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COUNCIL FOR UROLOGICAL INTERESTS

P.O. Box 9856
Chapel Hill, NC 27515
(910) 273-3098

Joseph Jenkins, M.D.
Chairman and Executive Director

September 14, 2007

Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1392-P
Comments on the Proposed Update of the Revised Ambulatory Surgical Center Payment System

Ladies and Gentlemen,

The Council for Urological Interests ("CUI") appreciates the opportunity to comment on the proposed changes to the Ambulatory Surgical Center Payment System and Calendar Year 2008 Payment Rates published in the Federal Register on August 2, 2007 (the "CY 2008 Proposed Rule").[1] CUI is a voluntary membership organization whose members form joint ventures with urologists to furnish lithotripsy, urological laser, and other services to hospitals and ambulatory surgery centers. CUI members were the principal members of the American Lithotripsy Society. The CUI members represent more than 4,900 investor urologists, approximately 50 percent of all urologists practicing throughout the United States.

Discussion

We believe that the adoption of the revised ambulatory surgical center ("ASC") payment system is unfair, unwise, and a violation of the Congressional mandate to the Centers for Medicare and Medicaid Services ("CMS"). For reasons explained in detail below, the revised ASC payment system will result in inadequate reimbursement for highly beneficial procedures, such as lithotripsy and urological laser procedures; failing to cover even an ASC's costs in performing certain procedures. The inadequate reimbursement will prevent many procedures from being performed in an ASC setting. This directly contradicts the stated and laudatory goal of CMS to increase the number and types of procedures that may be performed in an ASC in order to help Medicare beneficiaries "get the outpatient care they need in the most appropriate setting, by eliminating the payment differences that inappropriately favor one outpatient setting over another and that may add to Medicare costs."[2] Instead, the new ASC payment system as

[1] 72 FED. REG. 42628 (Aug. 2, 2007).
[2] Press Release, Centers for Medicare and Medicaid Services, CMS Proposes Changes to Policies and Payment for Outpatient Services: New Steps to Increase Value in Hospital Outpatient Care, with Major Revision of Ambulatory

finalized by CMS and as proposed in the CY 2008 Proposed Rule will foster inefficiencies and encourage inappropriate choices of outpatient settings for surgical procedures.

Under the Administrative Procedure Act, when promulgating regulations, CMS may not act in an arbitrary or capricious manner, abuse its discretion, or otherwise act in a manner not in accordance with the law.[3] We believe that CMS has failed to follow these standards in its adoption of, and proposed changes to, the revised ASC payment system required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA). CMS has neither based its rule on a "consideration of the relevant factors"[4] nor articulated "a rational connection between the facts found and the choice made."[5] Instead, CMS has acted arbitrarily and has failed entirely to consider important aspects of the issue[6] in order to reach an administratively convenient system. But, while the new ASC payment system may be administratively convenient, it will not contribute to meeting the goals set by CMS or envisioned by Congress. Indeed, it will prevent Medicare beneficiary access to valuable procedures in a safe, convenient, and cost-effective setting and will prevent the achievement of the cost savings desired by CMS and Congress.

Issues Relating to the Application of a Uniform Conversion Factor

We are very concerned with the decision by CMS to implement a deeply flawed ASC payment rate system. Rather than establish a payment system that adequately and accurately reimburses ASCs for the cost of Medicare procedures, furthers a policy of migrating ASC-suitable procedures from higher cost hospital outpatient departments to lower cost ASCs, and maintains budget neutrality, CMS has instead elected to implement an arbitrary uniform conversion factor. This decision, we believe, violates the Congressional mandate to CMS, clashes with CMS' own regulations, and undermines beneficiary access and cost-efficiency.

A. "Equipment-Intensive" Procedures

The proposed payment rates under the finalized system will not adequately cover an ASC's expenses for several services with fixed, site-neutral costs, including urological services such as lithotripsy (CPT Code 50590), laser treatment of the prostate (CPT Code 52648), other urological laser procedures, and certain ureteroscopic procedures, among others. Unfortunately, this will result in Medicare patients being denied access to these effective procedures in the convenient and cost-effective setting of an ASC, as ASC's will refuse to treat

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Surgical Centers Payments (quoting Dr. McClellan, CMS Administrator) (Aug. 8, 2006) (found at http://www.cmsttag.org/docs/cmspr11opps07nprm.pdf).

[3] 5 U.S.C. § 706(2)(A).

[4] *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971); *Indiana Forest Alliance, Inc. v. U.S. Forest Serv.*, 325 F.3d 851, 859 (7th Cir. 2003).

[5] *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285-86 (1974).

[6] *See, Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Medicare beneficiaries. The inevitable result will be that Medicare beneficiaries will not have access to these procedures, or they will be done in a hospital at a minimum of 50 percent greater price per procedure. We do not believe that this was the intent of CMS in promulgating the new ASC payment system.

CMS recognized in both the final ASC payment system rule and the CY 2008 Proposed Rule that it must make an exception to its application of a uniform conversion factor for device-intensive procedures. CMS agreed with the many commenters on this issue that applying a uniform conversion factor to the hospital outpatient prospective payment system ("OPPS") relative payment weights "could provide inadequate payment for device-intensive procedures."[7] But, CMS appears to have completely ignored the commenters' arguments that the revised payment system would produce similar inadequacy of payment for (what we will term) "equipment-intensive" procedures, such as lithotripsy, certain urological laser procedures, and certain ureteroscopic procedures. Thus, CMS has failed to consider and address such an important issue as the need to reimburse ASCs at a rate that, at a bare minimum, covers the costs incurred by the ASCs in performing these procedures. This is inexcusable.

Since precisely the same reasons that command the modified reimbursement methodology for device-intensive procedures exist for equipment-intensive procedures, CMS must also adopt a modified payment methodology for "equipment-intensive" procedures performed in an ASC. Just as CMS recognized with regard to device-intensive procedures, an ASC's costs for equipment would not differ significantly from the equipment costs of hospital outpatient departments. Instead, equipment costs are site-neutral—ASCs would not experience substantial efficiencies in their acquisition of equipment in comparison with hospital outpatient departments. In fact, ASCs may experience higher costs for obtaining equipment than hospitals because ASCs are generally smaller and, therefore, have weaker bargaining power to negotiate cheaper rental rates or purchase prices.

Lithotripsy is a useful example of an "equipment-intensive" procedure. A lithotripter is a site-neutral, fixed expense that is costly to purchase or lease. The proposed payment rate of $1,781.66 completely ignores the fixed cost of this technology and will prevent ASCs from performing lithotripsy services because the reimbursement rate will not cover the ASCs' costs of even renting or purchasing the lithotripters, let alone reimburse ASCs for their other necessary expenses in offering the procedure. In the final rule revising the ASC payment system CMS stated: "[w]e also continue to see no clinical basis that would support the differential relativity of costs for various procedures performed in the ASC or hospital outpatient department settings."[8] Clearly, the difference in necessary fixed expenses for performing lithotripsy, as compared with other procedures with lower site-neutral expenses, constitute a clinical basis that would support the differential relativity of costs for lithotripsy performed in the

[7] 72 FED. REG. 42470, 42504 (Aug. 2, 2007).
[8] *Id.* at 42492.

ASC or hospital outpatient department. We are at a loss as to how CMS sees otherwise. Although we do not disagree that, in general, the costs of performing procedures, even lithotripsy, in an ASC are less than the costs of performing the same procedures in a hospital outpatient department, we strenuously disagree that a uniform rate applicable to all procedures can adequately account for the decreased expenses. CMS must revise its payment system to account for the site-neutral, fixed expenses in providing lithotripsy services and other equipment-intensive procedures.

By failing to modify the payment system to account for the costs of procedures requiring either significant capital investments in equipment or significant rental costs of equipment (and failing to consider and address this issue at all), CMS is, in all practical sense, assuring that such procedures cannot be performed in an ASC. This completely discounts the purpose of the change to the list of approved ASC procedures, which is intended to allow and encourage the performance of as many procedures as possible in a safe, efficient, convenient, and cost-effective alternative to hospital outpatient departments. Failing to reimburse ASCs adequately for their costs in performing procedures will, therefore, inappropriately favor the hospital outpatient setting and prevent the migration of services to the ASC setting, preventing Medicare from realizing significant cost savings—precisely the opposite of the rationale for promulgating the revised ASC payment system. This result is unreasonable and a violation of the Congressional delegation of authority to CMS.

B. Lack of a Sufficient Rationale for the Uniform Conversion Factor

1. Failure to Consider and Adequately Explain the Basis for the Uniform Conversion Factor

Not only do we believe that the uniform conversion factor is an inappropriate and arbitrary method for calculating ASC payment rates, we further note that we can find no evidence that CMS has considered the suitability of a uniform conversion factor. While CMS, supported by the recommendations in the Government Accountability Office's ("GAO") November 2006 report, provides numerous arguments that seemingly substantiate the intuitive proposition that the cost of ASC procedures is related to the cost of the same procedures performed in hospital outpatient departments, it appears to assume that the only possible method upon which it could base ASC to OPPS relativity is a uniform conversion factor. Along these lines, CMS stated that "[a]pplying more than one ASC conversion factor to different procedures would imply that we believe the OPPS APC payment weight relativity is not applicable to the ASC setting contrary to our proposal and the GAO study result."[9] However, neither the explanation provided by CMS nor the GAO report provide any substantiation for this fundamental assumption. Indeed, the assumption is inconsistent with CMS' own decision to provide a separate payment system for device intensive procedures in § 416.171(b).

[9] 72 FED. REG. 42,492 (Aug. 2, 2007).

Whatever the basis for CMS' assumption that an OPPS-based ASC payment system necessarily entails a uniform conversion factor, it is clear that Congress did not share this assumption. Congress specifically directed the GAO, and by implication CMS, to consider both whether an OPPS-based payment system was appropriate *and* whether, within such a system, the rate should be constant or vary among different procedures.[10] Despite Congress' expectation that this would be an important factor in developing a revised payment system, CMS has given no indication that it considered the possibility of an OPPS-based ASC payment system that accounts for variations in ASC-to-OPPS relativity.

2. Faulty Reliance on a GAO Study

CMS has significantly relied—after the fact—on the recommendations of the GAO report, but this reliance is misplaced. In the same legislation that required CMS to develop a revised payment system for ASCs, Congress mandated that CMS take into account the recommendations of a report it commissioned from the GAO. Although the statutory deadline for this report was January 1, 2005, the GAO had not yet completed the report when CMS proposed the revised payment system in August 2006. The GAO then released its report in November 2006, addressing some, but not all, of the issues mandated by Congress. In its discussion of the final rules on the revised ASC payment system, CMS characterized the GAO report and its recommendations as "completely in accord" with the new payment system and found it unnecessary to consider any changes based on the GAO data.[11] We do not believe that the GAO study and its recommendations support the new uniform conversion factor.

First, we note that there are several problems with the GAO report itself and that the report does not appear to fulfill its statutory mandate. Congress required that the report include three specific recommendations: (i) whether it is appropriate to use OPPS groups and relative weights as the basis for ASC payments; (ii) if so, *whether* the ASC payments should be based on a uniform percentage of the OPPS rates or whether they should vary based on specific procedures or types of services; and (iii) whether a geographic adjustment should be used for ASC payments.[12] The sole recommendation for executive action contained in the GAO report is that CMS "implement a payment system for procedures performed in ASCs based on the OPPS . . . . tak[ing] into account the lower relative costs of procedures performed in ASCs."[13] To the extent that the GAO report failed to make all the required recommendations, we do not believe that the development of the new ASC payment system could possibly have complied with the statutory procedure.

