

August 29, 2008

Kerry Weems
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1404-P
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1404-P – Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates

Dear Administrator Weems:

The Ambulatory Surgery Center Association (the ASC Association) is pleased to submit these comments on the proposed rule updating the Medicare payment system for ambulatory surgical center (ASC) services for 2009. The ASC Association, formed through the recent merger of FASA and the American Association of Ambulatory Surgery Centers (AAASC), is the nation's leading ASC organization and represents more than 2,600 ASCs and the professionals who provide and the patients who receive high quality and cost-effective ASC services.

As an initial matter, the ASC Association is pleased that CMS has committed itself to an annual review and update of the new ASC payment system as part of the hospital outpatient prospective payment system (OPPS) rulemaking cycle. In years past, the lack of regular, predictable and timely updates to the Medicare ASC list resulted in a payment system that was almost perpetually out-of-date and that hindered Medicare beneficiary access to ASC services. We strongly believe that regular annual updates to the ASC payment system will help promote more timely access to advances in ambulatory surgical care for beneficiaries, as well as significant cost savings for the Medicare program. As a competitive alternative to hospital-based surgery, ASCs offer a number of important benefits, including lower costs, improved technology, a non-institutional, friendly environment and, in many cases, more convenient locations and scheduling than hospital outpatient departments (HOPDs).

That said, we also continue to believe the new Medicare ASC payment system falls short of promoting the kind of access and transparency that is needed to achieve the full competitive benefits of ASCs. In particular, to better promote full transparency across sites of service, we believe it would be preferable to base payments to ASCs on a flat percentage of the payment rates for the same services established under the OPPS. Moreover, we are extremely concerned about a rapidly widening gap between ASC and OPPS payment rates that bears no relationship to actual cost differences between the two care settings. By our calculation, the proposed rule would result in ASC payment rates for 2009 at 59 percent of OPPS rates for the same services,

down from 63 percent this year. As recently as 2003, however, ASC payments were at 86.5 percent of HOPD payments under OPPS.¹ In addition, a recent Government Accountability Office (GAO) study – which was ordered by Congress in connection with implementation of the revised ASC payment system – found that the median costs for procedures performed in ASCs was 84 percent of the median ambulatory payment classification (APC) costs for the same procedures under the OPPS (when weighted by Medicare volume).² If the ASC-OPPS payment gap continues to grow, we are concerned that certain procedures or classes of surgical services will not be viable in the ASC setting.

While the changes in reimbursement affect all ASCs, the degree of impact varies by procedure and among specialties. Under the 2009 proposed rule, we estimate that ASC reimbursement in gastroenterology and pain management will be cut by six percent each this year, the largest reductions of any specialties. This is on top of a five percent cut for gastroenterology in 2008. We further note that these two specialties accounted for approximately 52 percent of Medicare ASC volume in 2006. We believe such substantial payment reductions will lead to large numbers of procedures in these specialties being shifted to higher cost hospital settings, thus increasing expenditures both for the Medicare program and for beneficiaries.

In assessing the ability of ASCs to absorb the kinds of payment cuts contained in the proposed rule, two factors warrant particular consideration:

- *First, most ASCs are small businesses.* According to the ASC Association's 2008 ASC Employee Salary & Benefits Survey, 61 percent have 20 or fewer employees and according to CMS, approximately 73 percent of ASCs would be classified as small businesses under the standards of the Small Business Administration. Small businesses generally have less capability to absorb sudden payment decreases of the sort contemplated in the proposed rule.
- *Second, a significant percentage of ASCs are single-specialty* (43 percent according to the ASC Association's 2008 ASC Employee Salary & Benefits Survey). Increases in payment rates on certain procedures may allow some ASCs to make up for losses on other procedures. However, single-specialty ASCs – especially gastroenterology facilities, which comprise approximately 25 percent of all Medicare-certified ASCs – will have a limited ability to do so. Thus, we are convinced that many ASCs will be unable to continue absorbing these cuts and will discontinue providing services to Medicare beneficiaries. The impact on Medicare beneficiary access to gastroenterology procedures now commonly performed in ASCs may be particularly profound. CMS has suggested that single specialty ASCs negatively impacted by the new payment system should seek to diversify their mix of procedures, but that is far easier said than done and is neither an easy nor short-term solution. Indeed, diversification may be impossible to achieve because of simple physical space limitations, or in states with certificate of need

¹ This 86.5 percent figure is based on an analysis performed by CMS and provided to FASA in August 2003. The CMS analysis used a strict interpretation of budget neutrality and applied 2002 ASC volume data and 2003 ASC and HOPD payment rates to the then-current list of ASC covered procedures.

² *Medicare Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient Payment System*, GAO-07-86 (Nov. 30, 2006).

restrictions or in health professional shortage areas (HPSAs) lacking any physicians, let alone a diverse mix of surgeons and other specialists that ASCs can draw on to offset losses from the new Medicare payment system. Further, the large number of specialty gastroenterology ASCs suggests that this is an effective patient care model. Payment policy should not eliminate delivery models that work.

