Submitter : Mr. Matt Pate **Date:** 11/06/2006

Organization : USP1

Category : Health Care Professional or Association

Issue Areas/Comments

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.

Submitter : Ms. Cathy McCue **Date:** 11/06/2006

Organization : North Shore Same Day Surgery

Category : Ambulatory Surgical Center

Issue Areas/Comments

ASC Coinsurance

ASC Coinsurance

We support retaining the Medicare beneficiary coinsurance for ASC services at 20%. 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

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A 62% conversion factor is unaceeptable and often does not cover the cost of the procedure potentially forcing the facilities not to perform these procedures forcing the Medicare patient back into the more expensive hospital setting. We understantd 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 a industry comment letter. We encourage CMS to accept this industry model of a 73% conversion factor.

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 prbability of a good clinical outcome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his specific condition.

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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 opthalmmology, 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

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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. Algining 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

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ASC Updates

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We are pleased that CMS is committing to annual updates of the new ASC payment system, and agree it makes sense to do that conjuction 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.

Submitter : Mr. Matt Pate **Date:** 11/06/2006

Organization : USPI

Category : Health Care Professional or Association

Issue Areas/Comments

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Submitter : Ms. Rory Qaulls **Date:** 11/06/2006

Organization : Baylor Surgicare at Garland

Category : Ambulatory Surgical Center

Issue Areas/Comments

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Submitter : Ms. Tami Shea **Date:** 11/06/2006

Organization : Baylor Surgicare at Lewisville

Category : Ambulatory Surgical Center

Issue Areas/Comments

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ASC Wage Index

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Submitter : **Dr. Renato Bosita** **Date: 11/06/2006**

Organization : **Texas Back Institute**

Category : **Physician**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

Re: 2007 OPPS Proposed Rule (CMS-1506-P) Comments on Proposed Revised Ambulatory Surgical Center Payment System for Implementation January 1, 2008 (Seetion XVIII)

I am writing to you concerning the above Rulemaking published on June 12, 2006, regarding updates to rate-setting methodology, payment rates, payment policies, and the list of covered surgical procedures for ambulatory surgical centers. I am a spine surgeon in full-time practice in North Texas.

The goal for all of us--providers, physicians, and payors--is to create a health care system that delivers excellent clinical outcomes in a cost efficient environment.

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 antiquated cost data and crude payment categories underlying the current ASC system, we welcome the opportunity to link the ASC and hospital outpatient department (HOPD) payment systems. The following comments focus on three principles:

1. Maximize parity between the ASC and HOPD payment systems to prevent differences between the payment systems.

2. Ensure beneficiary access to a wide range of surgical procedures that can be safely and efficiently performed in the ASC.

3. Establish 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.

ASC Conversion Factor (Section XVIII.C.11)
62 % conversion factor is unacceptable and often does not cover the cost of the procedures. 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.
We ask that equal work be valued fairly in both an ambulatory and hospital setting. ASC s provide alternatives for health care delivery that maximize access, convenience, and quality for patients. They are a win-win situation for healthcare in our country.
ASC Ratesetting (Section XVIII.C.2); ASC Packaging (Section XVIII.C.3); ASC Payment for Office-Based Procedures (Section XVIII.C.5); ASC Multiple Procedure Discounting (Section XVIII.C.6); ASC Wage Index (Section XVIII.C.7); ASC Inflation (Section XVIII.C.8)
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 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.

ASC Phase-In (Section XVIII.C.10)
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.
If you have questions or would like to visit me about my comments, I can be reached at 972-608-5094 or rbosita@texasback.com and again I thank you for your time.

Submitter : Dr. Hemmo Bosscher **Date:** 11/06/2006

Organization : Hemmo A. Bosscher, M.D, P.A

Category : Other Health Care Professional

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

Re: CMS 1506-P

Dear Ms Norwalk,

I would like to make a few comments with respect to the proposed rule on the Medicare Program and the Ambulatory Surgical Center Payment System and Payment Rates for 2008. With the aging population, treatment of moderate to severe chronic pain will put significant demands on our resources (Medicare). 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.

Methods of treatment consist of medication, interventional pain management or observation. Treatment with medications will consist of prescribing time contingent narcotics. Even though this is of great interest to the Pharmaceutical industry (through Medicare D), it has significant ethical, financial and medical problems associated to it.

Appropriate interventional pain management targets the pain problem directly. It is more effective and provides better patient satisfaction. It is also a cheaper solution. However, it comes with certain expenses in the office. In addition, Interventional pain management involves treatment of neural elements with all its associated risks. Inadequate reimbursements for the physician may lead to the third solution which is observation, since pharmaceutical therapy alone is not a viable alternative in many pain management clinics.

Sincerely,

Hemmo A. Bosscher, M.D., P.A.

Submitter : Dr. jennifer Greger **Date:** 11/06/2006

Organization : Dr. jennifer Greger

Category : Physician

Issue Areas/Comments

ASC Payable Procedures

ASC Payable Procedures

This comment is submitted in response to the Proposed Rule encompassing the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates that was published in August 2006. In particular, this comment addresses the proposed exclusion of three continuous nerve block codes from payment of an ASC facility fee. These procedures may be safely procided in an ASC setting and should be included for payment.

According to the proposed rule, CMS prososes to use "beneficiary safety and the need for an overnight stay as the pricipal clinical considerations and factors determining wheter payment of an ASC facility fee would be allowed for a particular surgical procedure." CMS states that it has determined that services that are performedf in an inpatient setting more than 80% of the time pose significant safety risks for Medicare beneficiaries if performed in an ASC setting. CMS, in turn, is proposing to abondon the existing standard which states that covered surigal procedures are those that are commonly performed on an inpatient basis but may be safely performed in an ASC.

The proposed rlue includes continuous nerve block codes 64446(sciatic), 64448(femoral) and 64449(lumbar plexus) in the list of services to be excluded from payment of an ASC facility fee because at least 80% of Medicare cases are performed on an inpatient basis. We respectulyy posit that CMS' proposed rejection of the current standard for payment of an ASC facility fee in favor of a numeric threshold is misguided. By rejection this straightforward standard in favor of the 80% test, CMS is not servingthe principal clinical considerationit claims to be following. It would be replacing a direct test of safety, with an indirect test based upon speculation. CMS speculates that high inpatinet utilization frequencies are complex and likely to require a longer and more intensive level of care postoperatively than is offered in an ASC.Yet CMS offers no datta whatsoever to support this speculation. Further, such a standard works in opposition to the medically recognized fact that it is preferable to perform surgeries in an outpatinet and ASC setting for both cost and safety reasons.

Retention of the current standared including payment for procedures that may safely be performed in an ASC would warrant payment for procedures that mya safely be performed in an ASC would warrant payment for the continuous nerve block codes. As described below, codes 64446,64448, 64449(that have been included in the OPPS rules for some time) may indeed be performed safely in an ASC settin and should be included for payment of an ASC facility fee.

