



Liberty Place, Suite 700  
325 Seventh Street, NW  
Washington, DC 20004-2802  
(202) 638-1100 Phone  
www.aha.org

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.**



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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](mailto: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.<sup>1,2</sup> 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.<sup>3</sup>

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*.<sup>4</sup> 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<sub>5</sub> 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<sup>5</sup>

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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> 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).<sup>9</sup>

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.<sup>10</sup> 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).<sup>11</sup> 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**

<b>Additional Factors to be Considered</b>	<b>Rationale</b>
<b><i>Patient-specific Factors</i></b>	
Age 85 or greater	Patients of advanced age are more likely to develop complications and need the emergency back-up services available in hospitals. <sup>12</sup>
Prior inpatient hospital admission within six months	According to Fleisher LA, <i>et al.</i> , “The strongest predictor of inpatient hospital admission [following an outpatient surgical procedure] was the inpatient hospitalization history.” <sup>13</sup>
Morbid obesity (for instance, a body mass index (BMI) greater than 39) <sup>14</sup>	This patient population is subject to a greater number of complications with greater frequency. According to Starnes, <i>et al.</i> , “The capability for expeditious open femoral arterial repair is mandatory.” <sup>15</sup>
Patients in American Society of Anesthesiology (ASA) Physical Status Classification <sup>16</sup> 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 <sup>17</sup> 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.
<b><i>Organization-specific Factors</i></b>	
Factors supporting the ability to rescue the patient in event of a life- or limb-threatening complication	Organizational factors that should be considered include: <ul style="list-style-type: none"> <li>• distance to the hospital with which the ASC has arrangements for admission;</li> <li>• availability of blood and transfusion services;</li> <li>• ready availability of ambulance transport services for higher-risk patients (anesthesia level risk 3 or above)</li> <li>• post-anesthesia care unit factors, including qualifications and staffing appropriate for higher risk patients; and</li> <li>• availability of life-saving technology (e.g., automated external defibrillator).</li> </ul>

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.<sup>18,19</sup>

## **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."<sup>20</sup>

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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<sup>1</sup> 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.

<sup>2</sup> Fleisher LA, *et al.* "A Novel Index of Elevated Risk of Inpatient Hospital Admission Immediately Following Outpatient Surgery." Manuscript submitted for publication.

<sup>3</sup> DHHS, Office of Inspector General. *Quality Oversight of Ambulatory Surgical Centers*. February 2002.

<sup>4</sup> Seeley RR, Stephens TD, and Tate P. *Essentials of Anatomy & Physiology, 6<sup>th</sup> Edition*. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.

<sup>5</sup> Seeley RR, Stephens TD, and Tate P. *Essentials of Anatomy & Physiology, 6<sup>th</sup> Edition*. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.

<sup>6</sup> American College of Surgeons' *Advanced Trauma Life Support (ATLS)*.

<sup>7</sup> Akopian G and Katz SG. "Peripheral Angioplasty with Same-day Discharge in Patients with Intermittent Claudication." *J Vasc Surg.* 2006;44:115-8.

<sup>8</sup> Young N, *et al.* "Complications with Outpatient Angiography and Interventional Procedures." *Cardiovasc Intervent Radiol.* 2002; 25:123-126.

<sup>9</sup> Waugh JR, Sacharias N. "Arteriographic Complications in the DSA Era." *Radiology.* 1992; 182:243-246.

<sup>10</sup> Krankenberg H, *et al.* "Percutaneous Transluminal Angioplasty of Infrapopliteal Arteries in Patients with Intermittent Claudication: Acute and One-Year Results". *Catheter Cardiovasc Interv.* 2005; 64:12-17.

<sup>11</sup> Gray BH, *et al.* "Complex Endovascular Treatment for Critical Limb Ischemia in Poor Surgical Candidates: A Pilot Study." *J Endovasc Ther.* 2002; 9:599-604.

<sup>12</sup> 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.

<sup>13</sup> *Ibid.*

<sup>14</sup> <http://www.nlm.nih.gov/medlineplus/ency/article/003102.htm>. Note, however, that different authorities utilize different levels or ranges for defining morbid obesity.

<sup>15</sup> Starnes BW, *et al.* "Totally Percutaneous Aortic Aneurysm Repair: Experience and Prudence." *J Vasc Surg.* 2006; 43:270-6.

<sup>16</sup> <http://www.asahq.org/clinical/physicalstatus.htm>.

<sup>17</sup> Kruse JR, Cragg AH. "Safety of Short Stay Observations after Peripheral Vascular Intervention." *J Vasc Interv Radiol.* 2000; 11:45-49.

<sup>18</sup> 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.

<sup>19</sup> Fleisher LA, *et al.* "A Novel Index of Elevated Risk of Inpatient Hospital Admission Immediately Following Outpatient Surgery." Manuscript submitted for publication.

<sup>20</sup> MedPAC Report to the Congress: Medicare Payment Policy, March 2004.