

ASC COALITION

August 26, 2008

VIA HAND DELIVERY

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

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

Dear Acting Administrator Weems:

On behalf of the undersigned members of the ambulatory surgery center (ASC) community, please accept the following comments regarding the payment and quality issues related to ASCs in the proposed rule for CY 2009 payments (73 Fed. Reg. 41415, July 18, 2008). These comments are submitted by the ASC Coalition, a diverse coalition of associations and companies representing all types of ASCs – single- and multi-specialty, physician owned, joint ventures between hospitals and physicians, and joint ventures between physicians and management companies. These operations range from the very small to the very large and are located in all parts of the nation.

Since the inception of the Medicare benefit in 1982, ASCs have steadily expanded the role they play in meeting the surgical needs of Medicare beneficiaries. From the 97 procedures provided in 1982 to the more than 5,000 procedures that are now payable when provided to Medicare beneficiaries, ASCs have provided high quality, patient focused care at a savings to the Medicare program and its beneficiaries. This contribution has been recognized by the Department of Health and Human Services (HHS). According to the HHS's Office of Inspector General, its regulatory treatment of ASCs "recognizes the Department's historical policy of promoting greater utilization of ASCs" and that "ASCs can significantly reduce costs for Federal healthcare programs, while simultaneously benefiting patients."¹

The ASC Coalition continues to support CMS's decision to link the ASC and hospital outpatient prospective payment systems (OPPS). We appreciate the administrative and

¹ 64 Fed. Reg. 63537, 63536 (November 19, 1999).

policy synergy of CMS coordinating the annual review and update of the ASC system with the rule-making process for hospital outpatient departments. However, we remain concerned that CMS did not adopt a set of policies that would result in a fixed relationship between ASC and OPPS payments over time. CMS's goal should be a payment system that expands access, facilitates choice and reduces costs for the Medicare beneficiary.

Although the following comments address a number of issues, the Coalition wants to emphasize one message in particular: The application of the secondary scaling of the relative weights in the ASC is the single greatest threat to the integrity of the payment system in 2009 and beyond. The relative weight scaling is one contributor to the 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, aggregate ASC payment in 2009 will be 59 percent of OPPS expenditures for the same volume of services – down from 63 percent this year. If the payment gap continues to grow, certain procedures or classes of surgical services will not remain viable in the ASC setting.

We appreciate the diligent work of your staff to review and evaluate the proposed changes to the ASC payment system in 2009, and recognize the tremendous work that was necessary to implement the revised payment system in 2008. While we have limited experience under the new payment system, we describe below our initial response to the changes implemented in January and offer recommendations for improvement in 2009 and beyond.

OVERVIEW

CMS used its broad statutory authority to tie ASC payments to the hospital outpatient prospective payment system (OPPS). The OPPS represents the best proxy for the relative costliness of ASC services, particularly given the annual review and update process that helps ensure refinements occur over time. Tying ASCs to a discounted hospital payment rate produces savings for the federal government and Medicare beneficiaries. While we support linking to the two payment systems, we are concerned that several provisions of this proposed rule might reduce, rather than expand, access to surgical care due to the selective and incomplete application of OPPS policies in the ASC setting. Maintaining a direct connection to the OPPS relative weights is paramount in ensuring that the payment policies do not influence site of service selection.

In the sections below, we draw CMS's attention to several pressing issues that must be addressed to (1) ensure beneficiaries' access to services, (2) provide consumers with adequate data upon which to evaluate where to seek outpatient surgical services, and (3) preserve the integrity of the ASC payment system:

- CMS should stop scaling ASC relative weights, as it further exacerbates the gap between ASC and OPPS payments and inappropriately reduces payments to ASCs. Further, CMS has insufficient data on which to base such a calculation.

- 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 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 inflation pressure on health care facilities’ costs.
- CMS should use the OPSS wage index for ASC payments to improve the 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.
- 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 infrastructure for ASCs. We continue to believe Medicare beneficiaries should have provider quality information to support their surgery choices – and the ASC industry is eager to make this information available sooner rather than later.

We understand that the agency is considering finalizing CMS-3887-P, the proposed revision of ASC conditions for coverage, in conjunction with this final rule. In particular, we urge the agency not to finalize the new definition of ASCs as entities which operate exclusively for the purposes of providing outpatient surgical services not requiring an overnight stay. In our prior comments on this subject, we objected to the revised definition of ASCs, and urged CMS not to override existing state laws in at least 14 states that allow ASCs to provide extended recovery stays of up to 24, 48 and, in some cases, 72 hours in the ASC or separately licensed or certified recovery care units.² 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 and is consistent with the underlying statute.³

I. Scaling relative weights for ASC services

In the regulations establishing the new payment system for ASCs, CMS was given flexibility to scale the OPSS weights “as needed.” CMS should use its administrative

² Those states are Alabama, Arizona, Arkansas, Colorado, Georgia, Illinois, Kansas, Nevada, New York, North Carolina, Ohio, Oklahoma, Tennessee, and Utah.

