Submitter : **Ms. Brette McClellan** **Date: 11/06/2006**

Organization : **Alcon**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1506-P2-1092-Attach-1.DOC

CMS-1506-P2-1092-Attach-2.DOC

CMS-1506-P2-1092-Attach-3.WPD

#1092

November 6, 2006

ALCON LABORATORIES, INC.
6201 South Freeway
Fort Worth, Texas 76134-2099
(817) 293-0450

Via Electronic Mail

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

Re: Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-1506-P)

Dear Ms. Norwalk:

Alcon appreciates the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) Proposed 2008 Revised Ambulatory Surgical Center Payment System rule (CMS-1506-P, Federal Register, Vol. 71, No. 163, Tuesday, August 23, 2006, p. 49505). Alcon is the world's leading manufacturer of ophthalmic surgical supplies and devices that are used in procedures to treat cataracts, glaucoma, vitreoretinal diseases, corneal diseases, and other ocular disorders. A large percentage of ophthalmic surgical procedures are performed in ASCs. Thus, ophthalmic device manufacturers are significant stakeholders in the outcome of the new Ambulatory Surgical Center prospective payment system (ASCPPS).

Below we provide comments on the following five recommendations:

1. A uniform methodology for calculating payment rates should be applied consistently across all procedures and specialties
2. Devices that are eligible for new technology pass-through payments under the OPPS should receive comparable new technology payments in the new ASCPPS.
3. Office-based procedures should be added selectively to the ASC list of allowable procedures.
4. CMS should use the alternative model for determining the conversion factor and make corrections and changes to the calculations associated with that model.
5. The annual inflation update to the ASCPPS beginning in 2010 should not be different from the market basket update used in the OPPS.

1. **A uniform conversion factor for calculating payment rates should be applied consistently across all procedures and specialties.** In a new system that links ASC

payment rates to OPPS payment rates, it is unavoidable that payment rates for some procedures will be significantly reduced, because there was no formula-driven correlation between costs and payment rates in the old system. It would be inequitable to attempt to shelter a subset of procedures from this disruption by using a higher conversion factor for that subset, because the conversion factor for all other procedures would be significantly reduced to maintain budget neutrality. Total Medicare payments to ASCs are small as compared to total Medicare payments in other systems such as IPPS and OPPS. In a budget neutral environment, the small size of the ASC payment system makes it highly sensitive to deviations affecting one part of the system. The effect on the remaining parts of the system would be substantial, unjustified, and unpredictable.

Similarly, shielding high-cost devices from the effects of the conversion factor would signal that access to certain high-cost implantable devices in ASCs is more important than access in ASCs to all of the other devices, items, and services. Special protections for a limited group of device-dependent procedures would dilute the payment rates for all other services and should not be incorporated within the final regulation.

It is appropriate for CMS to mitigate the effects of payment rate changes by phasing in payment increases and decreases over a period of time for all procedures in the new system. We believe that the two-year phase-in proposed by CMS should be extended to at least three years.

2. **Devices that are eligible for new technology pass-through payments under the OPPS should receive comparable new technology payments in the new ASCPPS.** Currently, there are site-of-service differences in access to new technologies that are eligible for additional payment under the OPPS Transitional Pass-Through Payment System. Examples include perfluorocarbon liquid (C1784, ocular device, intraoperative, detached retina) and silicone oil (C1814, retinal tamponade device, silicone oil). While these categories were active in the OPPS, there was no additional payment to ASCs for these higher cost devices. Thus, patients undergoing retinal surgery in ASCs did not have access to them, whereas patients undergoing the same procedures in a HOPD did have access. In theory, patients who would have benefited clinically from these devices could have been referred to a HOPD. In practice, however, there are two factors that could have interfered with the decision to choose the HOPD setting: (1) most ASCs and physicians who do most of their surgery in ASCs were not aware of the additional payment for these devices in HOPDs, and (2) physicians who have an ownership interest in the ASC would be hurt financially by performing the surgery in a HOPD. Surgeons are passionate about achieving the best outcomes for their patients. Nonetheless, it is not good policy for site-of-service access disparities to create the potential for interference with clinical decision-making.

   Once CMS determines that it will establish a new-technology device pass-through payment category, the C-code and comparable additional payment should automatically be applicable in the ASC payment system. We recognize that

additional pass-through payments are calculated using HOPD-specific cost-to-charge ratios (CCRs) and that CCRs do not exist in the ASC payment system. We believe there are feasible solutions to this, such as using the average CCR of local HOPDs as a substitute for an ASC's CCR.

3. **Office-based procedures should be added selectively to the ASC list of allowable procedures.** In general, improvements in technology and techniques allow many surgical procedures to transition naturally from inpatient to outpatient settings and from HOPDs and ASCs to the physician's office. When the physician is an owner of an ASC, adding office-based procedures to the ASC list may affect this transition by creating a perverse incentive for office-based procedures to migrate to the ASC setting for purely financial reasons. In the proposed new system, the sum of the capped ASC payment plus the physician (facility) fee is greater than the physician (office) fee. We know from experience with ophthalmologists that the vast majority choose the setting that is best for their patients; however, it is not good policy for anomalies in payment systems to work against the clinically-based transition of procedures from one setting to another.

   We recommend that CMS carefully consider the input from specialty societies to determine which office-based procedures should be added to the ASC list. While some procedures should not be added for the reason described above, there are many procedures for which physicians have very valid reasons for selecting an ASC rather than the office. The patient's clinical condition might dictate that the ASC is the most appropriate environment for surgery. There may also be procedures for which only a few practices have the equipment and staffing level to properly perform an office-based procedure.

   Adding the office-based procedures for which there is sound rationale for the ASC setting is good policy, but adding office-based procedures for which there is no such rationale only serves to overburden an already-small payment system with procedures that do not belong there. The result of the latter is an unjustifiably lower conversion factor for the procedures that do belong there.

4. **CMS should use the alternative model described in the proposed rule for calculating the budget neutrality adjustment and make corrections and changes to the calculations associated with that model.** We believe that the best approach is the one that takes into account the migration of procedures between ASCs, physicians' offices, and HOPDs. We urge CMS to make the alternative approach more accurate by carefully considering the suggestions and observations from numerous commenters. For example, annual spending on surgical devices paid separately from the DMEPOS fee schedule to ASCs should be included in the numerator of the conversion factor, and total NTIOL payments made to ASCs in 2007 should be included in the numerator.

5. **The annual inflation update to the ASCPPS beginning in 2010 should not be different from the market basket update used in the OPPS.** CMS proposes to

adjust the ASC payment rates for inflation using the Consumer Price Index for urban areas (CPI-U) beginning in 2010. However, CMS updates the OPPS conversion factor using the hospital market basket. While the existing ASC payment system is required by statute to update rates using the CPI-U, the Medicare Modernization Act (MMA), which authorized the revision of the existing ASC payment system, does not require that CPI-U be used as the inflationary factor under the revised system. Therefore, in order to establish and maintain parity between the OPPS and ASC systems, we recommend that the ASC rates be updated using the hospital market basket. Using the market basket instead of CPI-U will ensure that procedures that are performed in both the outpatient and ASC settings receive the same inflationary updates so that future ASC and HOPD payment rates move in parallel to each other. We recommend that both the OPPS and ASC rates should be updated using the hospital market basket.

Alcon appreciates the hard work that the agency has put into creating its proposal, and we realize that there are myriad complexities that make reforming the ASC payment system a very challenging task. Reviewing the comment letters will no doubt be equally challenging as CMS attempts to assimilate and consider recommendations from different stakeholders. We anticipate that CMS will change several aspects of its proposal in response to these comments. Therefore, we strongly suggest that the public be given another chance to comment after CMS responds to comments on its first proposal and prior to the publication of a final rule.

Sincerely,

Brette McClellan
Director
Health Policy Government Relations

Submitter : **Ms. Heidi Vehko** **Date: 11/06/2006**

Organization : **DSA Surgery Center**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1506-P2-1093-Attach-1.PDF

#1093

November 6, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
ATTN: CMS-1506-P or CMS-4125-P
PO BOX 8011
Baltimore, MD 21244-1850

To whom it may concern:

I oppose the proposed rule for the revised payment system for Ambulatory Surgery Centers scheduled for implementation on January 1, 2008 for the following reasons:

- Physicians must retain the ability to choose which type of facility best meets their patients' needs clinically.
- Patients should not be forced to limit their choices of procedure facilities.
- In order for ASC's to survive they must be adequately compensated for their services, comparable to hospital reimbursement, not 38% less.
- ASC's have proven to be more economical for the patient due to the higher charge for the same procedure performed in a hospital setting.
- ASC's are more convenient for patients, and safer due to documented lower infection rates compared to hospitals.
- These proposed changes would force smaller ASC's to close. This would further limit patient choices and adversely impact the lives of the health care employees in those facilities.

Sincerely yours,

H. Vehko, BS, MPA
Administration/HRM
DermSurgery Associates, PA/DSA Surgery Center
7515 Main Street Suite 240
Houston TX 77030

Submitter : Ms. PATRICIA BEAM **Date:** 11/06/2006

Organization : CLEVELAND AMBULATORY SERVICES

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

WE FEEL THAT THE ASC LIST REFORM PROPOSED BY CMS IS TOO LIMITED. WE FELL CMS SHOULD EXPAND THE ASC LIST OF PROCEDURES TO INCLUDE ANY AND ALL PROCEDURES THAT CAN BE PERFORMED IN THE HOPD. CMS SHOULD EXCLUDE ONLY THOSE PROCEDURES THAT ARE ON THE INPATIENT ONLY LIST. WE FEEL THE ASC'S SHOULD BE UPDATED BASED UPON THE HOSPITAL MARKET BASKET BECAUSE THIS MORE APPROPRIATEDLY REFLECTS INFLATION IN PROVIDING SURGICAL SERVICES THAN DOES THE CONSUMER PRICE INDEX. ALSO, THE SAME RELATIVE WEIGHTS SHOULD BE USED IN ASC'S AHD HOSPITAL OUTPATIENT DEPARTMENTS. ALIGNING THE PAYMENT SYSTEMS FOR ASC'S AND HOSPITAL OURPATIENT DEPARTMENTS WILL IMPROVE THE TRANSPARENCY OF COST AND QUIALITY DATA USED TO EVALUATE OUTPAPTIENT SURGICAL SERVICES FOR MEDICARE BENEFICIARIES. WE BELIEVE THAT THE BENEFITS TO THE TAXPAYER AND THE MEDICARE CONSUMER WILL BE MAXIMIZED BY ALIGNING THE PAYMENT POLICIES TO THE GREASTEST EXPENT PERMITTED UNDER THE LAW. WE FEEL TO ASSURE MEDICARE BENEFICIARIESS' ACCESS TO ASC'S, CMS SHOULD BROADLY INTERPRET THE BUDGET NEUTRALITY PROVISION ENACTED BY CONGRESS. WE FEEL 62% IS SIMPLY NOT ADEQUATE. WE ARE CONCERNED FOR OUR CURRENT PATIENTS AND FUTURE PATIENTS THAT THEY ARE OFFERED THE OPTION TO COME TO AN ASC SETTING VERSUS A HOSPITAL OUTPATIENT SETTING.

Submitter : Mr. Thomas Buckley **Date:** 11/06/2006

Organization : Naples Day Surgery, LLC

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

I would like to request strong consideration be given to reimbursing ASC's no less than 75% of what hospital outpatient departments are paid for the same procedure. At our facility, Medicare makes up 45% of our patient mix. We have to pay our staff fairly to ensure we have quality nurses caring for our patients. Our fees have been frozen for some time and will continue to be frozen. Our wages have increased in order to retain staff in our high insurance and high fuel cost area of the state. We have had two multispecialty ASC's within 10 miles close within the past 12 months (Bonita Bay Surgery Center and Colonnade Surgery Center). When ASC's close and patients go to hospitals for care, it costs CMS and all taxpayers more money. ASC's have a mind set to operate efficiently and control costs. However, they will not operate at a loss to subsidize Medicare patients. It would seem prudent for CMS to pay ASC's fairly to ensure they are around to continue to provide high quality low cost care to Medicare patients. I believe reimbursing ASC's at 62% will result in the closure of many ASC's and ultimately will cost CMS more money due to Medicare patients having their treatment in the higher cost hospital settings. Thank you for your consideration.