We also understood that one of the primary goals for the new ASC payment system was supposed to be eliminating artificial incentives in the prior payment system that were driving site-of-service selection and the establishment of surgical specialty hospitals.³ Yet, a more than 40 percent differential in ASC and hospital payment rates would seem to perpetuate, rather than diminish, the incentives for the use and development of higher cost hospital surgical settings. Indeed, as long as these kinds of payment disparities persist, market pressures will tend to favor the growth of hospitals and impair the ability of ASCs to serve as a fully-effective competitive counterbalance to more costly hospital-based surgery.

In short, setting ASC payment rates too low has the potential to deny Medicare beneficiaries choices and increase their out-of-pocket costs, as well as increase overall expenditures for the Medicare program as procedures are shifted to more costly hospital settings. Thus, CMS should seek to set ASC payment rates at a reasonable and fair level to promote optimum access to ASCs. Simply put, we do not believe that 59 percent of HOPD rates is either reasonable or fair to ASCs. Given that ASCs and HOPDs perform similar services and have many comparable costs, the significantly lower payment rates provided to ASCs are inadequate to ensure continued provision of high quality care to Medicare beneficiaries and to prevent services from shifting to hospitals and reduced access to ASCs for certain services.

We note that Congress has recognized the growing disparity between ASC and HOPD payment rates. To address the issue, two bills (H.R. 1823 and S. 2250) have been introduced in the current Congress that propose to set and keep ASC payment rates at 75 percent of HOPD payments. The ASC Association strongly supports this legislation, which would save Medicare at least 25 cents on every dollar spent relative to HOPD rates. Even this rate would result in payments to ASCs significantly lower than what they received relative to HOPDs just a few years ago. However, we believe 75 percent balances Medicare's need for savings and a payment rate that could promote growth and development of ASCs and ultimately lead to greater long-term savings as an increased number of procedures were shifted out of more costly HOPDs.

In the meantime, we believe there a number of ways that CMS could more closely align payments between the two payment systems and otherwise improve the current ASC payment system. ***Perhaps the most important of these changes is eliminating the secondary rescaling of ASC relative weights, which inappropriately reduces payments to ASCs and further exacerbates the growing gap between ASC and HOPD payments.*** As a result, we believe this

³ Former CMS Administrator Mark McClellan discussed the elimination of these kinds of incentives in testimony before the Health Subcommittee of the House Energy and Commerce Committee in May 2005. Specifically, in his discussion of the disparity of payment systems for ASCs and hospital outpatient departments, Dr. McClellan indicated that "CMS is currently planning to reform the ASC fee schedule to diminish the divergence in payment levels that create artificial incentives for the creation of small orthopedic or surgical hospitals." *Hearings on Specialty Hospitals Before the Health Subcommittee of the House Energy and Commerce Committee* (May 12, 2005).

secondary rescaling threatens to undermine the entire ASC payment system if not corrected as suggested below. The other recommendations for improving the ASC payment system discussed in these comments include the following:

- ***CMS should adopt the hospital market basket as the measure of ASC cost increases, rather than using the CPI-U.*** The use of the CPI-U (the consumer price index for urban consumers) is a relic from the time of the initial implementation of the ASC benefit, since which time the agency has developed the hospital market basket, a more appropriate proxy for the inflationary pressure on health care facility costs.
- ***CMS should use the same wage indices for ASC and HOPD payments to improve consistency between the payment systems.*** The pre-floor, pre-reclassified wage index used to adjust ASC payments results in inappropriate differences in the rates for hospital outpatient and ASC services at the local level.
- ***CMS should link ASC and HOPD payment rates for implanted devices.*** The performance in ASCs of procedures involving implanted devices is being hindered by inadequate reimbursement.
- ***CMS should consider raising the threshold for designating procedures as office-based and using multiple years of data to determine whether a procedure meets the threshold.*** These measures would take data volatility into account and help CMS make more accurate determinations of when payment should be capped for procedures commonly performed in physician offices.
- ***The ASC procedure list should more closely mirror the HOPD procedure list.*** And in those instances where CMS excludes a procedure from the ASC list, it should disclose the reasoning behind such exclusion.
- ***CMS should continue to work with the ASC industry to design and implement a quality reporting system for ASCs.*** Quality is a hallmark of ASCs and the ASC Association supports CMS's ongoing quality initiatives. We encourage CMS to move as swiftly as possible towards implementation of quality reporting for ASCs and HOPDs in order to allow patients to compare the quality of care provided in different settings.

In adopting the final ASC payment system rule for 2009, we urge CMS to reconsider its approach on these issues to ensure that Medicare (1) covers the full scope of services that ASCs are capable of performing safely and efficiently, and (2) pays reasonable and adequate rates, so that ASCs actually are encouraged and able to expand their provision of services to Medicare beneficiaries, thereby lowering costs for the program and for beneficiaries and enhancing the Medicare benefit by improving access to a treatment setting preferred by an ever-growing number of patients.

In finalizing this rule, we also ask that CMS provide a listing of the fully implemented payment rates, as it has in the past. In the proposed and final rules published in 2007, CMS not only provided the 2008 rates that actually would be paid, but also provided the fully implemented rates. These rates are extremely helpful to ASCs and others basing payment on the Medicare

rates. For example, Texas workers' compensation rates will be based upon the fully implemented Medicare rates. Thus, we encourage CMS to publish fully implemented rates, along with the actual rates, in all of the proposed and final rules during the remainder of the transition period.