³ 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).

authority and not apply the secondary scaler to ASC relative weights in 2009. In this section, we will demonstrate that:

- Scaling is not only inappropriate at this time; and, if applied, in the future it will continue to erode the relationship between the OPPS and ASSC payment systems.
- Other payment adjustments are already depressing the payments for many procedures, including the freeze on ASC updates and the transition policy.
- Scaling has a disproportionate impact on some groups of codes; this is a particular problem for the dominant model of single-specialty ASCs.
- The lack of any volume data for nearly 40 percent of the codes in the system raises substantial methodological issues with applying the scaler this year.

In 2009, ASCs will begin their second year receiving payment under a substantially revised payment system. Procedures paid at or above the OPPS rate are being adjusted down to more than 35 percent less than the OPPS payment, while rates for other services are rising to that level. It is too early to tell what effects the speed and severity of the reductions are having on beneficiary access to ASC services, so we urge CMS to avoid implementing additional policies that will hasten the decrease in payment or result in a further decreases in payment to ASCs overall.

During this critical early implementation period, CMS should continually assess the impact of its decisions on the final payment levels. Scaling the ASC relative weights is consistent with CMS policy in other Medicare payment systems where the cost and volume data are directly derived from the providers affected by the scaler. However, because CMS based the ASC system off the OPPS relative weights, the weights should be equal in both settings. The scaler breaks the direct link between ASC and OPPS weights and becomes an unnecessary measurement of volume and case mix. The application of the scaler proposed in this rule produces payment differentials that are neither sensible nor good policy.

The scaling proposed in this rule does not result in true budget neutrality. In this section, we will describe how this scaling (1) results in an aggregate decrease in payments, (2) is duplicative of the budget neutrality adjustment proposed in the OPPS, and (3) is inconsistent with the maintenance of the OPPS relative weights as the basis for ASC payment. At a minimum, the agency has insufficient information from the claims experience under the revised payment system to implement a rational scaler for CY 2009.

There is only a partial connection to the OPPS relative weights in the ASC payment system proposed for 2009. Basing the scaler on the full panoply of OPPS relative weights and volume is inconsistent with the principle of scaling. When CMS transports the OPPS relative weights to ASC payments and then applies a budget neutrality adjustment, the agency's "neutrality" calculation assumes that differences in case mix constitute unanticipated spending increases. If CMS were to use a similar methodology to scale OPPS relative weights, based on only a portion of the HCPCs with volume and weight changes, hospitals would rightfully object that the scaler is inappropriately

attempting to balance neutrality on the backs of only a few services. Unfortunately, however, that is the effect of CMS's application of the scaler to ASC payments. The scaling that currently occurs in the OPSS results in a new set of weights and is the best proxy for cost increases at both the APC and HCPCs levels.