Submitter : **Dr. Leonard Goldberg** **Date: 11/06/2006**

Organization : **DermSurgery Associates**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare & Medicaid Services
Department of Health & Human Services
ATTN: CMS-1506-P2
P.O. Box 8011
Baltimore, MD 21244-1850

November 6, 2006

To whom it may concern:

I am writing to express my concern about the proposed changes to the ASC payment schedule. I feel that the changes regarding ASC costs and payment are based on inaccurate assumptions. As it stands, inaccurate rates in hospital outpatient methodology are being carried into ASC payment schedules. Site of service decisions should not be forced to be based on financial factors rather than clinical appropriateness. These proposed payment changes would limit the transition of procedures associated with ASC settings and also limit beneficiary access. Please consider these points in your review of the proposed changes to the ASC payment system.

Sincerely,

Leonard H. Goldberg, MD
DermSurgery Associates
7515 Main Street, Suite 240
Houston, Texas 77030
713-791-9966

Submitter : Mr. Ken McDonald **Date:** 11/06/2006

Organization : AmSurg

Category : Ambulatory Surgical Center

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-1097-Attach-1.DOC

1097

AMSURG
AMERICA'S SINGLE SPECIALTY SURGERY CENTER LEADER

NOVEMBER 6, 2006

VIA HAND DELIVERY

The Honorable Leslie Norwalk, Esq.
Acting 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; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Administrator Norwalk:

AmSurg is America's single specialty surgery center leader, with 153 centers in 31 states and the District of Columbia. We develop, acquire, own and operate ambulatory surgery centers (ASCs) in partnership with physician practices, and unlike many competing ASC firms, most of our centers focus on procedures related to a single medical specialty such as gastroenterology (GI) (104 centers) or Ophthalmology (42 centers). We believe this specialization makes us the most efficient operator in the industry, and provides us with exceptional insight into the economics associated with common GI and eye procedures. We also maintain a very high level of commitment to quality care at our facilities. All AmSurg centers are Medicare certified, and a majority are accredited by JCAHO or the Accreditation Association for Ambulatory Health Care (AAAHC). Large insurers contract with AmSurg ASCs as a preferred provider for their enrollees, and surveys indicate our patients are highly satisfied with the level of care they receive. Because of our geographic reach, specialty focus, cost efficiency, and commitment to quality, we believe we are exceptionally well-qualified to comment on the patient access and economic impacts of proposed changes to the Medicare ASC Payment System.

We provide the following comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Revised Ambulatory Surgical Center Payment System for Implementation January 1, 2008. 71 Fed. Reg. 49,506 (Aug. 23, 2006).

AmSurg strongly supports, and endorses with our signature, the comments filed on behalf of the ASC community. Because of our particular focus on single specialty ASCs, we would like to use these separate comments to emphasize a few particular concerns. The wide disparity created by the proposed rule, between those specialties that will receive significant payment decreases for common procedures and those specialties that will receive significant gains, indicates that this

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800 945-2301 - 615 665-1283 - FAX 615 665-0755

proposed rule is not appropriate. We are concerned that the revised ASC payment system, if finalized as proposed, will have a detrimental effect on Medicare beneficiary access to outpatient surgery. We believe CMS should make modifications to the proposed rule in order to ensure continued beneficiary access to low-cost, high-quality ASC services.

Specific Comments

ASC Conversion Factor: The proposed rule will have a disproportionate negative impact on two specialties: GI and pain management. Using the CMS-proposed 62% ASC conversion factor will lower ASC payments for GI and pain management procedures by approximately 30%. This severe cut to these two specialties may limit access to life-saving detection and early treatment of colon cancer for Medicare beneficiaries. CMS has recognized the importance of colonoscopies, and the potential for negative effects from the proposed rule. Specifically, CMS stated its desire not to "cause procedures currently performed in high volume in ASCs to migrate to hospital outpatient departments in response to sudden payment reductions." 71 Fed. Reg. 49,692 (Aug. 23, 2006). CMS listed colonoscopies as one of these high volume procedures. Id. However, we believe CMS' proposed approach may produce such migration.

Although the ASC payment update has been frozen for six straight years, payments for HOPD procedures have increased annually during the same time period. Yet, we have experienced the same escalation in costs that hospitals have experienced. We pay the same salaries and benefits for nursing personnel and confront the same increases in equipment costs. With escalating costs and frozen payment levels, we are losing ground financially. To compound that situation with an additional 30% cut in payment will put many ASCs in an untenable position.

ASC Phase In: The proposed rule represents a complete overhaul in the payment system to which ASCs have been subject for a quarter-century. However, CMS has proposed to phase in this major system revision over only two years. We believe that the new payment system should be phased in over at least four years, and that special payment rules should be adopted to protect centers for which precipitous payment decreases will compromise the ability to treat Medicare patients.

President Bush and CMS have placed an emphasis on increased health care price transparency. On August 21, 2006, CMS posted ASC transparency information as part of the Administration's commitment to making health care more affordable and accessible. AmSurg supports the Administration's efforts to increase transparency in all settings. However, transparency is best achieved in an environment where payment policy is neutral with regard to the setting where services are provided. We are concerned that CMS' proposed rule does not allow ASCs to remain a viable setting for many services currently offered to Medicare beneficiaries. Accordingly, we believe if this rule is implemented as proposed, efforts to improve transparency will be impaired.

AmSurg hopes that CMS will combine its drive towards pricing transparency with the promulgation of adequate reimbursement policies for ASCs, since transparency will only benefit health care consumers in the context of fair competition between outpatient surgical settings.

We appreciate CMS' consideration of our comments and hope that CMS will recognize the value ASCs provide to Medicare beneficiaries. President Bush and Congress recognize that fair competition among providers of similar services lowers Medicare costs, expands beneficiary access to care, and increases quality. CMS should ensure that the final rule achieves these goals.

If you have any questions regarding these comments, please contact me at 615-665-1283.

Sincerely,

Ken P. McDonald
President and Chief Executive Officer

Submitter : **Date: 11/06/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

As a practicing interventional pain physician, I am disappointed at CMS s proposed rule for ASC payments. This rule will create significant inequities between hospitals, ASCs, and beneficiaries access will be harmed

CMS-1506-P2-1098-Attach-1.DOC

#1098

Sergio J. Alvarado, MD
University Pain Clinic
7703 Floyd Curl Dr. , Mail code 7838
San Antonio, TX 78229
210-358-4543 (office)

November 6, 2006

Leslie V. Norwalk, Esq., Acting 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; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Ms. Norwalk:

As a practicing interventional pain physician, I am disappointed at CMS's proposed rule for ASC payments. This rule will create significant inequities between hospitals, ASCs, and beneficiaries' access will be harmed. While this may be good for some specialties, interventional pain management will suffer substantially (approximately 20% in 2008 and approximately 30% in 2009 and after). The various solutions proposed in the rule with regards to mixing and improving the case mix, etc., are not really feasible for single specialty centers. CMS should also realize that in general healthcare uses, the topdown methodology or bottom-up methodology used by Medicare is the primary indicator for other payers - everyone following with subsequent cuts. Using this methodology, Medicare will remove any incentive for other insurers to pay appropriately.

Based on this rationale, I suggest that the proposal be reversed and a means be established where surgery centers are reimbursed at least at the present rate and will not go below that rate. We understand there are multiple proposals to achieve this. If none of these proposals are feasible, Congress should repeal the previous mandate and leave the system alone as it is now. However, inflation adjustments must be immediately reinstated.

I hope this letter will assist in coming with appropriate conclusions that will help the elderly in the United States.

Sincerely,

Sergio J. Alvarado, MD

Submitter : Dr. Louis La Luna **Date:** 11/06/2006

Organization : Berks Center for Digestive Health

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachmcnt.

CMS-1506-P2-1099-Attach-1.DOC

CMS-1506-P2-1099-Attach-2.DOC

CMS-1506-P2-1099-Attach-3.DOC

To whom it may concern:

I am a partner at Digestive Disease Associates LTC (my practice) and part owner of Berks Center For Digestive Health, L.P. where I perform the majority of the outpatient procedures on my patients. The Berks Center for Digestive Health is an important part of the high quality health care I am able to provide in Berks County. I perform over 10,000 procedures on an outpatient basis each year. There is no way that the hospitals in this area would be able to perform the amount of procedures that are currently performed in our community without the Berks Center. Further our commitment to quality care and service excellence can be demonstrated through quality measures and patient satisfaction surveys. Below I have included some of the history of ASCs, why I believe that they represent a very positive development for patients and physicians in this country and what my concerns are with the proposed Medicare payment system. I hope you will take the time to read these comments.

The experience of ASCs is a rare example of a successful transformation in health care delivery. Thirty years ago, virtually all surgery was performed in hospitals. Waits of weeks or months for an appointment were not uncommon, and patients typically spent several days in the hospital and several weeks out of work in recovery. In many countries, surgery is still like this today, but not in the United States.

Both today and in the past, physicians have led the development of ASCs. The first facility was opened in 1970 by two physicians who saw an opportunity to establish a high-quality, cost-effective alternative to inpatient hospital care for surgical services. Faced with frustrations like scheduling delays, limited operating room availability, slow operating room

turnover times, and challenges in obtaining new equipment due to hospital budgets and policies, physicians were looking for a better way - and developed it in ASCs.

Physicians continue to provide the impetus for the development of new ASCs. By operating in ASCs instead of hospitals, physicians gain the opportunity to have more direct control over their surgical practices. In the ASC setting, physicians are able to schedule procedures more conveniently, are able to assemble teams of specially-trained and highly skilled staff, are able to ensure the equipment and supplies being used are best suited to their technique, and are able to design facilities tailored to their specialty. Simply stated, physicians are striving for, and have found in ASCs, the professional autonomy over their work environment and over the quality of care that has not been available to them in hospitals. These benefits explain why physicians who do not have ownership interest in ASCs (and therefore do not benefit financially from performing procedures in an ASC) choose to work in ASCs in such high numbers.

Overview

The broad statutory authority granted to the Secretary to design a new ASC payment system in the Medicare Modernization Act of 2003 presents the Medicare program with a unique opportunity to better align payments to providers of outpatient surgical services. Given the outdated cost data and crude payment categories underlying the current ASC system, I welcome the opportunity to link the ASC and hospital outpatient department (HOPD)

payment systems. Although the HOPD payment system is imperfect, it represents the best proxy for the relative cost of procedures performed in the ASC.

In the comments to follow, I focus on three basic principles:

- maximizing the alignment of the ASC and HOPD payment systems eliminate distortions between the payment systems that could inappropriately influence site of service selection,

- ensuring beneficiary access to a wide range of surgical procedures that can be safely and efficiently performed in the ASC, and

- establishing fair and reasonable payment rates to allow beneficiaries and the Medicare program to save money on procedures that can be safely performed at a lower cost in the ASC than the HOPD.

Alignment of ASC and HOPD Payment Policies

Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost data used to evaluate outpatient surgical services for Medicare beneficiaries. The benefits to the taxpayer and the Medicare consumer will be maximized by aligning the payment policies to the greatest extent permitted under the law. While I appreciate the many ways in which the agency proposes to align the payment system, I am concerned that the linkage is incomplete and may lead to further distortions between the payment systems. Many policies applied to payments for hospital outpatient services were not extended to the ASC setting, and these inconsistencies undermine the appropriateness

of the APC relative weights, create disparities in the relationship between the ASC and HOPD payment rates, and embed in the new payment system site of service incentives that will cost the taxpayer and the beneficiary more than necessary.

There are many components of the regulation where a more complete alignment of the ASC and HOPD payment systems is appropriate. Below is an overview of the major areas where further refinement of the proposed rule is warranted. These issues are discussed in greater detail under the relevant section heading in the text to follow.