I am an anesthesiologist who has been doing single shot nerve blocks for 11years and sending patients home with catheters for 9 years. I have spoken internationally and nationally on regional anesthesia and the benefit of postoperative pain management. I routinely perform blocks in an ASC setting and send patients home with catheters involing the femoral, scaitic and brachial plexus nerves. I have yet to have any kind of complication and the patients are incredibly satisfied with their care. I feel that alot of patients would not be able to go home without pain relief. This would only increase the dissatisfaction of the patient while also increase the cost of medical care to everyone.

Rejection of payment of a facility fee based upon a numeric threshold of inpatient cases ignores the physician's medical decision making in determining which procedures should be performed in an inpatient setting and which should be performed in and outpatinet/ASC setting. Further, use of a numeric threshold will hinder the utilization of state of the art technologies that are emerging as the standand of care. Technologies, such as continuous nerve blocks that allow many surgeries to safely be performed in an outpatient and ASC setting, will be hampered by such a rule. Physicians who understand the great benefits of such procedures will

ASC Payable Procedures

ASC Payable Procedures

be forced to perform surgeries on an inpatinet basis or at a hospital based outpatient surgery center when they could just as safely be perfomed at an ASC. Particularly in the case of surgeons who chose to admit their patients for inpatinet surgery instead os surgery at an ASC, the cost to both Medicare and the patient is greater. further, and more important, the risk to the patient of complications can be increased in an inpatient setting. It is common knowledge that hospital acquired infections and other related complications are a significant risk to the elderly. CMS should be encouraging surgeries that can safely be perfomed in an ASC setting rather that discourating them.

In sum, the stands should remain that payment of an ASC facility fee is based upon wheter the surgery can safely be performed in and ASC setting. Since continuous nerve blocks, 64446, 64448, and 64449 can be performed safely in an ASC setting , they should be ineluded in the list of payable codes.

Sincerly,
Jennifer Greger MD
30 Palmer Crest Ct
The Woodlands, Tx 77381

Submitter : **Dr. Reuben Sloan** **Date: 11/06/2006**

Organization : **Resurgens Orthopaedics**

Category : **Physician**

Issue Areas/Comments

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ASC Wage Index

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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 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.

Submitter : **Mrs. Janine Berryhill** **Date: 11/06/2006**

Organization : **USPI**

Category : **Individual**

Issue Areas/Comments

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.

ASC Payable Procedures

ASC Payable Procedures

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.

Submitter : Mrs. Janine Berryhill **Date:** 11/06/2006

Organization : USPI

Category : Individual

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 forcing 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 outcome. 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.

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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

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Submitter : Mr. Rick Pollack **Date:** 11/06/2006

Organization : American Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1506-P2-940-Attach-1.PDF

American Hospital Association

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November 6, 2006

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W., Rm 445-G
Washington, DC 20201

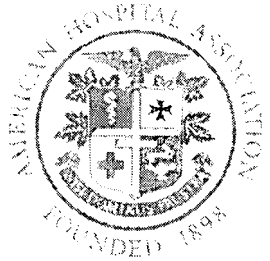
Ref: [CMS-1506-P] Medicare Program; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (71 Federal Register 49506), August 23, 2006.

Dear Ms. Norwalk:

On behalf of our nearly 5,000 member hospitals, health care systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to establish new policies and payment rates for ambulatory surgical centers (ASCs) in 2008. This proposed rule includes a major restructuring of the criteria used to determine which procedures may be covered in ASCs, as well as an overhaul of the payment system for services provided in ASCs.

We are concerned that CMS' proposed standards are inadequate for determining which services may be performed safely in ASCs. We also are concerned that the proposed 2008 broad expansion of the number and types of services that may be performed in ASCs could jeopardize patient safety and quality of care. The regulations and facility standards to which ASCs are subject fall far short of the requirements hospitals and their outpatient departments must meet with regard to patient safety, patient rights, quality assurance and operating standards. It also is not clear that either federal or state oversight would be rigorous enough to ensure patient safety if the volume of services and complexity of procedures furnished in ASCs were to increase, as would happen if this rule were finalized.

Therefore, we recommend that CMS defer implementing any changes to the current criteria for determining ASC payable procedures until the Medicare conditions of participation for ASCs and/or hospital outpatient departments are revised to ensure comparable patient protections for comparable services in these settings.



All providers of surgical services should meet comparable quality monitoring, operating room equipment, staffing, infection control, anesthesiology and other relevant standards.

Further, we recommend that CMS continue working with the Hospital Quality Alliance (HQA) and the AQA (formerly known as the Ambulatory Quality Alliance) to identify and implement measures that truly assess aspects of quality across all ambulatory care settings. The HQA has begun to include the measures of care used in the Surgical Care Improvement Project (SCIP), of which CMS, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the American College of Surgeons and the AHA are all founding members. We believe the SCIP goal of preventing complications in the care of a wide spectrum of surgical patients provides an appropriate starting point for determining the correct measures for assessing important aspects of the safety and quality of all types of ambulatory surgery. We urge CMS to work with its SCIP partners to identify measures that are important and appropriate for the care of surgical patients in the ambulatory setting.

Medicare payment for different settings should reflect the underlying costs and the types of patients served. Unfortunately, given the absence of any national set of ASC cost data, it is difficult to determine whether the proposed ASC payment system adheres to this principle. CMS should set the overall payment rate for ASCs significantly below that for hospital outpatient departments. As a result of additional and more stringent regulatory requirements – such as the *Emergency Medical Treatment and Labor Act* – 24-hour/seven days a week availability, higher indigent care rates and more medically complex patients, hospitals are more costly care settings.

In order to allow for future validation of the relative appropriateness of ASC payment weights and rates, CMS should seek congressional authority to require ASCs to report cost data. This could be accomplished through implementing an ASC cost-reporting system or a periodic collection of ASC cost data at the procedure level to monitor ASCs and to refine the relative weights to reflect the relative costs of various ASC services. **In addition, payments under the new ASC system should be held neutral to what payments would be under the current ASC system, as Congress intended – not to total outpatient payments.** It is critical that these payments are correct in order to help prevent financial incentives that would inappropriately shift services from one outpatient setting to another.

The AHA appreciates the opportunity to comment. The attached detailed comments expand on the above points. If you have questions, please feel free to contact me or Roslyne Schulman, AHA senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

The American Hospital Association's Detailed Comments on the Proposed Rule Revising the Ambulatory Surgical Center Payment System in 2008

In the *Medicare Modernization Act of 2003* (MMA), Congress mandated that the Centers for Medicare & Medicaid Services (CMS) create a new ambulatory surgical center (ASC) payment system no later than January 1, 2008, and that the revised system be budget neutral in 2008. Consistent with this mandate, the proposed ASC rule for 2008 includes significant revisions to the criteria for excluding services from ASC coverage and an entirely new payment structure based primarily upon the hospital outpatient prospective payment system (PPS) payment weights and policies.