Figure 1. Scaling causes the ASC-OPSS weight gap to increase over time

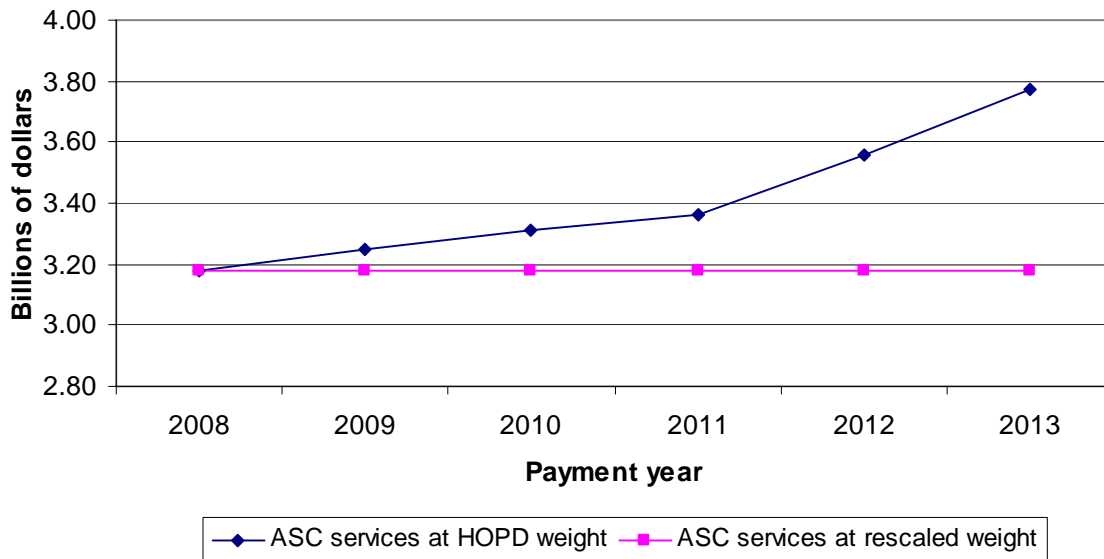


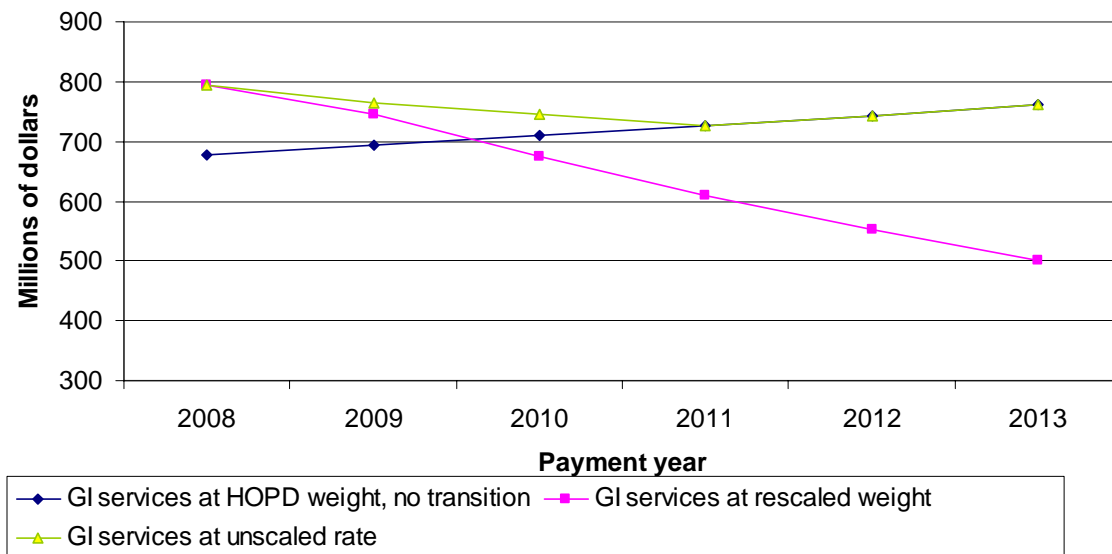
Figure 1 illustrates the growing gap in payment weights that would result from the application of the scaler. Both trend lines begin at the total payment weight for 2007 (the total number of procedures performed multiplied by their payments). To simplify the presentation, we have assumed that volume in ASCs remains the same. The trend begins to diverge in 2009, when the scaler of 0.9753 is applied to ASC payments. Historically, the OPSS relative weights for the most common ASC procedures have risen each year, and we do not anticipate this trend changing in the near future. In the figure above, the difference between the scaled payments and the directly linked payments begins at about \$80 million as the OPSS weights rise. The transition of the ASC payment system from 2007 payments to new system payments ameliorates the payment weight gap until 2012. After the transition ends, in 2012, the trends diverge more quickly. Again, the mechanics of the scaler ensure that money is not removed from the ASC system; so the total payment weight in this model remains the same but the payment weight gap in 2013 reaches 16 percent. We understand that a change in the OPSS relative weights for procedures commonly performed in the ASC could fall in the future, but believe a drop in the OPSS weights would signify a decrease in the cost of those services that should likewise be reflected in ASC payments.

Scaling also has a disproportionate impact on certain families of services. In Figure 2, we use the 2007 volume of gastroenterology (GI) services and the ASC and OPSS weight

changes from 2008 to 2009 to demonstrate the impact of the scaling on the payment for GI services. Unlike the aggregate example above, the weights for GI procedures erode over time if their OPPS weight gains do not keep pace with the size of the scaler. This outcome is possible given the amount of GI service volume in the ASC payment system.