- **Procedure list:** HOPDs are eligible for payment for any service not included on the inpatient only list. The CMS proposal would limit a physician's ability to determine appropriate site of service for a procedure excludes many surgical procedures appropriate for the ASC setting.

- **Treatment of unlisted codes:** Providers occasionally perform services or procedures for which CPT does not provide a specific code and therefore use an unlisted procedure code identify the service. HOPDs receive payment for such unlisted codes under OPPS; ASCs should also be eligible for payment of selected unlisted codes.

- **Different payment bundles:** Several of the policies for packaging ancillary and other procedure costs into the ASC payment bundle result in discrepancies between service costs represented in the APC relative weight. For example, when HOPDs perform services outside the surgical range that are not packaged, they receive additional payments for which ASCs should also be eligible.

- **Cap on office-based payments:** CMS proposes to cap payment for certain ASC procedures commonly performed in the office at the physician practice expense payment rate. No such limitation is applied to payments under the OPPS, presumably because the agency recognizes the cost of a procedure varies depending on the characteristics of the beneficiary and the resources available at the site of service. I likewise believe this cap is inappropriate for the ASC and should be omitted from the final regulation.

- **Different measures of inflation:** CMS updates the OPPS conversion factor for annual changes in inflation using the hospital market basket; however, the agency proposes to update ASC payments using the consumer price index for all urban consumers. The market basket is a better proxy for the inflationary pressures faced by ASCs, as it is the measure used by the agency to update payments to hospitals providing the same services.

- **Secondary rescaling of APC relative weights:** CMS applies a budget neutrality adjustment to the OPPS relative weight values after they are recalibrated with new cost data each year. The agency proposes a secondary recalibration of the relative weights before they are used by ASCs. This secondary recalibration will result in annual and potentially cumulative variation between ASC and HOPD payments without any evidence that the cost of providing services has further diverged between settings.

- **Non-application of HOPD policies to the ASC.** Over the years, CMS has implemented through statutory or administrative authority numerous policies to support services in the HOPD, including additional payment for high-cost outliers, transitional corridor and hold-harmless payments to rural and sole-community hospitals, and payments for new technologies. While not all of these policies are appropriate for the ASC, surgery centers should be eligible to receive new technology pass-through payments.

- **Use of different billing systems:** The HOPD and ASC use the UB-92 and CMS-1500, respectively, to submit claims to the government for services. Use of different forms prevents ASCs from documenting all the services provided to a Medicare beneficiary, therefore undermining the documentation of case mix differences between sites of service. Most commercial payors require ASCs to submit claims using the UB-92, and the Medicare program should likewise align the payment system at the claim level.

Ensuring Beneficiaries' Access to Services

Ambulatory surgery centers are an important component of beneficiaries' access to surgical services. As innovations in science and technology have progressed, ASCs have demonstrated tremendous capacity to meet the growing need for outpatient surgical services. In some areas and specialties, ASCs are performing more than 50% of the volume for

certain procedures. Sudden changes in payments for services can have a significant effect on Medicare beneficiaries' access to services predominantly performed in ASCs.

The implementation of the revised payment system proposed by Medicare will result in significant redistribution of payments for many specialties. Because ASCs are typically focused on a narrow spectrum of services that require similar equipment and physician expertise, they have a limited ability to respond to changes in the payment system other than to adjust their volume of Medicare patients. On the one hand, for procedures such as ophthalmology, there is a limited market for these services in the non-Medicare population. If the facility fee is insufficient to cover the cost of performing the procedure in an ASC, responding to the change may mean relocating their practice to the HOPD. Such a decision would increase expenditures for the government and the beneficiary. On the other hand, the demand for services such as diagnostic colonoscopies is extremely high in the non-Medicare population. If ASCs determine that the payment rates for such services are too low, they may be able to decrease the proportion of Medicare patients they see without reducing their total patient volume. In that case, beneficiaries may experience significant delays accessing important preventive services or treatment. Neither outcome is optimal for the beneficiary of the Medicare program.

Establishing Reasonable Reimbursement Rates

Medicare payment rates for ASC services have remained stagnant for nearly a decade. Over time, the industry has identified which services it can continue to offer to Medicare

beneficiaries through reductions in cost and improvements in efficiency. In the Medicare Payment Advisory Commission's first review of ASC payments in 2003, ASCs were paid more than the HOPD for eight of the top ten procedures most frequently performed in the ASC. One suggestion by the commission was that services migrated to the ASC because the payment rate was higher than the HOPD. However, a multi-year payment freeze on ASC services has turned the tables and now the HOPD rate in 2007 will be higher (or the same) for eight of the same ten ASC procedures. The continued growth of ASCs during the payment freeze is a strong testament to their ability to improve their efficiency and the preference of physicians and beneficiaries for an alternative to the hospital outpatient surgical environment.

The impact of HOPD payments eclipsing the ASC rates has had the perverse effect of increasing the "cost" of the budget neutrality requirement imposed by the Medicare Modernization Act on the future conversion factor for ASC payments. The Lewin Group estimates that the inflation updates applied to the HOPD rates since passage of the MMA account for 40 percent of the discount required to achieve budget neutrality under the agency's proposed rule. This, combined with the agency's narrow interpretation of budget neutrality, produce an unacceptably low conversion factor for ASC payments.

- Budget Neutrality: Adopt an expansive, realistic interpretation of budget neutrality. The new payment system and the expansion of the ASC list will result in migration of services from one site of service setting to another. CMS has the legal authority and the fiduciary responsibility to examine the consequences of the new ASC payment system on all sites of care – the physician office, ASCs, and HOPD.

- ASCs should comment on the possible negative effect on access to services, since the methodology proposed results in ASC payments equaling only 62% of HOPD.

- By setting rates this low, CMS would force doctors to move cases to the more expensive hospital setting, increasing the amount of money paid by Medicare beneficiaries and the government. Rather than paying

ASCs a set percentage of HOPD rates, the proposed rule establishes a complicated formula to link ASC payment to HOPD payment but does not link payment in a uniform manner. This will impede Medicare beneficiaries' ability to understand their real costs in alternative settings. In the words of President Bush, Medicare beneficiaries need to be able to make "apples to apples" comparisons in order to increase transparency in the health care sector.

- CMS failed to include on the procedure list many higher complexity services that have for years been safely and effectively performed in ASCs throughout the country. By not creating a truly exclusionary list, CMS is losing an opportunity to increase patient choice and rely on the clinical judgment of the surgeon.

Louis La Luna, MD
Berks Center for Digestive Health
Wyomissing PA 19610

Submitter : Terence Green **Date:** 11/06/2006

Organization : MGI PHARMA

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1506-P2-1100-Attach-1.PDF

#1100

MGI PHARMA

November 6, 2006

Terence Green
Vice President, Assistant General Counsel
MGI PHARMA, INC.
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Via Overnight Mail

Leslie Norwalk, Esq.
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4125-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-4125-P): Payments for Drugs in ASCs

Dear Ms. Norwalk:

MGI PHARMA appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services ("CMS") Proposed Rule on Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (CMS-4125-P) (the "Proposed Rule"), 71 Fed. Reg. 49,506 (August 23, 2006). MGI is an oncology and acute care-focused biopharmaceutical company that acquires, develops and commercializes proprietary products that address the unmet needs of patients in the United States. Aloxi® (palonosetron hydrochloride) injection is one of MGI's products that is made available in the ambulatory surgical center ("ASC") setting. It is a 5-HT_3 anti-emetic used to treat chemotherapy- induced nausea and vomiting.

We appreciate CMS providing this early opportunity to comment on the agency's plans for the reform of ASC payment and coverage policies beginning in 2008. We believe this dialogue with the stakeholder community offers an important opportunity to develop a policy framework that is responsive to both to Medicare program objectives and the needs of Medicare beneficiaries served by ASCs.

MGI PHARMA seeks to ensure that Medicare reimbursement for oncology drugs and other innovative pharmaceutical products is adequate to support Medicare beneficiary access to these therapies in ASCs. Our comments therefore focus on the Proposed Rule's provisions addressing packaging for drugs and biologicals under the revised ASC payment system.

ASC Packaging Proposal: CMS Should Provide Separate Payment for Certain Drugs and Biologicals

CMS is proposing major reforms to Medicare ASC payment policy. In short, beginning in 2008, revised Medicare ASC payment rates would be tied to the hospital outpatient prospective payment system ("OPPS") ambulatory payment classification ("APC") payment amounts. However, CMS would establish the ASC rate at a significantly reduced percentage of the OPPS rate. For 2008, CMS estimates that ASC rates would equal 62 percent of the corresponding OPPS payment rates. Despite CMS's plan to base ASC payment on the OPPS payment amount, CMS is proposing very different packaging rules for the two sites of service. In particular, CMS is proposing to include payment for all drugs and biologicals in the ASC payment rate, even though a number of drugs and biologicals are reimbursed separately in the OPPS context (that is, those with pass-through status and specified covered outpatient drugs that exceed a fixed packaging threshold). Thus, under CMS's proposal, Medicare reimbursement for ASC services would be less than the corresponding OPPS rate, yet the payment amount would be expected to cover a broader range of items, including expensive drugs and biologicals that are reimbursed separately under the OPPS system.

We are concerned that this proposal would not adequately compensate ASCs for their drug acquisition and pharmacy handling costs, which could threaten patient access to needed drugs. CMS itself acknowledges the need to guard against inadequate reimbursement for drug and biologicals in the OPPS setting, on which the proposed ASC payment system is based:

> Notwithstanding our commitment to package as many costs as possible, we are aware that packaging payments for certain drugs, biologicals, and radiopharmaceuticals, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services.[1]

The same concerns certainly hold true in the ASC setting and points to the need to ensure that expensive drugs and biologicals are not packaged into ASC rates.

Moreover, bundling payment for all drugs and biologicals in the ASC setting while providing separate reimbursement in the outpatient hospital setting could create inappropriate incentives to base care decisions on payment considerations, contrary to CMS's oft-stated goal of decreasing such site-of-service differentials. We agree with concerns raised by the Medicare Payment Advisory Commission ("MedPAC") in its formal comments on the Proposed Rule submitted to CMS on October 10, 2006:

1 71 Fed. Reg. 49582.

> We support CMS's proposal to expand the ASC payment bundle but encourage the agency to make the payment bundles in the ASC and hospital outpatient settings even more comparable. . . . Different bundling policies may lead to different relative payment amounts in each setting, even if the base payment rates share the same relative values in both settings.[2]

Such differentials would have a disproportionate impact on individuals undergoing cancer treatments and others needing expensive drug and biological products in conjunction with their care, since their site of service options could effectively be limited under this policy.

To prevent an inappropriate site-of-service differential between hospital outpatient and ASC setting and ensure beneficiary access to medically-necessary drugs and biologicals in ASCs, CMS should carve out payments for certain drugs and biologicals in the ASC setting from the facility fee. Specifically, we propose that CMS provide separate payments to ASCs for (1) those drugs and biologicals that qualify for pass-through status under the OPPS system, and (2) those drugs and biologicals whose costs exceed the OPPS packaging threshold ($50 in 2006). CMS could adopt these provisions as a temporary policy for two to three years as the agency collects ASC drug cost data and develops a mechanism to ensure that these costs are appropriately reflected in the ASC facility payment. This interim policy would help ensure adequate compensation for ASCs and safeguard Medicare beneficiary access to medically-necessary drugs and biologicals.

* * * * *

MGI appreciates this opportunity to present these comments to CMS. Please do not hesitate to contact us if you have any questions.

Sincerely,

Terence Green
Vice President, Assistant General Counsel

2 See http://www.medpac.gov/publications/other_reports/101106_PartB_comment_AW.pdf?CFID=9299012&CFTOKEN=78096660.

Submitter : Ms. Iris Sutherland **Date:** 11/06/2006

Organization : United Surgery Center Southeast

Category : Ambulatory Surgical Center

Issue Areas/Comments

ASC Coinsurance

ASC Coinsurance

We support retaining the Medicare beneficiary coinsurance for ASC services at 20 percent. For Medicare beneficiaries, lower coinsurance obligations will continue to be a significant advantage for choosing an ASC to meet their surgical needs. Beneficiaries will save significant dollars each year under the revised ASC payment system because ASC payments will in all cases be lower than the 20-40 percent HOPD coinsurance rates allowed under the OPPS.