We also understand that CMS is considering finalizing CMS-3887-P, the proposed revisions to the ASC conditions for coverage, as part of the ASC/OPPS final rule. Among other comments we have provided on the conditions for coverage proposed rule, we urge the agency in the strongest possible terms not to finalize the proposed definition of an ASC as an entity that operates exclusively for the purpose of providing surgical services not requiring an "overnight stay." In our prior comments on this subject, we objected to the proposed definition of ASC and urged CMS not to override existing state laws in at least 14 states that allow ASCs to provide extended recovery stays in an ASC or in separately licensed or certified recovery care units.⁴ The current definition of an ASC as an entity that operates for the purpose of providing surgical services to patients not requiring "hospitalization" continues to be appropriate for distinguishing ASCs from other provider types – namely, hospitals and physician offices – and is consistent with the underlying statute.⁵

Our comments on specific aspects of the 2009 ASC payment system proposed rule follow.

1. Secondary Rescaling of the APC Relative Weights for ASCs

For 2009, CMS proposes to create relative weights for use in setting ASC payments through a secondary rescaling of the OPSS relative weights. CMS explains that rather than using the OPSS relative weights in the ASC system, it is using a secondary rescaling to achieve year-to-year budget neutrality in the ASC payment system. Because the relative weights for surgical services are increasing – meaning the overall cost of performing those services is going up in both ASCs and HOPDs relative to other HOPD costs – this proposed secondary rescaling would, by itself, produce a 2.47 percent cut in ASC reimbursement for 2009. In the interest of avoiding additional and unnecessary rate cuts that could harm the quality of care furnished in ASCs and impede beneficiary access, we strongly urge CMS to abandon this secondary rescaling process for ASCs.

Indeed, it is important to emphasize that the APC relative weights already are rescaled once for budget neutrality under the OPSS rules. Since ASC rates in 2009 will be close to 60 percent of HOPD rates *even without the proposed secondary rescaling*, there does not appear to be any serious budget neutrality concerns with a differential in ASC relative weights relative to HOPDs. In fact, this is to be expected, given that ASCs are limited by the Medicare payment system and

⁴ Those states include Alabama, Arizona, Arkansas, Colorado, Georgia, Illinois, Kansas, Nevada, New York, North Carolina, Ohio, Oklahoma, Tennessee and Utah.

⁵ See 42 C.F.R. § 416.2. The origins of this regulatory definition can be found in Section 1833(i)(1)(A) of the Social Security Act, which establishes the ASC benefit and provides Medicare coverage for "those surgical procedures...performed on an inpatient basis *in a hospital* but which also can be performed safely on an ambulatory basis in an ambulatory surgical center" (emphasis supplied). In other words, the Medicare statute envisions ASCs as a surgical alternative for patients *not requiring hospitalization*, which is how ASCs have been defined since Medicare coverage was first established for ASC services in 1982.

the conditions for coverage to providing surgical services exclusively, while HOPDs perform a broader mix of services that include lower cost primary care and diagnostic services. Thus, because ASC payments are linked to OPPIs, a secondary rescaling process for ASCs does not so much achieve budget neutrality as it effectively penalizes ASCs for performing only surgical services, which is required by the Medicare program.

However, the performance of more costly procedures in ASCs should be encouraged by CMS because it has the potential to produce substantial overall cost savings for the Medicare program, which is the best means of ensuring true budget neutrality. In other words, to the extent that procedures which are increasing in cost are being performed in ASCs, rather than in hospitals, that is good for the Medicare program and should not be discouraged by a secondary rescaling process that will further reduce ASC reimbursement in a way that seriously threatens the ability of ASCs to continue providing high quality services to Medicare beneficiaries.

In practical terms, year-to-year increases in ASC relative weights reflect real changes in the costs of providing surgical services to Medicare beneficiaries. Yet, the secondary rescaling process for ASCs works to reduce Medicare payment for these very same costs. For example, Table 1 below reveals substantial cost increases for nine of the ten highest volume ASC procedures. Without secondary rescaling, Medicare payment for all but one of these procedures nevertheless would be reduced in 2009. With secondary rescaling, however, all of the rates are cut and the decreases are made significantly greater.