As you can see in this example, ASC payments for GI services are now higher than they would be if 100 percent of the payment was based on the OPPS relative weights. Without the secondary scaling, ASC relative weights and aggregate spending on GI services would meet the blue line representing spending on GI services using the OPPS relative weights in 2011, the year in which the transition is complete. Under CMS’s proposed application of the scaling, however; aggregate payment for the same volume of GI services will fall below the blue line by 2010. Scaling in future years would continue to erode the dollars spent on these services over time – reducing payments beyond the budget neutrality contemplated in the statute that was limited to the year in which the system was implemented.

Figure 2. Scaling disproportionately affects certain service lines



Using the ASC Association’s crosswalk of HCPCs to specialties, we analyzed the 2007 ASC claims data to identify how many ASCs focus on a limited universe of services. We found that 1,256 ASCs have more than 80 percent of their service volume in the GI specialty. If the scenario depicted above comes to fruition, these highly specialized ASCs – nearly 25 percent of the industry – will see the weights for their services drop precipitously. A similar scenario could be drawn for the 421 ASCs specializing in pain management services (i.e., pain management services make up 80 percent of the facility’s volume). The weight decreases will be partially offset by inflation updates applied to the ASC conversion factor starting in 2010. However, the CPI-U or market basket updates

are intended to increase payments for the inflation affecting the entire industry, not the procedure-level rise in relative costs.

Before implementing any final payment decisions, CMS should ensure that beneficiary access to ASCs is not endangered. Unlike the hospital outpatient department, about 50 percent of ASCs have more than 80 percent of their Medicare volume in a single specialty. As a result, the redistribution of weights among services is more difficult for the ASC industry to manage given their inability to offset losses in one service line with gains in another. If ASCs are no longer able to provide some services due to payment decreases and/or increased costs, beneficiary access may be more limited in the future.

A. Statutory and regulatory basis

CMS was granted broad administrative authority to establish a new payment system for ASCs based upon the recommendations of the Medicare Payment Advisory Commission (MedPAC) and the Government Accountability Office (GAO). The statute imposed no budgetary requirements on the system beyond the implementation year. We urge CMS to use the flexibility provided by the statute to use the actual OPPS relative weights in the ASC system.

In its March 2004 Report to the Congress, MedPAC recommended that “The Secretary should revise the ASC payment system so that its relative weights and procedure groups are aligned with those in the outpatient prospective payment system.” Subsequently, GAO was required by Congress to evaluate the appropriateness of the OPPS relative weights for the ASC setting. In GAO’s November 2006 report, it concluded that the relative weights were appropriate at the APC and HCPC level. Specifically, GAO concluded:

“GAO’s analysis of the ASC-to-APC and OPPS-to-APC cost ratios showed that 45 percent of all procedures in the analysis fell within a 0.10 point range of the ASC-to-APC median cost ratio, and 33 percent of procedures fell within a 0.10 point range of the OPPS-to-APC median cost ratio. These similar patterns of distribution around the median show that the APC groups reflect the relative costs of procedures provided by ASCs as well as they reflect the relative costs of procedures provided in hospital outpatient departments and can be used as the basis for the ASC payment system.”

The revised payment system implemented in 2008 bases payments for many services on the OPPS relative weights; however, only 10 percent of all procedures in 2009 will have payments based solely on a percentage of the OPPS relative weight. Several factors are undermining the linkage between ASC and OPPS rates envisioned by MedPAC, GAO, and the ASC industry. These factors include: the transition into the new payment system; the limitation on payment for so-called office-based procedures; and the cap on certain ancillary services at the Medicare Physician Fee Schedule nonfacility practice expense rate. The scaling of the relative weights does nothing to resolve the problems produced

by this misalignment, and in fact produces greater deviation from the OPPS relative weights.

In its regulations at §416.171(e)(2), CMS establishes a process by which it *may* make annual adjustments to the relative payment weights.

“(2) For CY2009 and subsequent calendar years, CMS adjusts the ASC relative payment weights under 416.167(b)(2) as needed so that any updates and adjustments made under 419.50(a) of this subchapter are budget neutral as estimated by CMS.”

The calculation of budget neutrality that CMS used to develop the ASC system codified at §416.171(e)(1) was designed to take into account the differences in case mix between the two settings and resulted in a conversion factor for ASCs at 63 percent of the OPPS rate. We continue to disagree with the initial budget neutrality conversion factor determined by CMS and articulated our concerns in a previous comment letter.⁴ We believed then – and our experience in the first half of 2008 would confirm – that CMS grossly overestimated the volume of office-based procedures that would migrate into the ASC. We also identified several other methodological issues with their calculation. Using our estimate of how the industry would respond to the new payment system, we produced data indicating that 73% of the OPPS conversion factor was budget neutral (see Appendix A for a summary of the methodology).