ASC Conversion Factor

ASC Conversion Factor

A 62 % conversion factor is unacceptable and often does not cover the cost of the procedure potentially forcing facilities not to perform these procedures foreing the Medicare patient back into the more expensive hospital setting. We understand that budget neutrality is mandated in the MMA of 2003; however, we believe that CMS made assumptions in order to reach budget neutrality with which we differ, most especially the migration of cases from and to the ASC. The ASC industry has worked together with our physicians and established a migration model that is being provided to CMS along with the data in an industry comment letter. We encourage CMS to accept this industry model of a 73% conversion factor.

ASC Inflation

ASC Inflation

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

ASC Office-Based Procedures

ASC Office-Based Procedures

We support CMS s proposal to extend the new ASC payment system to cover procedures that are commonly performed in physician offices. 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 outeome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his specific condition.

ASC Packaging

ASC Packaging

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

ASC Payable Procedures

ASC Payable Procedures

We support CMS s decision to adopt MedPAC s recommendation from 2004 to replace the current inclusive list of ASC-covered procedures with an exclusionary list of procedures that would not be covered in ASCs based on two clinical criteria: (i) beneficiary safety; and (ii) the need for an overnight stay. However, the ASC list reform proposed by CMS is too limited. CMS should expand the ASC list of procedures to include any and all procedures that can be performed in an HOPD. CMS should exclude only those procedures that are on the inpatient only list and follow the state regulations for overnight stays.

ASC Payment for Office-Based Procedures

ASC Payment for Office-Based Procedures

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

ASC Phase In

ASC Phase In

Given the size of the payment cuts contemplated under the proposed rule for certain procedures and specialties; especially GI, pain and ophthalmology, one year does not provide adequate time to adjust to the changes. Thus, we believe the new system should be phased-in over several years.

ASC Ratesetting

ASC Ratesetting

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

ASC Unlisted Procedures

ASC Unlisted Procedures

At a minimum, when all the specific codes in a given section of CPT are eligible for payment under the revised ASC payment system, the associated unlisted code also should be eligible for payment.

ASC Updates

ASC Updates

We are pleased that CMS is committing to annual updates of the new ASC payment system, and agree it makes sense to do that conjunction with the OPPS update cycle so as to help further advance transparency between the two systems. Regular, predictable and timely updates will promote beneficiary access to ASCs as changes in clinical practice and innovations in technology continue to expand the scope of services that can be safely performed on an outpatient basis.

ASC Wage Index

ASC Wage Index

We urge CMS to maximize alignment of the ASC and HOPD payment systems by adopting in the final rule the same packaging policies, the same payment caps for office-based procedures, the same multiple procedure discounts, the same wage index adjustments and the same inflation updates for ASCs and HOPDs. These facilities exist in the same communities and often in partnership with the community hospital. Aligning the payment systems for ASCs and hospital outpatient departments will improve the transparency of cost and quality data used to evaluate outpatient surgical services for Medicare beneficiaries. We believe that aligning the payment policies to the greatest extent permitted under the law will maximize the benefits to the taxpayer and the Medicare consumer.

Submitter : **Dr. John Oltean** **Date: 11/06/2006**

Organization : **Shoreline Vision ASC**

Category : **Physician**

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

My name is John Oltean and I am an ophthalmic surgeon in practice for 13+ years. I have been performing cataract and other ophthalmic surgeries at Shoreline ASC for the past 6 months. I believe that payment rate proposed is absolutely inadequate for the services performed. This percentage vs HOPD should be at least 75%, as the overhead for an ASC differs only in the administrative costs of the hospital. The supplies are the same, the staff costs are actually higher due to a higher staff to patient ratio (resulting in better patient care), and the costs in our state to obtain a CON, and build a first class eye surgery center are very high. After operating in both settings, there is NO DOUBT in my mind that the patient gets a higher quality surgical experience in the ASC setting. By setting payment rates at such poor reimbursement level, it will dissuade investment in this highly efficient/higher quality setting, thus taking a step backwards in health care.
Thank you

Submitter : **Mr. Anthony Valente** **Date: 11/06/2006**

Organization : **Johnson Surgery Center**

Category : **Ambulatory Surgical Center**

Issue Areas/Comments

ASC Ratesetting

ASC Ratesetting

I am dissatisfied with the Proposed Ruling on the new payment methodology for ASCs. At 62% of the HOPD rate it is simply too low and unacceptable to retain staff, purchase new equipment and meet the high costs of operations. CMS needs to allow any procedure that can be done in a HOPD to also be done in an ASC. CMS should exclude only those procedures that can only be done on an inpatient basis. The cost for M/S supplies, drugs, IVs, medical gases, surgical implants are not different in a hospital or an ASC. An anesthesia machine is sold to both hospitals and ASCs at the same price. ASCs can not hire and retain an operating room nurse at 62% of what a nurse is paid in a HOPD. Level the playing field, allow for the maximal reimbursement level for an ASC that approximates the HOPD rate then let consumer satisfaction, convenience, safety and outcomes dictate in a free market system where the patients will go. Reimbusing ASCs at 62% of the HOPD rate will cause some ASCs to close, then CMS will only have the higher cost HOPD in which Medicare beneficiaries can receive their care. How do you avoid that from happening raise ASC payments.

Thank You
Anthony Valente, VP
Johnson Surgery Center
148 Hazard Avenue
Enfield, CT 06082

Submitter : Ms. Marilyn Litka-Klein **Date:** 11/06/2006

Organization : Michigan Health & Hospital Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see our attached comment letter.

Thank you.

CMS-1506-P2-1104-Attach-1.DOC

#1104

MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

October 6, 2006

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Attn: CMS—1540—P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Medicare Program; Outpatient Prospective Payment System Rule for 2007; Proposed Rule.

Dear Dr. McClellan:

On behalf of Michigan's 145 nonprofit hospitals, the Michigan Health & Hospital Association (MHA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the 2007 proposed rule to update the Medicare outpatient prospective payment system (OPPS). The MHA is concerned about policy changes that would reduce Medicare outpatient payments to Michigan hospitals since this would further threaten the financial viability of hospitals. This is particularly concerning since the latest data available indicates that on an aggregate basis, Michigan hospitals have a negative margin of 7 percent on outpatient services and lose approximately $65 million annually on services provided to Medicare beneficiaries. Hospitals cannot sustain these financial losses and remain viable as the commercial and uninsured patients are unwilling to absorb the cost of government under financing.

HOSPITAL QUALITY DATA

The CMS proposes to require compliance with the inpatient prospective payment system (IPPS) Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program in order for hospitals to receive a full payment outpatient update in 2007. Under the IPPS, the annual payment update is linked to the collection of quality measures and hospitals that fail to comply with the program requirements receive a marketbasket update that is 2 percent less than the full update. Beginning in 2007, the CMS indicates it has the authority and proposes to also reduce the outpatient PPS conversion factor update by 2 percent for hospitals that are required to report quality data under the IPPS RHQDAPU. In addition, hospitals not submitting all of the inpatient measures required for 2008 would have their outpatient payment update for FY 2008 reduced by 2 percent. The CMS asserts that it is appropriate to link full payment for outpatient services to the submission of these inpatient measures because several of the measures assess

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care that is often provided in the emergency department (e.g., aspirin and beta blockers for those thought to be experiencing a heart attack), and therefore if the hospital improves the system for delivering these medications, quality improvement to other emergency and other ambulatory services have likely occurred as well.

The MHA strongly disagrees with the CMS' proposed linkage of the reporting of the inpatient measures to payments under the OPPS for the following reasons:

- Congress has already determined the inpatient penalty for hospitals that do not submit the inpatient data. In the Deficit Reduction Act (DRA), Congress specified that the penalty would be a 2 percent reduction in the IPPS market basket update. It did not authorize additional penalties for outpatient services. If Congress had intended to authorize outpatient penalties, it would have specified those in the DRA. We conclude that Congress did not intend additional penalties for hospital outpatient services.

- The CMS' proposed rule asserts that the authority for adding the penalty to the outpatient payment comes from its "equitable payment authority". The equitable payment provision in the Social Security Act was intended to enable the CMS to eliminate inequitable impact on a particular provider or group of providers. Implementation of the equitable payment provision must be done in a budget neutral manner. For OPPS, there are no inequities in outpatient payment. Rather, application of this requirement may result in less payment to OPPS providers

- The CMS states that inpatient measures provide insight into the clinical care in the ambulatory setting. There is no relationship between the measures being used to assess the adequacy of inpatient heart attack, heart failure, pneumonia and surgical care and the care of patients receiving diagnostic, radiological, pharmaceutical and other procedures covered under OPPS.

Prior to linking any set of measures to the payment for outpatient care, there should be clear evidence that the measures specifically have an impact on the quality and outcome of patients who are treated in hospital outpatient settings. Many measures that can provide insights into the quality in outpatient care settings are being reviewed by the Hospital Quality Alliance and the AQA (formerly known as the Ambulatory Quality Alliance). **The MHA urges the CMS to continue working with the HQA and the AQA to identify and implement measures that truly assess important aspects of outpatient care quality.** Once appropriate measures have been identified, the CMS should work with Congress to consider how the payment system should be modified to support the provision of high quality care in the outpatient setting. Since appropriate outpatient care measures have not been identified, **the CMS should remove any link between quality measures and outpatient care payments in this rule.**

PARTIAL HOSPITALIZATION

Partial hospitalization is an intensive outpatient psychiatric program provided to patients in place of inpatient psychiatric care and may be provided by a hospital outpatient department or a freestanding Community Mental Health Center (CMHC). Providers are paid on a per-diem basis for these services. The MHA is concerned that an additional proposed 15 percent reduction in the per diem payment rate for partial hospitalization services could harm the financial viability of partial hospitalization services in hospitals and health care systems, and could endanger Medicare beneficiary access to them. This will be the second consecutive year that the per diem rate was reduced by 15 percent and hospitals cannot sustain further reductions in the per diem rates. These services already are quite vulnerable, with many programs in recent years closing or limiting their patients.

We share the CMS's concern about volatility of the community mental health center data. However, it is inappropriate to penalize one set of providers for the performance of another.

Although the MHA recognizes that the CMS made the proposal to avoid an even more significant reduction in the payment rate for these services that would be derived from using the combined hospital-based and CMHC median per diem cost, we do not believe that hospitals offering partial hospitalization services should be penalized for the instability in data reporting that stems from CMHC-based services.

Instead, **the MHA recommends that for 2007, the CMS freeze payment rates for partial hospitalization services at the 2006 level of $245.65.** This approach will provide payment stability for these services and protect beneficiary access to hospital-based services while allowing the CMS adequate time to address the instability in the CMHC data. **We further request that the CMS require CMHCs to improve their reporting or have that provider group face economic consequences.**

OPPS: RURAL HOSPITAL HOLD HARMLESS TRANSITIONAL PAYMENTS

The MHA is concerned about the impact that the phase-out of the transitional corridor hold harmless payments will have on small rural hospitals. These are vulnerable facilities that provide important access to care in their communities. **The MHA supports S. 3606, "Save Our Safety (SOS) Net Act of 2006" which would permanently extend hold harmless payments to small rural hospitals and sole community hospitals, as is currently the case for cancer hospitals and children's hospitals.**

NEW TECHNOLOGY APCS

The CMS proposes to assign 23 services from new technology APCs to clinically appropriate APCs. The CMS generally retains a service within a New Technology APC group for at least two years, unless the agency believes it has collected sufficient claims data before that time. In the proposed rule, the CMS proposes to assign some services that have been paid under the New Technology APCs for less than two years to clinically appropriate APCs. An

example is as Positron Emission Tomography (PET)/Computed Tomography (CT) Scans, which were assigned to New Technology APC 1514 in 2005. Once approved by the CMS, there may be a delay in providing the services, resulting in less than 12 months full utilization in the first year of the CMS data files. **As a result, the MHA recommends that when the CMS assigns a new service to a new technology APC, the service should remain there for at least 2 years until sufficient claims data are collected.**

While new technology may increase outpatient cost, it frequently eliminates more invasive inpatient procedures that are most costly for Medicare. While this means that Medicare may be paying somewhat more for new technologies in hospital outpatient settings, in the end these costs are likely to be less than the cost of caring for such patient in an inpatient setting or using more invasive, but traditional, outpatient procedures.