Table 1. Changes in the Cost Bases and Payment Rates for High Volume ASC Procedures from CY 2008 to CY 2009

HCPCS and Specialty	Change in HOPD Median Cost	Change in ASC Payment, Without Secondary Rescaling	Change in ASC Payment, With Secondary Rescaling
66984 Ophthalmology	+3.81%	+1.18%	-1.52%
43239 Gastroenterology	+3.74%	-4.37%	-6.91%
45378 Gastroenterology	+3.71%	-3.55%	-6.12%
66821 Ophthalmology	+6.12%	-7.31%	-9.78%
45385 Gastroenterology	+3.83%	-3.55%	-6.12%
62311 Pain Management	+9.60%	-1.09%	-3.73%
45380 Gastroenterology	+3.76%	-3.55%	-6.12%
64476 Pain Management	-57.67%	-20.09%	-22.22%
64483 Pain Management	+4.30%	-1.09%	-3.73%
45384 Gastroenterology	+3.68%	-3.55%	-6.12%

Source: CMS-1392-FC and CMS 1404-P

Over time, the cumulative effect of these annual adjustments will substantially increase the already huge and growing gap between ASC and HOPD reimbursement in a way that threatens to undermine the very viability of the ASC payment system.⁶

In particular, the rate cuts that would result from the secondary rescaling process have a disproportionate impact on high volume ASC specialties, most notably gastroenterology, and thus threaten to exacerbate the already substantial rate cuts being experienced by those specialties in the transition to the new ASC payment system.⁷ As we noted above, it is almost impossible for gastroenterology specialty ASCs to deal with the substantial rate cuts they are experiencing under the revised ASC payment system other than by changing their payer mix and accepting fewer Medicare patients. This means reduced access for beneficiaries, as well as increased costs for the Medicare program as cases are shifted to more costly HOPDs. We are absolutely convinced that these results will follow if ASC payments continue on their current trend. Abandoning secondary rescaling is one step CMS can take to reverse this trend before significant harm is done to the ability of ASCs to serve Medicare beneficiaries.

There also are a number of fundamental conceptual flaws in CMS's application of a secondary rescaling process for ASCs:

- First, CMS lacks substantial data needed for a valid secondary rescaling calculation because it proposes to use the volume of procedures provided in 2007 as the basis for the rescaling calculation, even though 40 percent of the procedures now covered in ASCs were not added to the ASC list until 2008. Moreover, any shifts in site-of-service from the vast changes in payment occurring in 2008 are not reflected in this calculation.
- Second, the revised ASC payment system is subject to a number of payment adjustments that artificially distort the proposed secondary rescaling process, including a cap on reimbursement for office-based procedures and a transitional adjustment that will base 50 percent of ASC payment rates for 2009 on the 2007 ASC payment rates.
- Third, ASC rates will not be updated for inflation in 2009, which normally would offset the relative weight adjustment to at least some extent.

Notably, Congress did not impose any budget neutrality requirements on the revised ASC system beyond the initial implementation year. In addition, the ASC payment system rules provide that a secondary rescaling of the relative weights for ASCs will be performed only "as needed." In our view, secondary rescaling not only is not needed, but threatens to undermine the ASC payment system in a way that will inevitably increase overall costs for the Medicare program and impede beneficiary access to ASCs. Thus, we urge CMS in the strongest possible terms to abandon the proposed secondary rescaling of relative weights for ASCs.

⁶ A model of the potential impact of secondary rescaling on ASC reimbursement over the next several years is provided in separate comments on the proposed rule submitted by the ASC Coalition, a diverse group of ASC stakeholders of which the ASC Association is a member.

⁷ Models of the potential impact of secondary rescaling on gastroenterology specialty facilities and other high volume ASC services are provided in the ASC Coalition comments.

2. Inflation Update

Beginning in 2010, CMS will use the consumer price index for all urban consumers (CPI-U) to update ASC payments annually. As we have stressed in past comments, inflationary pressures on health care providers differ from those on general consumers, making the CPI-U an inappropriate inflation index for the ASC payment system. Instead of using the CPI-U, the ASC Association again urges CMS to use the hospital market basket to adjust ASC payments for inflation.

ASCs face the same inflationary pressures confronted by hospitals. Intense competition for nurses, rapidly rising medical device costs and a growing need to adopt new health information technology contribute to inflation across a variety of health care settings. CMS uses the hospital market basket, which takes these costs into account, as the inflation update for the OPPS system. Accordingly, we believe the hospital market basket unquestionably is a more appropriate basis for annual ASC updates than the CPI-U, a measure that is not used to update any other Medicare payment system. Rather, Medicare ties payments in other major payment systems, such as skilled nursing facility and home health services, to market baskets constructed to reflect the change in prices for the items used in each setting.

Use of the hospital market basket for ASCs would better reflect the higher rate of health care inflation, which regularly outstrips inflation in the general economy. Between 2002 and 2007, the average annual difference between the hospital market basket and the CPI-U was 0.6 percent. Although the annual differences may seem small, the cumulative effect of using different inflation update factors for HOPDs and ASCs would be a further widening of the gap in payment rates unrelated to differing costs. Both the Congressional Budget Office and the Office of Management and Budget project that the differential between CPI-U and the hospital market basket will persist for the foreseeable future, meaning that the difference in payment rates between HOPDs and ASCs will continue to grow.

Yet, it is the fact that ASCs have the same kinds of cost considerations as HOPDs that justifies linking the new ASC payment system to the OPPS relative payment weights and APC groups in the first place. Once that link is established, we see no sound policy basis for providing different inflation updates to ASCs and HOPDs. Indeed, we are concerned that over time, the cumulative effect of applying differing annual updates to ASCs and HOPDs will further exacerbate the already substantial disparity in payment rates between the two sites of service and create additional incentives for the creation and expansion of hospitals, rather than more cost-effective ASCs.

