preadministration payment was established to reimburse hospitals for actual costs they incur in furnishing IVIG in outpatient departments. These costs will not simply disappear in 2007. As such, we urge CMS to maintain the preadministration-related services payment. In addition, we strongly recommend that CMS consider other steps to ensure that OPPS payment rates for IVIG do not present an obstacle to access, as currently appears to be happening.

DISCUSSION

PAYMENT FOR EXTENDED INFUSIONS ["OPPS Drug Administration"]

In the Proposed Rule, following the recommendation of the APC Advisory Panel, CMS proposes to make separate payments for each additional hour of an intravenous infusion beyond the first hour. CMS recognizes that this policy is particularly appropriate for IVIG infusions, given the length and resource intensity of these infusions. 71 Fed. Reg. at 49603-04. We appreciate the agency's recognition of these costs. We note also that this proposal rightly would treat hospitals like physician offices, as in the latter setting, CMS has long made separate payments for each additional hour (after the first hour) of an intravenous infusion. For these reasons, we strongly recommend that CMS finalize its proposal to pay separately for each additional hour of an intravenous infusion beyond the first hour.

ENSURING ADEQUATE PAYMENT RATES FOR PLASMA PROTEIN THERAPIES ["OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"]

For 2007, CMS proposes to pay for drugs and biologicals that do not have pass-through status at ASP + 5%. This payment methodology is supposed to reimburse hospitals for the acquisition and overhead costs of drugs and biologicals they incur. The basis for CMS' proposal to pay for such products at ASP + 5%, rather than the current ASP + 6% payment methodology is an evaluation of the mean costs of drugs using hospital claims data compared to the ASP data CMS receives on a quarterly basis. 71 Fed. Reg. at 49584-85. This analysis contains a number of fundamental flaws and thus it cannot form the basis upon which CMS deviates from the current payment methodology.

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

Foremost among these flaws is the reliance in this evaluation on hospital claims data. With the apparent exception of CMS, every other interested party recognizes that hospital claims data used for OPPS, particularly on drugs and biologicals, is highly problematic because of an inability to code for drugs and units properly. At virtually every Ambulatory Payment Classification ("APC") Advisory Panel meeting, there are extensive discussions about the poor quality of the hospital claims data for this reason. The Panel members working in hospitals acknowledge this to be the case, so much so that the Panel created a Data Subcommittee to look into ways to improve the data that underlies OPPS. Earlier this year, the Data Subcommittee reported on its efforts, concluding that while CMS has made its best efforts, the problems with the data can only be solved at the individual hospital level, which has not been occurring. [3]

Moreover, the agency's proposed use of hospital claims data fails to consider the impact that charge compression has on such data at a time when the agency has engaged a contractor to study the charge compression issue for the inpatient prospective payment system. Specifically, the CMS contractor "will focus on methods of improving the accuracy of the adjustment of charges to cost to account for the fact that hospitals tend to markup high cost items to a lesser extent than they markup low cost items, a phenomenon known as charge compression." [4] The OPPS data on drugs and biologicals is subject to the same charge compression phenomenon CMS has decided to study because many of the products are high cost items that are subject to a lesser markup. We believe that CMS should not rely on claims data to make an OPPS drug payment methodology change without a full consideration of the effect of charge compression on the data.

Another potential flaw in CMS' evaluation involves the inclusion of claims data from the 340B program, which provides price discounts for certain health care entities. These prices are excluded from the ASP calculation. [5] Likewise, when the Government Accountability Office conducted a study of drug purchase prices in hospital outpatient departments, it excluded these prices. [6] This exclusion is appropriate because, by the design of the program, prices to these entities are lower than is available to other hospitals. As a result, their inclusion could lower the identified costs. While the GAO recognized this, it is not clear that CMS did when conducting the evaluation that led to the ASP + 5% proposal. To the extent that the agency included claims from the 340B program, that would make the data underlying the proposed ASP + 5% rate flawed.

In addition to these flaws, we view CMS' proposed change as troubling from a policy perspective. In particular, we believe that creating a differential in the payment

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[3] *See* "Report of the Advisory Panel on Ambulatory Payment Classification (APC) Groups, March 1-2, 2006," p. 10, available at http://www.cms.hhs.gov/FACA/Downloads/March1-2Mtg.zip.

[4] The CMS announcement is available at http://www.hfma.org/hfmanews/ct.ashx?id=fbe23a25-4001-471a-8743-.

[5] *See* "Report on Sales of Drugs and Biologicals to Large Volume Purchasers" (2006), at p. 3, available at http://www.cms.hhs.gov/reports/downloads/LVP_RTC_2_09_06.pdf.

[6] *See* "Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting" (Jun. 30, 2005), at p. 8, available at http://www.gao.gov/new.items/d05581r.pdf.

rates for products between the physician office and hospital outpatient sites of service would be detrimental to beneficiary access to drugs and biologicals. CMS took this very position in last year's OPPS final rule, stating:

> We agree with the commenters' statements about the use of similar resources to furnish clotting factors across all types of service settings and believe that it is appropriate to adopt a methodology for paying for clotting factors under the OPPS that is consistent with the methodology applied in the physician office setting and the inpatient hospital setting. 70 Fed. Reg. 68516, 68661 (Nov. 10, 2005).

We saw the negative impacts of payment differentials in 2005, when physician offices were reimbursed at ASP + 6% but hospital outpatient departments were paid based on the OPPS median cost methodology subject to certain average wholesale price floors and ceilings. This prompted changes in the site of service for various products including IVIG, disrupting treatment regimens and inconveniencing beneficiaries. Especially given the lack of foundation for an ASP + 5% payment methodology, we see no valid reason for recreating this environment and further jeopardizing beneficiary access to life sustaining therapies such as IVIG.

Finally, the agency has laudably attempted to streamline payment mechanisms to make them more straightforward and less confusing. The Proposed Rule would work in the opposite direction in that drugs and biologicals would be paid based on different methodologies depending upon their status – nonpass-through drugs at ASP + 5%, drugs with specific Healthcare Common Procedure Coding System ("HCPCS") codes but no OPPS claims data at ASP + 6%, and pass-through drugs at either ASP + 6% or at a competitive acquisition program rate if applicable. We believe that the added complexity of these various payment methodologies will be unnecessarily confusing for providers, contractors, and the general public. Accordingly, we urge CMS not to finalize its proposal to set payment rates for nonpass-through drugs at ASP + 5% in 2007.

CONTINUING THE PAYMENT FOR IVIG PREADMINISTRATION-RELATED SERVICES ["OPPS Drug Administration"]

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

As noted above, the proposal to pay for nonpass-through drugs at ASP + 5% would adversely affect access to this important product. Regrettably, that is not the only aspect of the Proposed Rule that would diminish access to IVIG. We are perplexed by the agency's proposal to discontinue the payment for the preadministration-related services for no apparent reason other than the vague statement that it "would not be necessary in CY 2007 to ensure Medicare beneficiary access to IVIG." 71 Fed. Reg. at 49604. Currently, Medicare makes a $75 payment for preadministration-related services to ensure that hospitals are adequately reimbursed for furnishing IVIG to beneficiaries on an outpatient basis. *See* 70 Fed. Reg. at 68649. We do not understand how CMS came to the conclusion that this payment is no longer necessary, when hospitals continue to struggle to be able to provide the proper IVIG product to Medicare beneficiaries, and are faced with possible cuts in 2007 payments for the product. CMS must continue to make this preadministration-related services payment in 2007.

SEPARATE HCPCS CODES FOR IVIG PRODUCTS ["OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"]

As you know, the OPPS payment methodology is applied to items and services on a HCPCS code basis. While payment for many items and services is determined through the OPPS median cost methodology, currently, payments for drugs and biologicals are set based on the ASP methodology. That methodology compiles manufacturer information by HCPCS code and computes an average sales price. IVIG is somewhat uniquely situated in this regard in that it is one of the few sole source therapies for which there are multiple brand name products, but no generic products, in the code. We believe that, in such unique circumstances, the ASP methodology does not generate representative payment rates for the different IVIG products. Rather, CMS should consider establishing unique HCPCS codes for each brand name product so that the ASP rate for each product is based on its own ASP information, as is the case for other biologicals. We believe that this would yield rates that are pertinent to each product and thus may enhance access to IVIG products. Simply dividing IVIG products by the liquid and lyophilized class does not go far enough in assuring that access to each unique brand is assured, and we suggest CMS consider free-standing HCPCS codes that carries with it distinct reimbursement for each IVIG product.