ASC PAYABLE PROCEDURES

Proposed Payable Procedures

CMS proposes significant changes to its criteria for determining the procedures for which Medicare will pay an ASC. Consistent with Section 1833(i)(1) of the *Social Security Act*, CMS currently publishes a list of nearly 2,500 surgical procedures that can be safely performed in an ASC. For 2008 and beyond, CMS plans to replace the current "inclusive" list of procedures for which Medicare allows payment of an ASC facility fee with an "exclusionary" list. Beginning January 1, 2008, ASCs would be paid for any surgical procedures allowed to be performed in a hospital outpatient department, except those surgical procedures that CMS determines are not payable under the ASC benefit. CMS proposes to exclude from coverage only those surgical procedures that could pose a significant safety risk when performed in an ASC, procedures that require an overnight stay and unlisted surgical current procedural terminology (CPT) procedure codes. These proposed policy changes would expand the ASC-allowed list by more than 750 procedures.

The AHA is concerned that, in moving from a framework of an "inclusive" list of procedures to a system in which *any* procedure may be done that is not specifically excluded, CMS has given inadequate consideration to all of the factors that must be considered to reasonably assure that the expanded services can be provided safely in the ASC setting. CMS has proposed the use of a limited number of procedure-specific factors to determine which services will be paid for in ASCs. Procedure-specific factors alone are inadequate to protect beneficiaries. Research suggests that patient outcomes are a function of three kinds of factors: (1) procedure-specific factors; (2) patient-specific factors; and (3) organization-specific factors.[1,2] These factors are inter-related with regard to their impact on risk and patient outcomes.

The AHA believes that, in addition to procedure-specific factors, CMS should develop exclusion criteria for patient-specific and organization-specific factors, such

as those outlined in our Table 1 on page 10. In the absence of such additional considerations, CMS has an inadequate basis upon which to draw to determine whether services may be safely performed in an ASC. In addition, organizations and surgeons must clearly understand what is meant by each term that is used in the defining criteria. In the proposed rule, CMS used ambiguous terms such as "major blood vessel." We recommend definitions for several of CMS' proposed procedure-specific clinical criteria, as well as two additional procedure-specific criteria for consideration.

Furthermore, the regulations and facility standards to which ASCs are subject fall short of the standards that hospitals and their outpatient departments must meet in areas such as patient safety, patient rights, quality assurance and operations (e.g., facilities, equipment, staffing, etc.). ASCs have fewer and often lesser standards, with infrequent compliance surveys, and are not required to report detailed cost and quality data to Medicare. State licensing requirements vary in the degree to which these gaps are filled.

CMS should defer implementing any changes to the current criteria for determining ASC payable procedures until and unless the Medicare conditions of coverage for ASCs and/or hospital outpatient departments' conditions of participation regarding patient safety, patient rights, quality assurance and operating standards are revised to ensure comparable patient protections for comparable services. We are aware of major differences between the safeguards currently in place for hospital outpatient surgical departments and those required for ASC and are concerned that these differences would place ASC patients undergoing some of the more difficult or hazardous procedures at unnecessary risk.

For example, in our review, we found critical gaps in the conditions of participation for ASCs relative to hospitals, including:

- No infection control standard exists in the ASC conditions of coverage that requires the presence of an infection control officer who develops and implements policies governing infections. Hospitals are required to have an infection control officer as part of their effective infection prevention programs.

- ASCs have no requirement for a facility-wide quality assurance and training program, as hospitals do.

- ASCs have no patients' rights standards. Hospital conditions of participation require them to comply with patients' rights requirements, such as establishing a process to promptly resolve grievances and the requirement that hospitals comply with patient advance directives.

- In hospitals, an experienced nurse or physician must supervise the operating room, the hospital must maintain a roster of practitioners, specifying the surgical privileges of each, and a complete history and physical workup must be included

in the patient's chart prior to surgery (with the exception of emergencies). None of these requirements apply to ASCs.

It is of special concern that the public is unaware of these differences in standards and assumes a greater degree of facility oversight and patient protection than exists.

In addition, a study on quality oversight of ASCs by the Department of Health and Human Services' Office of the Inspector General (OIG) found that the ability of states to oversee ASCs on behalf of Medicare is eroding because of the growth in the number of ASCs and states' limited resources. Of state-surveyed ASCs, one-third (872) had not undergone a recertification survey in over five years. The OIG also found that CMS gives little oversight to ASC surveys and accreditation and does not make findings readily available to the public, as it does for hospitals and other types of providers.[3]

The AHA believes that comparable standards and oversight should be applied to providers of comparable services. That is, health care standards should be service-specific, not setting-specific. Under CMS' proposal, 99 percent (in terms of both number of services and payment) of hospital outpatient department surgical services would be payable in the ASC setting. Achieving comparability should be driven by what is reasonably needed, regardless of setting, to ensure patient safety and quality. This ensures that patients have the same quality protections for similar services in every care setting.

In addition, we believe that ASCs should report quality data to the same extent as hospital outpatient departments. In other parts of the proposed rule, CMS proposes linking the receipt of a full outpatient payment update in 2007 and 2008 with the reporting of inpatient hospital quality measures. CMS further signals its intention to require reporting of outpatient-specific quality measures for purposes of determining the outpatient PPS update as early as 2009. Similar quality reporting requirements have not been proposed for ASCs.

The public deserves accountability for quality from all providers. It would not be prudent to expand the ASC procedures list so significantly in the absence of both comparable standards and quality reporting requirements. **We again recommend, as we did in our October 10 comment letter on the outpatient PPS, that CMS continue to work with the Hospital Quality Alliance (HQA) and AQA (formerly known as the Ambulatory Quality Alliance) to identify and implement measures that truly assess aspects of care quality across all ambulatory care settings. In the case of ASCs, we believe that the Surgical Care Improvement Project (SCIP) measures should be considered for their applicability to the ambulatory care setting.** Not all may be appropriate, but it is likely that many would be, and this program, which already makes use of scientifically sound measures that have been, or are in the process of being, endorsed by the National Quality Forum, would make it possible to rapidly embrace transparency on quality of care in the ambulatory setting.

Proposed Procedure-specific Criteria under a Revised ASC System
As noted earlier, CMS proposes to exclude from coverage in an ASC setting surgical procedures that could pose a significant safety risk when performed in an ASC or that require an overnight stay. To identify procedures that pose a significant safety risk, CMS proposes revised criteria that would exclude:

- procedures currently included on the outpatient PPS inpatient-only list;
- procedures that are performed 80 percent or more of the time in a hospital inpatient setting; and
- procedures that directly involve major blood vessels, result in extensive blood loss, require major or prolonged invasion of body cavities or are generally emergency or life-threatening in nature.

Finally, CMS proposes to no longer use certain other "time-based" criteria currently used to define surgical procedures that pose a significant safety risk. For instance, CMS proposes to no longer consider – for purposes of excluding procedures from the ASC coverage list – whether a procedure exceeds 90 minutes of operating time, four hours of recovery time or 90 minutes of anesthesia.