At its core, the budget neutrality calculation was designed to take into account the mix of services ASCs provide and establish a relationship between payments for procedures in the two settings. From this point forward, the relative difference in payments *between* the ASC and HOPD services at the aggregate and procedure level should be driven only by changes in the conversion factor. The 2009 relative weights reflect real growth in the relative cost of services performed in the HOPD. A scaler should not reclaim from the ASC payment system dollars reflecting cost growth in the relative weights for the surgical services performed in an ASC.

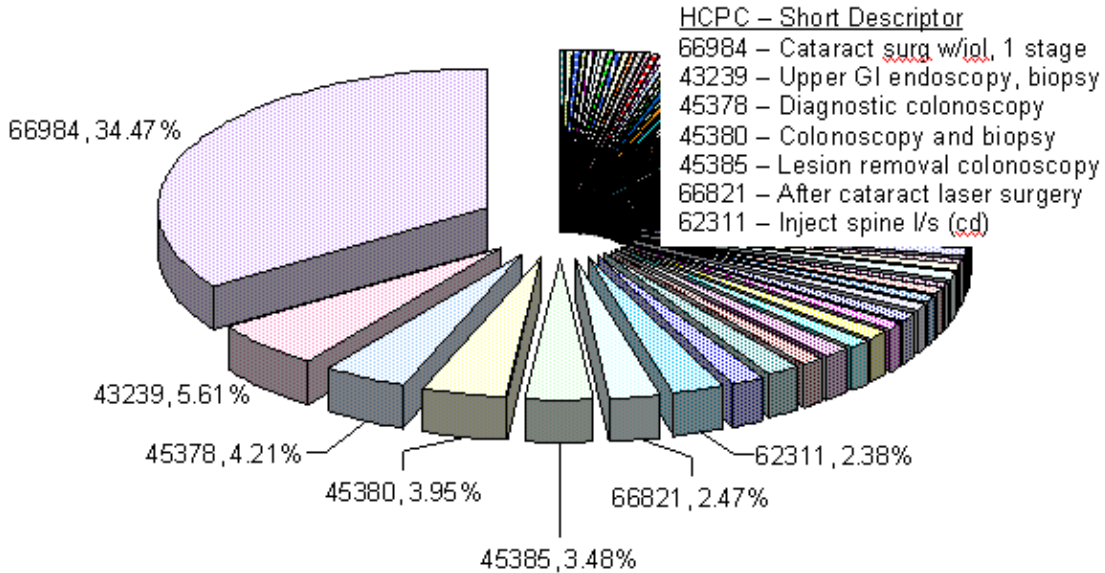
We acknowledge that suspending application of the scaler will result in an aggregate increase in spending in the ASC setting in 2009. However, the scaler is forcing procedures for which the OPPS median cost grew from 2008 to 2009 to finance the transitional payment policies implemented by CMS. Unfortunately, the procedures which the transitional payments were intended to aid are the same procedures financing the bulk of the scaler.

In the chart below, we show the seven highest volume ASC procedures' share of the dollars required by CMS's proposed scaling. Six of the same seven procedures also

⁴ ASC Coalition Comment Letter "Re: CMS-1506-P - Medicare Program; the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates." November 6, 2006.

shoulder a combined \$30 million reduction in payments as a result of the transition to lower payment rates.

Figure 3. Seven codes finance more than 50 percent of scaling



Because of the historical grouper payment rates and their high volume, these same procedures are absorbing large payment decreases – both in terms of dollars and percentage reduction in payments – as a result of the transition. With the exception of one procedure from this group (HCPC 66984), the transitional policy is decreasing payments for these services by more than \$30 million to be redistributed to other procedures whose grouper payment rates lagged far below the OPSS relative weights. For 66984, the 50:50 blend of ASC and OPSS payments in 2009 would have produced a small payment increase. However, the dollars recaptured by the scaler result in a reduction in spending on the same volume of services of \$27 million.

The OPSS median cost increases and the corresponding increases in the relative weights represent a real increase in the cost of providing ambulatory surgical services and are appropriately spent on the care of Medicare beneficiaries. It is also necessary to spend these dollars to maintain the relationship between aggregate ASC and OPSS expenditures at the level envisioned by the original budget neutrality adjuster. Given the absence of claims data under the new payment system; the obvious methodological issues this presents; and the lack of a statutory or administrative imperative to do so; we urge the agency not to apply the scaler to CY 2009 payments.