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

- Some products contain no sugars, which is beneficial for diabetics;
- Some products have low osmolality and low volume, which physicians sometimes prefer for patients with congestive heart failure or compromised renal function;

- Some products contain sucrose, which can create a higher risk of renal failure;
- Some products contain less immunoglobulin A ("IgA"), which is better for patients with IgA deficiencies; and
- Some products have a lower pH, which may be preferable for patients with small peripheral vascular access or a tendency toward phlebitis.

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

While, as noted above, we object to the use of the proposed ASP + 5% payment methodology for setting payment rates for drugs and biologicals in 2007, we suggest that separate codes should be established regardless of the applicable OPPS payment methodology. Specifically, we encourage CMS to provide each brand name IVIG product with its own HCPCS code so that, as is true with other biologicals, the OPPS payment rate will be set in a manner that is pertinent to each brand, which should enhance access to IVIG products.

We recognize that, in the final rule setting forth the 2006 payment rates, CMS considered establishing brand-specific HCPCS codes for IVIG, but did not find a "compelling" reason to override the standard practice of not establishing brand-specific codes. 70 Fed. Reg. at 68648. We respectfully disagree with the agency's statement and urge CMS to reconsider its position. Ironically, the standard practice for separately approved biologicals is to create separate HCPCS codes. Plasma protein therapies, including IVIG, are the exception to the standard practice of having separate codes for different biological products. Thus, we suggest that CMS articulate a "compelling" reason not to create separate codes for IVIG. Indeed, looking at the following statements made by CMS in its most recent OPPS final rule, it would appear that the agency itself demonstrated compelling reasons to have separate codes for IVIG products.

- "we continue to be concerned about CY 2005 reports of patients experiencing difficulties in accessing timely IVIG treatments and reports of providers experiencing difficulties in obtaining adequate amounts of IVIG on a consistent basis to meet their patients' needs in the current marketplace." Id.;
- "The Secretary's Advisory Committee on Blood Safety and Availability (ACBSA) has recommended immediate steps be taken to ensure access to IVIG so that patients' needs are being met." Id.;
- "the complexity of the IVIG marketplace makes it unclear what particular systematic approaches would be most effective in addressing the many

individual circumstances that have been shared with us while not exacerbating what appears to be a temporary disruption in the marketplace." Id.;

- "Historically, numerous factors, including decreased manufacturer capacity, increased usage, more sophisticated processing steps, and low demand for byproducts from IVIG fractionation have affected the supply of IVIG." Id.; and
- "Based on the potential access concerns, the growing demand for IVIG, and the unique features of IVIG detailed above, as well as our move to an ASP payment methodology for IVIG in the OPPS for CY 2006, as we seek to gain improved understanding of the contemporary, volatile marketplace, we will employ a two-pronged approach during CY 2006 to help ensure the availability of IVIG to physicians and hospital outpatient departments." 70 Fed. Reg. at 68469.

For these reasons, we suggest that CMS should establish separate HCPCS codes for IVIG products. Not only would individual codes improve the accuracy of the rate-setting for the various IVIG products, but they also may have the potential to enable CMS to reduce some of the complexity in the IVIG marketplace facilitating subsequent policy decisions on IVIG.

PAYMENT ADJUSTMENT FOR IVIG ["OPPS: Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals"]

In comments on the 2006 OPPS proposed rule, PPTA advocated for an add-on payment for IVIG that captures the acquisition, direct and indirect handling costs associated with the product. Although the agency rejected a number of recommended payment adjustments for IVIG, including an add-on payment, because of its belief that ASP data are reflective of hospital acquisition costs for IVIG, it nonetheless determined that Medicare should pay hospitals $75 for each administration of IVIG to compensate them for preadministration services related to IVIG. 70 Fed. Reg. at 68649-50.

We appreciated the agency's recognition of these types of costs incurred by hospitals in providing IVIG to beneficiaries, although that is tempered by the prospect of the discontinuation of that payment. However, even with the continuing payment for preadministration-related services, reimbursement for IVIG is insufficient to ensure continued access in the hospital outpatient setting. While it does reimburse hospitals for some of the costs that they incur related to IVIG, other costs would remain uncompensated.

We suggest CMS consider a payment adjustment to the current ASP formula to ensure that providers are made whole on the purchase cost of the IVIG therapies so that they receive a fair return in their investments in care. This payment adjustment should be reflective of providers' true costs to make IVIG available to their patients in the hospital outpatient setting. The payment adjustment could be based on independent data from the two current IVIG access studies being done by the Office of Inspector General and HHS' Assistant Secretary of Planning and Evaluation.

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

To ensure Medicare beneficiaries have the best available access to the life-saving IVIG therapies, CMS should consider providing a payment adjustment to the current ASP reimbursement methodology to enable providers in the hospital outpatient setting to cover the costs incurred for acquiring IVIG. The blood-clotting furnishing fee is a precedent-setting provision for plasma protein therapies, one which CMS has the authority to issue for IVIG. Without such a payment adjustment, we fear that patients will continue to be at risk of not being able to obtain the best access to care as possible.

CONCLUSION

We appreciate the opportunity to comment on the Proposed Rule. We are deeply concerned about the impact the Proposed Rule could have on the lives of patients who depend upon plasma protein therapies, particularly IVIG. Regrettably, in many respects, the Proposed Rule would represent a step back in efforts to ensure beneficiary access to these therapies. The proposed change to an ASP + 5% payment methodology is based on flawed data and policy, and must not be finalized. Similarly, the agency's proposal to discontinue payment for preadministration-related services in connection with IVIG lacks any foundation. CMS must continue to make this payment in 2007 so that the hospitals will continue to be reimbursed for the range of costs they incur in furnishing IVIG to Medicare beneficiaries. As you know, we continue to be very concerned that reimbursement for IVIG is impeding access to the product. We believe that this concern could be alleviated to a significant degree by the establishment of separate codes for each brand name IVIG product and through an IVIG payment adjustment. We suggest that CMS consider implementing these recommendations for its 2007 payments to hospitals. Finally, we welcome the agency's proposal to pay separately for the additional hours of an intravenous infusion, as this will help hospitals recoup their costs of furnishing a number of plasma protein therapies.

We look forward to working with CMS to ensure continued access to plasma protein therapies in the hospital outpatient setting. Thank you for your attention to this very important matter.

Respectfully submitted,

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

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Morton Plant Mease Health Services

Morton Plant Mease Bardmoor Outpatient Center
8787 Bryan Dairy Road
Largo, FL 33777

October 5, 2006

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P - Medicare Program; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List

Dear Dr. McClellan:

I am the Administrator of Morton Plant Mease Bardmoor Outpatient Center, a multi-specialty ASC in Largo, Florida Each year, our surgery center provides surgical, pain management and endoscopic procedures to approximately 3,020 Medicare beneficiaries. Medicare patients represent about 45% percent of our business and ensuring appropriate payment for their services is vital to our ability to serve our community. We are a not-for-profit ASC that is fully owned by a large hospital system.

We provide safe, cost-effective and quality care that is comparable to those of our associated and competitor hospital outpatient departments. For example, in 2005, of the 6,706 total patients served, 13 required further care in an emergency room or hospital within 24 hours of their surgery and none of those events were considered major, grave or life threatening. We had no falls, wrong site surgeries, medication errors or specimen errors. No state reportable events. The eight "cardiac or respiratory" events in 2005 were

intrinsic to the patient and handled correctly and effectively, for example patients suffering chest pain or arrhythmias who were identified and their procedures cancelled.

Please accept the following comments regarding Section XVII of the proposed rule, which would make revisions to policies affecting ambulatory surgical centers for CY 2007. 71 Fed. Reg. 49505 (August 23, 2006).

I. Proposed ASC List Update Effective for Services Furnished On or After January 1, 2007

A. Criteria for Additions to or Deletions from the ASC List

We commend CMS for proposing to update the ASC list for CY 2007, but believe the update falls short by not making extensive revisions to the criteria used to determine which procedures may be reimbursed in the ASC setting. As a result, beneficiary access to ASC services will continue to be limited by arbitrary criteria in CY 2007.

1. The inclusionary ASC list should be abandoned.

Our center is equipped and staffed to safely perform a significant number of the procedures performed in an HOPD. With an all-physician anesthesia team, all board-certified physicians on staff, up-to-date equipment and a fully trained clinical staff, the artificial limitation of cases due to the inclusionary list inappropriately limits Medicare recipients from choosing a location that is near their homes, cost effective, easier access and efficient for their care.