Several of these procedure-specific exclusionary factors, such as "major blood vessel," "extensive blood loss" and "major or prolonged invasion of body cavities," are not further defined within the scope of the ASC regulation and, as such, are largely subjective in nature. As noted earlier, given the differences in standards between the hospital outpatient and ASC settings, and the fact that these clinical criteria will be used in the absence of any more objective numeric criteria that exist under current regulation, establishing clear definitions of these terms is an important step toward ensuring the safety and quality of care for Medicare beneficiaries. Therefore, as CMS seeks to expand access to procedures in ASCs, it is more important than ever to define parameters and criteria that clearly distinguish procedures that are appropriate or inappropriate for this alternative care site.

We recommend clarifications to the definitions of several current exclusion criteria, as well as additions to the current list of exclusion criteria. Specifically, the AHA recommends the following definitions for current clinical criteria.

"Major Blood Vessels." The AHA recommends that CMS adopt the definition of "major blood vessel" advanced by Seeley, Stephens and Tate in their medical textbook, *Essentials of Anatomy & Physiology, 6th Edition.*[4] This list includes not only the heart and the aorta, but also vessels providing primary blood supply to major limbs and organs, including the legs and the kidneys.

Please note that because procedures involving some of the vessels defined as "major" by Seeley, *et al.*, are already performed safely in ASCs (e.g., thrombectomy, percutaneous, arteriovenous fistula), we have omitted these vessels from the list. As a result, the

following vessels should be included in the definition of "major blood vessels" and should, in general, be excluded from the ASC list:

- Heart
- Divisions and Branches of the Aorta
    - Ascending aorta
    - Aortic arch
    - Descending aorta (thoracic and abdominal aorta)
- Arteries of the Shoulder and Upper Limb
    - Right and left subclavian arteries
    - Axillary arteries
- Arteries of the Head and Neck
    - Common, external and internal carotid arteries
    - Vertebral arteries
- Major Branches of the Abdominal Aorta
    - Celiac trunk
    - Superior and inferior mesenteric arteries
    - Renal arteries (supplier of blood to kidneys)
    - Gonadal arteries
    - Common iliac arteries (at L_5 level; sole supply of blood to legs)
- Arteries of the Pelvis and Lower Limb
    - Right or left common iliac artery
    - Femoral artery
    - Posterior tibial artery
    - Anterior tibial artery
- Veins Entering the Right Atrium
    - Coronary sinus veins
    - Superior and inferior vena cava
- Veins of the Head and Neck
    - External and internal jugular veins
    - Vertebral vein
- Veins of Abdomen and Pelvis
    - Hepatic veins
    - Renal veins
    - Gonadal veins
    - Right and left common iliac veins

- Veins of Lower Limb
    - Anterior and posterior tibial veins
- Hepatic Portal System
    - Hepatic portal vein
    - Mesenteric veins
    - Gastric veins
    - Cystic vein[5]

The clarification of these definitions is intended to help appropriately limit the expansion of procedures to the ASC setting. Exceptions would be made for procedures involving these vessels that are safely performed in ASCs today.

"Extensive Blood Loss." We recommend that CMS further define the term "extensive blood loss" to refer to procedures that typically result in the loss of 15 percent or more of total blood volume during the routine performance of the procedure (excluding any peri-procedural complications). According to the American College of Surgeons, the loss of less than 15 percent of total blood volume typically results in no change in vital signs, and fluid resuscitation is usually unnecessary.[6] Therefore, a patient losing less than 15 percent of total blood volume could reasonably be managed in an ASC.

"Major or Prolonged Invasion of Body Cavities." The AHA recommends that CMS define "prolonged" invasion as referring to any procedure in which the patient is under anesthesia for a period of 90 minutes or longer, since there is a correlation between a higher rate of adverse events and prolonged anesthesia time. We also propose that CMS expand this definition to include not only major body cavities, but also major blood vessels.

We also recommend that the following three criteria be added as factors that would exclude a procedure from payment in an ASC.

Access Methodology Exclusion. Interventional procedures requiring puncture of the femoral artery to gain access should be excluded from payment in an ASC. The rationale for this recommendation is related to the risks associated with transporting patients that have complications involving these types of interventional procedures. When complications necessitating hospital-based management arise in a physician office or ASC setting, they require transport to a hospital for further management while maintaining open femoral access. Transporting a patient with an open femoral puncture can result in dissection or infection. Interventional procedures involving femoral artery access are associated with a significant rate of peri-procedural complications. For example, in one study of 97 patients [112 interventions], 3 percent of patients had to be admitted to hospitals due to complications related to femoral puncture. These

complications included a major puncture site hematoma requiring blood transfusion.[7] In another study of 197 interventional procedures, 177 of which were balloon dilations requiring femoral access, there were 68 complications (35 percent), including five patients (2.5 percent) who had significant problems that required admission and active therapy.[8] Waugh and Sacharias described a significant complication rate of 3.6 percent among patients undergoing peripheral interventional procedures (63 percent of which were balloon angioplasty procedures).[9]

Lytic Therapy Exclusion. The AHA recommends excluding from payment in an ASC procedures involving blood vessels where, if occluded, inpatient lytic therapy would be required. Occlusion is commonly found in, or may be a complication of, peripheral vascular interventions, and is often managed with inpatient lytic therapy. In one study of 181 lesions in 166 vessels, 55 percent of lesions were either occluded or stenosed and occluded.[10] In another study of 23 patients with critical limb ischemia, patients typically presented with combined stenoses and occlusions in 15 (60 percent) limbs, stenoses alone in four (16 percent), and occlusions alone in six (24 percent).[11] Lytic therapy is administered on an inpatient basis typically via intra-arterial catheters. It would therefore necessitate transfer with an open catheter site from an ASC or physician office to a hospital. Movement associated with transfer could result in dissection/perforation. Moreover, transfer involves movement of the patient in non-sterile environments, increasing the risk of infection.

Using the exclusionary procedure-based criteria above, we recommend that the following procedures be removed from the list of ASC-approved procedures:

- CPT 32002 Thoracentesis with insertion of tube with or without water seal (eg, for pneumothorax);
- CPT 35473 Transluminal balloon angioplasty, percutaneous; iliac;
- CPT 35474 Transluminal balloon angioplasty, percutaneous; femoral-popliteal;
- CPT 35476 Transluminal balloon angioplasty, percutaneous; venous;
- CPT 35492 Transluminal peripheral atherectomy, percutaneous; iliac;
- CPT 35761 Exploration (not followed by surgical repair), with or without lysis of artery; other vessels;
- CPT 37205 Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel;
- CPT 37206 Transcatheter placement of an intravascular stent(s), (except coronary, carotid and vertebral vessel), percutaneous; each additional vessel;
- CPT 37250 Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel; and
- CPT 37251 Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel.

Patient-specific and Organization-specific Criteria. The AHA believes that, while procedure-specific clinical criteria are important, these criteria alone are insufficient to determine which services can be safely furnished in an ASC setting. Research indicates that risk is a multivariate phenomenon in which patient outcomes also are a function of patient-specific and organization-specific factors, such as those listed in Table 1. We recommend that CMS consider these factors in determining what services are excluded from payment in ASCs.