Therefore, since CMS acknowledges that it has "flexibility under the statute to employ a different update mechanism,"⁸ we urge CMS to update ASC payments using the hospital market basket.

⁸ 72 Fed. Reg. 42627, 42778 (Aug. 2, 2007).

3. Wage Index

The ASC Association also encourages CMS to use the same wage indices for both ASCs and HOPDs. Again, the two providers furnish the same type of services and directly compete for the same employees, especially nurses. Thus, the ASC Association believes that use of the same wage indices for ASCs and HOPDs would help further ensure that any payment differences between the two settings are attributable to actual differences in cost. With the same wage indices in place, only the conversion factor would drive any variation between ASC and hospital payments.

CMS noted in the August 23, 2006 ASC-OPPS proposed rule that there is a "significant overlap between surgical procedures furnished in hospital outpatient settings and those performed in ASCs. Currently, of the 150 highest volume surgical procedures furnished in hospital outpatient departments, more than half (80) are also among the highest volume procedures performed in ASCs." In order to provide a similar mix of services, ASCs and HOPDs must employ the same types of employees. In any geographic labor market, ASCs directly compete with hospitals for nurses and other professionals. Accordingly, they should be paid using the same adjustment for geographic differences in costs.

CMS currently sets the ASC wage index to the "pre-floor, pre-reclassified hospital wage index" using hospital cost report data from 2005, the most recent complete year of data available. For the inpatient and outpatient hospital payment systems, however, CMS applies several adjustments to the wage index to address market-specific or provider-specific competition for labor. These adjustments include:

- imputing a statewide rural area wage index for states with no counties outside of an urban area;
- preventing the wage index of any urban area from falling below the statewide rural area wage index (including the imputed floor);
- preventing the wage index of an urban area crossing state lines from falling below the state-specific rural floor;
- applying an adjustment to the wage index for certain counties where a significant proportion of residents commute to other high wage index counties for work; and
- calculating a reclassified hospital wage index value for hospitals that are paid using the wage index of a medical service area in which they are not physically located.

In recognition of the comparable employee base of HOPDs and ASCs, CMS should apply these same adjustments to ASCs. Otherwise, use of these adjustments only for HOPDs generally results in a higher wage index for HOPDs as compared to ASCs in most geographic areas, thus further contributing to the growing payment differential between the two settings.

4. Payment for Procedures With Fixed Device Costs

We are concerned that the current payment methodologies for ASC procedures with high, fixed device costs are insufficient to encourage ASCs to provide device-related services, thus mitigating the cost-savings potential of ASCs. Therefore, CMS should link OPPS and ASC payment rates for devices by treating device-dependent APCs as device-intensive in the ASC payment system.

More specifically, in the OPPS, CMS has established a category of services called device-dependent APCs. These APCs are populated by HCPCS codes that usually require a device be implanted or used to perform the procedure. CMS uses hospital claims data to calculate median costs, and then groups services into the device-dependent APCs. The resulting APC weights, when multiplied by the OPPS conversion factor, represent the best proxy for the cost of the device and procedure when performed in HOPDs. Unfortunately, many of the procedures that CMS identifies as device-dependent in the OPPS are not likewise treated as device-intensive for ASCs. As a result, the application of the ASC conversion factor to the full relative weight for these procedures results in payment rates that are too low for these services. If an ASC-approved procedure appears on the device-dependent list under the OPPS, it should likewise be protected from full application of the ASC conversion factor to account for the fixed cost of the device.

CMS also should not adjust the device portion of the payment by the wage index. Given that the acquisition of devices occurs on a national market, ASCs in rural parts of the country are paying roughly the same for medical devices and equipment as are facilities in the nation's most expensive labor markets. The rationale for this policy is analogous to the agency's decision not to apply the wage index adjustment to payments for items like drugs and biologics.

We further appreciate that the transitional policies implemented by CMS are mitigating payment reductions for certain procedures with historical rates higher than the fully-implemented ASC payment rates. For services with significant device costs, however, ASCs simply cannot afford to perform the procedures during a transition period in which no compensation for the device cost is factored into a substantial portion of the ASC payment (50 percent for 2009). Therefore, we also recommend that CMS pay for services designated as device-intensive at the fully-implemented payment rates beginning in 2009.

5. Payment for Office-Based Procedures

Although the ASC Association is pleased that the revised ASC payment system covers procedures that are commonly performed in physician offices, we stress the need for adequate payment for such procedures. For certain designated office-based services, CMS limits payment to the non-facility practice expense payment available to physicians. CMS has argued in the past that this policy may help prevent migration of some services from physician offices into ASCs. However, we believe it also may inappropriately force some services to remain in higher-priced HOPDs in cases where a facility setting is needed to achieve an optimal clinical outcome. In the first eight months of experience under the revised payment system, evidence from a number of our members seems to indicate that these low-complexity services are not migrating to ASCs. Thus, we believe CMS should consider raising the threshold for designating services as office-based and using multiple years of data to determine whether a procedure meets the threshold.