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[10] MMA § 626(d)(2), 117 Stat. 2319.
[11] 72 FED. REG. 42,492.
[12] MMA § 626(d)(2)
[13] GOVERNMENT ACCOUNTABILITY OFFICE, MEDICARE: PAYMENT FOR AMBULATORY SURGICAL CENTERS SHOULD BE BASED ON THE HOSPITAL OUTPATIENT PAYMENT SYSTEM 15 (2006)

We further note that CMS' reliance on the GAO report recommendations as an after-the-fact confirmation of the suitability of the revised ASC payment system is inappropriate. Although CMS claims that the GAO report recommendations are "completely in accord" with the new payment system, the GAO report expressed no opinion on the appropriateness of a uniform conversion factor. Indeed, it is difficult to see how the GAO report could have opined on this matter, given that the GAO study, like CMS, fails to take into account the essential difference between fixed, site-neutral costs and the variable costs that contribute to the overall cost savings of ASCs. Thus we continue to believe that CMS could not reasonably or rationally have relied on the GAO report to support its adoption of a uniform conversion factor. As noted earlier, CMS did not otherwise justify its decision to adopt a uniform conversion factor on the basis of audited costs, statistically verifiable projection, or any other basis.

With respect to the GAO report, we thus conclude that CMS could not possibly have fulfilled the statutory mandate that it "tak[e] into account the recommendations in the report under section 626(d) of the [MMA]," because the GAO has not yet completed a statutorily sufficient report. Furthermore, given the inadequacy of the GAO report, CMS could not rationally have relied on the report to reach the conclusions it did regarding a uniform conversion factor for ASC payments. To wit, the GAO report did *not* recommend a uniform conversion factor. The GAO report did not take into account the influx of new ASC procedures allowed under the new rule. And the GAO report certainly did not say that ASC payments should be 65 percent of the OPPS rate across the board.

3. Failure to Consider All Relevant Factors and Alternatives

Initially, we note that we generally approve the change from an inclusive list of ASC procedures to an exclusive list. We believe that this change, if combined with a properly designed payment rate system, will result in a favorable migration of services from hospital outpatient departments to ASCs. The expanded range of procedures allowed at ASCs would, we are certain, result in increased beneficiary access to the procedures, lower costs for both beneficiaries and Medicare, and better overall service.

We are concerned, however, that CMS has not adequately evaluated the impact of such a massive influx of new procedures into the ASC payment system. As far as we can tell, CMS has not explained why it believes that the new procedures will generally fit with the uniform conversion factor used by the revised payment system. Nor does the GAO report provide a rational basis for such an assumption. Whatever the validity of the GAO report's study of 2004 data, it is difficult to imagine that an increase in the number of ASC procedures by nearly 40% does not affect the applicability of that data today. While the GAO could not have included such information in its report, given that no ASC cost data yet exists for the new procedures, we would have expected CMS to anticipate and consider how such a massive change would affect its underlying assumptions. Yet, as far as we are aware, no attempt has been made

to determine how the influx of nearly 950 new procedures since 2004 impacts the new payment system.

The problem is compounded by the nature of the expansion of allowable ASC procedures. The vast majority of the new procedures result from neither the development of new comparable procedures nor the gradual improvement of procedures already performed in hospital outpatient centers, but rather from a deliberate change in the standards controlling ASC procedures. This, we believe, lessens the likelihood that the relationship between ASC and OPPS rates for the new procedures will accurately mirror that of existing ASC procedures. Again, we are unaware of any attempt by CMS to ensure that the change in the ASC standards for approved procedures has not undermined the reliability of a rate system based on older data. It is our understanding that CMS does not know, or have any intention of determining, the actual costs of the new procedures or their relationship to the costs of the same procedures performed in hospital outpatient departments. We are concerned that as a result of the dramatic change in the range of procedures that may be performed at an ASC, the new ASC payment system runs the risk of becoming completely disconnected from the actual costs of the procedures themselves. Such an arbitrary result could hardly have been what Congress intended when it mandated that CMS develop a new payment system.

We believe, furthermore, that many of the potential benefits of increased ASC service will be eviscerated by the uniform conversion factor of the revised payment system. The result of this divorce between actual costs and payments rates will be predictable. Many of the potential benefits to the expansion of allowable ASC procedures will fail to materialize if they are hampered by a system that specifies a dramatically insufficient payment rate. As prior comments by urologists have made clear, it will be impossible for ASCs to offer lithotripsy, laser treatment of the prostate, or other similarly situated services, at the payment rate specified in the proposed ASC rates for 2008. Lithotripsy procedures would remain almost exclusively in hospital outpatient departments, even where ASCs could provide better access to beneficiaries at lower cost.

Urologists already have a minute interest in ASC's nationwide, despite the undeniable fact that they are surgeons. The reason is that the existing reimbursement for urological procedures is so low in comparison to orthopedics and other high-use procedures. The revised payment system, for reasons set out in these comments, fails to remedy this imbalance, assuring that ASCs will not be the venue of choice for urologists. The addition of new procedures to the ASC list, although laudatory in theory, will do little to address this unfortunate situation, given the inadequate payment rates for urological procedures under the revised payment system. Thus, Medicare patients will be denied the more patient-friendly, and efficient site of service, and Medicare will pay on average 50% more per procedure in hospital outpatient department settings.

4. The Role of Budget Neutrality

We recognize that, in addition to developing a new ASC payment system that fairly compensates ASCs for the procedures they perform, CMS is operating under a Congressional budget neutrality requirement. We are, however, concerned about the handling of this requirement for several reasons. First, we are concerned that the budget neutrality requirement has been overemphasized at the expense of—indeed to the exclusion of—the overall rationality of the new payment system. Second, we are at a loss to determine the rational, empirical basis for many of the assumptions CMS has made in its budget neutrality calculations. Finally, while we certainly understand that the overall result of the new payment system must meet the budget neutrality requirement, we note that CMS has not explored the budget neutrality ramifications of proposed alternative systems, such as variable ASC-to-OPPS relativity.

While CMS claims to have taken the GAO findings into account, it appears that CMS was far more focused on the budget neutrality requirement. As discussed above, however, CMS takes out of context the GAO's conclusion that APC groups are appropriate for ASC-to-OPPS correlation purposes. The GAO report did not recommend a uniform conversion factor. Rather than building on the GAO report to design a fair and rational payment system, CMS has paid attention only to budget neutrality and rendered the rulemaking process essentially irrelevant. While CMS made superficial changes to the implementation of the proposed system, it seems to have ignored the many comments that called into question fundamental assumptions regarding the uniform conversion factor and migration estimates. The final product looks more like a math exercise with inexplicable projections and dubious migration theories than a rational exercise in rulemaking.

Not only does CMS focus on the budget neutrality calculation to the exclusion of other considerations, its budget neutrality estimates are themselves suspect. For example, CMS proposed—and maintained despite critical comment—a 25 percent migration for new ASC procedures from hospital outpatient departments to ASCs, and a 15 percent migration from physicians' offices to ASCs. The sole rationale provided for this assumption was that it roughly tracked current ASC and hospital outpatient department utilization rates. There is simply no basis for assuming constant utilization rates for a system that will experience massive growth in the number of allowable procedures. While CMS acknowledges that some negative migration will occur for procedures with decreased compensation under the new system, it assumes—without citing any empirical sources—that this will be offset by migration to ASCs for those existing procedures with increased compensation. This sort of unfounded speculation is hardly a rational way to design a payment system or ensure that it meets the budget neutrality requirement.

While CMS cites the budget neutrality requirement as one of its reasons for basing the new payment system on the OPPS,[14] CMS does not appear to have considered how

[14] 72 FED. REG. 42491.

differential ASC-to-OPPS relativity would impact budget neutrality. While we cannot, with certainty, predict what that impact would be, we regret the failure of CMS to consider seriously the alternatives proposed. Furthermore, given the number and magnitude of the changes to the ASC rule, it is no surprise that CMS had to resort to unsubstantiated speculation in its budget neutrality calculations. We question why, given the focus of CMS on budget neutrality, it did not consider implementing its changes in a more limited fashion. CMS could, while remaining in compliance with the statutory mandates, elect to postpone or phase in the revisions to the ASC approved procedure list. This would allow CMS to examine how the new payment system, a dramatic change in itself, affects CMS' current assumptions prior to inundating the system with hundreds of new procedures for which CMS does not have adequate data.

The dollar impact of the new additions had, given budget neutrality and the uniform conversion factor, the mathematical impact of lowering significantly the payments for all of the existing procedures. Without apparently assessing the impact of that upon the adequacy of the rates, and concomitant adverse impact on Medicare beneficiary access, CMS could not have made a rational decision between facts found and choices made. We are confident that if CMS engaged in a rational consideration of all the pertinent factors, it could propose a cost-effective, budget-neutral system that is convenient to administer, and, more importantly, fairly compensates ASCs for the services they provide to Medicare beneficiaries.

Conclusion

For the above-mentioned reasons, we urge CMS to reconsider its adoption of a uniform conversion factor. At a minimum, CMS should make an exception to the application of the uniform conversion factor for equipment intensive procedures. Please do not hesitate to contact me if you need further clarification of the Council for Urological Interests' concerns.

Sincerely,

Joseph Jenkins, M.D.
Chairman and Executive Director

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AMERICAN ASSOCIATION OF AAASC AMBULATORY SURGERY CENTERS

P.O. Box 5271, Johnson City, TN 37602-5271
423 915 1001 fax 423 282 3712
www.AAASC.org

September 14, 2007

VIA HAND DELIVERY

Acting Administrator Kerry Weems
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P - Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Acting Administrator Weems:

On behalf of the American Association of Ambulatory Surgery Centers (AAASC), please accept the following comments regarding changes proposed for the ASC and hospital outpatient prospective payment systems (OPPS) for Calendar Year 2008 in 72 Fed. Reg. 148 (August 2, 2007). AAASC is a professional medical association of physicians, nurses, and administrators who specialize in providing surgical procedures in cost-effective outpatient environments, primarily in Medicare-certified ASCs. Most AAASC members own or operate in Medicare-certified ASCs, and so have considerable experience with and interest in the criteria utilized to determine whether a procedure is appropriate for performance within an ASC. We appreciate the careful consideration and effort that has gone into developing the proposal for a new payment system for implementation in 2008.

At the outset, we would like to commend the Centers for Medicare and Medicaid Services for the careful consideration and effort that has gone into developing the new ASC payment system for implementation in 2008. The final rule implementing a new payment system for ASCs (CMS-1517-F) made significant strides towards aligning the ASC and hospital outpatient department (HOPD) payment systems. We want to thank CMS for linking

the rule-making process for hospital outpatient departments (HOPDs) and ASCs. We commend you specifically for making a number of changes between the proposed and final rule implementing the ASC payment reform that result in better alignment between the two payments systems. One such example is allowing ASCs to bill for certain ancillary services separately payable under the OPPS. This alignment will also help to mitigate the unnecessary movement of procedures from the ASC back into the HOPD at a cost to both the government and Medicare beneficiaries. However, we remain very concerned that CMS did not adopt a set of policies that would result in a fixed relationship between ASC and HOPD payment over time. CMS's goal should be a payment system that does not impede Medicare beneficiaries' ability to understand their real costs in alternative settings and their ability to make direct comparisons.