The limited, inclusionary list of covered ASC procedures is no longer the best way to address the safety and appropriateness of ASC services. Within currently accepted standards of medical practice - in which vast numbers of procedures may performed in a variety of outpatient settings - use of the ASC list has undesired consequences for the most optimal delivery of outpatient procedural services.

First, and most importantly, the ASC list limits the ability of physicians to select the site of service they believe is most clinically appropriate for their patients. A physician's assessment of the medical needs of the patient and the capabilities of the facility should determine whether a patient receives care in the ASC setting.

Second, the list limits Medicare beneficiaries' access to procedures that many other patients routinely receive in ASCs. Private payers do not restrict the access of their insureds to ASC services. Decisions regarding the site of service are recognized to be the province of the insured's physician. As a result, several minimally invasive procedures not available to Medicare patients in the ASC setting, such as spinal disc decompression and laparoscopic cholecystectomy, are commonly performed for selected privately insured patients - at significant savings to the patient and to the insurer. As long as CMS continues to maintain an ASC list, Medicare beneficiaries' access to appropriate services will always lag behind that of the private sector.

The ASC list should be abandoned. In its place, CMS should adopt the recommendations of the Medicare Payment Advisory Commission (MedPAC) and develop a list of services specifically excluded from coverage. In fact, CMS already has such an exclusionary list; for purposes of hospital outpatient payment under the Outpatient Prospective Payment System, CMS has developed and uses an "inpatient only" list. Because Medicare-certified ASCs have proven over the past two decades that they are capable of safely performing the same scope of services provided in hospital outpatient departments, this list may also be used to identify procedures excluded from coverage in ASCs.

Alternatively, if CMS develops a separate exclusionary list for ASCs, then that list should be based on the criteria identified by MedPAC in their March 2004 report. Specifically, MedPAC recommended the current list of ASC approved procedures by replaced "with a list of procedures that are excluded from payment based on clinical safety standards and whether the service requires an overnight stay".

2. The criteria used to revise the Medicare list of procedures that may be performed in an ASC are outdated and do not serve the interest of the Medicare program or its beneficiaries.

Section 1833(i)(1) of the Social Security Act requires CMS to determine which surgical services are safely and appropriately offered in an ASC. CMS selects the services represented on the current list of approved procedures based on criteria outlined in the Code of Federal Regulations at §416.65.We believe CMS is inappropriately limiting beneficiary site-of-service choices by continuing to make procedure list determinations using obsolete and outdated criteria that CMS itself previously proposed to substantially revise (63 Fed. Reg. at 32298).

a. Requirement that procedures be commonly performed in an inpatient setting.

When the Medicare ASC benefit was originally implemented in the 1980s, most surgical procedures were performed in an inpatient setting. In the intervening decades, the outpatient setting has become the accepted setting for many types of surgical procedures. As new clinical approaches to surgery, anesthesia and pain management have been incorporated into standard medical practice, certain procedures have moved almost exclusively to the outpatient environment. New procedures have evolved that were never commonly performed in an inpatient setting. Examples include newer arthroscopic and endoscopic interventions, and surgical treatments using laser or radiofrequency instrumentation. These procedures were developed predominately in an outpatient setting and are performed safely and cost-effectively on thousands of commercial insurance and self-pay patients each year.

To continue to require that a procedure be commonly performed in the inpatient setting before it can be deemed appropriate for the ambulatory surgery setting is no longer consistent with current standards of practice. We recommend general standard (1) "Covered surgical procedures are those surgical and other medical procedures that are commonly performed on an inpatient basis in hospitals, but may be safely performed in

an ASC" be eliminated as obsolete. This recommendation is also supported by MedPAC's 2004 report which specifically states, "it no longer makes sense to consider inpatient volume when updating the ASC list."

c. Requirement that a procedure not be commonly performed in physicians' offices

Current CMS guidelines provide that a procedure performed 50 percent or more of the time in a physician's office cannot be reimbursed in an ASC. In effect, this limits a physician's options to an inpatient or HOPD setting for patients for whom an office setting would be inappropriate. The higher costs generally associated with inpatient and HOPD reimbursement as compared to ASC reimbursement rates have been well documented by the OIG and MedPAC. Eliminating ASCs as an option for procedures which can be safely performed in the outpatient setting imposes unnecessary costs on both the Medicare program and individual beneficiaries. Conversely, allowing ASCs to serve as a site-of-service option to HOPDs for care has allowed the Medicare program to achieve significant cost savings.

While physicians may safely perform many procedures on healthy Medicare beneficiaries in the office setting, sicker beneficiaries may require the additional infrastructure and safeguards of an ASC to maximize the probability of a good clinical outcome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his specific condition. Even when a procedure is frequently performed in an office there are circumstances when the office is an inappropriate or unavailable setting. A brief summary of these factors follows.

Patient Characteristics – Patient characteristics affect the selection of the appropriate site of service. Factors such as body habitus, co-morbid conditions and even the patient's ability to lie in certain positions or hold still for long periods of time may affect whether a procedure can or should be performed in a physician office.

Another consideration is whether other procedures are being performed at the same time. If a patient is having a procedure performed in an ASC and another procedure that can be performed in an office is also needed, the patient and the Medicare program benefit from having both procedures performed at the same time.

Additionally, a procedure may be scheduled for a facility when the physician thinks it likely that a diagnostic procedure will result in the need for a therapeutic intervention. For example, a diagnostic cystoscopy (CPT code 52000) may be scheduled at an ASC because the physician thinks it likely that a cystoscopy with biopsy (CPT code 52204), requiring instruments and cautery not available in the office, will be necessary.

Procedure Differences –Procedures that are coded the same are not always identical. To some extent, the variations found in site of service may reflect the variation in procedures within the same CPT code. A prostate needle biopsy, 55700, provides a good example. The number of biopsies described by this code varies widely according to practice patterns. Some physicians routinely take 12-20 biopsies. Due to the more

invasive nature of multiple biopsies, conscious sedation is used, making a facility the more appropriate setting unless the performing physician has specialized staff and equipment.

Office Differences – Physician offices vary greatly in terms of equipment and personnel. To a great extent, this varies based upon the volume in the office. A small office may simply not be able to afford certain equipment. Offices also have vastly different personnel. For example, some offices have certified registered nurse anesthetists or nurses trained in advanced cardiac life support and others do not. The procedures that can be performed in an office vary greatly based upon the staff available to assist the physician performing the procedure.

Medical Liability Policy Differences – In order to lower premiums for medical liability insurance, physicians may agree not to perform certain procedures in their office. For example, policies may vary in the types of surgery covered or the types of anesthesia covered.

State Laws and Regulations – State laws and regulations impose limitations on what can be done in offices. To be able to perform certain types of procedures, these state provisions may require specific equipment, staff or even accreditation. If the office does not meet these requirements, these procedures cannot be performed in the office. For example, Indiana prohibits physicians that do not have specified continuing medical education in anesthesia from performing surgery involving conscious sedation in an office setting. Also, some state regulations limit anesthesia in the office to patients in certain American Society of Anesthesiologists (ASA) physical status classifications, meaning that some patients can have procedures involving anesthesia in the office but others cannot.

As was noted in the preamble to the interim final rule of May 2005, the rate of performance in ASCs of the physician office procedures originally proposed for deletion has remained relatively stable over the past 10 years. In other words, the inclusion of these procedures on the ASC list has not induced substantial shifts in sites of service, which suggests site-of-service selection is being driven by clinical need. If CMS remains concerned about the potential for financial incentives to improperly influence site-of-service selection, then the logical solution is to address any unjustified payment variations in the new payment system, rather than denying ASC coverage for procedures commonly performed in physician offices.

MedPAC has also recommended that CMS abandon the requirement that procedures be performed less than 50 percent of the time in physician offices to be added to the list. The Commission has specifically stated, "Physicians should have the discretion to decide which setting is most clinically appropriate for individual patients."

c. Operating and recovery time limits are unnecessary.

The ASC industry supported CMS's 1998 proposal (63 Fed. Reg. at 32298) to discontinue using the time limits on operating, anesthesia, and recovery time currently defined under 42 C.F.R. § 416.65(b), which are used as a basis for determining whether a procedure should be added to or deleted from the ASC List. The numeric threshold rules presently employed by CMS are obsolete and too often result in the exclusion of procedures that are entirely appropriate for the ASC setting. The current rule that the ASC List should be restricted to procedures that generally do not require more than 90 minutes operating time or 4 hours recovery time is outdated. This standard was developed in the early 1980s and predates numerous technological advances that are now standard in the ASC setting. Both thresholds are arbitrary and without clinical significance.