Separate comments on the proposed rule submitted by the ASC Coalition present data showing significant volatility in site-of-service selection from state-to-state and year-to-year. If the goal of capping ASC payment rates at the physician fee schedule amount is to pay for services in the most clinically appropriate setting, CMS should be more flexible in determining which procedures should be designated as "office-based." State-level variation suggests that national volume data fails to represent many local practice patterns. By raising the threshold for deeming services office-based, CMS could better account for these regional variations. In addition, CMS should not designate a procedure as office-based until it has met the threshold level for multiple years. Both of these measures would help CMS take data volatility into account and result in a more accurate determination of procedures that are commonly performed in physician offices across the country.

6. ASC Covered Procedures

We support the agency's addition of nine procedures to the ASC list for CY 2009 and concur with the assessment that these procedures can be safely performed in ASCs without the need for an overnight stay. Several of our members are already performing these procedures on their non-Medicare patients and look forward to making the ASC a viable option for Medicare beneficiaries to receive such services as well. We believe CMS also should add a number of additional procedures to the ASC list, including procedures specifically suggested in separate comments from the ASC Coalition.

Although CMS has significantly expanded the list of covered procedures through implementation of the revised ASC payment system, we encourage the agency to continually re-evaluate its coverage decisions in order to ensure that as many procedures as is clinically appropriate are performed in ASCs, rather than in the more costly HOPD setting. Towards that end, we suggest that CMS:

- provide more thorough explanations of its coverage decisions to permit more meaningful comment by the industry and other interested parties;
- ensure parallel coverage in ASC and HOPD settings by paying for the same procedures in both whenever clinically appropriate;
- establish ASC industry representation on the APC Panel;
- cover unlisted procedures performed in ASCs, as the agency does unlisted procedures performed in HOPDs; and
- devise a way to pay for surgical procedures that are bundled into radiology or other non-surgical services currently excluded from ASC payment .

A. Increased Transparency in Coverage Decisions

The ASC Association urges CMS to develop a more transparent process for identifying and reporting changes to the list of ASC covered procedures. The process should include evaluation of all procedures that are removed from the inpatient-only list to determine whether the procedures can be safely performed in ASCs. In instances where CMS excludes a procedure

(other than one on the inpatient-only list) from the ASC list, the agency should specify the clinical basis for the 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.

We are concerned that CMS's approval process for ASC services continues to result in exclusion of procedures that can be safely performed in ASCs. Of the procedures eligible for HOPD payment, CMS declined to add to the ASC list: (1) ten items proposed for removal from the inpatient only list; (2) 213 HCPCS codes about which the agency reported no specific safety concerns; and (3) an additional 78 HCPCS codes representing unlisted procedures. Many of these exclusions unnecessarily restrict Medicare beneficiaries' choice to hospitals, and we urge CMS to share its reasoning for exclusion so that we can provide informed comments addressing specific concerns. Such increased communication would result in CMS receiving better data from industry experts on which it can base its coverage decisions.

B. More Consistent Coverage of HOPD-Payable Procedures

In addition to improving the transparency of the ASC list, CMS also should ensure the ASC list is more closely correlated to the OPPS list of covered procedures. CMS applies three criteria to determine which procedures to exclude from payment under OPPS as inpatient procedures: (1) the nature of the procedure; (2) the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged; and (3) the underlying physical condition of the patient. While these are generally similar to the safety criteria that CMS uses for ASCs (i.e., extensive blood loss, major or prolonged invasion of body cavities, etc.), we see no inherent safety differences between ASCs and HOPDs to justify the use of different safety criteria. 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 also note that many procedures excluded from ASC coverage have been identified through the APC classification system as clinically similar to other services already on the ASC list. In many APCs, all but one or two of the HCPCS codes paid under that APC are eligible for ASC payment. For example, the table below shows all the HCPCS codes that comprise APC 0075, Level V Endoscopy Upper Airway.

Table 2. HCPCS Codes Paid Under APC 0075, Level V Endoscopy Upper Airway

HCPCS Code	Short Descriptor	Proposed CY 2009 ASC Payment Indicator	CY 2008 Exclusion Code (CMS-1392-FC)
31239	Nasal/sinus endoscopy, surg	A2	
31254	Revision of ethmoid sinus	A2	
31255	Removal of ethmoid sinus	A2	
31256	Exploration maxillary sinus	A2	

31267	Endoscopy, maxillary sinus	A2	
31276	Sinus endoscopy, surgical	A2	
31287	Nasal/sinus endoscopy, surg	A2	
31288	Nasal/sinus endoscopy, surg	A2	
31292	Nasal/sinus endoscopy, surg		X5
31293	Nasal/sinus endoscopy, surg	G2	X5
31294	Nasal/sinus endoscopy, surg		X5
31526	Dx laryngoscopy w/oper scope	A2	
31527	Laryngoscopy for treatment	A2	
31530	Laryngoscopy w/fb removal	A2	
31531	Laryngoscopy w/fb & op scope	A2	
31535	Laryngoscopy w/biopsy	A2	
31536	Laryngoscopy w/bx & op scope	A2	
31540	Laryngoscopy w/exc of tumor	A2	
31541	Laryngosc w/tumr exc + scope	A2	
31545	Remove vc lesion w/scope	A2	
31546	Remove vc lesion scope/graft	A2	
31560	Laryngosc w/arytenoidectom	A2	
31561	Laryngosc, remve cart + scop	A2	
31571	Laryngosc w/vc inj + scope	A2	
31576	Laryngoscopy with biopsy	A2	
31578	Removal of larynx lesion	A2	