Proposed Payment for Specified Covered Outpatient Drugs (SCODs). The MHA is concerned about the CMS's proposal to reduce payments for specified covered outpatient drugs (SCODs) to ASP plus 5 percent in 2007. This represents a one percent reduction from the ASP plus 6 percent rate in 2006. This payment reduction means that drugs and biologicals provided in hospital outpatient departments would be reimbursed for the same drug paid in physician office settings. **The MHA believes that consistency in payment for drugs and biologicals across settings is important and recommends that the CMS maintain the payment rates for drugs at the rate of ASP plus 6 percent for 2007.**

Payment Policy for Radiopharmaceuticals. The CMS proposes to no longer pay for radiopharmaceutical agents at hospital charge reduced to cost but instead pay for them at aggregate hospital mean costs as derived from the 2005 claims data. For brachytherapy sources, the CMS proposes to pay on the basis of claims-based median cost per source for each brachytherapy device. Due to concerns that the claims data may be incomplete due to frequent code and descriptor changes for radiopharmaceuticals, we believe that it is too soon to end the current policy of paying at hospital costs. **As a result, the MHA recommends that for 2007, the CMS continue using the current methodology of payment at charges reduced to costs for radiopharmaceuticals and brachytherapy sources.**

EVALUATION & MANAGEMENT (E/M) CODES

Despite the CMS's previous assurances that they would not create new codes to replace existing CPT E/M codes until national guidelines were developed, for 2007, the CMS proposes to establish new Health Care Procedure Coding System (HCPCS) level II G codes to describe hospital clinic visits, emergency department (ED) visits and critical care services. The CMS proposes five levels of clinic visit G codes, five levels of ED visit G codes for two different types of EDs, and two critical care G codes. Until national guidelines are formally proposed and finalized, the CMS states that hospitals may continue to utilize their existing internal guidelines for determining the visit levels to be reported with the new G codes, or they can adjust their guidelines to reflect the new codes and policies.

The MHA continues to believe that the CMS should not implement new codes for hospital clinic and ED visits in the absence of accompanying national code definitions and national guidelines for their application. **The MHA recommends that the CMS support the continued use of the current five level CPT codes, which would be assigned to the three existing APCs for hospital clinic and ED services until such a time as national coding definitions and guidelines are formally proposed, subjected to stakeholder review and finalized.** Creating temporary G-codes without a fully developed set of national guidelines will increase confusion and add a new administrative burden requiring hospitals to manage two sets of codes – G-codes for Medicare and CPT codes for non-Medicare payers – without the benefit of a standardized methodology or better claims data. Instead, our approach would provide for stability for hospitals in terms of coding and payment policy and would allow the CMS and stakeholders to focus instead on the development and fine-tuning of a set of national hospital visit guidelines that could be applied to a new set of E/M codes in the future.

OBSERVATION SERVICES

For 2007, the CMS proposes to continue applying the criteria for separate payment for observation services and the coding and payment methodology for observation services that were implemented in 2006. The MHA continues to support the CMS's concept of allowing the outpatient code editor (OCE) logic to determine whether observation services are separately payable. This has resulted in a simpler and less burdensome process for ensuring payment for covered outpatient observation services.

In addition, since the process for determining whether observation is separately payable is largely "automated", the MHA believes the CMS should consider expanding diagnoses for which observation may be separately paid. As a result, the MHA supports the APC Panel's recommendation that the CMS consider adding syncope and dehydration as diagnoses for which observation services qualify for separate payment

CRITICAL ACCESS HOSPITALS: EMERGENCY MEDICAL SCREENING

The MHA supports the CMS's proposal to change the critical access hospital (CAH) conditions of participation to allow registered nurses to serve as qualified medical personnel for screening individuals who present to the CAH emergency department, if the nature of the patient's request is within the registered nurse's scope of practice under state law and such screening is permitted under facility bylaws.

This change provides hospitals with the staffing flexibility needed to maintain access and provide efficient emergency and urgent care services in CAHs. However that there is an inconsistency between the CMS's preamble language and the regulatory text being proposed in this section. While the preamble indicates that the CAH would have to include this change in their bylaws, the regulatory text does not mention CAH bylaws. **The MHA recommends that the CMS clarify this requirement in the final OPPS rule for 2007.**

OUTLIER PAYMENTS

Outlier payments are additional payments to the APC amount to mitigate hospital losses when treating high-cost cases. For 2007, the CMS proposes to retain the outlier pool at 1 percent of total outpatient PPS payments. Further, the CMS proposes to increase the fixed-dollar threshold to $1,875 – $625, or 50 percent, more than in 2006 – to ensure that outlier spending does not exceed the reduced outlier target. This increase in the fixed-dollar threshold is largely due to the projected overpayment of outliers resulting from the change in the CCR methodology. To qualify for an outlier payment, the cost of a service would have to be more than 1.75 times the APC payment rate and at least $1,875 more than the APC rate.

While the MHA supports the continued need for an outlier policy in all prospective payment systems, including the outpatient PPS, the CMS proposed outlier threshold is too high. With the significant changes to outlier policies, including the methodology for calculating the hospital-specific CCR proposed for 2007, the MHA is concerned that Medicare may not actually spend the outlier target set-aside. **The CMS should publish the annual outlier payments as a percent of total expenditures for 2005 and prior. The outlier threshold increase should be limited to the increase in APC rates, or 3.4 percent, unless clear evidence exists that proves the outlier payments exceed the allocated pool.**

Proposed Critical Care Coding. The MHA is opposed to the proposed structuring of critical care coding on the basis of time. Tracking and documenting time for critical care services would pose a significant burden to hospitals and could be subject to gaming. Time has never been incorporated as a component of critical care coding and billing instructions for hospitals since the inception of the OPPS. In fact, the April 7, 2000 final rule establishing the OPPS clearly states, "In addition, we believe it would be burdensome for hospitals to keep track of minutes for billing purposes. Therefore we will pay for critical care as the most resource intensive visit possible as defined by CPT code 99291."

While the 30-minute threshold has applied to physician professional service billing, it has long been understood that hospital resources for critical care are not linked to time, but rather reflect the immediate intensity of care provided to patients receiving these services. The goal of the ED is to stabilize the patient as quickly as possible, which involves multiple hospital staff to be simultaneously present, and may even require a multidisciplinary team. It would be extremely burdensome and confusing to track time for different individuals involved in providing critical care services. **The MHA recommends that the CMS eliminate the reference to time in the definition of the new critical care codes and instead continue with its long-standing OPPS policy concerning coding and billing for critical care services.**

PROPOSED PROCEDURES THAT WILL BE PAID ONLY AS INPATIENT PROCEDURES

CMS proposes to remove 8 codes from the inpatient list, which identifies services that are unable to receive payment if they are performed in an outpatient setting and then assigns them to clinically appropriate APCs.

The MHA remains concerned about the inconsistency between Medicare payment policy for physicians and for hospitals with regard to procedures that are on the inpatient list. It is our understanding that while Medicare will not pay hospitals if procedures on the inpatient list are performed in outpatient settings, that physicians would be paid their professional fee in such circumstances. There are a variety of circumstances that may result in such services being performed without an inpatient admission. For instance, because the inpatient list changes annually, physicians may not always be aware of that a procedure they have scheduled for performance in an outpatient department is on the inpatient list. There may also be other reasonable, but rare, clinical circumstances that may result in these procedures taking place in the absence of an inpatient admission.

The MHA again recommends that the CMS consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would give the provider an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without a more costly inpatient admission.

MEDICARE CONTRACTING REFORM MANDATE

In the rule, the CMS proposes conforming changes to the regulations in order to implement the Medicare contracting reform provisions of the Medicare Modernization Act (MMA). Hospitals will be integral customers of the Medicare Administrative Contractors (MAC), and a significant proportion of hospital revenue will depend on appropriate contractor's performance.

The MMA requires that the Secretary of the Department of Health and Human Services consult with providers of services on the MAC performance requirements and standards, and the MHA appreciates the many opportunities that hospitals and other providers have had in contributing to this process. With the advent of competitive procedures for the selection of MACs, the MHA believes that such provider input is critical.

However, we encourage the CMS to further include providers in the contractor selection and renewal process. Furthermore, to address any serious problems with the selected MACs, providers also should be permitted to provide formal mid-contract reviews of their performance. We are concerned that with the introduction of competitive procedures for the selection of the MACs, it is likely that some contractors may bid so low that they may not be able to adequately perform at the level that HHS and providers require. Hospitals have had first-hand experience with contractors who submit "low-ball" bids and then cannot do their job adequately in the Medicaid program, where competitive bidding is often used to select contractors. Therefore, hospitals should have input on both the selection and termination of MACs.

The MHA also requests that the CMS to do everything within its authority to ensure that MACs are accountable to the agency and providers for the services they provide. It is critical that the selected contractors understand how hospitals and health care systems function,

and that MAC staff have the necessary technical expertise to efficiently and correctly process hospital claims.

In addition, given that each defined A/B MAC jurisdiction will include several states, the CMS **must ensure that the chosen contractor is able to maintain a significant local presence.** This includes the ability to work within different time zones, availability and accessibility within typical hospital administrative hours of operation, and the ability to conduct face-to-face meetings and teleconferences with individual hospitals or groups of hospitals on a regular basis.

FY 2008 IPPS RHQDAPU

In the proposed rule, the CMS announces the measures hospitals paid under the Medicare acute care hospital inpatient PPS must submit in order to get the full inpatient payment to which they would otherwise be entitled in FY 2008. Under the DRA, hospitals that fail to submit these measures and the other quality measures that are currently required would suffer a penalty of having their FY 2008 inpatient payments reduced by two percent.

The MHA is supportive of the CMS utilizing quality measures that have already been adopted as part of the Hospital Quality Alliance's efforts to promote public reporting of hospital quality data. These are well-designed measures chosen because they represent aspects of care that are important to patients, and that provide insights into the safety, efficiency, effectiveness and patient-centeredness of care. **We strongly urge the CMS to continue to align its choices of measures to link to payment with the measures chosen by the HQA to provide a public accountability for quality.** This alignment will reinforce the importance of the public transparency on quality and help to focus quality improvement efforts on the chosen high priority areas of care.

We also support the CMS for publishing information on what measures hospitals will be expected to report to continue to receive their full inpatient payments early enough for them to put the proper data collection processes in place. As we said in our earlier comments on the Inpatient Prospective Payment System rule, if hospitals are not told until August what quality data they will be expected to report, they are unable to put the proper data collection processes in place quickly enough to ensure reliable abstraction of the information from patient records.

HEALTH INFORMATION TECHNOLOGY (HIT)

The proposed rule states that it "supports the adoption of health IT as a normal cost of doing business to ensure patients receive high quality care." It also notes that the quality and efficiency benefits of health IT may provide a policy rationale for promoting the use of health IT through the Medicare program.

The MHA strongly believes that health IT is a very important tool for improving the safety and quality of health care, and our members are committed to adopting IT as part of their quality

improvement strategies. They also view IT as a public good that requires a **shared investment between the providers and purchasers of care.**

Health IT is a very costly tool, requiring both upfront and ongoing spending. A 2005 American Hospital Association (AHA) survey noted that the median amount hospitals invested annually on health IT was greater than $700,000, 15 percent of total capital expenses. Hospitals spent even greater amounts - a median of $1.7 million or 2 percent of all operating expenses - on operating costs related to IT. Survey respondents identified the upfront and ongoing costs of IT as the greatest barriers to further adoption. The survey also found that hospitals with negative margins and those with lower revenues use less IT.