As MedPAC has observed, these time requirements are "unnecessarily rigid," particularly given the numerous technological advances that are now standard in the ASC setting. With the development of short-acting general anesthetics, the length of operating time is immaterial in determining whether a procedure is appropriately performed in an ASC. The key question is when is the patient ready to be discharged, not how long the surgery takes. Moreover, with respect to the four-hour limit on recovery time, a number of states have expanded the concept of "ambulatory" over the 20 years by permitting ASCs to perform procedures requiring stays of up to 24 hours.

B. Procedures Proposed for Addition to the ASC List

We commend CMS for updating the ASC list again for 2007. These regular updates help ensure Medicare beneficiaries have access to more of the services ASCs routinely and safely offer to non-Medicare patients.

All of the proposed additions are clearly clinically appropriate. However, we are concerned the payment group assignments for certain of the procedures will result in reimbursement at a level insufficient to cover the cost of performing the procedure.

We are concerned about the payment group assignment for CPT code 22522, which describes percutaneous vertebroplasty performed at additional levels. The proposed payment group assignment is a Group 1 ($333.00). The cost of the kit used at each level varies from $700 to $1400, depending on the supplier (Stryker, Arthrocare). Therefore, the proposed level of reimbursement would not be sufficient to cover supply costs for the procedure. In light of this, we recommend revising the payment group assignment to a Group 9 ($1339.00). Because this particular code is an add-on code, and therefore will always be subject to multiple procedure payment reduction, even assignment to payment Group 9 will only cover supply costs. Further, using the median cost information supplied in the HOPD, CMS has established the APC payment for this service at $1542.47. We believe the HOPD data is a more reliable proxy for the cost of providing this service.

We are also concerned about CPT codes 37205 and 37206, which describe transcatheter placement of an intravascular stent. The proposed payment group assignments are Group 9 ($1339.00) and Group 1 ($333.00), respectively. The cost of the intravascular stent averages $1725 (see CMS's 2005 file which calculates device related percentages for APC 0229), which exceeds the current maximum Group 9 reimbursement level. Therefore, no level of reimbursement currently available to ASCs would be sufficient to cover the device costs for these procedures. Unfortunately, there is no real opportunity for ASCs to receive separate reimbursement for the stent. Because there is no specific Level II HCPCS code that describes this stent, this device would have to be reported using L8699. ASCs experience considerable difficulty securing reimbursement from Medicare carriers for devices reported using L8699. In light of this, we believe ASCs will not be able to cover the costs of performing these procedures under the current reimbursement methodology. However, we still believe CMS should add the procedures to the list because they are clinically appropriate services and doing so will allow those patients whose private health plans look to CMS's ASC list for coverage decisions to access these procedures in the ASC setting.

C. Suggested Additions Not Accepted

1. Procedures suggested for addition, but not accepted because they are commonly performed in physician offices

Many procedures that were suggested through public comment for addition were rejected on the basis that they are commonly performed in the physician offices. CMS has determined if a procedure is performed 50 percent or more of the time in the office setting, it is inappropriate for addition to the ASC list. CMS relies on Part B claims data when determining the frequency with which procedures are performed in various settings. However, it has been well established by the OIG that site of service reporting on physician claims can be a highly unreliable indicator of the actual site of service; significant error rates (80 % and higher) for selected services have been reported. Given the probability of significant flaws in the data CMS uses to make these decisions, we do not believe continued reliance on this data is appropriate.

As noted above, there is no evidence that including procedures on the ASC list that are frequently performed in the office setting leads to overutilization of those procedures in the ASC setting. CMS itself has acknowledged that inclusion of certain services on the ASC list - although commonly performed in the physician office - has not resulted in excessive utilization of ASCs (70 Fed. Reg. at 23696).

Most of the procedures CMS has indicated it will not add to the ASC list are typically performed as secondary procedures for non-Medicare beneficiaries. Failure to add the requested procedures because they are commonly performed in the office setting deprives both the Medicare program and its beneficiaries of the efficiencies of care and added affordability that other patients enjoy as a result of use of the ASC setting.

For example, there are patients requiring endoscopic evaluation for reanastomosis following a partial colectomy with colostomy, in which both a colonoscopy via stoma (CPT code 44388) and flexible sigmoidoscopy (CPT code 45330) are needed for a complete evaluation. Non-Medicare patients can have both procedures performed at the same session in an ASC. This is not the case for Medicare beneficiaries. While the colonoscopy via stoma (CPT code 44388) is an ASC list procedure, the flexible sigmoidoscopy (CPT code 45330) is not. In order to have both procedures performed concurrently as an outpatient, the Medicare beneficiary must been seen at the HOPD.

Not only does this policy lead the Medicare program to miss opportunities for efficiencies of care, it also costs both the program and its beneficiaries significantly more. Having both these procedures performed in an HOPD costs the Medicare program $649.44, with a minimum beneficiary copayment of $129.89. If the Medicare program would allow the flexible sigmoidoscopy in the ASC setting, assuming a Group 1 payment assignment, the cost of the two procedures together would be $458.82, with a beneficiary copayment of $91.76.

As is the case with many procedures commonly performed in the physician office, there are certain patients whose medical condition requires a procedure be performed in a facility setting. In the case of flexible sigmoidoscopy, this would include patients with anal stenosis and anastomotic strictures, who require sedation for a humane examination. Current CMS policy does not allow these patients to access care in the more affordable ASC setting.

Though certain procedures are commonly performed in the office setting, the physician should not be restricted in the exercise of professional judgment when determining the most appropriate site of service. Hospital outpatient departments are not restricted in their ability to serve as the site of service when the physician determines the office setting will not meet the needs of the patient. When medically necessary, ASCs should also be an option for those Medicare beneficiaries requiring the services of a facility for appropriate and safe care. Therefore, we urge CMS to reconsider its decision to forgo adding the services presented in Table 42 (71 Fed. Reg. at 49629) because they are predominantly performed in the physician office.

2. Procedures suggested for addition, but not accepted because CMS states they do not meet current clinical criteria

a. Osteochondral arthroscopic grafting

Several commenters suggested the addition of CPT codes 29866 and 29867 describing arthroscopic knee procedures in which osteochondral autografts or allografts are placed. These procedures meet the current clinical criteria for addition to the ASC list. Surgery and anesthesia times are under 90 minutes, and recovery times generally average four hours. As with other arthroscopic knee procedures, blood loss is minimal.

b. Laparoscopic cholecystectomy

A number of commenters suggested the addition of CPT codes 47562, 47563, and 47564 describing laparoscopic cholecystectomies. The first laparoscopic cholecystectomy performed in the United States was performed at an ambulatory surgical center in 1988. Now, these procedures are commonly performed for non-Medicare patients in the ASC setting. Although CMS has not included these procedures on the ASC list to date, CMS data shows these procedures are routinely performed on an outpatient basis in Medicare patients; Medicare volume data shows these procedures were being performed on an outpatient basis 51%, 48% and 24% of the time, respectively.

CMS indicated it was not including these procedures on the ASC list because an overnight stay would often be required for Medicare patients. In light of the volume data presented above, we believe many Medicare beneficiaries are having laparoscopic cholecystectomies performed without an overnight stay in the HOPD. We recognize that an ASC will not be the appropriate site for all Medicare beneficiaries. However, by not adding these procedures to the ASC list, CMS effectively denies all Medicare beneficiaries access to the ASC.

CMS has also rejected the procedures on the basis of "a substantial risk that the laparoscopic procedure will not be successful and that an open procedure will have to be performed instead." (70 Fed. Reg. at 23700). CMS stated that if an open procedure were required, the patient would have to be transported to the hospital for the procedure.

It is unclear what clinical data was used to determine "substantial risk." The literature contains many studies of laparoscopic cholecystectomy in a variety of surgical settings, with different patient populations and differing levels of patient acuity. **<<I/We>>** are aware of just one recent study which exclusively evaluated the outcomes of outpatient ambulatory laparoscopic cholecystectomy in the United States, as reported by Lau and Brooks in the World Journal of Surgery in September of 2002. In this retrospective analysis of 200 procedures, no patient required conversion to an open cholecystectomy. While conversion to an open cholecystectomy is possible, it is not common. In fact, based on available data, the risk appears to be slight rather than substantial.