B. Methodological concerns with the proposed scaling

We describe below methodological concerns that we believe necessitate terminating the annual scaling adjustment to the relative weights used to calculate the payments for procedures performed in ASCs. Scaling exacerbates the ASC system’s failure to ensure

that reimbursement levels keep pace with rising costs—due to the freeze in the base payment—by removing measurable growth in costs of procedures performed in ASCs. We will also show that the calculation of the scaling factor disregards offsetting decreases to payments elsewhere in the ASC payment system.

The lack of cost data in the ASC system led CMS to use the weights that are calculated and scaled in the OPSS to set payments in the ASC. However, as CMS has developed the new ASC system, they have introduced payment adjustments (e.g., capping some procedures at the physician nonfacility fee schedule rate) which distort the OPSS weights. The scaling is yet another adjustment that contravenes the otherwise clear intent to apply information on the relative costliness of procedures developed for the OPSS.

C. Regulatory decisions related to application of scaling

The concept of scaling the OPSS relative weights and applying an adjusted version of those weights was introduced in the August 23, 2006 proposed rule (CMS-1506-P):

We are proposing to scale the relative payment weights annually because we believe that the purpose of using relative payment weights as part of the rate setting methodology under the revised ASC system is to establish appropriate relativity among surgical procedures paid for in the ASC (71 Fed.Reg. 49657) .

The challenges of scaling became evident in implementation: the payments for many services in the ASC system were not wholly determined by OPSS weights. In the final rule (CMS-1517-F), CMS stated that scaling in 2009 would not apply to services with predetermined payment rates, but these services would be included in the budget neutrality comparison. Also, services with weights that would be based on OPSS weights if payment limitations did not apply would be scaled even though their payment is based on an entirely different payment system (e.g., the physician fee schedule).

Table 1. Few ASC rates are based on the full OPSS weights in 2009

Payment type	Payment codes	Percent
Payment based on OPSS relative payment weight	G2, P2, R2	10
Payment based on 50/50 blend of OPSS and ASC rates	A2	60
Conditional separate payment	H2, K2, Z2	14
Device-intensive adjusted rate	H8, J8	1
Payment based on physician fee schedule	P3, Z3	14

*** Note: The ASC PPS also uses L1 and N1 codes, although those codes are not used to calibrate the ASC system; however, the costs are part of the OPSS recalibration.*

The number of services with payments that do not have a direct relationship with the OPSS is significant. Because the ASC payment system is still in transition, CMS has had to create a separate ASC relative weight scale that reflects policy determinations about how much the government will pay for services, not the relative costliness of those services. Application of the scaler then is reducing both the OPSS relative weight as well as the ASC grouper rate for services in transition. In the rule establishing policies for the

new payment system, (CMS-1517-F) states that CY 09 rates will be based 50 percent on the grouper rate, not 50 percent of the scaled grouper rate multiplied by 0.9753.

Further, CMS proposes to move more services into the “capped” category by designating them as office-based, the relationship will deteriorate further. Among the codes proposed for CY 2009, only 10 percent of procedure codes for ASC payment are strictly “based on OPPS relative weight.”

D. Rising costs for ASC surgical procedures

While CMS’s proposal to scale the relative weights of the ASC payment system may be consistent with how this policy is applied in other settings it is inconsistent with the construction and intent of the ASC payment system. Instead of maintaining budget neutrality in the ASC payment system, the scaler is requiring budget neutrality as if its volume and case mix were the same as the hospital outpatient department. As a result, it inappropriately removes millions of dollars from ASC payments.

The table below shows that the HOPD-based measure of median costs for nine of the ten of the most common procedures in ASCs grew from 2008 to 2009. However, ASC payments for those procedures are not reflecting the increase in costs. ASC payment base levels were frozen in 2008 and will remain frozen until 2010. Also, the ASC payment system is in transition, so the rates are a blend of the new system based on OPPS rates and the previous system of payments. This transition causes payments for some procedures to rise and payments for other procedures to fall.

The second column in the table below illustrates the decrease in payment rates for common ASC procedures, even before scaling is applied. This data demonstrates the effect of those other policies which are designed to prevent ASC payments from outpacing the growth in costs. Despite these policies, however, CMS proposes to scale the ASC payment weights. The third column in the table below illustrates the impact of scaling as it pulls the weights for these procedures down, even further behind the measured growth in HOPD.