The proposed rule highlights the anticipated benefits of health IT as laid out by the RAND Corporation. **However, it overlooks another of the study's major findings - that the financial benefits of IT investments accrue more to the payers and purchasers of care than the hospitals and health systems that pay for them.**

Simply put, our members have not seen financial returns greater than the costs of implementing clinical IT systems, particularly in the short term. They adopt clinical IT because it is the right thing to do for improving patient safety and quality of care, not because it saves them money. Thus, while IT may be a "normal cost of doing business," it systematically raises those costs. **Given that they reap many of the financial benefits of IT, the MHA believes that the payers and purchasers of care should share in the costs of IT.**

Finally, we learned through the HIPAA process that efficient health information exchange requires all parties to upgrade their systems and work from a common set of standards. As we moved toward implementation of health IT in hospitals, payers - including the federal government - must modify their own systems to accept electronic data.

Statutory Authority. The broad question of whether the CMS has statutory authority to encourage adoption and use of health IT will depend on the specific mechanisms it selects. For example, the CMS has some authority to pursue demonstration projects. However, more systematic approaches, such as value-based purchasing or payment adjustments, would require legislative action.

Value-based Purchasing. The MHA believes that any value-based purchasing program should not be punitive. **With regard to IT, only programs that add funds to the inpatient PPS should be pursued because IT is costly, requiring both upfront and ongoing expenditures.** Decreasing payments to those that have not been able to afford IT further limits their ability to invest. A budget-neutral approach also ignores the reality that health IT systematically increases hospitals' costs.

The MHA also believes that value-based purchasing programs should build off the consensus measures endorsed by the broad spectrum of organizations - including the CMS - that participate in the HQA. In general, the HQA favors measures that address quality outcomes, rather than the tools used to get there.

Health IT can play a role in reducing the burden of quality reporting. Presently, electronic health records (EHRs) and other clinical IT systems do not automatically generate quality measures. Most hospitals still require special calculations - including expensive manual chart abstraction and use of third-party contractors - to submit quality data. The CMS could advance the quality agenda by investing in the development of algorithms for the calculation of the quality measures it wants reported from EHRs and encouraging vendors to include them in their products.

Rather than including health IT in a value-based purchasing program, the CMS **could support adoption of health IT through a payment adjustment funded with new money.** For example, it could increase payments to hospitals that use health IT that improves the safety and quality of care by 1 percent. This kind of payment adjustment represents Medicare's share of the necessary investment to achieve this goal and would recognize the greater costs of a "wired" health care system. The MHA will pursue legislation authorizing such a payment adjustment. Other mechanisms, such as loan guarantees and grant funds, are needed to help hospitals finance the upfront costs of implementing health IT.

Conditions of Participation. The MHA firmly believes that **the CMS should not include health IT in the Medicare conditions of participation (COP) for hospitals.** The COPs address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, the commercial health IT applications available do not always meet hospitals' needs. The evidence on health IT does not yet support this level of requirement and would amount to an unfunded mandate. A recent report supported by the AHRQ found that the existing research on the quality benefits of health IT is limited to a handful of leadership institutions that generally developed their own systems. And, while promising, the results are not yet generalizable to the average community hospital using the vendor systems currently on the market.

While the MHA appreciates the efforts of the Certification Commission on Health Information Technology (CCHIT) to provide the market with better confidence in vendor product, we do not believe those efforts are sufficiently advanced to warrant inclusion in any adoption incentives the CMS might pursue. CCHIT is only at the beginning stages of looking into certification of hospital inpatient products. CCHIT's work on ambulatory products is more advanced but, while it shows promise, has not yet proven itself in the marketplace.

HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE

In 2006, the Department of Health and Human Services (HHS) proposes to undertake a new effort to expand the availability of information on health care quality and pricing. The HHS intends to identify several regions in the United States with high health care costs and use its leadership role in health care policy to help lead change in those areas.

The MHA, the Federation of American Hospitals and the Association of American Medical Colleges partnered with the CMS and others to form the Hospital Quality Alliance (HQA). The work of the HQA has led to the voluntary reporting of 21 quality measures on the Hospital Compare Web site and more measures of hospital quality and patient satisfaction are planned for the future.

While progress has been made in quality transparency, similar information on hospital pricing is less accessible. The proposed rule discusses the CMS perspective on the difficulties in providing information for health care consumers and offers several options to consider.

Providing *meaningful* information to consumers about the price of their hospital care is the most significant challenge hospitals, and the CMS, face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

- Presenting information in a way that is easy for consumers to understand and use;
- Making information easy for consumers to access;
- Using common definitions and language to describe pricing information for consumers;
- Explaining to consumers how and why the price of their care can vary; and
- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

The MHA recommends that the CMS convene a workgroup comprised of representatives from hospitals, the MHA and state associations, and Medicare beneficiaries to identify the core issue to be resolved by the transparency initiative. Once that is identified, the hospital industry can provide valuable input toward resolution.

Another option the CMS offered is establishing a Medicare condition of participation to post prices on assistance programs for uninsured. While many hospitals are moving toward transparency in this area, including this as a condition of participation seems punitive and will not resolve the CMS core issue of what hospitals are doing to assist the uninsured. It is important for the CMS to understand that the income level of the uninsured varies by community and charity care policies will also vary. **Therefore, the MHA objects to the CMS expanding the conditions of participation to include posting of prices on assistance programs to the uninsured.**

Although we have learned much about the type of information consumers want about the quality of their health care, we know significantly less about what they want in regard to pricing information. Depending upon whether and how they are insured, consumers need different types of price information as illustrated below:

- **Traditional Insurance.** Because traditional insurance typically covers nearly all of the cost of hospital care, individuals with this type of coverage are likely to want information about what their personal out-of-pocket cost would be if they receive care at one hospital versus another.

- **Health Maintenance Organization (HMO) Insurance.** Individuals who have HMO coverage will have more specific price information needs since they typically face no additional cost for care beyond their premium and applicable deductibles and co-payments. Persons covered by an HMO must agree to use physicians and hospitals that are participating in that HMO plan. As a result, these individuals likely have little, if any need for specific price information.

- **High-Deductible or Health Savings Account (HSA) Insurance.** Individuals with HSAs have more interest regarding price information compare to a typically-insured person since these plans are designed to make consumers more price-sensitive and encourage consumers to be prudent "shoppers" for the care they need. Since a typical plan of this type has a deductible of $2,500, consumers with HSA coverage are likely to be more interested in price information for physician and ambulatory care than for inpatient hospital care.

- **Uninsured Individuals of Limited Means.** Uninsured individuals have limited means to pay for the health care services they receive and need to know how much of their hospital or physician bill they may be responsible for paying. In the case of hospital care, the information these patients need must be provided directly by the hospital, after the hospital can ascertain whether the individual is eligible for state insurance programs of which they were unaware, charity care provided by the hospital, or other financial assistance.

Again, the MHA appreciates this opportunity to provide input to the CMS and urge you to modify the OPPS proposed rule based on our comments above. If you have questions or require additional information, please contact me at (517) 703-8608 or mklein@mha.org.

Sincerely,

Marilyn Litka-Klein

Marilyn Litka-Klein
Senior Director, Health Policy

Submitter : **Ms. Barbara Peck** **Date: 11/06/2006**

Organization : **American College of Surgeons**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1506-P2-1105-Attach-1.PDF

#1105

American College of Surgeons

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November 6, 2006

Ms. Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1506-P
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: *CMS-1506-P Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates*

Dear Ms. Norwalk:

On behalf of the 71,000 Fellows of the American College of Surgeons (College), I am pleased to submit the following comments on the Proposed Rule published in the *Federal Register* on August 23, 2006. We will address ASC payable procedures, including the proposed definition of a surgical procedure, procedures that use limited resources, significant safety risk, criteria for evaluating safety risks, overnight stay, treatment of office-based procedures and the ASC rate setting method, including ASC packaging, ASC inflation, ASC phase-in and the ASC conversion factor.

I. ASC Payable Procedures

The American College of Surgeons supports the Medicare Payment Advisory Commission's (MedPAC) March 2004 recommendation of replacing the current "inclusive" list of procedures with an "exclusionary" list and allowing payment to an ASC facility for any surgical procedure except those that CMS explicitly excludes from payment. In addition, we also support MedPAC's recommendation that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from payment of an ASC facility fee. While the Agency states in the proposed rule that it also supports MedPAC's recommendations, we do not believe several of the proposed policies are consistent with this premise. We believe with some modifications the concept of an exclusionary list will serve Medicare beneficiaries, the Medicare program and physicians well.

We view the two exclusionary criteria as having separate functions and purposes. We believe the recommendation regarding "clinical safety standards" involves the reviewing the actual surgical procedure itself and its complexity, intensity and possible complications. The recommendation related to an overnight stay involves the standard of care for what happens after the surgery is completed and the needs of the patient while recovering. The need for an overnight stay does not necessarily reflect on the safety of the surgery itself, but instead reflects on the patient recovery and mobility, wound care, ability to eat, etc. We believe it is important to make this distinction because the policy set by CMS for evaluating the appropriate site of service should reflect this premise: Is the procedure being excluded because there is a clinical safety concern regarding the actual procedure itself, or is the procedure being excluded because patients often require an overnight stay, which an ASC by definition is not equipped to provide?

A. Proposed Definition of Surgical Procedure

We believe appraising ranges of CPT codes is a good place to begin analyzing what procedures can be performed at an ASC. However, we do not believe the analysis should end there. The process for assigning CPT codes to procedures is not a science. There are many "surgery like" procedures that fall outside of the commonly recognized surgical code range, but are nonetheless being safely performed in the ASC setting. In addition, procedures and technologies change over time and it is not uncommon for a procedure that was once viewed as "diagnostic", and assigned an appropriate CPT code, to evolve into a "treatment" method. We do not believe it is in the patient's best interest to declare that a procedure cannot be performed in an ASC simply because of the CPT number it is assigned.

In some instances, relatively similar procedures are located in different CPT categories. For example, the traditional breast biopsy codes are located in CPT codes 19100-19103 and include:

19100 – biopsy of the breast; needle core, not using image guidance

19101 – open incisional

19102 – percutaneous, needle core, using image guidance

19103 – percutaneous, automated vacuum assisted or rotating biopsy devise, using image guidance

However, stereotactic breast biopsy has been assigned CPT code 76095, which is outside the range of traditional surgical codes. We note that diagnostic radiologists perform 80 percent of the volume of code 19102, a "surgical code", but that general surgeons provide more than 25 percent of the volume of code 76095, a "radiology" code. The other approximately 20 stereotactic procedures assigned CPT codes have been assigned codes that do fall within the range "traditionally assigned to surgery" (including 61750, 61751, 63215, 61790, 61720-61735, 61770 and 61791). In particular, we note that code 61750 is an almost identical procedure to code 76095, but performed on a different section of the body, yet these codes are in two different categories of CPT codes. General surgeons perform tens of thousands of stereotactic breast biopsies on Medicare beneficiaries each year and we anticipate this number will increase as the technology advances further and this procedure is used in lieu of more invasive biopsy and treatment techniques. We do not believe it is reasonable to exclude stereotactic breast biopsy from the ASC procedure list simply because of the CPT code it has been assigned when the procedure:

- is often performed by surgeons,
- is similar to other procedures on the list and
- meets the ASC criteria regarding an overnight stay and safety.

There are other "surgery like" codes in the diagnostic and medicine sections of the CPT list that also deserve consideration. Many of these procedures are lumped into the field of "interventional radiology", which is, in fact, interventional, not diagnostic, and not necessarily performed by radiologists. There are also similar misnomers exemplified by many catheterization codes, with some spread throughout the traditional surgical codes, others listed in the medicine codes and still others listed under radiology. The Agency should recognize with its rulings that it is the safety of these procedures and the necessity for an overnight stay that should determine whether these procedures are excluded from receiving an ASC facility fee, not where they happen to fall on a list of CPT codes.

We would like to call to the Agency's attention that many procedures have a corresponding diagnostic code that is performed in conjunction with a specific surgical procedure but in some instances the procedure is on the approved list while the corresponding diagnostic code is not. For example, code 47563 (Laparoscopy, surgical; cholecystectomy with cholangiography) can be performed in an ASC, but code 74300 (Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation), which is performed in conjunction with this procedure, is not.