The AAASC also appreciates the agency's recognition that budget neutrality in the new payment system should be assessed by looking at the universe of outpatient surgical services across all three ambulatory settings. We strongly disagree with the agency's assessment that the migration of procedures currently on the ASC list into and out of the ASC setting will result in no net change in Medicare expenditures. Because many procedures currently on the ASC list are rarely performed in ASCs because the payment rates are too low to cover the cost of providing them, we believe the migration of procedures into the ASC from the HOPD will greatly exceed that of any migration that increases costs to the Medicare program. As a result, our analysis showed that budget neutrality was most likely to be achieved when the conversion factor is 73 percent of the HOPD one. Further, we are concerned that CMS underestimated the volume of migration of certain procedures from the ASC to the more expensive hospital setting that will occur when payments are about 35 percent less than the OPPS rates. By using these incorrect migration estimates CMS has underestimated the payment rate for ASCs at which budget neutrality will be achieved. The resulting rates, paying ASCs 65 percent of HOPD payments, are inadequate and will have a dramatic impact on payments for some of the most common ASC procedures. These low rates may result in physicians moving cases to the more expensive hospital setting, increasing the costs borne by Medicare beneficiaries and the government rather than the savings that could have been achieved.

The low ASC conversion factor may have a profound effect on many procedures negatively affected under the revised ASC payment system. For example, gastroenterology procedures, many of which are commonly performed in the ASC setting would experience significant rate reductions. It would be extremely difficult for single specialty gastroenterology ASC—or any other facility focused on a narrow range of services negatively impacted by the new system—to alter their case mix. These facilities represent an extension of the physicians' practices into which substantial capital investments for equipment and an appropriate physical plant have been made. Additionally, many certificate-of-need states narrowly specify the use of the facility, not allowing for a change in case mix. The magnitude of the negative financial impact on such facilities may have undesired consequences on Medicare beneficiary access, particularly for the already underutilized screening colonoscopy benefit. We urge the agency to use their broad statutory authority to mitigate the potential adverse effect on access to services.

Finally, we commend CMS for deciding not to implement ASC reporting of quality measures prior to January 1, 2009. We anticipate ASC quality measures will be endorsed by the National Quality Forum (NQF) by the end of this year. By 2009, the congressionally mandated implementation date, nationally endorsed measures specific to ASC facilities will be available. The ASC Quality Collaboration, a collaborative group of ASC stakeholders, is working to ensure that ASC quality data is appropriately developed and reported and has spearheaded the development of quality measures now pending before the

NQF. Its members include ASC companies, associations, physician societies, accrediting bodies and government entities.

The major goal of any change in Medicare ASC payment policy should be to expand Medicare beneficiaries' access to high quality, cost effective surgical care. In the comments that follow, we share our views on how existing access can be preserved and expanded.

OVERVIEW

In its final rule issued in August, the agency took advantage of its broad statutory authority to design a new ASC payment system. Although tying ASC payment to the payment system already established for OPPS brings the latter's imperfections to the ASC setting, the AAASC believes that the OPPS represents a reasonable proxy for the relative cost of procedures performed in the ASC. For many of the procedures newly eligible for payment in the ASC, the reimbursement that will be available under the fully implemented payment system will provide an economically viable alternative, allowing beneficiaries to receive services outside the hospital. However, certain individual and classes of surgical services will not become, or will no longer be, economically viable in the ASC. In general, our comments below address procedures disadvantaged by provisions in the final ASC or proposed ASC/HOPD rule that, notwithstanding provisions in these rules, could be safely and efficiently performed in the ASC.

We reiterate our comments of last November that three core principles should drive policies for the ASC payment system. The policies should:

- Ensure meaningful beneficiary access to the wide range of surgical procedures that can be safely and efficiently performed in the ASC;
- Provide 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, rather than in the HOPD; and
- Align the ASC and HOPD payment systems to the maximum extent possible to provide Medicare beneficiaries with greater price transparency and eliminate distortions between the payment systems.

1. Ensuring Beneficiaries' Access to Services

Medicare beneficiaries have diverse needs for the type and complexity of surgical services offered in outpatient settings. Ensuring that beneficiaries receive their surgical care in the setting best suited to their medical needs, as determined by their physician in consultation with the patient and their family, should be the primary objective of ambulatory surgery payment policies.

We support the expansion of access to a large number of new procedures in the ASC setting. This will offer convenience and access to Medicare beneficiaries. At the same time, we believe that this expansion can and should be carried further to include a number of other surgical procedures appropriate for the ASC setting. However, CMS policies would limit a physician's ability to determine the appropriate site of service because it does not allow payment for many surgical procedures that are clinically appropriate in the ASC.

2. Establishing Reasonable Reimbursement Rates
We believe that the payment system for ASCs can and should achieve the following policy goals, discussed in more detail in the sections that follow:

- Achieve savings to the Medicare program and its beneficiaries;
- Promote payment neutrality across sites of service delivery and competition among surgical service providers; and
- Encourage increased transparency of information on Medicare providers.

3. Alignment of ASC and HOPD Payment Policies
Aligning the payment systems for ASCs and HOPDs will enhance the transparency of the cost of obtaining surgical care in different settings, thus allowing Medicare beneficiaries to make better choices regarding their surgical care. While we appreciate that the revised payment system moves towards consistency between the ASC and HOPD systems, there are several instances in which alignment of the ASC and HOPD payment systems is incomplete or inconsistent. In particular, we draw your attention to the following inconsistencies.

DISCUSSION

A. Covered Procedures
We are pleased that in the final rule, CMS has moved toward the recommendations of the Medicare Payment Advisory Commission's (MedPAC) March 2004 Report to the Congress. We do not believe the agency's rule fully embraces the policies articulated by the Commission. We fully support MedPAC's recommendation and CMS's stated view that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from payment of an ASC facility fee. This use of an exclusionary, rather than inclusionary, list allows Medicare beneficiaries access to the broader range of the ASC services that are currently safely offered to non-Medicare patients. Further, as new procedures are developed, Medicare beneficiaries are more likely to be assured timely access to these technological advances in ambulatory surgical care.

B. Criteria for Excluding Procedures
The AAASC supports MedPAC's recommendations for reforming the ASC procedure list as described above. Instead, CMS plans to implement criteria for excluding procedures from the ASC setting will result in continued barriers to beneficiaries' access to the broad spectrum of services that can be safely and efficiently performed in an ASC. The AAASC believes the additional criteria CMS finalized are unnecessary. CMS uses three criteria to determine which procedures required inpatient care: 1) the invasive nature of the procedure, 2) the need for at least 24 hours of post-operative recovery time or monitoring before the patient can be safely discharged, or 3) the underlying physical condition of the patient. These standards remain in place today and are used to distinguish non-covered inpatient services from covered outpatient services. We continue to believe that the same criteria applied to determine which procedures are excluded from the outpatient setting in hospitals should be used to determine procedures excluded from payment in ASCs.

Given that the wording and intent of the exclusionary guidelines under OPPS parallel those under the ASC payment system, it is not necessary to have different language determine the exclusions for outpatient surgery. Rather than maintaining two separate sets of criteria for defining appropriate outpatient surgery, CMS should apply one uniform set of standards. The OPPS standards have proven sufficient to safeguard patients in the hospital outpatient setting and therefore can be reasonably applied to the ASC setting. We

believe that physicians should, in consultation with their patients, retain the ability to determine the site of service for a given procedure.

Under this rule, CMS proposes to exclude from ASC payment in 2008 a number of procedures payable under the OPPS, but has not provided any rationale for the exclusions. It also should include a requirement that if CMS proposes a procedure for exclusion from ASC coverage (other than procedures on the inpatient list), the agency must specify the clinical basis for exclusion, with the data it relied on and supporting arguments, and then provide the industry with an opportunity to respond with its own data, arguments and medical experts with ASC experience. As a general rule, a procedure should not be excluded from ASC coverage if it can be safely performed in an outpatient surgical setting pursuant to reasonable and generally accepted patient selection criteria, which are best applied by physicians applying their medical judgment, rather than CMS erring on the side of exclusion.

It is essential that ASCs have the opportunity to understand the basis on which CMS deems procedures to meet the criteria for exclusion from the ASC list. Without this information, our opportunity to meaningfully comment on the government's proposal is impaired. Appendix C contains procedures that are currently safely performed in ASCs without an overnight stay that CMS has excluded from the ASC list. We strongly urge CMS to reconsider these procedures. We are eager to discuss these procedures and our experiences performing them with CMS.

Definition of Surgical Procedure. We are pleased that CMS expanded the definition to include certain categories of procedures as recommended by the AAASC. We support CMS's decision to allow payment for a number of covered ancillary services when they are furnished on the same day as a covered surgical procedure and are integral to the performance of that procedure in the ASC setting including certain radiology and other ancillary services. We appreciate the addition of 29 interventional radiology codes to the ASC list of payable procedures. However, we continue to believe that any X-ray, fluoroscopy, or ultrasound procedures described within the range of CPT Category I codes that the AMA defines as "radiology" that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice should be payable in ASC setting due to their invasive nature.

Overnight Stay. We support CMS's elimination of the four-hour recovery time limit when determining what procedures should be payable in ASC setting. However, in adopting midnight as the defining measure of an overnight stay, the final rule implements a coverage standard that is at odds with the growing number of states that have expanded the concept of "ambulatory" surgery over the past 20 years by permitting ASCs to perform procedures involving stays of up to 23 or 24 hours.[1]

CMS has stated three reasons for its selection of midnight as the defining measure of an overnight stay. The first is that a patient's location at midnight is a generally accepted standard for determining his or her status as a hospital inpatient or skilled nursing facility patient, and that therefore CMS believes this concept is reasonably applied to the ASC setting. These generally accepted standards were in fact created by CMS to facilitate its regulation of inpatient hospitals

[1] We are aware of at least 14 states that permit ASCs to retain patients for up to 23 or 24 hours of overnight recovery care: Alabama, Arizona, Arkansas, Colorado, Georgia, Illinois, Kansas, Nevada, New York, North Carolina, Ohio, Oklahoma, Tennessee, and Utah. A number of states also permit stays beyond 24 hours in separately licensed or certified recovery care units.

and skilled nursing facilities. The patient's location at midnight is used in the inpatient hospital setting as the basis for census counting for hospital cost reporting purposes. In the case of skilled nursing facilities, midnight provides a specific reference point in time for situations involving interrupted stays and consolidated billing. These are *inpatient* settings and the processes being regulated under the midnight concept in these cases are *administrative* ones. We are not aware of any other manner in which CMS has historically used the concept of midnight and in no case in the past has CMS employed midnight in defining a clinical coverage policy.

As we have stated in previous comments, midnight may be useful for administrative functions such establishing clear billing guidelines or taking a patient census, but midnight has no clinical significance. On the other hand, length of stay is clinically meaningful and relevant to standard medical practice. In coverage policies elsewhere, CMS has defined a clinically appropriate length of stay, most notably its definition of an appropriate postoperative recovery period for the hospital outpatient department. In this *outpatient* setting, CMS excludes from coverage those procedures for which there is the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. Length of stay should be a guiding principle in establishing coverage policies for ASCs as well.

In asking whether a procedure would require active medical monitoring and care at midnight, one would have to know when the procedure began in order to make a reasonable determination. Taken alone, midnight has no clinical significance. It is only when considered *in relation to another time* that midnight acquires any clinical relevance. Thus, consideration of length of stay is implicitly and inextricably part of the decision-making process confronting CMS clinical staff and medical advisors making determinations regarding ASC coverage exclusions. CMS should make that length of stay explicit in its coverage policies for ASCs, rather than basing policy on an arbitrary time of day.