All of the services in this APC were on the ASC list in 2007; however, CMS continued to exclude three procedures in 2008, citing safety concerns. We were pleased to see that the agency was convinced of the safety of HCPCS 31293 and has proposed its addition in 2009, but believe the agency also should add the two closely related procedures in cost and clinical characteristics, HCPCS 31292 and 31294. In fact, CPT code 31292 describes a less extensive service than 31293; the former includes decompression of *both* the medial and inferior orbital walls, while the latter describes decompression of *either* the medial or inferior orbital wall.

Since the APCs are intended to reflect a clinically similar grouping of procedures, we recommend that CMS review other APCs where a substantial majority of the included procedures are covered in ASCs to determine whether there may be additional procedures in those APCs that are appropriate for ASC coverage.

We also request that CMS reexamine the procedures being removed from the inpatient list and consider them for addition to the ASC list. In CY 2009, CMS proposes to allow HOPDs to perform ten procedures that previously had been restricted to hospital inpatient care. We believe several of these procedures could be safely performed in ASCs. In particular, CPT codes 21386 and 21387 describe open treatment approaches for orbital floor blowout fractures. While the majority of these cases result from blunt force trauma and, therefore, present to the emergency room of a hospital, delayed presentation occasionally occurs. When that is the case, we believe the ASC setting is an appropriate site-of-service option. These procedures are performed under general anesthesia. The orbital floor is exposed through a periorbital or combined approach, fracture fragments are elevated and any herniated contents are repositioned in their normal anatomic location. Blood loss is minimal and recovery does not require an overnight stay.

In cases where CMS permits a previously inpatient-only procedure to be performed in the HOPD, but does not add the procedure to the ASC list, we request that CMS provide a reason for its decision in the final rule.

C. APC Panel Representation

The ASC Association urges CMS to seek formal ASC industry input on APC groups and payment weights. For the OPPS system, CMS consults an outside panel of experts, the Advisory Panel on Ambulatory Payment Classification Groups (the APC Panel) on the clinical integrity of the payment groups and their weights. Given that the ASC payment system uses the same APC assignments as the OPPS, the ASC industry should join hospitals in having an active role in shaping the payment groups by having a designated representative on the APC Panel. Further, as recommended earlier in our comments, we believe CMS should concurrently review procedures proposed for removal from the OPPS inpatient-only list for addition to the ASC list. As the APC panel is the advisory body responsible for recommending services for removal from the inpatient only list, we believe it is appropriate to have ASC representation on this body to ensure full representation of the settings that will be responsible for providing these services.

D. Unlisted Procedures

The ASC Association objects to CMS's continued refusal to pay ASCs for unlisted CPT codes. By paying for unlisted codes under certain circumstances, CMS can encourage physicians to pioneer new, more efficient and effective approaches to surgical procedures. Citing concerns about the potential for safety risks, however, CMS prohibits ASC payment for *any* procedures that are reported with unlisted procedure codes. In contrast, the agency leaves payment for unlisted codes in OPPS to the discretion of the Medicare carriers. Given the similarities between ASC and HOPD facilities, we see no rational basis for assuming that the safety risks associated with the performance of unlisted procedures in ASCs is greater than the risk in HOPDs.

Even if an ASC conceivably could use an unlisted code to report a procedure that is inappropriate for the ASC setting, it seems unnecessary to eliminate the entire unlisted procedure code payment mechanism on that basis. Certainly, there are other, more effective safeguards against the performance of unsafe procedures, including licensure, certification, tort liability and the Medicare Quality Improvement Organization (QIO) Program.

Particularly where all codes in a section of CPT are covered except for the unlisted code, there should not be additional safety concerns and innovation should be encouraged. Therefore, at a minimum, when all the specific codes in a given section of CPT are eligible for payment under the revised ASC payment system, the associated unlisted code should be eligible for payment as well. For example, all the specific codes in the hysteroscopy subsection in CPT are currently on the ASC list. Given that CMS has concluded that all these procedures meet current safety criteria for the ASC setting, we believe that any unlisted hysteroscopy procedure performed in an ASC would not pose a safety risk. Similarly, all the specific codes in the posterior segment subsection of CPT are currently classified as ASC list procedures or physician office procedures. As with the hysteroscopy subsection, unlisted procedures on the posterior segment of the eye would not pose additional safety risks beyond the covered posterior segment procedures.

E. Packaged Surgical Procedures and Payment Bundling

We remain concerned about the exclusion from ASC coverage of certain surgical services that under OPPS are packaged into radiology or other non-surgical services. The application of the OPPS packaging policies should not have the inappropriate affect of excluding services from ASC payment that otherwise meets CMS's coverage criteria.

For example, services such as discography 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, however, 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 under OPPS, but these are not covered services for ASCs.

CMS's packaging of ASC-payable procedures into non-covered codes means that these procedures likely will remain in HOPDs, rather than migrate to less costly ASCs.