Table 1

Additional Factors to be Considered	Rationale
Patient-specific Factors	
Age 85 or greater	Patients of advanced age are more likely to develop complications and need the emergency back-up services available in hospitals.[12]
Prior inpatient hospital admission within six months	According to Fleisher LA, *et al.*, "The strongest predictor of inpatient hospital admission [following an outpatient surgical procedure] was the inpatient hospitalization history."[13]
Morbid obesity (for instance, a body mass index (BMI) greater than 39)[14]	This patient population is subject to a greater number of complications with greater frequency. According to Starnes, *et al.*, "The capability for expeditious open femoral arterial repair is mandatory."[15]
Patients in American Society of Anesthesiology (ASA) Physical Status Classification[16] level 3 or above	Patients in these classification levels have one or more severe comorbid conditions that may lead to complications during or after an ASC procedure and the need for rescue or emergent hospital admission.
Comorbid condition exclusion	CMS should consider excluding more complex and invasive procedures from coverage in an ASC if they involve patients with specific comorbidities that are shown to place the patient at higher risk, even if the procedure itself is generally allowable in the ASC. Comorbidities such as poorly controlled diabetes, uncontrolled hypertension, significant renal insufficiency, cardio-pulmonary failure and coagulopathy[17] should be considered.
Patients with implanted cardiac defibrillators (ICD)	If cardiac complications arise for a patient with an ICD, the ASC is not likely to have the technology to address it.
Organization-specific Factors	
Factors supporting the ability to rescue the patient in event of a life- or limb-threatening complication	Organizational factors that should be considered include: • distance to the hospital with which the ASC has arrangements for admission; • availability of blood and transfusion services; • ready availability of ambulance transport services for higher-risk patients (anesthesia level risk 3 or above) • post-anesthesia care unit factors, including qualifications and staffing appropriate for higher risk patients; and • availability of life-saving technology (e.g., automated external defibrillator).

Before CMS subjects beneficiaries to an unacceptable level of risk, it needs to conduct more research in these three areas in order to determine which procedures can be done in an ASC and under what combination of patient and organizational factors. This would involve some exploration of the inter-relatedness between these factors. For instance, while it may be safe to perform a minimally invasive procedure on a Medicare beneficiary with an ASA 3 classification, it may not be safe to perform a more invasive procedure due to potential complications that the ASC would be unable to handle.

CMS needs to monitor whether the expansion of procedures allowable in ASCs subjects beneficiaries to additional risk. Available research suggests that an excellent measure would be to track the extent to which beneficiaries undergoing procedures in ASCs are subsequently admitted to a hospital or are treated in an emergency department within seven days of the ASC procedure.[18,19]

ASC RATE-SETTING AND CONVERSION FACTOR

CMS proposes replacing the current ASC payment system, which consists of nine payment groups with rates based on 1986 ASC cost data updated for inflation, with a new system that would use the outpatient PPS' Ambulatory Payment Classifications (APC) groups. Outpatient hospital surgical APCs would serve as the basis for the ASC payment groups and relative payment weights. The conversion factor would be based on a budget-neutral adjustment designed to keep total payments under the new ASC payment system equal to those under the old ASC system.

We are concerned that while the rate-setting methodology based on the existing nine ASC payment groups is clearly outdated and should be replaced, there is no actual ASC cost data that CMS or interested stakeholders can use to validate whether this proposed policy is appropriate. We recommend, and Congress intended, that CMS ensure that Medicare payment weights and rates for ASC services reflect underlying costs and the types of patients served. It is critical that CMS get the payment system weights and rates right; otherwise, payment variations could create financial incentives to inappropriately shift services from one outpatient setting to another.

Section 626 of the MMA mandated that CMS implement a new ASC payment system by January 1, 2008, taking into account the recommendations of a study conducted by the Government Accountability Office (GAO). The GAO was required to conduct a study, using data submitted by ASCs, comparing the relative costs of procedures furnished in ASCs to those furnished in hospital outpatient departments under the outpatient PPS, including an examination of the accuracy of the APC categories with respect to the procedures furnished in ASCs. The GAO was required to submit its report to Congress by January 2005, with recommendations regarding: (1) the appropriateness of using groups and relative weights established for the outpatient PPS as the basis of the new ASC payment system; (2) if such weights are appropriate, whether the ASC payments

should be based on a uniform percentage of such weights, whether the percentages should vary, or whether the weights should be revised for certain procedures or types of services; and (3) the appropriateness of a geographic adjustment in the ASC payment system and, if appropriate, the labor and non-labor shares of such payment. *This GAO report has never been issued.*

In the absence of this study and its recommendations, it is nearly impossible for stakeholders to provide informed comment. More importantly, without any current ASC cost data, it is difficult to determine the validity of the proposal and its use of the hospital outpatient APC groupings and relative weights, the proposed geographic adjustment and the proposed ASC payment rates.

All that we can say with assurance is that it is appropriate that CMS has proposed a conversion factor for ASC services that is less than that in the hospital outpatient department setting. The rates for services provided in hospital-based settings should be set at a higher level in order to reflect their higher costs due to additional regulatory requirements, 24/7 availability, EMTALA-related costs, a more acutely ill population with more comorbidities and higher uncompensated care rates. This is consistent with the Medicare Payment Advisory Commission's (MedPAC) findings in its 2003 and 2004 reports that "outpatient departments are subject to additional regulatory requirements, which are likely to increase their overhead costs, and treat patients who are more medically complex. Thus, outpatient departments probably incur higher costs than ASCs for similar procedures."[20]

It is unfortunate that the GAO has not met its mandate from Congress to provide the data needed to set appropriate payment rates in ASCs. **In order to allow for future validation of the appropriateness of ASC payment weights and rates, CMS should seek congressional authority to require reporting of cost data in ASCs.** This could be accomplished through implementing an ASC cost-reporting system or, as MedPAC recommended in its March 2004 report, the periodic collection of ASC cost data at the procedure level.

CMS also should monitor how the significant revisions in its payment policies will impact the volume and types of services that migrate from one ambulatory setting to another, as well as trends in the acuity of patients undergoing similar procedures in hospital outpatient departments versus ASCs. These proposed changes could lead to a migration of lower-acuity patients to ASCs, which would leave hospital outpatient departments with an even higher proportion of sicker patients. While this migration may be appropriate based on the capabilities of these settings, hospitals would see higher costs due to the increased volume and intensity of services provided to sicker patients undergoing the same procedures and increased time per patient (resulting in reduced throughput in outpatient departments). CMS would need to evaluate the effect on procedure median costs in hospitals and how the conversion factor is calculated in an ASC. Because ASC payment groups and weights are proposed to be identical to the

hospital outpatient PPS, a significant trend of this sort could misalign the ASC and the outpatient PPS, resulting in additional financial incentives to inappropriately shift services between settings.