The second reason CMS states for using midnight as the defining measure of an overnight stay is that overnight care is not within the scope of ASC services for which Medicare makes payment. ASCs have sought clarification regarding overnight care in the past. Neither midnight nor any other specified times have ever been included in CMS's policy clarifications regarding this matter. Rather, CMS has previously responded by referencing length of stay. In correspondence to the Federated Ambulatory Surgery Association dated May 18, 2005, CMS states that an overnight stay is a planned stay of over 24 hours and conversely that when the "length of stay is less than 24 hours, it is not considered an overnight stay." Adopting midnight as the defining measure of overnight stay is therefore also at odds with previous CMS statements, which providers have viewed as definitive and upon which they have structured their clinical operations.

The final reason CMS provides for implementing midnight as its definition of overnight stay is that midnight is straightforward and easily understood. Though this is true, it is not persuasive, particularly since the more appropriate concept of length of stay is just as straightforward and easily understood, in addition to being clinically relevant.

We are extremely troubled by a recent agency proposal that apparently would prohibit a Medicare-certified ASC from performing *any* procedures -- including procedures for non-Medicare patients – requiring active medical monitoring beyond midnight, *even if such stays are permitted for non-Medicare patients in the state where the ASC is licensed.*

More specifically, in the August 31, 2007 proposed modifications to the ASC conditions for coverage ("CfC"), an ASC is defined as a distinct entity that operates "exclusively" for the purpose of providing surgical services to patients not requiring an "overnight stay" – that is, recovery which requires active monitoring beyond midnight, "regardless of whether it is provided in the ASC."[2] While we intend to submit extensive comments on the CfC proposed rule, it should be noted that this particular proposal seems to reflect a radical departure from longstanding Medicare policy, which currently allows overnight stays for non-Medicare patients, either in the ASC itself or in a separate recovery care unit, where such stays are permitted under state law. In reliance on the current policy, ASCs throughout the country have invested significant time, money, and resources in developing recovery care programs for non-Medicare patients that may be needlessly jeopardized by the CfC proposed rule. There is no apparent reason for the substantial harm and disruption that would occur from overriding state licensure laws and extending this coverage limitation to non-Medicare patients through the CfC definition of an ASC.

Unlisted Codes. The final rule excludes unlisted surgical procedure codes from ASC payment under the revised ASC payment system. This policy, in addition to being incongruent with the approach CMS takes to reimbursement of unlisted codes under OPPS, is unnecessarily restrictive. CMS has indicated that, due to a lack of specific procedural descriptions, it is not possible to determine whether such procedures would pose safety risks to Medicare beneficiaries.

In our comments on the August 2006 proposed rule, we noted the existence of several subsections of the CPT manual in which all the specific CPT codes within the clinical grouping are payable in the ASC setting. In these instances, such as procedures on the posterior segment of the eye, we argued that the unlisted codes for such sections would not reasonably pose a safety risk. In response, CMS has indicated that without knowing the specific procedure, it is not possible to evaluate whether the procedure performed would have been excluded from ASC payment due to established safety criteria. In particular, CMS has stated that it would not be able to determine whether the procedure in question involved major blood vessels, major or prolonged invasion of body cavities, or extensive blood loss, or was emergent or life-threatening in nature.

Although unlisted surgical CPT codes do not allow reporting of specific procedures, they do allow reporting of the anatomic region of the procedure. This anatomic location is sometimes quite precisely defined. In some instances, unlisted codes also identify a specific surgical technique or a specific medical condition. Knowing the anatomic location, and occasionally the surgical technique and medical condition for which the procedure is performed, allows evaluation of safety of the entire spectrum of procedures reportable by the unlisted code. By considering the entire range of possible procedures for the particular anatomic location against the safety criteria to be satisfied, one can determine whether there is reason to exclude the unlisted code in question. Asking whether or not any procedure performed on the anatomic structure(s) in question would 1) involve major blood vessels, 2) require major or prolonged invasion of body cavities, 3) result in extensive blood loss, 4) be emergent or life-threatening in nature, 5) require systemic thrombolytic therapy, 6) be included on the inpatient list or 7) require an overnight stay allows a logical and comprehensive assessment of safety risk based on the criteria that CMS has established.

[2] 72 Fed Reg. 50469, 50471-72 (Aug. 31, 2007).

The Ocular Adnexa section of CPT provides a useful example of how such an appraisal could be performed. The unlisted procedure code for this particular section is 67399, *Unlisted procedure, ocular muscle*. It is possible, based on clinical knowledge of all the possible procedures performed on the ocular muscles, to evaluate the full spectrum of those possibilities against safety criteria CMS uses to determine whether a procedure should be excluded from ASC payment due to safety concerns. In this particular example, the questions asked would be as follows:

1) Does any procedure performed on the ocular muscles involve major blood vessels?
2) Does any procedure performed on the ocular muscles require major or prolonged invasion of body cavities?
3) Does any procedure performed on the ocular muscles result in extensive blood loss?
4) Is any procedure performed on the ocular muscles emergent or life threatening in nature?
5) Does any procedure performed on the ocular muscles involve systemic thrombolytic therapy?
6) Are any of the procedures performed on the ocular muscles on the inpatient list?
7) Would any procedure performed on the ocular muscles require an overnight stay?

Based on clinical knowledge of the ocular muscles and an understanding of the operative techniques and approaches to the ocular muscles, it is possible to answer all the questions above for any procedure that might be appropriately coded as CPT 67399. In this case the answer to all questions would be no. Therefore, no procedure on the ocular muscles would pose a safety concern. Given this, CMS should not exclude CPT 67399 from ASC payment.

Other unlisted surgical CPT codes should be evaluated with this same series of questions. For example, an assessment of 67299, *Unlisted procedure, posterior segment of the eye* should ask whether any procedure performed on the vitreous, retina, or choroid of the eye would involve major blood vessels, require major or prolonged invasion of body cavities, result in extensive blood loss, be emergent or life-threatening in nature, require systemic thrombolytic therapy, be included on the inpatient list or require an overnight stay. Because none of these criteria are concerns for the entire extent of procedures performed on the posterior segment of the eye, there is no reason to exclude an unlisted procedure on the posterior segment of the eye based on established safety criteria. CPT code 67299 should therefore be payable in the ASC setting.

On the other hand, a similar evaluation of CPT code 33999, *Unlisted procedure, cardiac surgery*, based on knowledge of the potential universe of cardiac procedures, would highlight multiple safety concerns. When considering cardiac surgeries, the evaluator would determine that these operations involve major blood vessels, may require major or prolonged invasion of body cavities, may result in extensive blood loss, and may be emergent or life-threatening in nature, and so on. Therefore, based on current criteria, CPT code 33999 would be appropriately excluded from ASC payment.

CMS should be consistent and evaluate unlisted codes for potential safety risks in both the ASC setting and the HOPD setting. The approach outlined above could be modified for HOPDs by incorporating the specific criteria that CMS uses to determine which procedures should be on the inpatient list under the hospital OPPS. This approach would allow CMS to assure beneficiary safety without being unduly restrictive.

C. Payment Bundles

The final rule made significant strides toward better aligning the payment bundle for ASCs and HOPDs. Allowing ASCs to bill separately for ancillary services integral to the primary procedure and separately payable under the OPPS is a significant improvement to the alignment of the payment systems. We remain concerned, however, that discounting the payment to ASCs for many of these ancillary services does not recognize that the difference in costs for these services does not vary significantly between the ASC and HOPD.

In principle, we agree that services that are "packaged" under OPPS, and therefore not separately payable to HOPDs, should not be eligible for payment of a separate ASC facility fee. However, the proposed changes to the OPPS packaging policies will exacerbate problems that arise directly from limiting payment for surgical procedures performed in ASCs to those that fall in the range of CPT codes 10000-69999. While we agree with much of the agency's underlying logic to expand the size of the payment bundle in the OPPS, the practical application of the revised bundles in the ASC payment system create several concerns discussed in detail below.

In the agency's expanded packaging policies, even more procedures safely performed in an ASC will be packaged with services outside the CPT surgical range (CPT 1000-69999). Several of the procedures proposed for packaging have been, or could be safely performed in an ASC. Under the proposed policy change, these procedures would no longer be available in the ASC. When this happens, a procedure that had been (or would otherwise be) eligible for payment in the ASC becomes newly ineligible because of a change in OPPS packaging policy couples that CPT code with a service outside the surgical CPT range—not because there has been a determination that the procedure is unsafe in the ASC. We strongly urge the agency not to exclude radiologic services that include procedures in the CPT surgical range that would otherwise be eligible for ASC payment. If the agency does not adopt this policy prospectively, we ask that CMS at least adopt such a policy for procedures on the ASC list in 2007.

Specifically, the current OPPS policy creates barriers for ASCs to continue performing selected services that meet CMS's definition of ASC surgical services (CPTs 10000-69999). Procedures such as diskography have both an injection component and a radiographic component. In CPT, the injection portion of the service is described by a code in the surgical range (in this example, 62290 or 62291), while the radiographic portion of the service is described by a code in the radiology range (in this example, 72285 and 72295). Under OPPS, the injection portion of the procedure is packaged into the radiographic portion of the procedure. As a result, only CPT codes 72285 and 72295 are payable in the HOPD.

In our comments regarding the August 2006 proposed rule, we noted that ASCs may not be able to offer these services to Medicare beneficiaries unless they had the opportunity to bill for the combined service under the associated radiology code. Although CMS has adopted policies that will allow ASCs to bill for selected radiology services as ancillary services when provided integral to the surgical service under the revised ASC payment system, the codes for radiology services that package a surgical service have not been designated as separately payable. CMS has stated that it sees no rationale for offering separate payment for the surgical portion of these services. However, the surgical service is a necessary precedent to the radiologic service in these cases and the radiologic service cannot be properly performed in absence of the surgical injection procedure.

In this proposed rule, CMS has outlined expanded OPPS packaging policies that would further affect the payment of these services. As proposed, the radiologic services in question would be packaged into the

APC payment for other associated independent services, and would no longer be separately payable when performed with other services under OPPS. CMS has recognized that these imaging guidance and radiologic supervision and interpretation services are occasionally performed independently. Accordingly, a new status indicator, "Q," has been devised that would allow OPPS payment when these radiologic services are the only ones reported on the claim.

ASCs should also have the opportunity to receive separate reimbursement for these services when they are the only service reported on the claim. Applying this policy to both payment systems acknowledges that a surgical service has in fact been performed and allows payment for services rendered. We propose CMS implement status indicator "Q" (or an equivalent) to allow separate ASC payment of services similarly designated under OPPS, if performed in isolation.

Under the revised payment system all radiological services will be treated as ancillary services. Therefore, if the radiologic service code was or is the only one billed on the ASC claim, no "primary" surgical service would be noted on the claim because the surgical service is packaged with the radiology service. In light of this, it may be necessary to create a special payment modifier to facilitate the processing of the ASC claim. This modifier could be appended to the radiologic service code to indicate that a surgical service has also been rendered in addition to the radiologic service. CMS could require reporting of the surgical service code as a means of ensuring the ASC certifies both components of the service have been rendered.

If CMS does not elect to adopt this proposal, we request that the agency outline an alternative approach for ASC providers who wish to offer these surgical services to Medicare beneficiaries. As we have pointed out in the past, one of the predominant trends in today's clinical practice is the integration of multiple disciplines and modalities to streamline patient care. These integrated care processes enhance efficiency and quality. However, payment policies that view these services in separates silos can disrupt these interrelationships and limit beneficiary access to efficiently integrated services, particularly in the ASC setting.