When determining the site of service for an ambulatory elective laparoscopic cholecystectomy, the surgeon may be rigorous in the application of patient selection criteria, thereby minimizing the risk of a subsequent conversion to an open procedure. This is not the case when the patient requires an emergent procedure. It is true that laparoscopic cholecystectomies are converted to open procedures at a rate of 5 to 10 percent in national studies of *hospital* discharge data (Livingston and Rege, American Journal of Surgery, September 2004). However, these conversion rates reflect procedures performed in the hospital setting, in unselected patient populations, and under both emergent and elective conditions.

Finally, it is important to note that if the laparoscopic approach is unsuccessful in the ASC setting, the patient does not have to be transported to the hospital for the open procedure. Generally, the laparoscopic procedure can be converted to an open procedure and completed at the ASC. The patient is then transported to the hospital following completion of the procedure and postoperative stabilization. Again, the application of patient selection criteria would make such conversions a rare occurrence.

c. Lumbar disc decompression

CPT code 63030 describes lumbar disc decompression. As a result of today's minimally invasive approaches, more of these procedures are being safely and successfully performed in the outpatient setting. Anesthesia and operating times are less than 90 minutes. Though recovery times can extend beyond four hours, these procedures can be performed without an overnight stay. As we noted above, we believe the continued imposition of specific operating and recovery time limits is unduly restrictive, a point which has been recognized by MedPAC and CMS itself in the past. Patients with private insurance routinely have these procedures performed in the ASC setting and therefore we urge CMS to allow Medicare patients to access these procedures in the ASC setting as well.

D. Other Appropriate Additions Not Addressed in the Proposed Rule

In this notice of proposed rulemaking, CMS proposes to add CPT codes 13102, 13122 and 13133 to the ASC list effective January 1, 2007. CPT code 13153 is also included in this series of codes and describes complex repair of the eyelids, nose, ears and/or lips in excess of 7.5 cm in size. However, this code is not currently on the ASC list, nor has CMS proposed its addition. By definition, complex repairs require time-consuming interventions such as scar revision, debridement, and extensive undermining. Work on the areas of the face described by this CPT code requires meticulous attention to detail for optimal outcomes, and a repair of this magnitude adds to the complexity of the procedure. Time in the operating room may be significantly extended by each additional 5 cm requiring this type of repair. All the other codes in this series, 13150-13152, are currently on the ASC list and assigned to payment group 3. Excluding more extensive repairs from the ASC setting is not consistent. Based its similarity to the other proposed additions, CPT code 13153 should also be added to the ASC list effective January 1, 2007.

CMS should also add G0289, which describes a knee arthroscopy for removal of a loose body, foreign body, or chondroplasty concurrent with another surgical knee arthroscopy in a different compartment of the same knee. CMS guidelines stipulate that G0289 may only be reported when the procedures described by this code require at least an additional 15 minutes of operating time. The use of this amount of additional operating room time – with attendant staff, equipment and supplies – should be recognized for additional reimbursement. Therefore we urge CMS to add G0289 to the ASC list effective January 1, 2007.

There are several procedures that are appropriate additions to the ASC list. We believe that CMS should add these procedures to the list with an effective date of January 1, 2007.

CPT Code	Descriptor
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid
43257	Upper gastrointestinal endoscopy with delivery of thermal energy to the lower esophageal sphincter
62290	Injection procedure for diskography, each level; lumbar
62291	Injection procedure for diskography, each level; cervical or thoracic
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion with programming
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
64402	Injection, anesthetic agent; facial nerve
64405	Injection, anesthetic agent; greater occipital nerve
64408	Injection, anesthetic agent; vagus nerve
64412	Injection, anesthetic agent; spinal accessory nerve
64413	Injection, anesthetic agent; cervical plexus
64418	Injection, anesthetic agent; suprascapular nerve
64425	Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves
64435	Injection, anesthetic agent; paracervical (uterine) nerve
64445	Injection, anesthetic agent; sciatic nerve, single
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter
64505	Injection, anesthetic agent; sphenopalatine ganglion
64508	Injection, anesthetic agent; carotid sinus (separate procedure)
64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g. for blepharospasm, hemifacial spasm)

E. Concern regarding Implant Costs Not Addressed in the Proposed Rule

We are also concerned about the inability of the ASC to secure reimbursement for exceptional expenses related to procedures that are performed, specifically such things as orthopedic, podiatric and pain management implants; radioactive seeds used for prostate brachytherapy, and uro-vaginal slings for incontinence procedures. This poses the ASC with the responsibility to provide Medicare recipients with certain ASC-approved procedures which result in significant financial loss to the ASC, again limiting the viability of this type of cost-effective

entity location to provide services and forcing procedures such as shoulder arthroscopy, prostate brachytherapy, and insertion of pain pumps into the higher cost hospital setting, increasing the overall cost to the Medicare program.

II. Proposal to Modify the Current ASC Process for Adjusting Payment for New Technology Intraocular Lenses

We are supportive of CMS's plans to streamline the process of recognizing intraocular lenses that qualify for a payment adjustment as a new technology intraocular lens (NTIOL). We also agree it would be more efficient to incorporate this into the annual update of ASC rates for the following calendar year. Including a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published would be very helpful, but we do not believe the proposed 30 day comment period is sufficient. Given the highly technical nature of NTIOLs, we believe a 60 day comment period would be more appropriate.

While we also generally agree with the list of examples of superior outcomes provided by CMS, we believe any revision of §416.195 should make it clear that these are strictly examples. Given the rapid pace of technological advances, it would be unfortunate if the revised language did not provide sufficient flexibility to accommodate future innovations because they are not specifically outlined as a superior outcome. Specifically, we suggest §416.195(a)(4) be modified to read, "Evidence demonstrated that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Examples of superior outcomes include, but are not limited to:".

We are also concerned about CMS's proposal to revise the language at §416.190 to require that the content of each request for an IOL review include information specified on the CMS web site. It is our belief that the items CMS finds necessary for review should be published in the Federal Register, as any change in regulation should be open to review and comment by the public before being implemented.

* * * * *

Thank you for considering our comments. If you have any questions or need additional information, please do not hesitate to call me at 727-394-5375.

Sincerely,

Nancy Burden

Nancy Burden
Administrator

Newton Memorial Hospital

It's Your Life, Live It Well

Date: October 6, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

To Whom It May Concern:

Re: PPS-CMS-1506-P; CY 2007 Proposed Daily Rate for APC Code 0033 - Partial Hospitalization Programs and 0322, 0323, 0324, 0325 – Outpatient psychiatric services

The Newton Memorial Hospital Acute Partial Hospital Program is a hospital based Partial Hospital Program in Newton, New Jersey. We serve approximately 300 patients on an annual basis. We provide Acute Partial Hospital and Intensive Outpatients Services as an alternative to inpatient hospital for a population experiencing Acute Symptoms of Mental Illness.

In 1985 our average inpatient length of stay was 28 days and today it is 5 to 6 days. We are able to do this and keep relapse rates down largely through the existence of Partial Hospital and Intensive Outpatient programs. We are also able to avert many hospitalizations. Our average length of stay in program is 10 days. Providing the intensity of services we do to patients who are still symptomatic and at times presenting suicide risk requires adequate staff resources. Increasing regulatory requirements mean huge amounts of time spent on documentation. We also need time to reach out to families, ongoing or new outpatient providers, provide referrals to and coordination of social services, referrals for self help services, and referrals for medical care. A large portion of our patients are in crisis, many are destitute, homeless, and in need of many interventions to adequately support recovery from acute psychiatric illness. We have a high rate of success in moving patients into recovery and have evidence of success and satisfaction with outcomes. Working intensively as we do with the whole person while they are in the community is very effective. Having worked for years on inpatient services, I believe that this level of services can much more effectively help a patient recover functioning in the community than longer and more costly hospitalizations. I am fearful that if any providers continue this service at the proposed rate it will be half hearted and only consist of bare bones groups, sessions and documentation and not provide the critical case management components required for successful outcome with the majority of our patients.

Performing this kind of work in a compressed time frame of 10 days or so as we do requires staffing levels not supported by the proposed rate. Our latest survey of costs shows our per diem cost of service is nearly twice the published CMS figures for average cost and approximately $100 per day more than the new proposed rate for 2007. Already, my hospital is taking a significant loss on these services due to lack of adequate reimbursement. Other providers across the country report to me that the proposed rate also does not come close to meeting their costs. I am hearing from my professional organization that the CMS methodology for calculating the costs is seriously flawed. I believe this is the case. I know of no program that can responsibly provide the level of service and documentation demanded by Medicare at the new rate. I would be suspicious of any that said they could.