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[1] Fleisher LA, *et al.* "Inpatient Hospital Admission and Death after Outpatient Surgery in Elderly Patients: Important of Patient and System Characteristics and Location of Care." *Arch. Surg.* 2004;139:67-72.
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[12] Fleisher LA, *et al.* "Inpatient Hospital Admission and Death after Outpatient Surgery in Elderly Patients: Important of Patient and System Characteristics and Location of Care." *Arch. Surg.* 2004;139:67-72.
[13] Ibid.
[14] http://www.nlm.nih.gov/medlineplus/ency/article/003102.htm. Note, however, that different authorities utilize different levels or ranges for defining morbid obesity.
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[18] Fleisher LA, *et al.* "Inpatient Hospital Admission and Death after Outpatient Surgery in Elderly Patients: Important of Patient and System Characteristics and Location of Care." *Arch. Surg.* 2004;139:67-72.
[19] Fleisher LA, *et al.* "A Novel Index of Elevated Risk of Inpatient Hospital Admission Immediately Following Outpatient Surgery." Manuscript submitted for publication.
[20] MedPAC Report to the Congress: Medicare Payment Policy, March 2004.

Submitter : **Mr. Randy Edmundson** **Date: 11/06/2006**

Organization : **Mr. Randy Edmundson**

Category : **Health Care Industry**

Issue Areas/Comments

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.

Submitter : Mrs. stephanie Dyson **Date:** 11/06/2006

Organization : DaVita

Category : End-Stage Renal Disease Facility

Issue Areas/Comments

ASC Office-Based Procedures

ASC Office-Based Procedures

B. ASC Payment for Office-Based Procedures: CMS proposes to allow payment of an ASC facility fee for office based procedures that have been historically excluded form the ASC 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 has concerns 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. We believe that for a given procedure, physicians should be able to determine the site of service that 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 outcomes. For this patient population, physicians are NOT likely to perform procedures in their office, and will therefore elect the more expensive hospital setting, yielding greater costs to the Medicare program while neglecting physician and patient choice. We believe the best policy is to allow physicians to select the site of service they believe is most clinically appropriate for their patients

ASC Packaging

ASC Packaging

4. ASC Packaging
CMS has proposed to model the ASC payment methodology on the OPPS payment system. In stark contrast, the OPPS/APC provides for pass-through (C Codes) of certain technology costs. The proposed rule upholds the practice of bundling the payment for direct and indirect costs incurred by the facility to perform the procedure into a single ASC facility. We question why the new ASC payment system (which is modeled after the OPPS system), would not provide the same reimbursement for supplies as the APC system does. As proposed, this payment structure will not facilitate the achievement of Secretary Leavitt s and CMS goal of ASC reform goal, as it does not afford ASCs the reimbursement equity as currently allowed in the hospitals and outpatient departments. Further, we understand that the Office of Inspector General has concerns regarding place of service coding, as between ASCs and HOPDs, because of the differences in Medicare payment based on site of service and plans to devote audit resources to monitoring in this area.

In closing, Congress has given the Department of Health and Human Services (HHS) broad authority to develop a new Medicare payment system for ambulatory surgical centers (ASCs). HHS and CMS should use this opportunity to achieve cost savings for the Medicare program; more closely align payments across the different sites of service for outpatient surgery; and provide patients and physicians with options in which to choose the appropriate setting while maintaining optimal patient outcomes.

ASC Payable Procedures

ASC Payable Procedures

1. ASC Payable Procedures (Exclusion Criteria):
CMS, in its revised FY 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. We strongly endorse this practice. Since the agency first began the process of developing criteria for determining which codes are appropriately performed in ASCs in 1987, CMS has often reexamined its policies as technology improves and practice patterns change. CMS also considers evidence about whether procedures are safe to perform in ambulatory settings. In the Final Rule for the Hospital Outpatient Prospective Payment System (OPPS) released on November 1, 2006, CMS reconsidered its proposal to add CPT codes 37205 and 37206 to the list of approved procedures, stating it would be in the best interests of Medicare beneficiaries to continue to deny payment for them in ASC facilities." We are requesting the Ageney reconsider these codes for the FY 2008 ASC Payment system, as there is strong evidence of their safety and efficacy. In addition, both codes meet the MedPac recommended criteria as neither poses a significant safety risk nor require an overnight stay.

" Similar to the new G codes (G0392 and G0393) created specifically for hemodialysis vascular access, we urge CMS to create similar codes for stent procedures performed for hemodialysis vascular access care in the ASC setting.
" The inclusion of these CPT codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access repair and maintenance procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting. Despite the initiative, (which we fully support), which was introduced in 2004 to encourage the use of fistulae, the rate remains significantly less than the targeted rate of 66% by 2009.
" In the OPPS Final Rule, you rescinded these codes stating, they are virtually never performed in a physicians office, require > 4hours of recovery and almost require an overnight stay. RMS Lifeline s strong clinical record suggest otherwise. We have successfully performed these procedures in our Lifeline centers, while ensuring a high level of patient safety.
" Lastly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting, as it provide them with a more efficient and accessible option to ensure that their life-saving access is properly maintained. RMS Lifeline s monthly patient satisfaction survey shows that historically, 91% of rated their experience at RMS Lifeline managed centers as either very good or excellent.

Incorporating a full-range of vascular access procedures into the ASC setting will result in important savings to the Medicare program (approximately $1.25 billion over 10 years). In 1999, Dr. Allan Collins and his colleagues found that shifting vascular access-related procedures from the inpatient to the outpatient setting resulted in savings of more than $9,000 per event/procedure. They concluded that: significant savings on [vascular access (VA)] procedures for hemodialysis patients can be achieved if an appropriate infrastructure and incentives are provided to encourage this site of care. Creative reimbursement systems for VA should be considered to encourage more cost-effective delivery of uncomplicated VA interventions. Although Dr. Collin s conclusions were based upon comparisons between inpatient and outpatient settings, DaVita believes that based upon CMS reimbursement policy, the ASC setting would provide the lowest

cost opportunities for performing these procedures while also ensuring a high level of patient safety.

ASC Ratesetting

ASC Ratesetting

2. ASC Reimbursement Rates
We support CMS proposal to replace the current ASC system with one based on the OPPS procedure groups (APCs) and relative weights, so that ASC rates are more aligned with surgical procedures provided in hospital outpatient departments. Such alignments would make payments more accurate and promote higher quality and value in outpatient care. We are concerned, however, with CMS proposal that ASCs be paid based upon a methodology that results in ASCs being paid no more than 62 percent of the HOPD rates in 2008 and even less in 2009.

Although the 62 percent payment rate, as well as the expanded ASC coverage policy, will make it possible to provide some services in ASCs that are now commonly provided in hospital outpatient departments, this payment rate represents a sharp reduction for a number of services that are already being frequently provided in ASCs and may result in ASC centers closing altogether. As such, we encourage CMS to reconsider its assumptions about utilization rates under the new payment system and work to achieve the highest possible level of comparability between the ASC and OPPS rates. These adjustments will minimize any unintended adverse impact on patient access to care and physician ability to choose appropriate sites of service for patient care.