Table 1 presents those surgical service codes in the CPT Surgery section that are impacted by the newly proposed OPPS packaging policies. The corresponding radiologic service codes are all proposed for assignment to status indicator "Q." Given potential changes with the upcoming 2008 CPT revisions, these codes should not be viewed as definitive, but rather as examples under the current version of CPT.

Of particular interest in this table are CPT codes 19290 and 19291, which have been covered ASC services for many years and have been paid by CMS as separately identifiable services. These services have been packaged into CPT codes 77031 and 77032 under OPPS. Under the newly proposed policies, CMS has not assigned a status indicator "Q" to CPTs 77031 or 77032, but rather a status indicator "N". We believe this is an error, as these services are occasionally performed as the sole service, and wish to draw the agency's attention to the need for correction.

Table 1
Surgical Services Packaged into SI "Q" Radiologic Services under OPPS

Surgical Code(s)	Corresponding CPT Code(s) for Radiologic Service	Descriptor of Payable Radiologic Service Code
68850	70170	X-ray exam of tear duct
21116	70332	X-ray exam of jaw joint

31708	70373	Contrast x-ray of larynx
42550	70390	X-ray exam of salivary duct
31708, 31710, 31715	71040-60	Contrast x-ray of bronchi
62284	72240-70	Contrast x-ray of spine
62291	72285	Diskography, cervical or thoracic
62290	72295	Diskography, lumbar
23350	73040	Contrast x-ray of shoulder
24220	73085	Contrast x-ray of elbow
25246	73115	Contrast x-ray of wrist
27093, 27095	73525	Contrast x-ray of hip
27370	73580	Contrast x-ray of knee joint
27648	73615	Contrast x-ray of ankle
49400	74190	X-ray exam of peritoneum
47505	74305	X-ray bile ducts/pancreas
47500	74320	Contrast x-ray of bile ducts
50394, 50684, 50690	74425	Contrast x-ray, urinary tract
51600, 51605	74430	Contrast x-ray, bladder
55300	74440	X-ray, male genital tract
54230	74445	X-ray exam of penis
51610	74450	X-ray, urethra/bladder
51600	74455	X-ray, urethra/bladder
58340	74740	Hysterosalpingography
38790	75801-07	Lymph vessel x-ray
49427	75809	Nonvascular shunt, x-ray
38200	75810	Vein x-ray, spleen/liver
36481	75885-87	Vein x-ray, liver
20501, 49424	76080	X-ray exam of fistula
19290, 19291	77031	Stereotactic guidance breast biopsy or needle
19290, 19291	77032	Mammographic guidance, placement breast needle
19030	77053, 77054	X-ray of mammary duct

D. Device-Intensive Services

We appreciate the agency's recognition that application of the discount of approximately 35% to the device portion of certain procedures would result in an ASC facility fee that fails to cover the cost of the device and the surgical service. We urge the agency to monitor the migration of procedures involving devices from hospital outpatient departments during the four transition years and consider accelerating the transition period for these procedures if warranted. The AAASC has concerns about the effect of the transition on two specific categories of procedures involving devices.

There are a number of procedures currently performed in ASCs which receive separate and additional payment for implantable devices and which have not been designated by CMS as device intensive procedures in the new payment system. During the first years of the transition, as the rates are phased in, the payment for these types of procedures may not adequately cover the costs for the procedure and the cost of the implants. CMS may also want to consider reducing the threshold for identifying procedures to be paid as device-intensive if services that could migrate to the ASC setting remain in the hospital outpatient department. In these cases, the cost of the device may be less than 50 percent of the APC rate, but more than what the ASC can afford under the discounted conversion factor.

One example of this type of procedure is CPT 66180, commonly known as a glaucoma drainage implant (Baerveldt, Molteno, Ahmed shunts), which was performed 40 percent of the time (almost 2750 times) in ASCs setting in 2005. For the sickest glaucoma patients facing irreversible vision damage, the standard

trabeculectomy procedure performed to move fluid out of the eye and relieve pressure may not be an option, or may have been tried and failed. For these patients, inserting a shunt to relieve intraocular pressure is necessary. For some of these high-risk patients there may be other medical indications, such as anatomic anomalies or scarring, for shunt placement. Under the new ASC payment system, the shunt used in these cases will no longer be separately payable. However, CMS has not included CPT 66180 on the list of device-intensive procedures. The total expected payment in the ASC for code 66180 in 2008 is only $940.81. On average, the typical shunt device costs approximately $650 and the pericardial graft tissue used to cover the tube shunt is an additional $255, for a total device cost of $905. Previously, the ASC facility payment for this service was $717, plus additional payment for the devices of about $964, for a total of $1681, which typically covered the facility's costs. The total expected payment in the ASC for code 66180 in 2008 is only $940.81.

A second example is CPT 57288, repair bladder defect, which is included in a device-dependent APC (202) under OPPS, but not classified as device-intensive under the revised ASC payment system. The proposed payment for the first year of the transition is $985.14. The cost of the sling alone is $1095.00, which exceeds the proposed reimbursement (Johnson & Johnson, Gynecare TVT Secur®).

Another example of this category of procedure is CPT 51715, endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck. As with the previous example, this is a procedure for which an implantable product, injectable bulking agent, is currently paid separately, but will not be under the new payment system. The ability of ASCs to perform this procedure during the early years of the transition period should be closely monitored by CMS.

Another category of procedure that should be monitored by CMS during the transition period is one that has been added to the ASC list in the recent past, but has been virtually never performed since its addition because of an inadequate payment associated with it. A procedure in this category is CPT 55873, prostate cryosurgery. This procedure was added to the list of ASC procedures in July 2005 and, because of the associated device costs, has rarely been performed in ASCs for Medicare beneficiaries due to the cost of the device, for which ASCs have been unsuccessful in receiving separate payment. In 2005, according to physician claims, this procedure was performed 11 times in an ASC and in 2006 only once. A transition payment policy for a procedure that is virtually never performed because of inadequate payment does not make sense. Such procedures may need to be treated in the same manner as procedures added to the ASC list in 2008 and subsequent years. Again, CMS should closely monitor these types of procedures and adjust payment policies if appropriate.

If one major purpose of the new ASC payment system is to encourage the migration of procedures from HOPD to ASCs, it will be imperative for CMS to closely monitor the effect of the four year transition on ASC procedures for which separate payment for implants is currently made and for procedures that are virtually never performed because the rate is insufficient to cover the included implant. The AAASC suspects that the speed with which these types of procedures migrate could be significantly retarded if payment levels during the early years of the transition are inadequate. As a result, these services will continue to be provided primarily in the more expensive hospital setting. The AAASC believes that the number of procedures that fall into these categories is small and that any adjustment in the payment policies for them would not adversely affect average rates for other procedures even in the context of maintaining budget neutrality.

E. Payment Limits

Although we applaud CMS's expansion of the ASC procedure list, we continue to oppose CMS's payment cap on office-based procedures. CMS has decided that those procedures it determines are commonly performed in physicians' offices or are otherwise determined to be office-based, shall be paid the lesser of the applicable ASC rate or the applicable Medicare physician fee schedule (MPFS) rate. The unfairness of this policy is underscored by the fact that the "lesser of" rule is not applied to payment to hospital outpatient departments. CMS has not demonstrated that procedures commonly performed in physicians' offices are more likely to migrate to an ASC than a hospital outpatient department. Therefore, this "lesser of" rule should either be abandoned completely or applied to payment to ASCs as well as hospital outpatient services. CMS appears to be using payment rates to address the agency's concerns about provider's financial interests rather than the clinical needs of patients.

The payment limit will force patients who are not appropriately treated in the physician office or who go to a physician who does not have appropriate equipment or staff in their office for the procedure to go to an HOPD, bypassing the ASC where the service could safely and cost-effectively be performed. Physician offices generally treat a less complex and severely ill patient case mix. As such, the office is less likely to have the staff and equipment resources to provide on a regular basis many of the services that a more medically complex patient might require. Capping payment at the physician office rate undermines the stepped reimbursement policies that underlie the level of resources available to the physician and beneficiary at the ASC and physician office.

Although we disagree with CMS's assertion that significant volume of these procedures will move from the physician office into the ASC, we recognize that the agency wants to discourage migration of services into a more expensive setting. However, in previous cases where CMS has made exceptions to allow ASC payment for procedures primarily performed in the office, there have not been significant shifts in the site of service for those procedures.[3]

These findings are in accord with findings we have made, which are that physicians typically do not bring procedures to the ASC when those procedures can be appropriately performed in their offices. Physicians seek to provide services in the most convenient setting that is appropriate. Physicians who have acquired the equipment and personnel to perform these procedures will want to continue to provide such services in their office. Unfortunately, capping payments for these procedures will primarily hurt the beneficiary and ultimately raise costs for the beneficiary and the Medicare program. Further, we are concerned with the agency's process for identifying and permanently designating procedures as "office-based" services.

CMS should not limit payment for services that draw on costly facility resources for patients for whom the physician office is not the clinically appropriate site of service. First, using 50 percent as the threshold for identifying office-based procedures means that for some services, they are just as frequently performed in another outpatient setting like the ASC or HOPD. That said, there must be a clinical need for facility-level resources since the remaining half of the Medicare beneficiaries receiving the service are treated in the ASC or HOPD. Failing to provide adequate payment to ASCs to perform the procedures may lead to higher volume in the HOPD rather than contributing to the migration of ASC volume into the physician office. CMS should set the threshold for designating a service at office-based significantly higher so that the designation applies only to services where facility-level care is infrequently warranted.

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[3] 70 Fed. Reg., 23696 (May 4, 2005). CMS stated, "Consistently, the physician office is the predominate service setting even though the procedures were included on the ASC list."

We are also concerned by CMS' plan to permanently designate a service as office-based using only one year of volume data. Especially for low-volume procedures, the distribution of services between settings can vary substantially from year-to-year. An office-based designation set at the 50 percent threshold should not be a permanent designation. If this policy remains, CMS should, at a minimum, use multiple years of data to assess whether the procedure is consistently performed in the office setting. For procedures with low volume in which a small number of services can make a large difference, or those whose percentage hovers close to the threshold, we believe a multi-year average is a more appropriate measure of whether a service has truly migrated into the physician office.

Finally, we are very concerned that CMS will use unidentified data as a secondary mechanism to designate "office-based services." As discussed in both the proposed and final rule, when CMS is designating codes as office based, it is not solely identifying procedures based on the latest volume data but evaluating clinical information and comparable data for related procedures "as appropriate." Without identifying the data CMS will use to make a determination that a procedure is office-based, it will be impossible to assess whether such a determination is rational and fair. We urge CMS to adopt a more transparent mechanism to designate office based procedures.

In the final rule implementing ASC payment system reform, CMS designated almost 70 procedures as "office-based services" that also do not meet the "predominantly performed" volume threshold. (Appendix B). In this proposed rule, CMS is proposing an additional 12 procedures to be designated as office-based which do not meet the "predominantly performed" volume threshold. (Appendix A). Physicians are already performing many of the "office-based" procedures in the ASC setting on patients that may require the additional services available in the ASC, rather than taking these procedures to the more expensive hospital setting.

The policy limiting payment for procedures designated as "office-based services" should be eliminated unless it is equally applied to the hospital outpatient department. Site of service volume characteristics are arbitrary and without clinical basis and should not be used to determine ASC payment. However, should CMS choose to do so, services should not be designated "office-based services" indefinitely but should be evaluated solely based on whether or not they are infrequently performed in the HOPD or ASC. The 50 percent threshold is too low and should higher. Further, CMS should not use clinical information or comparable data *for related procedures* to determine what should be office-based. If CMS continues to use other data, it should provide the data and rationale employed in making that determination.