We are requesting that CMS not go forward with the proposed CY 2007 15% rate cut for Partial Hospitalization (PHP) and psychiatric Outpatient Services. Coupled with last year's 12.5% reduction for PHP, the proposed rate will make it impossible to cover the costs needed to provide an intensive program.

We strongly support the position of the Association of Ambulatory Behavioral Healthcare regarding their proposed considerations, as the response from the organization goes into specific detail concerning the long reaching effects the rate cut will have on the patients who are in need of outpatient psychiatric services.

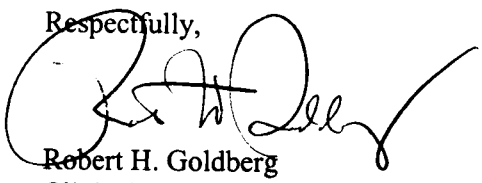
We believe that the cuts are likely to result in closing of many programs. This is likely to lead to an increased use of higher cost services, with detrimental affects on patients, families, communities, and budgets. The cost of reestablishing such services when the need is realized will be far greater than continuing well established services. The perception of unstable funding and lack of commitment to a reasonable payment methodology will make many hospitals and other provider organizations reluctant to reestablish needed programs when the need is realized in the future. In sum, I have reason to believe this cut would have disastrous negative effects on this country's Mental Health infrastructure for many years to come.

These less expensive outpatient programs need to be supported by reasonable reimbursement rates that adequately cover the costs of providing the services.

We are asking CMS to allow time and resources to develop a reasonable payment methodology by working with provider and community organizations who would welcome the opportunity to work with CMS to develop a payment rate that is fair, consistent and predictable.

Thank you, for the opportunity to respond to this critical issue.

Respectfully,



Robert H. Goldberg
Clinical Manager
Acute Partial Hospital Program

2006

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CEDAR LAKE SURGERY CENTER

October 06, 2006

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1506-P - Medicare Program; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List

Dear Dr. McClellan:

I am the Administrator of Cedar Lake Surgery Center in Biloxi, Mississippi. Each year, our surgery center provides approximately 2,000 procedures to approximately 1,700 Medicare beneficiaries. Medicare patients represent approximately twenty-five percent of our business and ensuring appropriate payment for their services is vital to our ability to serve our community. Please accept the following comments regarding Section XVII of the proposed rule, which would make revisions to policies affecting ambulatory surgical centers for CY 2007. 71 Fed. Reg. 49505 (August 23, 2006).

I. Proposed ASC List Update Effective for Services Furnished On or After January 1, 2007

A. Criteria for Additions to or Deletions from the ASC List

I commend CMS for proposing to update the ASC list for CY 2007, but believe the update falls short by not making extensive revisions to the criteria used to determine which procedures may be reimbursed in the ASC setting. As a result, beneficiary access to ASC services will continue to be limited by arbitrary criteria in CY 2007.

1. The inclusionary ASC list should be abandoned.

The limited, inclusionary list of covered ASC procedures is no longer the best way to address the safety and appropriateness of ASC services. Within currently accepted standards of medical practice - in which vast numbers of procedures may performed in a variety of outpatient settings - use of the ASC list has undesired consequences for the most optimal delivery of outpatient procedural services.

First, and most importantly, the ASC list limits the ability of physicians to select the site of service they believe is most clinically appropriate for their patients. A physician's assessment

1720 B Medical Park Drive, Biloxi, MS 39532 PHONE 228.702.2000 FAX 228.702.2018

performed in a variety of outpatient settings - use of the ASC list has undesired consequences for the most optimal delivery of outpatient procedural services.

First, and most importantly, the ASC list limits the ability of physicians to select the site of service they believe is most clinically appropriate for their patients. A physician's assessment of the medical needs of the patient and the capabilities of the facility should determine whether a patient receives care in the ASC setting.

Second, the list limits Medicare beneficiaries' access to procedures that many other patients routinely receive in ASCs. Private payers do not restrict the access of their insureds to ASC services. Decisions regarding the site of service are recognized to be the province of the insured's physician. As a result, several minimally invasive procedures not available to Medicare patients in the ASC setting, such as spinal disc decompression and laparoscopic cholecystectomy, are commonly performed for selected privately insured patients - at significant savings to the patient and to the insurer. As long as CMS continues to maintain an ASC list, Medicare beneficiaries' access to appropriate services will always lag behind that of the private sector.

The ASC list should be abandoned. In its place, CMS should adopt the recommendations of the Medicare Payment Advisory Commission (MedPAC) and develop a list of services specifically excluded from coverage. In fact, CMS already has such an exclusionary list; for purposes of hospital outpatient payment under the Outpatient Prospective Payment System, CMS has developed and uses an "inpatient only" list. Because Medicare-certified ASCs have proven over the past two decades that they are capable of safely performing the same scope of services provided in hospital outpatient departments, this list may also be used to identify procedures excluded from coverage in ASCs.

Alternatively, if CMS develops a separate exclusionary list for ASCs, then that list should be based on the criteria identified by MedPAC in their March 2004 report. Specifically, MedPAC recommended the current list of ASC approved procedures by replaced "with a list of procedures that are excluded from payment based on clinical safety standards and whether the service requires an overnight stay".

2. The criteria used to revise the Medicare list of procedures that may be performed in an ASC are outdated and do not serve the interest of the Medicare program or its beneficiaries.

Section 1833(i)(1) of the Social Security Act requires CMS to determine which surgical services are safely and appropriately offered in an ASC. CMS selects the services represented on the current list of approved procedures based on criteria outlined in the Code of Federal Regulations at §416.65. I believe CMS is inappropriately limiting beneficiary site-of-service choices by continuing to make procedure list determinations using obsolete and outdated criteria that CMS itself previously proposed to substantially revise (63 Fed. Reg. at 32298).

a. Requirement that procedures be commonly performed in an inpatient setting.

When the Medicare ASC benefit was originally implemented in the 1980s, most surgical procedures were performed in an inpatient setting. In the intervening decades, the outpatient setting has become the accepted setting for many types of surgical procedures. As new clinical approaches to surgery, anesthesia and pain management have been incorporated into standard medical practice, certain procedures have moved almost exclusively to the outpatient environment. New procedures have evolved that were never commonly performed in an inpatient setting. Examples include newer arthroscopic and endoscopic interventions, and surgical treatments using laser or radiofrequency instrumentation. These procedures were developed predominately in an outpatient setting and are performed safely and cost-effectively on thousands of commercial insurance and self-pay patients each year.

To continue to require that a procedure be commonly performed in the inpatient setting before it can be deemed appropriate for the ambulatory surgery setting is no longer consistent with current standards of practice. I recommend general standard (1) "Covered surgical procedures are those surgical and other medical procedures that are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC" be eliminated as obsolete. This recommendation is also supported by MedPAC's 2004 report which specifically states, "it no longer makes sense to consider inpatient volume when updating the ASC list."

c. Requirement that a procedure not be commonly performed in physicians' offices

Current CMS guidelines provide that a procedure performed 50 percent or more of the time in a physician's office cannot be reimbursed in an ASC. In effect, this limits a physician's options to an inpatient or HOPD setting for patients for whom an office setting would be inappropriate. The higher costs generally associated with inpatient and HOPD reimbursement as compared to ASC reimbursement rates have been well documented by the OIG and MedPAC. Eliminating ASCs as an option for procedures which can be safely performed in the outpatient setting imposes unnecessary costs on both the Medicare program and individual beneficiaries. Conversely, allowing ASCs to serve as a site-of-service option to HOPDs for care has allowed the Medicare program to achieve significant cost savings.

While physicians may safely perform many procedures on healthy Medicare beneficiaries in the office setting, sicker beneficiaries may require the additional infrastructure and safeguards of an ASC to maximize the probability of a good clinical outcome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his specific condition. Even when a procedure is frequently performed in an office there are circumstances when the office is an inappropriate or unavailable setting. A brief summary of these factors follows.

Patient Characteristics – Patient characteristics affect the selection of the appropriate site of service. Factors such as body habitus, comorbid conditions and even

the patient's ability to lie in certain positions or hold still for long periods of time may affect whether a procedure can or should be performed in a physician office.

Another consideration is whether other procedures are being performed at the same time. If a patient is having a procedure performed in an ASC and another procedure that can be performed in an office is also needed, the patient and the Medicare program benefit from having both procedures performed at the same time.

Additionally, a procedure may be scheduled for a facility when the physician thinks it likely that a diagnostic procedure will result in the need for a therapeutic intervention. For example, a diagnostic cystoscopy (CPT code 52000) may be scheduled at an ASC because the physician thinks it likely that a cystoscopy with biopsy (CPT code 52204), requiring instruments and cautery not available in the office, will be necessary.