Finally, we also note that there are numerous complex imaging procedures that list hospital outpatient procedure departments as the most common site of service. While this may be appropriate in some instances, in others the obstacle may be that the necessary equipment is too expensive for the traditional medical practice, or that independent diagnostic testing facilities cannot meet the direct physician supervision requirement. We

believe some of these procedures, including many angiography procedures, may be safely and appropriately performed in ambulatory surgery centers at less cost to the taxpayer, while maintaining quality delivery of care to the patient, where the proper staffing and equipment is available.

In conclusion, we recommend that the ASC procedure list be expanded to include all procedures that can also be performed in a hospital outpatient department, including imaging and sophisticated medicine procedures, unless they do not meet the safety or overnight criteria. We also recommend that the same payment rules that apply to the rest of the ASC procedure list apply to these codes, including any caps on payment levels.

B. Procedures that Use Limited Resources

In the proposed rule, the Agency asks for comments on what should be done with procedures that are defined as surgical procedures, but use limited resources. We do not believe the level of resources used should determine whether a procedure can be performed at an ASC. In some instances, these "low resource" procedures are performed in conjunction with other, more intense procedures and it is very beneficial to the patient to receive both procedures simultaneously. In addition, the physician must have the autonomy to decide where the best site of service is for a particular patient based upon his medical judgment and not based upon an arbitrary rule based upon resource utilization. We believe the Agency's proposals regarding procedures that are frequently performed in an office setting will address any concerns regarding an unjustified shift in the site of service. If a particular procedure is not done in the physician office frequently that must mean it is done in the hospital outpatient quite often and must be assigned to an APC group. The same policies that apply to how these limited resource use procedures are reimbursed in a hospital outpatient department should apply to an ASC.

C. Significant Safety Risk

1. Inpatient Only List

We agree that procedures that are on the "inpatient only" list should not be performed in an ASC. We believe the Agency, the hospitals and the physician community work diligently to evaluate this list and that it is the single best determination as to what procedures should not be performed on an outpatient basis.

2. 80 Percent Rule

In the rule, the Agency has proposed to exclude from the ASC procedure list any procedure that is performed in a hospital inpatient setting more than 80 percent of the time. The Agency selected 80 percent because it "believes that an 80 percent level of inpatient

performance is a fair indicator that a procedure is most appropriately performed on an inpatient basis and as such, would pose significant safety risks for Medicare beneficiaries if performed in an ASC."

We do not agree with the proposed "80 percent rule" for several reasons. First, it is inconsistent with MedPAC's recommendation that clinical safety standards and an overnight stay are the only criteria for excluding a procedure from the ASC list. Second, requiring that a procedure be performed on an inpatient basis less than 80 percent of the time is not in itself a clinical safety standard, but in fact assumes that the only reason a procedure is performed on an inpatient basis is because of clinical safety reasons. In reality, this is not necessarily the case. In some instances, the patients frequently in need of the procedure may be physically located in a hospital inpatient unit and this may dictate where the surgery is performed rather than the safety concerns regarding the surgery itself. For example, many patients in need of a procedure to place a feeding tube are physically located in a hospital inpatient department and their procedures are logically done as inpatients because of the continued needs of the patient for further hospital care. However, there are no actual clinical safety reasons why the procedure could not be done in an ASC. In addition, other factors, including equipment location, also influence where in the hospital a procedure is performed.

We do not expect the removal of the 80 percent rule to have a significant impact on the number of procedures that can be performed in an ASC because many of these procedures will likely be excluded for clinical safety reasons or the requirement of an overnight stay. We do believe however, that the 80 percent rule is unnecessary and redundant given these other requirements. What we are objecting to is a blanket rule that excludes hundreds of procedures that have not been evaluated on their own merits and are merely being excluded because they do not meet an arbitrarily set threshold. We believe this policy violates the spirit of an exclusionary rule, which insinuates that the procedures being excluded have actually been reviewed and analyzed and have been determined to have a specific safety concern that can be clearly articulated. We believe the 80 percent threshold is a good first-level filter of potential excluded procedures, but it should not be the final determinant for whether a specific procedure is excluded.

3. Criteria for Evaluating Safety Risks

In the proposed rule, the Agency has determined that "procedures that involve major blood vessels; prolonged or extensive invasion of body cavities; extensive blood loss; or are emergent or life-threatening in nature could, be definition, pose a significant safety risk. Therefore, we are proposing to exclude from payment of an ASC facility fee, procedures that may be expected to involve any of these characteristics based on evaluation by our medical advisors." These criteria were also used in the past when creating the "inclusionary"

ASC procedure list. We note that the Agency used the word "could" pose a significant safety risk, and again have concerns about excluding procedures have not been evaluated on their merits.

As with the 80 percent rule, we again have concerns over blanket statements and rules regarding clinical safety risks. For example, there currently is a multitude of procedures currently on the ASC list that "involve major blood vessels." There are other procedures that "involve major blood vessels" that will not be added to the list in 2008 that we strongly feel can and should be performed in an ASC. And, there are still other procedures that "involve major blood vessels" that we absolutely feel should not be performed at an ASC. In addition, it is not clear to us how the Agency is defining "major blood vessel" when making the determination of which procedures can be performed in an ASC and, quite honestly, the surgical community itself does not have a clear definition of a "major blood vessel" versus and "minor blood vessel." From this we conclude that "involving major blood vessels" is not a good absolute standard to use when determining what procedures can be safely performed at an ASC, but instead factors such as the likelihood of complications for a given procedure; the nature of common complications; and ability to address common complications intraoperatively with the personnel and resources traditionally available at an ASC should determine which procedures should be included in the ASC list. For example, a procedure that involves a major blood vessel that has a low overall complication rate and complications that are not generally immediately life-threatening and can be easily treated by the operating surgeon with the standard equipment available could be performed in an ASC. An example of this would include the insertion of a portacath into the vena cava. On the other hand, procedures with significant complication rates and/or catastrophic complications that require additional personnel / resources should be excluded from the ASC list. On the other hand, procedures with significant complication rates and/or complications that are catastrophic in nature and often require additional personnel or a different specialty to handle, additional equipment or supplies that are not normally available in an ASC or require the surgeon to perform a procedure that has been excluded from the ASC list should not be performed in an ASC. For example, if a likely complication would require the use of a cell saver, a piece of equipment not normally available in an ASC, or a heart lung bypass machine, we believe this procedure should not be performed in an ASC.

We have the same concerns regarding the other nebulous criteria CMS has set forth, including "prolonged and extensive invasion of body cavities", "extensive blood loss" and "emergent and life threatening in nature." In each of these instances, we find procedures that are currently on the ASC list that may occasionally fall under one or more of these categories and procedures that are being excluded that could reasonably safely be performed in an ASC. These criteria are neither defined nor do they have common medical

significance to the surgical community. Finally, we find there are still other procedures that are and should be excluded from the ASC procedure list that technically do meet any of these criteria (in particular, a multitude of brain and spine procedures).

We again believe that procedures involving "major blood vessels," prolonged or extensive invasion of body cavities; extensive blood loss; or are emergent or life-threatening in nature are nonetheless a good initial determination of what procedures might be "tagged" as needing further consideration and evaluation. We do not believe the analysis should end there, however. We also note that when the ASC procedure list was first created, there was scant safety data to rely upon when making a determination of whether a procedure could be appropriately done in an ASC. This dynamic has changed over the past 15 years with the proliferation of the National Surgical Quality Improvement Project (NSQIP) and other outcomes databases; patient and device registries; as well as other patient safety and quality improvement projects. We no longer have to guess about a procedure's safety and possible complications – but in fact, we now have actual data that can concretely demonstrate the risks, complications and overall safety of a given procedure. We encourage the Agency to work with the College to use those valid data sources to further refine the rule.

As with the 80 percent rule, we recognize that what we are proposing is not an "easy" way to create the ASC exclusionary list and that bright clear lines are more simply administered by the Agency. However, we do not think this is consistent with the spirit of an exclusionary list or MedPAC's recommendation. We again believe a procedure should be evaluated on its own merits before it is excluded because of safety concerns.

We believe there are three ways the Agency can accomplish this goal:

1) it can review procedures that are of specific concern and articulate a position about the specific procedure in question;
2) it can ask outside organizations to perform much of the clinical and research work needed to make these types of determinations. The American College of Surgeons has in the past worked closely with the Agency to review procedures for safety concerns and appropriate site of service and we would be more than happy to do whatever the Agency needs us to do in order to make this process run smoothly and efficiently; and
3) at a minimum the Agency could at least allow for exceptions and put the onus on the surgical society to demonstrate safety for a specific procedure.

4) Overnight Stay

In the proposed rule, CMS has proposed that procedures for which prevailing medical practice dictates an overnight stay should be excluded from the ASC procedure list

and has defined overnight stay as "typically expecting to require active medical monitoring and care at midnight following the procedure." We agree procedures that require and overnight stay should not be performed at an ASC and with the Agency's definition of overnight stay. We also believe this definition is consistent with other accepted definitions and standards of the term.

C. Treatment of Office-Based Procedures

In the proposed rule, the Agency proposes to allow procedures that are commonly performed in the office to be performed in an ASC. This change in policy is responsible for a large majority of the procedures being added to the ASC procedure list. In order a prevent an inappropriate shift in the site of service from the office to an ASC, CMS proposes to limit the ASC facility payment for procedures done in the office more than 50 percent of the time to the Medicare physician fee schedule non-facility practice expense amount.

We agree that procedures that are commonly done in the office should be allowed to be performed in an ASC. An ASC provides an alternative between the physician office and a hospital outpatient that may be appropriate for many patients who do not quite fit the profile of an office patient, but do not need the intensity of the hospital outpatient department. In addition, many of these procedures may be performed in conjunction with other procedures that do require an ASC facility. We also do not want to encourage an inappropriate shift in service from the office to an ASC.

We do, however, have concerns about the "50 percent rule." If a procedure is performed in an office 50 percent of the time, that means half the time the physician has determined that the office is NOT the appropriate setting for specific patients. We feel this number is significant. There are often very significant clinical reasons why one patient may have a procedure performed in an office and another require the services of an ASC. The policy proposed by CMS insinuates that the site of service selection is the physician's "choice," but often it is the clinical circumstances that dictate, not the physician's personal preference.

The Agency's proposal presumes that the procedure that is done in the office is the exact same procedure that is done in the ASC. This is often not the case. Our experience has been that surgeons often do a procedure in the office when anesthesia is not required and perform it in an ASC when anesthesia is required due to the complexity of an individual procedure or patient factors. The necessity of anesthesia is often the determining factor. A procedure performed in an ASC with anesthesia certainly cannot be done for the same cost as the same procedure in a physician office without anesthesia. The Medicare physician fee schedule's non-facility practice expense component would not cover these costs and we

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do not feel ASCs nor the Medicare beneficiary should be penalized with an unreasonable payment for services rendered We similarly do not want to implement a policy that encourages surgeons to perform procedures in their offices without anesthesia.

We share the Agency's concern regarding an unjustified shift in the site of service. In order to balance this concern with the need to support cases that are justly performed in an ASC, we recommend the Agency:

1) consider raising the threshold above 50 percent to a number that shows the clear majority of cases are performed in the office; and
2) allow an exemption to the cap for procedures that are performed in an ASC because of the necessity of anesthesia.

We believe the Agency could implement this policy through the use of a modifier that indicates the surgeon selected the ASC over the physician office as the site of service because of the necessity of anesthesia or patient factors. We believe this is a fair policy because it recognizes that there are many specific clinical reasons for utilizing the ASC as well as actual additional costs associated with the procedure that are not normally present when the procedure is performed in an office.