F. Inflation Update

CMS should utilize the same market basket annual inflation to determine the annual update for ASCs. ASCs are affected by the same inflationary costs as hospitals, such as hiring nurses and purchasing medical devices, which are unrelated to general consumer price increases. CMS has presented no evidence that the relative costliness of procedures in the ASC and HOPD diverge over time. The broad discretionary authority granted to the Secretary to implement the new payment system should be used to apply the hospital market basket to the ASC payment system. Absent that adjustment, this bifurcated update process will result in annual, larger variation between the rates paid for ASC and hospital outpatient services.

G. Secondary Rescaling of APC Relative Weights

CMS applies a budget neutrality adjustment to the OPPS relative weight values after they are recalibrated with new cost data each year and decided to apply a secondary rescaling of the ASC weights. As expected, the relative costliness of surgical services continues to outpace the cost growth of non-surgical services in the OPPS. Applying a secondary recalibration to the ASC, absent evidence that ASC services became relatively less expensive than the HOPD, will drive unjustified variation in the payment rates between the ASC and HOPD. We question whether policies that lead to government paying increasingly higher rates under the OPPS is appropriate and justifiable given that many patients could have safely received their procedure in an ASC if one were available.

H. Application of HOPD Policies to the ASC

We appreciate CMS using their authority to extend several HOPD policies to the new ASC payment system. Although few items are eligible for pass-through status each year, accelerating the diffusion of new technologies to ambulatory settings is an important policy objective for the payment systems. As CMS considers future policies in the OPPS, we urge the agency to apply the same policies to the ASC.

In this proposed rule, the agency used their authority under 1833(t)(2)E) to adjust payment under the OPPS for several gastroenterology procedures that would have otherwise been paid the lower ASC discounted rate under a policy enacted in the Balanced Budget Act of 1997. Specifically, CMS stated that the payment for screening flexible sigmoidoscopies and screening colonoscopies would be too low if CMS followed the statute and paid for the services at the lesser of the ASC or OPPS rates as required under the BBA. Instead, the agency will pay for the services at the standard OPPS rate. On the other hand, CMS has not taken similar steps to ensure that that beneficiary access to services in the ASC will not be negatively affected. Because the preventative screening benefit is currently under-utilized, we urge the agency to carefully monitor the utilization of the benefit and make adjustments as necessary.

I. Billing Systems

In the final rule, CMS decided to continue to require the use of the CMS 1500 form for providers to submit claims for their services. As CMS and providers gain experience with the new payment system, we urge the agency to complete the alignment of the payment system by migrating to the UB-04 for ASC claims submission. Many commercial payers require ASCs to submit claims using the UB-04. CMS should initiate a transition process for providers and the agency's administrative contractors to implement the UB-04 form for ASCs in 2010 to allow providers time to acclimate to the new payment system in 2008 and the reporting of quality measures in 2009.

K. Beneficiary Liability for Non-Covered Services.

Current OPPS payment policy prohibits facility payments to a hospital for non-covered services, such as surgical procedures on the OPPS inpatient list. In those cases, the beneficiary is liable for the hospital charges. CMS has proposed to implement a similar policy for non-covered ASC services. This policy assumes that all non-covered procedures are scheduled as such and does not acknowledge the possibility that a covered procedure was planned, but not performed for legitimate reasons that could not be anticipated in advance, resulting in a non-covered procedure being performed instead.

Though not typical, it is possible for intraoperative findings to alter the course of a planned procedure. When these unpredictable events occur, it is not reasonable to burden the beneficiary with full financial liability for the non-covered procedure. Acknowledging that the course of a planned procedure cannot always be determined in advance and allowing for contractor-based adjudication allows for more

equitable treatment of beneficiaries under these circumstances. Under such circumstances, standard cost-sharing formulas should remain in effect. A modifier could be created that allows communication of these circumstances on both ASC and HOPD claims. In these cases, payment would be at contractor-priced rates following a review of the operative report. Any concerns regarding billing practices could be readily audited, since scheduling a procedure creates a record of the planned intervention. We urge CMS to alter its current policy under OPPS and apply this modified policy to the ASC and HOPD setting.

L. Reporting Quality Data for Annual Payment Rate Updates as it pertains to ASCs

We commend CMS for deciding not to implement ASC reporting of quality measures prior to January 1, 2009. With the implementation of the revised ASC payment system in 2008, the ASC community will have a significant transition and we are pleased additional requirements will not be introduced simultaneously. The current absence of any nationally endorsed ASC quality measures for public reporting and accountability would have been a further barrier to implementation in 2008. However, we anticipate ASC quality measures will be endorsed by the National Quality Forum (NQF) by the end of 2007 and available for implementation in 2009. The ASC Quality Collaboration, a cooperative effort of organizations and companies interested in ensuring that ASC quality data is appropriately developed and reported, is developing standardized ASC quality measures. Its members include ASC companies, associations, physician societies, accrediting bodies and government entities.

Quality Measures. The ASC Quality Collaboration has submitted a series of measures to the NQF, which have been reviewed by a technical advisory panel and a steering committee of the National Quality Forum (NQF). As a result of these evaluations, five measures have been recommended for endorsement and have recently been open to public and NQF member comment. We anticipate that final action on these measures could be taken as early as November 2007. We are not aware of any other measures specifically addressing facility quality in the delivery of outpatient surgical services that have either been nationally endorsed or are in the process of evaluation for endorsement. Therefore, we strongly recommend CMS consider these five facility-specific measures for ASC reporting if they are endorsed by the NQF.

Of the five measures, four are outcome measures that have applicability to all outpatient surgical facilities and thereby ensure broad facility participation regardless of case mix. These measures focus on 1) patient falls, 2) patient burns, 3) hospital transfer/admission and 4) wrong site/wrong side/wrong patient/wrong procedure/wrong implant. The fifth measure is a process measure that evaluates the timing of the administration of intravenous antibiotics for prophylaxis of surgical site infection. This prophylactic antibiotic timing measure has been specifically designed to harmonize with, and be complementary to, similar measures (PQRI #20 and PQRI #21) developed to evaluate physician performance in this area.

ASC Data Collection. Our evaluation of alternative reporting methodologies has focused on their complexity, staff resources needed for implementation, requirements for hardware and software, training requirements, and additional expenses, particularly related to contracting with data submission vendors. In all these areas, we find the administrative claims approach to be the most practical, feasible and economical solution for ASCs. We have carefully evaluated these alternative approaches, taking into account the characteristics and resources of the typical ASC. Though there is significant variability, CMS data indicates a median of two operating/procedures rooms per facility (mean = 2.5). FASA's 2007 ASC Salary & Benefits Survey shows that the majority (61.2%) of ASCs have 20 or fewer total full-time equivalents, including both clinical and

non-clinical staff. It is unusual for an ASC to have a medical records department staffed with multiple individuals.

The administrative and financial burden of reporting quality measures should be fully considered. CMS has estimated that approximately 73 percent of ASCs would be considered small businesses according to the Small Business Administration (SBA) size standards (see 72 Fed. Reg. 42538 (August 2, 2007) and 72 Fed. Reg. 42812 (August 2, 2007)). In this respect, ASCs more closely resemble individual physician practices than hospitals.

Further, ASCs will continue submitting their Medicare claims using the CMS-1500 at least through 2008. Therefore, ASCs are in a position to report quality data in the same manner as physicians, which will allow CMS to leverage the processes it has already developed under the Physician's Quality Reporting Initiative (PQRI). If ASCs move to the UB-04 in the future (a change we support), these codes can continue to be reported on the new form and comparisons made across multiple years remains feasible.

We request CMS work with ASC leaders to develop HCPCS Level II G codes that would allow facility-level quality measures to be reported using a claims-based approach. Reporting data on the claim form using HCPCS codes is achievable across ambulatory settings and can be accommodated on both the CMS-1500 and the UB-04.

Publication of Quality Data Collected. The demand for more publicly available health care information is being driven by federal and some state actions and by employers in an effort to control escalating health insurance costs and improve quality. The AAASC is supportive of transparency oriented efforts motivated by a desire to provide consumers with information they can use in a meaningful way to improve their health and lower the cost of their care. Access to cost and quality information will become even more important to consumers as the health insurance industry moves to more consumer driven health care through Health Savings Accounts (HSAs), Health Reimbursement Accounts (HRAs) and Flexible Spending Accounts (FSAs).

The AAASC urges CMS to ensure that any transparency regarding ASC cost and quality information is meaningful and presented in a way that assists consumers in making decisions. The success of transparency efforts is closely linked to how effectively information is shared with the public. A data reporting infrastructure should allow patients and payers to compare quality across Medicare's payment silos when a service or procedure can be delivered in multiple ambulatory settings.

Consumers should be able to access quality and cost information on websites that are organized to allow easy comparisons, while also protecting the rights of providers to assure the information is correct, up-to-date and clearly presented. Specifically, web-based presentation of quality and cost data should address or incorporate the following principles:

1) Information should be presented on all available sites of service so consumers can compare a hospital outpatient department and an ASC for a procedure that could be performed in both locations,

2) There should be a mechanism for providers to raise concerns with any information to be posted prior to its public presentation,

3) There should be a provider narrative section for each provider-specific item presented to the consumer. This narrative box would allow the provider to advise the consumer of any concerns the provider has regarding the reliability or accuracy of the information presented, and

4) In addition to reporting quality measures, other useful information such as accreditation status, state licensure and Medicare certification should be made available.

The AAASC urges CMS to provide for more detailed consideration and expanded description on this vital matter from CMS in future rulemaking.

* * * * *

We appreciate the agency's consideration of our comments on behalf of the ASC community. Inadequate payment will force providers to respond in a variety of ways – the end result of which may limit patients' ability to have their surgical service performed in a low cost environment. The implementation of the revised ASC payment system will result in significant redistribution of dollars within the ASC payment system and as such, we strongly urge CMS to use its broad discretionary authority to ensure a smooth transition to the new payment system. As leaders in the ASC industry, we want to ensure patient access is not jeopardized by abrupt changes in the payment system.

Thank you for considering our comments. If you have any questions or need additional information, we would be happy to assist you.