A. Migration Assumptions/Budget Neutrality: We understand that the Medicare Modernization Act of 2003 (MMA) dictates that changes to the ASC payment system must be made in a budget neutral manner (interpreted by CMS to mean the Agency spends the same amount on ASC services under the revised system that it would have spent without the changes). However, we believe that the assumptions used to arrive at the payment rate of 62% of the OPPS rate should be re-examined. To achieve the policy goals set forth above, we believe it is essential that the budget neutrality provisions in MMA be interpreted and applied to include cost savings that will be realized from the inevitable shift of services currently performed in HOPDs to lower cost ASCs following the implementation of the new payment system. Otherwise, if budget neutrality is applied only to ASC services, the result will be substantial cuts in ASC reimbursement that will significantly undermine the viability of ASCs serving as an effective competitive alternative site of service and will likely have a negative impact on beneficiary access to care.
A. Migration Assumptions/Budget Neutrality: We understand that the Medicare Modernization Act of 2003 (MMA) dictates that changes to the ASC payment system must be made in a budget neutral manner (interpreted by CMS to mean the Agency spends the same amount on ASC services under the revised system that it would have spent without the changes). However, we believe that the assumptions used to arrive at the payment rate of 62% of the OPPS rate should be re-examined. To achieve the policy goals set forth above, we believe it is essential that the budget neutrality provisions in MMA be interpreted and applied to include cost savings that will be realized from the inevitable shift of services currently performed in HOPDs to lower cost ASCs following the implementation of the new payment system. Otherwise, if budget neutrality is applied only to ASC services, the result will be substantial cuts in ASC reimbursement that will significantly undermine the viability of ASCs serving as an effective competitive alternative site of service and will likely have a negative impact on beneficiary access to care.

Submitter : **Mr. Randy Edmundson** **Date: 11/06/2006**

Organization : **Mr. Randy Edmundson**

Category : **Health Care Industry**

Issue Areas/Comments

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.

Submitter : **Mr. Randy Edmundson** **Date: 11/06/2006**

Organization : **Mr. Randy Edmundson**

Category : **Health Care Industry**

Issue Areas/Comments

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 outcome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his specific condition.

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

Organization :

Category : **Health Care Industry**

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

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. Bruce Moseley **Date:** 11/06/2006

Organization : Kirby Surgical Center

Category : Ambulatory Surgical Center

Issue Areas/Comments

CY 2008 ASC Impact

CY 2008 ASC Impact

See attached letter

CMS-1506-P2-946-Attach-1.DOC

#9146

Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare & 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

Dear Administrator Norwalk:

I am a physician who works in and is a part owner of an ambulatory surgery center. I am opposed to the proposed rules changes in the ASC payment system which will eliminate the historic grouper payments and adopt a relative weight system of payment to ASCs.

The proposed payment reform will be detrimental to ASCs and thus to Medicare beneficiaries because the proposed payment system will not adequately reimburse ASCs for their costs, and it will require more time and resources to participate in the new payment system. Furthermore, the proposed ASC list of procedures is too limited, and it should be changed to include any procedure done in a hospital outpatient setting. The only procedures which CMS should exclude from the ASC list are those that need inpatient treatment.

As a physician who works extensively in both ASCs and hospitals, I feel strongly that ASCs have multiple advantages over hospitals in regard to patient care, efficiency, and cost effectiveness. I believe that ASCs and hospital outpatient departments should be paid and evaluated similarly. By doing this, ASCs will be paid more fairly, costs for ASCs and hospitals can be compared more accurately, and the quality of care that both ASCs and hospitals provide can be compared more accurately. I am confident that once we compare apples to apples, we will see that ASCs provide a higher standard of care at a reduced cost compared to hospital outpatient departments.

Thank you for your attention to this matter.

Sincerely,

Bruce Moseley M.D.

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

Organization :

Category : **Health Care Industry**

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.

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

Organization :

Category : **Health Care Industry**

Issue Areas/Comments

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.

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

Organization :

Category : **Health Care Industry**

Issue Areas/Comments

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 forcing 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.

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

Organization :

Category : **Health Care Industry**

Issue Areas/Comments

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.

Submitter : **Dr. Deborah Bash** **Date: 11/06/2006**

Organization : **American Society of Plastic Surgeons**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1506-P2-951-Attach-1.PDF

#957

AMERICAN SOCIETY OF PLASTIC SURGEONS

November 6, 2006

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

RE: Medicare Program; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed Rule

Submitted Electronically: http://www.cms.hhs.gov/eRulemaking

Dear Dr. Norwalk:

The American Society of Plastic Surgeons (ASPS) is the largest association of plastic surgeons in the world, representing surgeons certified by the American Board of Plastic Surgery. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, and cancer. ASPS promotes the highest quality patient care, professional, and ethical standards and supports the education, research and public service activities of plastic surgeons.

ASPS offers the following comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule for "CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; Ambulatory Surgical Center Payment System and CY 2008 Payment Rates" that was published in the August 23, 2006 issue of the *Federal Register*. We appreciate the significant effort CMS has made in proposing a new Ambulatory Surgical

Center (ASC) payment system. We are hopeful that this new system, once implemented, will result in equalizing the choice of facility site between ASCs and hospital outpatient departments, so that the patient's best interests will be the primary consideration when planning surgical procedures. We do have concerns about some of the specific measures in the proposed new system, which are outlined below.

Unsafe Procedures for ASCs

We appreciate the Agency's consideration of our comments on previous regulations regarding procedures performed in ASCs. In light of this, we are surprised to see that CMS has added procedure codes, such as 21215, 40700, 40701, 42200, 42205, 42210, 42215, and 42220 to the ASC covered list. We have previously cited safety concerns, such as the need for post-operative observation and airway monitoring, as justification for covering these procedures solely in the inpatient setting, and we continue to stand by that recommendation for these procedures. The procedure described by CPT code 21215 is unsafe to perform in an ASC, particularly for larger grafts. General anesthesia and post-operative monitoring of the airway is required. CPT Codes 40700, 40701, 42200, 42205, 42210, 42215, and 42220 also require close airway monitoring post-operatively, which is beyond the typical ASC scope of observation. In addition, these procedures are largely performed outside the Medicare population on very young children. Therefore, the effect of removing these codes from the ASC list should be minimal for Medicare beneficiaries. However, we are concerned that private insurance carriers might also choose to adopt this policy and could potentially misinterpret it to mean that these procedures should not be approved for coverage in the inpatient setting. This could be devastating for our young patients. **We strongly recommend that these codes be removed from the ASC covered list.**

ASC Payment for Office-Based Procedures

In this regulation, CMS proposes a major expansion to the list of covered procedures by discontinuing the restriction on payment for procedures performed in an ASC that "are commonly performed, or that may be safely performed, in physicians' offices." Although physicians may safely perform many procedures on Medicare beneficiaries in the office setting, it is unrealistic and questionable patient care to expect that every patient will have a good surgical outcome if the procedures are always performed in the office. The typical elderly Medicare patient commonly has associated medical conditions that are not suited to simple office settings. Therefore, we agree in theory with the Agency's decision to expand the list in this manner.