Procedure Differences –Procedures that are coded the same are not always identical. To some extent, the variations found in site of service may reflect the variation in procedures within the same CPT code. A prostate needle biopsy, 55700, provides a good example. The number of biopsies described by this code varies widely according to practice patterns. Some physicians routinely take 12-20 biopsies. Due to the more invasive nature of multiple biopsies, conscious sedation is used, making a facility the more appropriate setting unless the performing physician has specialized staff and equipment.

Office Differences – Physician offices vary greatly in terms of equipment and personnel. To a great extent, this varies based upon the volume in the office. A small office may simply not be able to afford certain equipment. Offices also have vastly different personnel. For example, some offices have certified registered nurse anesthetists or nurses trained in advanced cardiac life support and others do not. The procedures that can be performed in an office vary greatly based upon the staff available to assist the physician performing the procedure.

Medical Liability Policy Differences – In order to lower premiums for medical liability insurance, physicians may agree not to perform certain procedures in their office. For example, policies may vary in the types of surgery covered or the types of anesthesia covered.

State Laws and Regulations – State laws and regulations impose limitations on what can be done in offices. To be able to perform certain types of procedures, these state provisions may require specific equipment, staff or even accreditation. If the office does not meet these requirements, these procedures cannot be performed in the office. For example, Indiana prohibits physicians that do not have specified continuing medical education in anesthesia from performing surgery involving conscious sedation in an office setting. Also, some state regulations limit anesthesia in the office to patients in certain American Society of Anesthesiologists (ASA) physical status classifications, meaning that some patients can have procedures involving anesthesia in the office but others cannot.

As was noted in the preamble to the interim final rule of May 2005, the rate of performance in ASCs of the physician office procedures originally proposed for deletion has remained relatively stable over the past 10 years. In other words, the inclusion of these procedures on the ASC list has not induced substantial shifts in sites of service, which suggests site-of-service selection is being driven by clinical need. If CMS remains concerned about the potential for financial incentives to improperly influence site-of-service selection, then the logical solution is to address any unjustified payment variations in the new payment system, rather than denying ASC coverage for procedures commonly performed in physician offices.

MedPAC has also recommended that CMS abandon the requirement that procedures be performed less than 50 percent of the time in physician offices to be added to the list. The Commission has specifically stated, "Physicians should have the discretion to decide which setting is most clinically appropriate for individual patients."

c. Operating and recovery time limits are unnecessary.

The ASC industry supported CMS's 1998 proposal (63 Fed. Reg. at 32298) to discontinue using the time limits on operating, anesthesia, and recovery time currently defined under 42 C.F.R. § 416.65(b), which are used as a basis for determining whether a procedure should be added to or deleted from the ASC List. The numeric threshold rules presently employed by CMS are obsolete and too often result in the exclusion of procedures that are entirely appropriate for the ASC setting. The current rule that the ASC List should be restricted to procedures that generally do not require more than 90 minutes operating time or 4 hours recovery time is outdated. This standard was developed in the early 1980s and predates numerous technological advances that are now standard in the ASC setting. Both thresholds are arbitrary and without clinical significance.

As MedPAC has observed, these time requirements are "unnecessarily rigid," particularly given the numerous technological advances that are now standard in the ASC setting. With the development of short-acting general anesthetics, the length of operating time is immaterial in determining whether a procedure is appropriately performed in an ASC. The key question is when is the patient ready to be discharged, not how long the surgery takes. Moreover, with respect to the four-hour limit on recovery time, a number of states have expanded the concept of "ambulatory" over the 20 years by permitting ASCs to perform procedures requiring stays of up to 24 hours.

B. Procedures Proposed for Addition to the ASC List

I commend CMS for updating the ASC list again for 2007. These regular updates help ensure Medicare beneficiaries have access to more of the services ASCs routinely and safely offer to non-Medicare patients.

All of the proposed additions are clearly clinically appropriate. However, we are concerned the payment group assignments for certain of the procedures will result in reimbursement at a level insufficient to cover the cost of performing the procedure.

I am concerned about the payment group assignment for CPT code 22522, which describes percutaneous vertebroplasty performed at additional levels. The proposed payment group assignment is a Group 1 ($333.00). The cost of the kit used at each level varies from $700 to $1400, depending on the supplier (Stryker, Arthrocare). Therefore, the proposed level of reimbursement would not be sufficient to cover supply costs for the procedure. In light of this, we recommend revising the payment group assignment to a Group 9 ($1339.00). Because this particular code is an add-on code, and therefore will always be subject to multiple procedure payment reduction, even assignment to payment Group 9 will only cover supply costs. Further, using the median cost information supplied in the HOPD, CMS has established the APC payment for this service at $1542.47. I believe the HOPD data is a more reliable proxy for the cost of providing this and many other services.

I am also concerned about CPT codes 37205 and 37206, which describe transcatheter placement of an intravascular stent. The proposed payment group assignments are Group 9 ($1339.00) and Group 1 ($333.00), respectively. The cost of the intravascular stent averages $1725 (see CMS's 2005 file which calculates device related percentages for APC 0229), which exceeds the current maximum Group 9 reimbursement level. Therefore, no level of reimbursement currently available to ASCs would be sufficient to cover the device costs for these procedures. Unfortunately, there is no real opportunity for ASCs to receive separate reimbursement for the stent. Because there is no specific Level II HCPCS code that describes this stent, this device would have to be reported using L8699. ASCs experience considerable difficulty securing reimbursement from Medicare carriers for devices reported using L8699. In light of this, we believe ASCs will not be able to cover the costs of performing these procedures under the current reimbursement methodology. However, we still believe CMS should add the procedures to the list because they are clinically appropriate services and doing so will allow those patients whose private health plans look to CMS's ASC list for coverage decisions to access these procedures in the ASC setting.

C. Suggested Additions Not Accepted

1. Procedures suggested for addition, but not accepted because they are commonly performed in physician offices

Many procedures that were suggested through public comment for addition were rejected on the basis that they are commonly performed in the physician offices. CMS has determined if a procedure is performed 50 percent or more of the time in the office setting, it is inappropriate for addition to the ASC list. CMS relies on Part B claims data when determining the frequency with which procedures are performed in various settings. However, it has been well established by the OIG that site of service reporting on physician claims can be a highly unreliable indicator of the actual site of service;

significant error rates (80 % and higher) for selected services have been reported. Given the probability of significant flaws in the data CMS uses to make these decisions, we do not believe continued reliance on this data is appropriate.

As noted above, there is no evidence that including procedures on the ASC list that are frequently performed in the office setting leads to overutilization of those procedures in the ASC setting. CMS itself has acknowledged that inclusion of certain services on the ASC list - although commonly performed in the physician office - has not resulted in excessive utilization of ASCs (70 Fed. Reg. at 23696).

Most of the procedures CMS has indicated it will not add to the ASC list are typically performed as secondary procedures for non-Medicare beneficiaries. Failure to add the requested procedures because they are commonly performed in the office setting deprives both the Medicare program and its beneficiaries of the efficiencies of care and added affordability that other patients enjoy as a result of use of the ASC setting.

For example, there are patients requiring endoscopic evaluation for reanastomosis following a partial colectomy with colostomy, in which both a colonoscopy via stoma (CPT code 44388) and flexible sigmoidoscopy (CPT code 45330) are needed for a complete evaluation. Non-Medicare patients can have both procedures performed at the same session in an ASC. This is not the case for Medicare beneficiaries. While the colonoscopy via stoma (CPT code 44388) is an ASC list procedure, the flexible sigmoidoscopy (CPT code 45330) is not. In order to have both procedures performed concurrently as an outpatient, the Medicare beneficiary must been seen at the HOPD.

Not only does this policy lead the Medicare program to miss opportunities for efficiencies of care, it also costs both the program and its beneficiaries significantly more. Having both these procedures performed in an HOPD costs the Medicare program $649.44, with a minimum beneficiary copayment of $129.89. If the Medicare program would allow the flexible sigmoidoscopy in the ASC setting, assuming a Group 1 payment assignment, the cost of the two procedures together would be $458.82, with a beneficiary copayment of $91.76.

As is the case with many procedures commonly performed in the physician office, there are certain patients whose medical condition requires a procedure be performed in a facility setting. In the case of flexible sigmoidoscopy, this would include patients with anal stenosis and anastomotic strictures, who require sedation for a humane examination. Current CMS policy does not allow these patients to access care in the more affordable ASC setting.