Sincerely,

Joseph Banno, MD
President
American Association of Ambulatory Surgery Centers

APPENDIX A

PROCEDURES PROPOSED FOR DESIGNATION AS OFFICE-BASED BUT PERFORMED LESS THAN 50% OF TIME IN THE PHYSICIAN OFFICE IN 2006

HCPCS	SHORT DESCRIPTION	FINAL RULE INDICATOR	PROPOSED RULE INDICATOR	CY 2006 OPPS UNITS	CY 2006 MPFS IN OFFICE ALLOWED SERVICES	TOTAL VOLUME	% MD OFFICE
24640	Treat elbow dislocation	G2	P3	51	18	69	26.09%
26641	Treat thumb dislocation	G2	P2	66	29	95	30.53%
26670	Treat hand dislocation	G2	P2	72	29	101	28.71%
26700	Treat knuckle dislocation	G2	P2	522	106	628	16.88%
26775	Treat finger dislocation	G2	P3	264	217	481	45.11%
28630	Treat toe dislocation	G2	P3	100	95	195	48.72%
28660	Treat toe dislocation	G2	P2	295	159	454	35.02%
29505	Application, long leg splint	G2	P3	19482	1106	20588	5.37%
29515	Application lower leg splint	G2	P3	56482	17910	74392	24.08%
36469	Injection(s), spider veins	G2	R2	3	1	4	25.00%
46505	Chemodenervation anal musc	G2	P3	163	37	200	18.50%
64447	Nblock inj fem, single	G2	R2	1381	950	2331	40.76%

APPENDIX B

PROCEDURES PERFORMED LESS THAN 50% OF TIME IN PHYSICIAN OFFICES WHEN DESIGNATED AS OFFICE-BASED IN THE FINAL RULE

CPT	SHORT DESCRIPTION	CY 2005 OPPS UNITS	CY 2005 MPFS IN OFFICE ALLOWED SERVICES	TOTAL VOLUME	% MD
0046T	Cath lavage, mammary duct(s)	3	1	4	25.00%
0047T	Cath lavage, mammary duct(s)	0	0	0	--
11950	Therapy for contour defects	39	32	71	45.07%
11951	Therapy for contour defects	43	10	53	18.87%
11952	Therapy for contour defects	19	6	25	24.00%
11954	Therapy for contour defects	196	34	230	14.78%
11976	Removal of contraceptive cap	31	11	42	26.19%
12001	Repair superficial wound(s)	132984	36471	169455	21.52%
12002	Repair superficial wound(s)	98727	23901	122628	19.49%
12004	Repair superficial wound(s)	14338	2748	17086	16.08%
12011	Repair superficial wound(s)	70950	9485	80435	11.79%
12013	Repair superficial wound(s)	39628	4734	44362	10.67%
12014	Repair superficial wound(s)	5222	548	5770	9.50%
15340	Apply cult skin substitute	15359	6617	21976	30.11%
15783	Abrasion treatment of skin	86	25	111	22.52%
15786	Abrasion, lesion, single	472	373	845	44.14%
15787	Abrasion, lesions, add-on	155	54	209	25.84%
26010	Drainage of finger abscess	1975	1790	3765	47.54%
29010	Application of body cast	3	2	5	40.00%
29049	Application of figure eight	22	14	36	38.89%
29055	Application of shoulder cast	27	21	48	43.75%
29058	Application of shoulder cast	118	43	161	26.71%
29086	Apply finger cast	580	228	808	28.22%
29105	Apply long arm splint	18280	9569	27849	34.36%
29125	Apply forearm splint	120178	32832	153010	21.46%
29126	Apply forearm splint	6623	702	7325	9.58%
29130	Application of finger splint	26636	8515	35151	24.22%
29131	Application of finger splint	1534	459	1993	23.03%
29240	Strapping of shoulder	17263	6576	23839	27.59%
29260	Strapping of elbow or wrist	6187	5690	11877	47.91%
29358	Apply long leg cast brace	146	91	237	38.40%
29530	Strapping of knee	18662	13284	31946	41.58%
29700	Removal/revision of cast	3525	2380	5905	40.30%
29710	Removal/revision of cast	17	4	21	19.05%
29715	Removal/revision of cast	12	2	14	14.29%

CPT	SHORT DESCRIPTION	CY 2005 OPPS UNITS	CY 2005 MPFS IN OFFICE ALLOWED SERVICES	TOTAL VOLUME	% MD
30901	Control of nosebleed	67943	60188	128131	46.97%
36430	Blood transfusion service	477254	15877	493131	3.22%
36440	Bl push transfuse, 2 yr or <	24	7	31	22.58%
36450	Bl exchange/transfuse, nb	59	30	89	33.71%
36468	Injection(s), spider veins	68	42	110	38.18%
36550	Declot vascular device	12215	11617	23832	48.75%
36598	Inj w/fluor, eval cv device	6388	3343	9731	34.35%
38242	Lymphocyte infuse transplant	37	8	45	17.78%
41820	Excision, gum, each quadrant	376	1	377	0.27%
41822	Excision of gum lesion	27	14	41	34.15%
41823	Excision of gum lesion	95	41	136	30.15%
41830	Removal of gum tissue	218	107	325	32.92%
41850	Treatment of gum lesion	26	4	30	13.33%
41872	Repair gum	422	0	422	0.00%
41874	Repair tooth socket	4473	573	5046	11.36%
46606	Anoscopy and biopsy	876	619	1495	41.40%
46910	Destruction, anal lesion(s)	531	340	871	39.04%
46945	Ligation of hemorrhoids	1108	1068	2176	49.08%
51702	Insert temp bladder cath	1211839	145409	1357248	10.71%
53025	Incision of urethra	0	0	0	--
55450	Ligation of sperm duct	8	5	13	38.46%
55870	Electroejaculation	16	4	20	20.00%
55876	Place rt device/marker, pros	1293	245	1538	15.93%
58345	Reopen fallopian tube	5	3	8	37.50%
58356	Endometrial cryoablation	21	16	37	43.24%
59001	Amniocentesis, therapeutic	8	4	12	33.33%
59015	Chorion biopsy	18	9	27	33.33%
59020	Fetal contract stress test	357	9	366	2.46%
59025	Fetal non-stress test	11562	5260	16822	31.27%
60100	Biopsy of thyroid	12967	7236	20203	35.82%
63615	Remove lesion of spinal cord	4	2	6	33.33%
64402	Nblock inj, facial	1312	874	2186	39.98%
67208	Treatment of retinal lesion	454	374	828	45.17%

APPENDIX C

OTHER PROCEDURES FOR ADDITION TO THE ASC LIST FOR 2008

CPT	DESCRIPTION	COMMENTS
22526 22527	Percutaneous intradiscal electrothermal annuloplasty (IDET or IDEA)	These are minimally invasive surgical procedures for the treatment of discogenic lumbar pain. These procedures are commonly performed in the outpatient setting, with discharge on the day of the procedure. Following placement of a local anesthetic and administration of sedation, an introducer is placed through a small incision and fluoroscopically guided to the affected lumbar disc. An electrothermal catheter is passed through the introducer and positioned in the annulus. Electrothermal energy is applied via the catheter for a period of 15 to 20 minutes. These procedures are clinically similar to 0062T/0063T, which are included in Addendum AA for ASC coverage.
29866 29867 29868	Knee arthroscopy with autograft implantation or meniscal transplantation	These knee arthroscopy procedures were added as CPT codes in 2005 and are clinically similar to the 29800-29888 series of codes, which are on the ASC list. They typically require approximately 45 minutes of operating time and do not require an overnight stay.
35470	Transluminal balloon angioplasty	This procedure is safe to perform in the ASC and does not require an overnight stay. It involves peripheral vessels, takes approximately one hour and does not require overnight recovery. It is similar to, but less invasive than, 37205 and 37206, which CMS added to the ASC list in 2005.
35493	Transluminal peripheral artherectomy	This procedure involves peripheral vessels and is safe to perform in an outpatient setting. The procedure typically takes approximately one hour to complete and does not require an overnight stay.
63030 63035 63042 63047	Low back disk surgery	While Medicare patients primarily have lower back disc surgery performed on an inpatient basis, a growing number of non-Medicare patients (and some Medicare patients who choose to pay out of pocket) are having these procedures performed in ASCs, often using endoscopically-assisted approaches. The procedures are non-emergent, do not involve a major or prolonged invasion of a body cavity and do not involve major blood loss. In ASC settings, these procedures involve 60 to 90 minutes of operating room time and do not require an overnight stay.
64448 64449	Injection of anesthetic agent (nerve block) for femoral nerve or lumbar plexus, with continuous	These procedures are already being performed on a regular basis for non-Medicare patients in the ASC setting. CMS should make these procedures available to Medicare beneficiaries as they often are performed in conjunction with

CPT	DESCRIPTION	COMMENTS
	infusion by catheter	other pain management procedures. By denying Medicare coverage for these procedures, CMS creates an obstacle to their efficient performance with other procedures in ASCs.
0088T	Submucosal radiofrequency volume reduction of the tongue base, or somnoplasty	This is a commonly performed outpatient procedure for the treatment of obstructive sleep apnea or upper airway resistance syndrome. The radiofrequency probe is inserted into the tongue muscle and then heated, producing tissue injury that, after healing, reduces the volume of the tongue. Patients typically receive local anesthesia. Procedure time is less than 45 minutes and patients are discharged home on the day of the procedure. The procedure is clinically similar to, though less invasive than, excisional procedures involving the tongue described by CPTs 41110 and 41113, both of which will be covered in the ASC setting.
0135T	Percutaneous cryosurgery of renal tumors	This procedure is a minimally invasive treatment option for patients with small cortical renal tumors. The procedure requires general or regional anesthesia. Ultrasound or other guidance modalities are used to guide placement of the cryoablation needles and thermal sensors. Following completion of two freeze thaw cycles, the patient is monitored in recovery and discharged on the day of the procedure. This procedure is clinically similar to CPT 50592, Percutaneous radiofrequency ablation of renal tumor(s), which is included in Addendum AA for coverage in the ASC setting.
0137T	Prostate saturation biopsy	Prostate saturation biopsy is typically performed in an outpatient setting using intravenous sedation. This procedure involves taking a greater number of prostate biopsies than have traditionally been taken during one procedure. The patient is discharged on the same day. This procedure is clinically similar to CPTs 55700 and 55705 describing prostate biopsy, which are currently covered in the ASC setting.
0170T	Anal fistula repair with a biodegradable porcine small intestinal mucosal plug	This procedure is an outpatient surgical procedure that can be performed under general, spinal or local anesthesia. Following identification of the internal and external fistula tract openings, the plug is pulled into the tract using suture ligatures and subsequently sutured in place. Patients are discharged home on the day of the procedure. The procedure is clinically similar to CPT 46706, Repair of anal fistula with fibrin glue, which currently on the ASC list of covered procedures.
0184T	Transanal endoscopic resection of a rectal tumor	This Category III CPT code will be implemented on January 1, 2008. Transanal endoscopic microsurgery is a minimally invasive procedure for the excision of precancerous lesions or

CPT	DESCRIPTION	COMMENTS
		early cancers of the rectum. This procedure can be performed on an outpatient basis, with discharge on the same day. It is clinically similar to CPT 45170, Excision of rectal tumor, which is currently on the ASC list of covered procedures.
0186T	Suprachoroidal drug delivery	This Category III CPT code will be implemented on January 1, 2008. A microcannula is introduced into the suprachoroidal space and used as a means to deliver drugs to the macula, optic nerve and posterior pole. This in an outpatient procedure and patients are discharged on the same day. The procedure is clinically similar to CPTs 67027 and 67028 (describing intravitreal drug delivery), which are both included in Addendum AA for ASC coverage in CY 2008.

(70)

SCA

Surgical Care Affiliates

September 14, 2007

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-P - Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Dear Acting Administrator Weems:

On behalf of Surgical Care Affiliates, please accept the following comments regarding this rule, which proposes the covered services and payment rates for the ambulatory surgical center (ASC) payment system for Calendar Year 2008. 72 Fed. Reg. 148 (August 2, 2007). We appreciate the significant consideration and work that have gone into developing the policies governing the revised ASC payment system.

With interests in 139 ASCs in 34 states, Surgical Care Affiliates is one of the largest operators of ASCs in the United States. ASCs offer outpatient surgery in a convenient, safe environment characterized by superior patient care.