However, for procedures done in the office more than 50% of the time, CMS proposes to cap payments at the lesser of the non-facility practice expense payment under Medicare's Physician Fee Schedule or the ASC payment rate. This cap would result in reimbursement levels that make it economically unfeasible for many ASCs to continue offering certain procedures. For example, the need for anesthesia may be a determining factor in choosing to perform a procedure in an ASC versus the office setting. Clearly, if

anesthesia is required, the cost of offering the procedure increases and may not be covered by the capped payment. As a result, if the surgeon's ability to choose to perform the procedure on a patient whose medical condition requires a more extensively equipped ASC is removed, the physician will have to travel to the hospital to do the procedure. This is unnecessarily costly to the Medicare program and individual beneficiaries and is inefficient use of the physician's time. In addition, our members state that scheduling patients in the hospital is becoming increasingly difficult, which translates into a longer wait for the patient to receive care and a potential access problem. The potentially ill effects of this proposal are exacerbated by the fact that many of these lower intensity services are performed in conjunction with other more invasive services, increasing the likelihood that the surgeon will be left with no choice but to perform the procedure in the more expensive hospital setting.

CMS indicates that it is concerned that allowing payment for office-based procedures when performed in an ASC may create an incentive for physicians to inappropriately shift their office surgery to an ASC. While we understand this concern, we do not think that capping payments at a level that in many cases will not cover the cost of performing the procedure is a viable solution. We support the recommendations of the American College of Surgeons (ACS) that CMS should consider raising the threshold above 50 percent to a number that shows the clear majority of cases are performed in the office and allow an exemption to the cap for procedures that are performed in an ASC because of the necessity of anesthesia or other appropriate justification. The College's recommendation to allow use of a modifier to indicate the surgeon's reason for selecting the ASC over the physician's office as the site of service is a potentially feasible option. We refer you to the ACS comment letter for further information on this issue.

In our view, CMS should develop a payment system that adequately covers costs if performing the procedure in an ASC is indeed appropriate. If, however, CMS does decide to finalize this cap, in the interest of promoting a system whereby site of service decisions are made based upon a patient's best interests, we urge the Agency to apply the cap uniformly to both ASCs and hospital outpatient departments.

Procedures Excluded from ASC List

CMS has proposed to exclude several procedures from the ASC list that our members believe are appropriate for this setting. CPT 16020 (*Dressings and/or debridement of partial thickness burns, initial or subsequent; small, less than 5% total body surface area*), while common in the office setting, is one of a family of codes that replaced code 16015 which was formerly on the ASC list. The remainder of the family (CPT 16025 and 16030) are currently on the covered list, and we believe 16020 should be added.

CMS has also proposed to exclude CPT codes 15170-15176 *(acellular dermal replacement (e.g., Integra))* from ASC facility fee payment on the basis that the procedures require an overnight stay. However, CMS has included all CPT skin substitute and skin replacement codes, including 15170-15176, in its list of procedures

that are eligible for payment in the outpatient hospital setting. Furthermore, CMS includes all remaining CPT codes for skin substitutes/skin replacements, including autografts, in the list of procedures approved for ASC payment. We believe it is inconsistent policy to exclude CPT 15170-15176 from ASC coverage. Our members indicate these procedures are safe to perform in the ambulatory setting. We understand that members of the American Burn Association also believe these procedures should be eligible for coverage and will be making a similar request for consideration by CMS. We refer you to their letter for further discussion on this issue.

ASC Inflation and Conversion Factor

ASPS is pleased that CMS is proposing to link ASC payments to the rates paid to Hospital Outpatient Departments (HOPDs). We share the concerns expressed by the ACS and the American Medical Association (AMA), however, that CMS is proposing that ASCs be paid based upon a methodology that results in ASCs being paid no more than 62 percent of the HOPD rates in 2008 and even less in 2009.

While we understand that this low percentage is driven by CMS's interpretation of the Medicare Modernization Act's requirement that the new system be implemented in a budget neutral manner, we believe that CMS' interpretation is based upon unproven assumptions and is unduly narrow. There are a number of assumptions behind the Agency's calculation that budget neutrality requires the new ASC rates to be set at 62 percent of the Outpatient Prospective Payment System (OPPS) rate for the same service. Although the 62 percent payment rate, as well as the expanded ASC coverage policy, will make it possible to provide some services in ASCs that are now commonly provided in hospital outpatient departments, this payment rate also represents a sharp reduction for a number of services that are already being frequently provided in ASCs.

We encourage CMS to reconsider its assumptions about utilization rates under the new payment system and work to achieve the highest possible level of comparability between the ASC and OPPS rates. For example, CMS should not assume migration of procedures that currently are provided in physician offices into ASCs. Many services defined as surgery, such as dermatological procedures, are highly unlikely to migrate from physician offices to ASCs. The services that are most likely to be done more frequently in ASCs under the new payment system are those that are primarily done in hospitals currently due to significant underpayment in ASCs.

We also urge CMS to interpret broadly the budget neutrality requirement. Providing Medicare beneficiaries with access to ASCs offers them more choices and enhances their access to services in a timely manner. In addition, it provides significant economic savings to the Medicare program and its beneficiaries. Maintaining ASC access, however, requires reasonable payment rates, and since current ASC rates are based upon outdated data, a broad interpretation of budget neutrality is necessary to establish such rates and allow Medicare and its beneficiaries to take advantage of the myriad benefits of ASCs.

Furthermore, like hospitals, ASC rates should be updated based upon the hospital market basket rather than the Consumer Price Index for all urban Consumers (CPI-U). The hospital market basket more appropriately reflects inflation in providing surgical services. Moreover, alignment with hospital updates would achieve parity and transparency in the market and assure that facility decisions are made based upon what is best for the patient, rather than economic considerations.

Finally, under the proposed rule, the new payment rates would be phased in over a two-year period. For 2008, CMS would pay a blended amount equal to 50 percent of the rate under the existing payment system and 50 percent of the rate under the new system. Starting in 2009, payment rates would be tied entirely to the new methodology. ASPS is concerned that such a short transition period could threaten the viability of many centers and recommends that CMS provide more time for phasing in the new methodology.

As always, we appreciate your consideration of these comments and would be happy to answer any questions you might have. Meanwhile, ASPS will continue to carefully monitor future correspondence on this and other relevant health care issues.

Sincerely,

Deborah J Bash MD

Deborah Bash, MD
Chair, Payment Policy Committee

Submitter : Ms. ROSE PANTOJA **Date:** 11/06/2006

Organization : IDAHO SURGERY CENTER

Category : Ambulatory Surgical Center

Issue Areas/Comments

ASC Payable Procedures

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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.

Submitter : Ms. ROSE PANTOJA **Date:** 11/06/2006

Organization : IDAHO SURGERY CENTER

Category : Ambulatory Surgical Center

Issue Areas/Comments

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.

Submitter : Mrs. Patricia Wamsley **Date:** 11/06/2006

Organization : 25 East Same Day Srugery

Category : Ambulatory Surgical Center

Issue Areas/Comments

ASC Coinsurance

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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.

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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 outcome. In other words, for a given procedure, the appropriate site of service is dependent on the individual patient and his specific condition.

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 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 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.