Though certain procedures are commonly performed in the office setting, the physician should not be restricted in the exercise of professional judgment when determining the most appropriate site of service. Hospital outpatient departments are not restricted in their ability to serve as the site of service when the physician determines the office setting will not meet the needs of the patient. When medically necessary, ASCs should also be an option for those Medicare beneficiaries requiring the services of a

facility for appropriate and safe care. Therefore, we urge CMS to reconsider its decision to forgo adding the services presented in Table 42 (71 Fed. Reg. at 49629) because they are predominantly performed in the physician office.

2. Procedures suggested for addition, but not accepted because CMS states they do not meet current clinical criteria

a. Osteochondral arthroscopic grafting

Several commenters suggested the addition of CPT codes 29866 and 29867 describing arthroscopic knee procedures in which osteochondral autografts or allografts are placed. These procedures meet the current clinical criteria for addition to the ASC list. Surgery and anesthesia times are under 90 minutes, and recovery times generally average four hours. As with other arthroscopic knee procedures, blood loss is minimal.

b. Laparoscopic cholecystectomy

A number of commenters suggested the addition of CPT codes 47562, 47563, and 47564 describing laparoscopic cholecystectomies. The first laparoscopic cholecystectomy performed in the United States was performed at an ambulatory surgical center in 1988. Now, these procedures are commonly performed for non-Medicare patients in the ASC setting. Although CMS has not included these procedures on the ASC list to date, CMS data shows these procedures are routinely performed on an outpatient basis in Medicare patients; Medicare volume data shows these procedures were being performed on an outpatient basis 51%, 48% and 24% of the time, respectively.

CMS indicated it was not including these procedures on the ASC list because an overnight stay would often be required for Medicare patients. In light of the volume data presented above, we believe many Medicare beneficiaries are having laparoscopic cholecystectomies performed without an overnight stay in the HOPD. I recognize an ASC will not be the appropriate site for all Medicare beneficiaries. However, by not adding these procedures to the ASC list, CMS effectively denies all Medicare beneficiaries access to the ASC.

CMS has also rejected the procedures on the basis of "a substantial risk that the laparoscopic procedure will not be successful and that an open procedure will have to be performed instead." (70 Fed. Reg. at 23700). CMS stated that if an open procedure were required, the patient would have to be transported to the hospital for the procedure.

It is unclear what clinical data was used to determine "substantial risk." The literature contains many studies of laparoscopic cholecystectomy in a variety of surgical settings, with different patient populations and differing levels of patient acuity. I am aware of just one recent study which exclusively evaluated the outcomes of outpatient ambulatory laparoscopic cholecystectomy in the United States, as reported by Lau and Brooks in the World Journal of Surgery in September of 2002. In this retrospective

analysis of 200 procedures, no patient required conversion to an open cholecystectomy. While conversion to an open cholecystectomy is possible, it is not common. In fact, based on available data, the risk appears to be slight rather than substantial.

When determining the site of service for an ambulatory elective laparoscopic cholecystectomy, the surgeon may be rigorous in the application of patient selection criteria, thereby minimizing the risk of a subsequent conversion to an open procedure. This is not the case when the patient requires an emergent procedure. It is true that laparoscopic cholecystectomies are converted to open procedures at a rate of 5 to 10 percent in national studies of *hospital* discharge data (Livingston and Rege, American Journal of Surgery, September 2004). However, these conversion rates reflect procedures performed in the hospital setting, in unselected patient populations, and under both emergent and elective conditions.

Finally, it is important to note that if the laparoscopic approach is unsuccessful in the ASC setting, the patient does not have to be transported to the hospital for the open procedure. Generally, the laparoscopic procedure can be converted to an open procedure and completed at the ASC. The patient is then transported to the hospital following completion of the procedure and postoperative stabilization. Again, the application of patient selection criteria would make such conversions a rare occurrence.

c. Lumbar disc decompression

CPT code 63030 describes lumbar disc decompression. As a result of today's minimally invasive approaches, more of these procedures are being safely and successfully performed in the outpatient setting. Anesthesia and operating times are less than 90 minutes. Though recovery times can extend beyond four hours, these procedures can be performed without an overnight stay. As we noted above, we believe the continued imposition of specific operating and recovery time limits is unduly restrictive, a point which has been recognized by MedPAC and CMS itself in the past. Patients with private insurance routinely have these procedures performed in the ASC setting and therefore we urge CMS to allow Medicare patients to access these procedures in the ASC setting as well.

D. Other Appropriate Additions Not Addressed in the Proposed Rule

In this notice of proposed rulemaking, CMS proposes to add CPT codes 13102, 13122 and 13133 to the ASC list effective January 1, 2007. CPT code 13153 is also included in this series of codes and describes complex repair of the eyelids, nose, ears and/or lips in excess of 7.5 cm in size. However, this code is not currently on the ASC list, nor has CMS proposed its addition. By definition, complex repairs require time-consuming interventions such as scar revision, debridement, and extensive undermining. Work on the areas of the face described by this CPT code requires meticulous attention to detail for optimal outcomes, and a repair of this magnitude adds to the complexity of the procedure. Time in the operating room may be significantly extended by each additional 5 cm requiring this type of repair. All the other codes in this series, 13150-13152, are

currently on the ASC list and assigned to payment group 3. Excluding more extensive repairs from the ASC setting is not consistent. Based its similarity to the other proposed additions, CPT code 13153 should also be added to the ASC list effective January 1, 2007.

CMS should also add G0289, which describes a knee arthroscopy for removal of a loose body, foreign body, or chondroplasty concurrent with another surgical knee arthroscopy in a different compartment of the same knee. CMS guidelines stipulate that G0289 may only be reported when the procedures described by this code require at least an additional 15 minutes of operating time. The use of this amount of additional operating room time – with attendant staff, equipment and supplies – should be recognized for additional reimbursement. Therefore we urge CMS to add G0289 to the ASC list effective January 1, 2007.

There are several procedures that are appropriate additions to the ASC list. I believe that CMS should add these procedures to the list with an effective date of January 1, 2007.

CPT Code	**Descriptor**
20610	Arthrocentesis, aspiration and/or injection; major joint or bursa
27096	Injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid
43257	Upper gastrointestinal endoscopy with delivery of thermal energy to the lower esophageal sphincter
62290	Injection procedure for diskography, each level; lumbar
62291	Injection procedure for diskography, each level; cervical or thoracic
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion with programming
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
64402	Injection, anesthetic agent; facial nerve
64405	Injection, anesthetic agent; greater occipital nerve
64408	Injection, anesthetic agent; vagus nerve
64412	Injection, anesthetic agent; spinal accessory nerve
64413	Injection, anesthetic agent; cervical plexus
64418	Injection, anesthetic agent; suprascapular nerve
64425	Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves
64435	Injection, anesthetic agent; paracervical (uterine) nerve
64445	Injection, anesthetic agent; sciatic nerve, single
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter
64505	Injection, anesthetic agent; sphenopalatine ganglion
64508	Injection, anesthetic agent; carotid sinus (separate procedure)
64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)

64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g. for blepharospasm, hemifacial spasm)

II. Proposal to Modify the Current ASC Process for Adjusting Payment for New Technology Intraocular Lenses

I am supportive of CMS's plans to streamline the process of recognizing intraocular lenses that qualify for a payment adjustment as a new technology intraocular lens (NTIOL). I also agree it would be more efficient to incorporate this into the annual update of ASC rates for the following calendar year. Including a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published would be very helpful, but we do not believe the proposed 30 day comment period is sufficient. Given the highly technical nature of NTIOLs, we believe a 60 day comment period would be more appropriate.

While we also generally agree with the list of examples of superior outcomes provided by CMS, we believe any revision of §416.195 should make it clear that these are strictly examples. Given the rapid pace of technological advances, it would be unfortunate if the revised language did not provide sufficient flexibility to accommodate future innovations because they are not specifically outlined as a superior outcome. Specifically, we suggest §416.195(a)(4) be modified to read, "Evidence demonstrated that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Examples of superior outcomes include, but are not limited to:".

I am also concerned about CMS's proposal to revise the language at §416.190 to require that the content of each request for an IOL review include information specified on the CMS web site. It is our belief that the items CMS finds necessary for review should be published in the Federal Register, as any change in regulation should be open to review and comment by the public before being implemented.

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Thank you for considering our comments. If you have any questions or need additional information, please do not hesitate to call me at 228-702-2000.

Sincerely,

Michael T. Gossman
Administrator