I. The Revised ASC Payment System

We support the comments which have been submitted under separate cover from the ASC Coalition, of which we are a member. Those comments provide detailed recommendations regarding the CY 2008 implementation of the revised ASC payment system. While we support many of the policies CMS has put in place, by failing to fully align the ASC and hospital outpatient department (HOPD) reimbursement systems and by setting the ASC conversion factor too low, CMS has missed an important opportunity to achieve additional permanent savings to both the Medicare program and to Medicare beneficiaries. In particular, we draw your attention to the following key points:

ASC conversion factor: We are pleased by CMS's decision to use its "alternative formula" for calculation of the ASC conversion factor, allowing consideration of the dynamic forces that will drive shifts of services between outpatient surgical settings. However, the estimated 15% migration of services from the physician office to the ASC is significantly overstated. Our facilities have little interest in using their specialized physical plant, personnel, and equipment to perform minor procedures on a routine basis for reimbursement that is below cost, and physicians have no reason to move cases from the office to the ASC setting unless it is medically necessary to do so. Moreover, we do not believe the net migration of currently eligible ASC procedures will be negligible. Many of the most commonly performed ASC procedures will see substantial payment reductions, significantly impacting the ability of ASCs to continue to deliver those services to Medicare beneficiaries. Using more reasonable migration assumptions would result in a more appropriate ASC conversion factor. We encourage CMS to revisit its migration assumptions and evaluate their accuracy once the revised ASC payment system has been implemented.

Impact on selected high volume ASC services: As noted above, the low ASC conversion factor will have a profound effect on selected procedures commonly performed in the ASC setting, particularly gastroenterology and pain management services. Contrary to CMS statements, it would be no small matter for single specialty ASCs to alter their case mix. These facilities represent an extension of physicians' practices into which substantial capital investments for equipment and an appropriate physical plant have been made. Additionally, many states with certificate of need requirements narrowly specify the use of the facility, not allowing for a change in case mix. The magnitude of the negative financial impact on such facilities may have undesired consequences on Medicare beneficiary access, particularly for the already underutilized screening colonoscopy benefit. To mitigate the potential effect on access to services or for reverse migration to the more costly HOPD setting, CMS should establish payments for colon cancer screening procedures at rates that will ensure utilization of the screening benefit is not undermined by insufficient reimbursement in the ASC setting.

ASC adjustment for inflation: ASC adjustments for inflation should be made using the hospital market basket rather than the CPI-U. The CPI-U is a measure of consumer inflation and its inputs do not reflect the items and services that ASCs must purchase in order to provide care for their patients. On the other hand, the hospital market basket is based on expense categories that are shared by both hospitals and ASCs. Given that CMS is not bound by statute to use the CPI-U to adjust ASC payments for inflation, the agency should adopt the hospital market basket for ASC updates, recognizing the similar resource requirements and inflationary pressures facing ASCs and HOPDs.

Reimbursement of implanted devices: We are pleased CMS acknowledged its proposed policy regarding the payment of implantable devices without pass-through status would have made device dependent procedures economically unfeasible in the ASC setting. However, the policy the agency has established for reimbursement of device-intensive procedures falls short by setting the threshold for full payment of devices too high. In order to allow access to these services in the ASC setting, CMS should consider policy options such as allowing full payment to ASCs for the device portion of any device dependent APC, regardless of the percentage the

device represents in relation to the total APC reimbursement, and/or an accelerated transition for these services. As stated previously, establishing policies that allow adequate reimbursement rates for ASCs ultimately results in savings both to the Medicare program and its beneficiaries as compared to the generally more costly HOPD setting.

Secondary rescaling of ASC payment weights: Applying a secondary recalibration to the ASC setting, without evidence that ASC services became relatively less expensive than the HOPD, will drive unjustified variation in the payment rates between the ASC and HOPD. Unlike the statute governing the HOPD payment system, the only provision relating to budget neutrality for ASC payments is the one that applies to the year of implementation. Use of this secondary rescaling will cause the two payment systems to diverge over time.

Coverage policies for ASCs: We are pleased by the expanded list of procedures eligible for ASC reimbursement and by the ability to offer Medicare beneficiaries integral ancillary services. However, we believe any decision to exclude a service from coverage should be accompanied by an explicit statement of the criterion or criteria that led to exclusion in order to allow evaluation of CMS decision-making. We are also very concerned by the definition of overnight stay CMS has adopted. From a clinical standpoint, it would be much more appropriate to define a length of stay. Further, the use of midnight as the equivalent of overnight is not only counter to previous CMS statements on this matter, which defined an overnight stay as a stay of less than 24 hours in duration, but also at odds with numerous state regulations.

II. Development of the ASC Quality Reporting System

We also wish to express our support for the comments that have been submitted under separate cover by the ASC Quality Collaboration, another organization of which we are a member. Although this notice of proposed rulemaking does not put forth CMS's specific proposals for a quality reporting system for ASCs, the ASC Quality Collaboration's remarks highlight important considerations for future rulemaking. Specifically, we wish to emphasize the following:

Quality measures for ASCs: We are pleased that ASCs will have the opportunity to report quality measures to CMS and the public in the near future. CMS should select quality measures with careful attention to whether the measure assesses processes or outcomes of care that are attributable to and reasonably the responsibility of the facility, as opposed to the physician. Given the broad range of surgical services offered in the ASC setting, we also encourage CMS to adopt measures that reflect processes or outcomes that are common to the various surgical and procedural subspecialties in order to allow broad facility participation regardless of case mix.

Quality reporting system for ASCs: CMS should implement a claims-based quality reporting system for ASCs, similar to the quality reporting system the agency has implemented for physicians. Such a system would allow patient-level data collection without undue financial and administrative burden.

Publication of quality measures for outpatient surgery settings, including ASCs: The manner in which quality data is shared with the public should be carefully considered. At a minimum, CMS should develop a method for sharing data that would allow interested parties to easily and directly compare the quality of outpatient surgical facility services across facility types.

***

Thank you for considering the comments submitted here and under the auspices of the ASC Coalition and the ASC Quality Collaboration. We appreciate the opportunity to share our views on these important aspects of the revised ASC payment system and the future ASC quality reporting system.

Sincerely,

Joe Clark
Executive Vice President and Chief Operating Officer
Surgical Care Affiliates
P.O. Box 382497
Birmingham, AL 35243

Foundation for
AMBULATORY
SURGERY in America
MEETING AMERICA'S SURGICAL NEEDS

1012 Cameron Street
Alexandria, VA 22314

703.836.8808
(fax) 703.549.0976

www.fasa.org
FASA@fasa.org

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September 14, 2007

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1392-P; Quality Data

Dear Acting Administrator Weems:

The Foundation for Ambulatory Surgery in America (Foundation) is pleased to submit these comments on CMS-1392-P, Section XVII Reporting Quality Data for Annual Payment Rate Updates. The Foundation is a national, nonprofit association that seeks to advance access to and the quality of ambulatory surgery services through education, research and information dissemination to ASC professionals, policy makers and the public.

At the outset, we want to thank the Centers for Medicare and Medicaid Services (CMS) for its ongoing communication with the Foundation and the ASC Quality Collaboration, which the Foundation is a member of, to obtain guidance from the ASC community on appropriate quality measures, data collection processes and data reporting mechanisms for outpatient surgical procedures. For many of the most common outpatient surgical services, Medicare beneficiaries have choices as to where to have that procedure. Access to national quality information will go a long way to assist beneficiaries when choosing in consultation with their physician their site of care.

In addition, we want to thank CMS for not implementing ASC reporting of quality measures prior to January 1, 2009. 2008 may prove to be a challenging year for many ASCs across the nation as they struggle to adjust to the largest payment reform since the Medicare benefit began in the early 1980s. The industry is facing a significant transition and we are thankful that additional requirements will not be introduced simultaneously. In addition, the Foundation through the ASC Quality Collaboration is working on the acceptance by the National Quality Forum (NQF) of certain ASC quality measures. We anticipate these quality measures will be endorsed by the NQF by the end of the year. By waiting until 2009 to implement, we believe that CMS will be able to utilize nationally endorsed measures when implementing quality reporting in 2009. This will be a benefit to patients and ASCs.

The specific recommendations that follow mirror the comments submitted by the ASC Quality Collaboration and others in the industry working together on this important task.

I. Quality Measures for Outpatient Surgery

After a detailed evaluation of existing nationally recognized quality measures to determine which could be directly applied to the outpatient surgery facility setting, the ASC Quality Collaboration developed a number of facility-level measures of ASC quality. These measures were based on those already commonly used by the ASC community for internal quality assessment and external benchmarking. To date, these measures have been reviewed by a technical advisory panel and a steering committee of the National Quality Forum (NQF). As a result of these evaluations, five measures have been recommended for endorsement and have recently been open to public and NQF member comment. Final action on these measures could be taken as early as November 2007.

We strongly recommend CMS consider these five facility-specific measures for ASC reporting if they are endorsed by the NQF Of the five measures, four are outcome measures that have applicability to all outpatient surgical facilities and thereby ensure broad facility participation regardless of case mix. These measures focus on 1) patient falls, 2) patient burns, 3) hospital transfer/admission and 4) wrong site/wrong side/wrong patient/wrong procedure/wrong implant. The fifth measure is a process measure which evaluates the timing of the administration of intravenous antibiotics for prophylaxis of surgical site infection. This prophylactic antibiotic timing measure has been specifically designed to harmonize with, and be complementary to, similar measures (PQRI #20 and PQRI #21) developed to evaluate physician performance in this area.

FASA, a national ASC membership association, has an ongoing association-wide outcomes monitoring project that has been in existent for more than a decade. Data collected from 500 ASCs as part of this project shows that for all of the above measures except timely prohphylactic IV antibiotic administration, at least 86% of ASCs are already collecting the data. This also suggests that these measures are appropriate ones to pursue for reporting. We urge CMS to select measures that should be applicable to all facilities offering ambulatory surgery, allowing comparison of quality across sites of service. The ASC measures identified above are appropriate for other outpatient surgical settings. It is also essential CMS select measures that reflect the facility's processes or outcomes of care that are attributable to and reasonably the responsibility of the facility itself - its staff, the equipment, the environment of care offered to its patients, and its roles in the delivery of patient care.

II. ASC Data Collection

When selecting data collection mechanisms, CMS must consider the administrative and financial burden of reporting the quality measures will have on ASCs. CMS has estimated that approximately 73 percent of ASCs would be considered small businesses according to the Small Business Administration (SBA) size standards (see 72 Fed. Reg. 42538 (August 2, 2007) and 72

Fed. Reg. 42812 (August 2, 2007)). In this respect, ASCs more closely resemble individual physician practices than hospitals.

To date, CMS has implemented a number of quality reporting systems that employ a variety of methods to collect patient-level quality data. Most of these systems require that data be submitted electronically to a repository. For example, as proposed in this rule, hospital outpatient departments, similar to the inpatient departments, would be required to abstract clinical data based on chart review, compile the data and submit it in specific XML format to an approved data submission vendor. In contrast, the Physician's Quality Reporting Initiative (PQRI) requires physicians to report patient-level quality data using administrative claims, which requires less administrative burden. FASA's 2007 ASC Salary & Benefits Survey shows that the majority (61.2%) of ASCs have 20 or fewer total full-time equivalents, including both clinical and non-clinical staff. We urge CMS to take into consideration the administrative burden on the small staff of the ASC when evaluating data collection mechanisms.

III. Publication of Quality Data Collected

The Foundation is fully supportive of providing transparency oriented efforts. However, consumers must have access to meaningful information presented in a manner which supports transparency across settings. The method CMS selects for sharing data should allow Medicare beneficiaries and others to compare quality across settings when a service or procedure can be delivered in multiple ambulatory settings. Consumers must be able to access quality information in a manner that allows for easy comparisons, while also protecting the rights of providers to assure the information is correct, up-to-date and clearly presented. We request more detailed consideration and expanded description on the publication of quality data from CMS in future rulemaking.

Thank you for considering our comments. We look forward to working with you to implement a quality reporting system that will assist the public in evaluating the excellent quality of care provided in ASCs across the nation.

Sincerely,

Kathy Bryant

Kathy J. Bryant
President