Table 2. Changes in the cost of top surgical procedures, from CY 2008 to CY 2009, from the true median costs by HCPCS

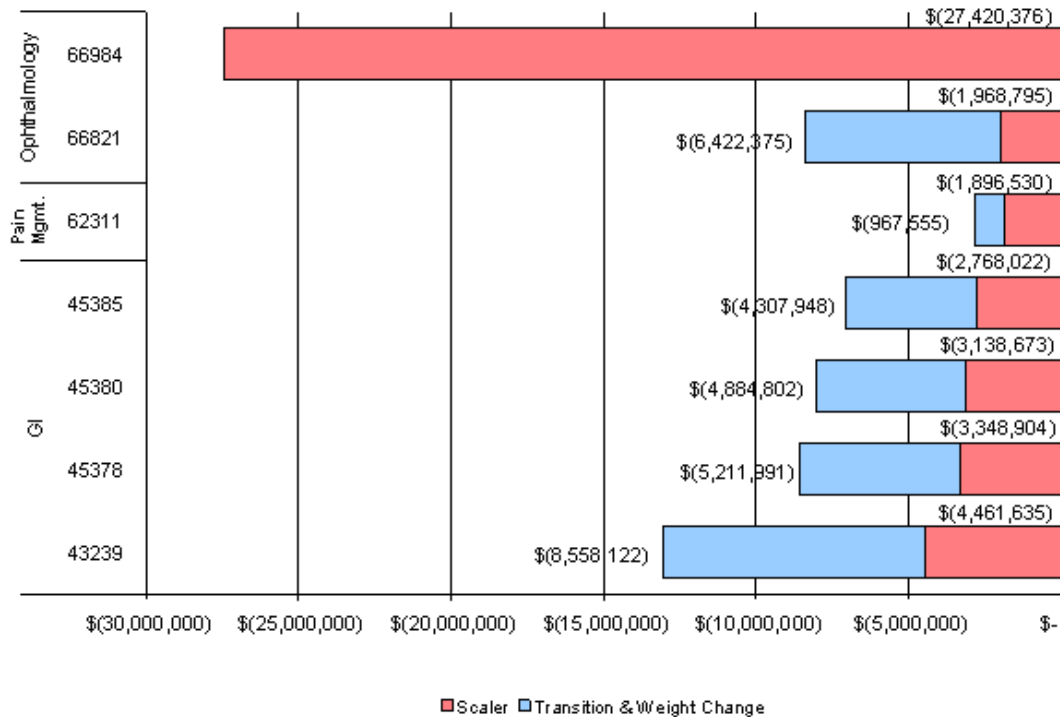
HCPCS and specialty	Percent change in HOPD cost from 2008 to 2009	Percent change in ASC pay, without scaling, from 2008 to 2009	Percent change in ASC pay, with scaling, from 2008 to 2009
66984 Ophthalmology	3.81	1.18	-1.52
43239 Gastroenterology	3.74	-4.37	-6.91
45378 Gastroenterology	3.71	-3.55	-6.12
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

The percent changes above highlight the inability of the scaler to maintain the relationship of the ASC weights to the OPPS relative weights. The combination of the transitional policies and the application of the updated OPPS weights results in CMS applying a 2.5 percent scaler to recapture \$80 million from the ASC payment system. In Figure 4, we use a subset of the procedures listed above to show the change in expenditures on several of the commonly performed ASC procedures. For all but one procedure, the move from 25 to 50 percent of payment based on the OPPS relative weight results in sizable decreases in expenditures. These are the procedures for which the four-year phase in was intended to limit the year-to-year decline in payments. As a result, these services are “giving back” *both* through the scaler and the transition.

Figure 4. The combined impact of the transition and scaler reduce payments for seven services by \$70 million



Many ASCs specialize in just one type of procedure, meaning that they cannot cross-subsidize losses from one procedure or line of business with gains in another. The services shown in the table and figure above come from the three specialties most likely to be operating a single-specialty ASC: GI, ophthalmology, and pain management. These specialized providers represent 51 percent of ASC centers nationwide. We urge the

agency to exercise extreme caution in implementing policies that have a disproportionate affect on providers largely unable to respond to changes in payment by means other than changing their payer mix. For some specialized providers – particularly ophthalmology providers – the Medicare population is the primary source of patients. For these ASCs, modifications to their payer mix are not an option. We are extremely concerned about the long-term ramifications of the proposed scaling on beneficiary access to services.

E. Divergence between OPSS and ASC relative weights

Many payment adjustments in the ASC system distort the relative weights established in the OPSS. Capping 12 percent of the ASC procedures at the physician office rate changes the relative weight of all of those procedures. The transition from the CY2007 system also has an impact on the final relative weights.