We also have concerns regarding the Agency's proposal related to procedures that initially fell under the office procedure cap. In the rule, the Agency states that once a procedure is performed in the office setting more than 50 percent of the time, it will forever be subject to the MFS non-facility practice expense cap. While we agree that it would be unlikely for a procedure that is commonly performed in an office setting to later require the services of an ASC or HOPD, it does happen. Most likely such a change would be caused by a change in patient population or technology. For example, the development of a new drug therapy, imaging device or procedure may shift the simplest patients away from a commonly performed procedure and leave only the most complex patients. In addition, a procedure that was once used to treat diagnosis A may change to treating diagnosis B, which could make the procedure itself more complex and no longer routinely performed in the office setting or could again lead to a change in patient population. We note that procedures listed on the Medicare fee schedule are constantly being revised, rewritten and revalued and there are a multitude of changes that could lead to a change in the site of service. We request that there be a reasonable, fair, and efficient mechanism for removing a procedure from the non-facility practice expense payment limit list if the site of service does change for a legitimate clinical reason.

D. Comments on the Exclusion of Specific Procedures

In the proposed rule, CMS provided two separate lists of codes that are being excluded and asked commenters to review the list and provide concrete, scientific evidence if they believe the codes are unfairly being excluded. We find this a difficult exercise to do at this time because, as our comments above have noted, we do not agree with many of the criteria CMS has use to exclude procedures from the ASC list. It is difficult for us to provide evidence that certain procedures do not meet standards that we do not believe in.

In general, however, we believe the following seven codes have been unjustly excluded from the ASC list:

44970 – lap appendectomy
45541 – correct rectal prolapse
47011- precut drain liver lesion
47562 – lap cholocystectomy
47563 – lap cholecystecomy/graph
47564 – lap cholocystoenterostomy
48511 – drain pancreatic pseudocyst

Using the criteria CMS has set forth, we find that none of these codes are performed on an inpatient basis more than 80 percent of the time. The fact that these procedures are performed on an outpatient basis more than 20 percent of the time demonstrates that an overnight stay is not "required" for any of them. Moving to the "clinical safety standards" articulated by CMS in the rule, we find that none of these procedures involve major blood vessels. In addition, there is not a significant threat of extensive blood loss for any of them and, as most of them are laparoscopic in nature, they do not involve extensive or prolonged invasion of a body cavity. While it is fairly common for appendicitis to be emergent or life-threatening in nature, this is not always the case and find that most cases scheduled in an ASC would be elective and, therefore, not emergent or life-threatening by definition. The other six procedures are not life-threatening or emergent in nature. Based on the criteria set forth by CMS, we request that these seven procedures be added to the 2008 ASC procedure list.

II. Ratesetting Method

A. GAO Report

As is the Agency, we are frustrated that the Congressionally-mandated GAO report comparing ASC costs with hospital outpatient department (HOPD) costs is not yet available, despite a deadline of almost two years ago. We appreciate CMS' decision to

move forward with the proposed new payment system in order to give ample time for the ambulatory surgical community to review and prepare for the changes, but note that the very premise that there is any correlation between HOPD costs and ASC costs and what the relationship might be is really a completely guess without the GAO report. We also observe that the overriding consensus was that specialty hospitals had lesser costs than community hospitals and further analysis demonstrated that this is not in fact the case. While it seems logical that ASCs would have lower costs than HOPDs in some areas, it also seems reasonable that certain capital costs and large ticket items like medical liability insurance are higher because they are not spread out across multiple cost centers. How these factors would balance out we really do not know. We feel that it is difficult to evaluate whether linking HOPD costs to ASC payment is a good idea and whether the proposed 62 percent of HOPD payment rate is adequate reimbursement for ASCs without the benefit of actual data and analysis. We suggest that CMS continue to pressure GAO for this report, or at least conduct its own study, before implementing a payment system that could be based on a faulty premise.

B. ASC Packaging

Under the current system, CMS pays ASCs a facility fee that includes drugs, biologicals, contrast agents, anesthesia materials and imaging services, but pays a separate fee for implantable prosthetic devices and DME inserted surgically. In an HOPD, the opposite is true and the facility fee includes implantable devices, but CMS pays HOPDs separately for drugs, biologicals, contrast agents, anesthesia materials and imaging services. While CMS claims its goal is to align the two payment systems, it proposes to maintain the current payment structure for HOPDs, but eliminate all additional payments to ASC, including those for implantable devices. We do not agree with this policy.

First, we note that if ASC payment rates are to be based on HOPD costs, then the payment for the two systems has to be based on the same inclusions. Because the costs of drugs and biologicals are paid separately in an HOPD, we assume these costs are not considered when classifying a procedure into a specific APC category and assigning a payment rate. However, when the same procedure is performed in an ASC, and it is assigned the same APC category, these costs will be included. In many instances, these costs are significant and the ASC payment rate would not even take them into account.

In addition, while we agree the two payment system should be aligned, it cannot be forgotten that a budget neutrality adjustment is being made to the ASC payment rate. In many instances the cost of an implantable device will be a huge portion of the cost involved in providing a procedure. In many instances, after the 62 percent budget neutrality adjustment is made to the HOPD rate, the ASC reimbursement will not even cover the cost of the implantable device, let alone the costs of actually doing the procedure.

In the proposed rule, CMS states it proposed this policy because it is "consistent with the principles of a prospective payment system." However, it is not consistent with the principles of a prospective payment system to reimburse a facility less than its costs for providing a procedure, especially when it cannot control the cost of certain devices it must purchase from outside vendors. CMS also states "we believe that ASCs are less likely to provide on a regular basis many of the separately paid items and services that patients might receive more consistently in a hospital outpatient setting." CMS provides no basis or citation for this statement and we find it to be completely unfounded. In addition, if CMS truly believes this then we do not see why it would object to add-on payments for these services because if the ASCs really do not provide them, CMS will not have to pay for them. We are also troubled by the fact that this is again another blanket statement and ignores the fact that there is great variety in the types of procedures ASCs perform.

Finally, we believe the policy encourages providers to make their site of service determination based on payment policy and rates and not on safety and beneficiary benefit. We recommend that payment for implantable devices and drugs and biologicals be made separately to ensure that reimbursement is covering at least their costs.

C. ASC Payment for Office-Based Procedures

As we have stated above, we support the performance of office-based procedures in an ASC when appropriate.

D. ASC Inflation

We are confused by CMS' proposal to update the ASC payment system using the CPI-U adjustment rather than the hospital market-basket update. We believe CMS has the authority to update the ASC payment system using the market basket update and believe this is the most consistent and fair approach.

We note that throughout the entire proposed rule, CMS states its goal is to align the two payment system. We believe aligning the two updates supports this goal. In addition, the rule is premised on the fact that there is a correlation between HOPD costs and ASC costs and, if this is true, it seems like both types of providers would have similar inflation-related yearly cost increases. Finally, we note that if the payment rates for one system increase at a higher level than the other system, this will affect the budget neutrality adjustment. For example, if HOPD rates rise at a rate of 3 percent a year and ASC rates rise at a rate of 1 percent a year and CMS maintains the .62 budget neutrality adjustment, if this pattern continues, in 20 years ASC will be paid at 42 percent of the rate of HOPDs.

E. ASC Phase-In

We appreciate CMS' proposal to phase-in the new payment rates over two years. However, given the drastic changes in reimbursement some procedures will see, we do not believe two years is a long enough phase-in period. While CMS states the two year period will give ASCs enough time to change their procedure mix in order to offset procedures that are being cut with greater volume in procedures that are experiencing increases, this premise assumes that all ASCs are multi-specialty and have this capability. This is not true and many ASCs are single specialty only and do not have the ability, expertise or equipment to take advantage of the rising reimbursement in other areas. For example, many cataract procedures are performed in ASCs that focus exclusively on this procedure, which is pegged to receive significant cuts under the proposed rule. A cataract-focused ASC cannot simply add arthroscopic knee surgery, which will see significant increases in reimbursement, to its caseload in order to offset its losses. We fear the drastic cuts to some procedures will lead to some single-specialty ASCs to closing their doors. We do not foresee other multi-specialty ASCs pursuing this business because they will likely be focusing on procedures that saw increases, not procedures that were cut so dramatically it drove previous ASC owners out of business. The only option left for this specialty is to move the procedure back into the HOPD, at an increased cost to the Medicare program and beneficiaries. We do not see how this would benefit anyone and urge CMS to extend the phase-in period.

F. ASC Conversion Factor

We have concerns regarding CMS calculations and assumptions when determining the 2008 ASC conversion factor. First, we note that the costs related to the separate payments made for implantable devices in 2007 do not appear to have been included in the 2007 costs. These costs are incurred by the program and should be included when in the 2007 figures used to determine budget neutrality. Second, we question several of the utilization assumptions CMS made when determining the budget neutrality adjustment and find that these assumptions unnecessarily lowered the conversion factor. Finally, we ask that CMS interpret the budget neutrality adjustment in the most broad method possible.

Sincerely,

Thomas R. Russell, MD, FACS
Executive Director

WO:TRR:bp/td

Submitter : Ms. Anna Weinstein **Date:** 11/06/2006

Organization : Susan G. Komen Foundation

Category : Consumer Group

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

ASC Payable Procedures

ASC Payable Procedures

2. ASC Payable Procedures (Exclusion Criteria)

CMS, in its revised CY 2008 ASC payment system, proposes to include all procedures that do not pose a significant safety risk when performed in an ASC and do not require an overnight stay. Like MedPAC, the Komen Foundation endorses this policy proposal. We urge the agency to consistently evaluate procedures based on these two criteria, and do so through an open, public process.

We thank the agency for listening to those who commented on the CY 2007 Update to ASC Procedures List, and corrected the omission of CPT codes 19290 and 19291 (Preoperative placement of needle wire, breast), from the ASC-approved procedures list for CY 2007. We trust that the agency will make the same correction to the list of CY 2008 covered procedures. In addition, we are pleased that in CY 2008, CPT codes 19000 and 19001 (Puncture, aspiration of breast cyst), have been added to the list of ASC covered procedures. (We regret, however, that these procedures are not listed in the CY 2007 OPPS final rule as being covered by Medicare in CY 2007.)

Komen also extends our appreciation to the agency for adding CPT code 19297 (Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioclement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy), to the list of ASC approved procedures in CYs 2007 and 2008. However, we are extremely troubled by the drastic rate reduetion from CY 2007 to CY 2008 proposed for a related procedure, CPT code 19298 (Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioclement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance) (88%). We are also concerned about the reductions for other procedures listed in the chart below, all of which are absolutely critical to the early detection of breast cancer and improving the quality of life for breast cancer survivors:

APC HCPCS/CPT Descriptor Percent Reduction From 2007 Rate to 2008 Proposed Rate
0005 19100 Biopsy of breast; percutaneous, needle core, not using imaging guidance (18%)
0005 19102 Biopsy of breast; percutaneous, needle core, using imaging guidance (18%)
0658 19103 Biopsy of breast; percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance (18%)
0029 19297 Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (17%)
1524 19298 Placement of radiotherapy afterloading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance (88%)

3. Effect on Beneficiaries

Under the new methodology, CMS proposes to allow payment of an ASC facility fee for certain office-based procedures that have been, historically, excluded from the ASC-approved list because the agency agrees with commenters that these procedures do not pose a significant safety risk and do not require and overnight stay. However, CMS expresses concern that allowing office-based procedures to be performed in an ASC may provide incentives for physicians to convert their offices into ASCs or to move office based procedures to the ASC setting. While we understand CMS desire not to induce inappropriate shifts in site of services, we believe that for a given procedure, physicians must be able to determine what setting is most appropriate given the patient s specific condition. Although physicians may be able to perform a particular procedure in his/her office, some patients are sicker or more frail and may require the additional infrastructure and safeguards that an ASC can provide to help ensure safe and effective

ASC Ratesetting

ASC Ratesetting

Dear Acting Administrator Norwalk:

The Susan G. Komen Breast Cancer Foundation is pleased to have the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments on the proposed changes to the Ambulatory Surgery Center (ASC) payment methodology for CY 2008.

The Komen Foundation is a global leader in the war against breast cancer. Founded in 1982, the Komen Foundation is now comprised of 121 Affiliates nationwide, three international Affiliates and 75,000 volunteers. Komen has invested more than $630 million dollars for breast cancer research, education, screening and treatment programs, and actively addresses the gaps and disparities in the needs of the medically underserved.

The Foundation appreciates the work CMS has done in the past to help ensure access to quality breast health care and breast cancer care. Our main points