7. Quality Reporting

The ASC Association strongly supports use of quality reporting across all health care settings to promote high quality care. CMS has the statutory authority to implement a quality reporting system for ASCs and reduce the annual payment update by two percentage points for ASCs that fail to submit required data. In this proposed rule, however, CMS indicates that it intends to wait until a future rulemaking to propose quality reporting for ASCs. We look forward to working with CMS to implement quality reporting for ASCs in order to facilitate patient selection of the highest quality providers.

Using quality data to improve outcomes is a hallmark of the ASC industry. Since the mid-1990s members of the ASC Association have participated in a voluntary data reporting project. Currently more than 500 ASCs regularly report on more than 30 clinical outcomes and operations measures. These measures include the following (along with the percentage of participating facilities that track and report each clinical indicator):

- Unexpected Complications (91%)
- Post-Surgical Wound Infection (96%)
- Unscheduled Direct Transfers (97%)
- Patient Death (94%)
- Return to Surgery (91%)
- Wrong Site, Side, Procedure, Implant or Patient (96%)
- Prophylactic IV Antibiotic Administration On-Time (33%)

Other measures tracked by our Outcomes Monitoring Project include medication errors, patient burns, patient falls and retained foreign objects. Most recently, the ASC Association and the Missouri ASC Association (MASCA) took a major step in expanding consumer information on ASCs in order to advance transparency in ambulatory surgery. Using data from the Outcomes Monitoring Project, our associations designed a web site to provide more clinical and cost information to patients. The web site provides a variety of data to patients including data on patient satisfaction, transfer rates and wrong site surgery for ASCs in Missouri.

In addition to participating in voluntary quality reporting, the ASC industry has made progress towards developing standardized measures. Early in 2006, the ASC Quality Collaboration began developing facility-level ASC quality measures. The ASC Association supports inclusion in the ASC measure set of the five ASC facility-level quality measures developed by the ASC Quality Collaboration and endorsed by the National Quality Forum (NQF).

The ASC Association strongly supports transparency across different care settings, and we believe use of comparable quality measures would further this goal. The ASC facility-level measures currently endorsed by the NQF are appropriate for other outpatient surgical settings. Like a number of the ASC Association's voluntary measures, the NQF-endorsed measures focus on (1) patient falls, (2) patient burns, (3) hospital transfer/admission, (4) wrong site/wrong side/wrong patient/wrong procedure/wrong implant, and (5) the timing of the administration of intravenous antibiotics for prophylaxis of surgical site infection. The first four measures have applicability to all outpatient surgical facilities, and the fifth measure has been specifically designed to correspond to similar measures (PQRI #20 and PQRI #21) developed to evaluate physician performance in this area. We suggest CMS include these five measures in any future proposed ASC and HOPD quality measure set. By including these measures for reporting by all providers of outpatient surgical services, CMS would provide consistent measures across different settings and facilitate consumers' efforts to make quality comparisons between providers offering the same services.

As CMS develops its proposals for an ASC quality reporting system, it should focus on minimizing the administrative and financial burden of reporting quality measures. To encourage and facilitate participation, we believe the system the agency selects for data collection should be as straightforward as possible, while still ensuring reliable reporting.

The ASC Association encourages CMS to adopt claims-based reporting for ASCs. Our members make very limited use of electronic medical records. A claims-based system offers the opportunity to use an existing process modified merely by the addition of new codes designed for quality reporting, as suggested by the ASC Quality Collaboration in correspondence with CMS dated November 21, 2007. By refraining from creating additional documentation burdens, CMS would encourage participation in quality reporting.

With the goal of facilitating comparisons between providers, the ASC Association also supports public reporting of quality data. 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. CMS should ensure that its internet-based public reporting:

- presents information on sites for all relevant provider settings, so consumers can compare HOPDs, ASCs and even physician offices for procedures that can be performed in different provider settings;
- permits providers to raise concerns with any information to be posted prior to its publication;
- includes a provider narrative section to allow providers to advise consumers of any concerns a provider has regarding the reliability or accuracy of the information presented; and
- includes other useful provider information such as accreditation status, state licensure and Medicare certification.

In this rule, CMS proposes its system for HOPD reporting of quality data for annual payment rate updates. Given that the ASC Association supports consistent reporting across settings to the extent possible, we encourage CMS to incorporate the following, as proposed for HOPD reporting, in the ASC reporting system:

- an appropriate method of applying the required reduction to payments for providers that do not meet requirements; and
- a mandatory reconsideration and appeals process, provided that data under reconsideration or appeal is not publicly displayed until the resolution of such reconsideration or appeal.

* * *

Thank you for your consideration of our comments. We hope CMS will continue to make ASCs a viable alternative to HOPDs. In order to do so, the disparity between payments in ASCs and HOPDs will need to be reduced. The single most important action CMS can take to reduce this disparity is elimination of secondary scaling of the relative weights in the ASC payment system.

We look forward to continuing to work with CMS to improve the revised payment system for ASCs so that our members can continue to provide cost-effective, high quality care to Medicare patients.

Sincerely,



Kathy J. Bryant
President