Thus, despite CMS's stated intent to maintain the relativity of weights from the OPSS system to the ASC system, many procedures have a far different weight from the comparable OPSS procedure. For example, though HCPCS 25446, a major surgery of the wrist, is the 22nd most heavily weighted procedure in the OPSS, it falls to 54th in the ASC system. The rank is neither maintained nor restored by the scaling. Several examples of diverging codes illustrate the point.

Table 3. Changes in the weights assigned to surgical procedures, from CY 2008 to CY 2009

	Change in weight in Outpatient PPS	Change in weight in ASC payment system
Inject/treat eye socket	3.0	-80.4
Repair radius & ulna	7.6	-39.9
Repair elbow, perc	0.9	-1.6
Removal foreign body, jawbone	5.3	7.7

Source: Addendum "AA" and Addendum "B" of CMS-1392-FC and CMS 1404-P

The wide divergence of weights between the OPSS system and the ASC suggests that the two scales are not truly equivalent; scaling the ASC weights does nothing to improve the integrity of the ASC procedure weights.

The proposed rule suggests that CMS could not include the capped procedures due to data constraints. Only 2007 ASC volume was available to calculate the scaling ratio. These capped procedures were not included in the 2007 ASC payment system, thus, CMS could not include an estimate for the impact of capping 14 percent of the ASC codes that were introduced in CY2008 and beyond and capped at the physician fee schedule rate.

In this section of our comments on the methodological issues described in the proposed rule, we have raised several issues about scaling the ASC relative weights. Our most fundamental objection is that the proposed scaling results in ASC payments that do not keep pace with rising costs; in this year and in future years the scaling process will

further erode ASC payments and the relationship between the ASC and the OPPS rates. Moreover, altering the ASC weights is contrary to the intent of using the cost-based OPPS measurements to determine the relative payments for the same procedures in the ASC. Scaling does nothing to maintain the relative weights of procedures that are subject to other payment policies, such as the payment transition or the physician office rate cap. And finally, given the absence of volume data for the substantial number of new procedures added for ASC coverage in 2008, we do not believe it is appropriate to apply rescaling to the calculation of CY 2009 payment rates.

II. ASC Inflation

When the ASC payment system was first developed in 1982, CMS had not created the hospital market basket and so adopted the consumer price index for all urban consumers (CPI-U) as the tool for updating ASC payments. The CPI-U is an inaccurate measure of inflation in the ASC setting, and we urge CMS to use the market basket increase applied to the OPPS for future ASC payment updates. In the comments below, we describe why the hospital market basket is a more appropriate measure for the ASC payment system. Beginning in 2010, CMS will update the ASC payment system using the CPI-U. The CPI-U is a poor tool to measure price changes in ASCs for several reasons: it has inherent methodological biases, it is designed to capture household spending rather than health care provider spending, and its deviation from the hospital market basket adds to the gap between ASC payment and the hospital outpatient department payment.

We believe CMS has the authority to make this improvement in the inflation factor update and we urge them to exercise the broad discretion granted to the Secretary by the statute. In response to comments on the proposed rule (CMS-1517-P), CMS described its authority in the following manner⁵:

“[T]he statute gives the Secretary broad authority in designing the specific features of the revised system. In particular, the statute gives the Secretary considerable discretion in determining an appropriate update mechanism for the revised ASC payment system. Section 1833(i)(2)(C)(i) of the Act requires that the Secretary update the payment amounts established under the revised system “by the percentage increase in the Consumer Price Index for all urban consumers,” but only if the Secretary has not otherwise “updated amounts established” under the revised system for that year. The statute, therefore, does not mandate the adoption of any particular update mechanism, but it does establish the CPI-U as the default update mechanism in the absence of any other update.”

The statute’s authority allows CMS to use an alternative update mechanism. For the reasons described in detail below, we submit that moving away from the CPI-U to the market basket is permissible and appropriate.

⁵ Federal Register, Vol. 72, No. 148, Thursday, August 2, 2007 (42518-42519)

Compiled and constructed by the Bureau of Labor Statistics (BLS), the CPI-U measures the average change in prices over time of all goods and services purchased by households and covers roughly 87% of the population.⁶ Household purchases, however, are very different from the basket of goods and services purchased by ASCs, making the CPI-U inappropriate for updating ASC payments. Additionally, the CPI-U has faced criticism from independent researchers and economists, with experts repeatedly documenting biases in the methodology that result in the CPI-U consistently underestimating the rate of inflation.⁷ Even CMS's actuarial consultant, Global Insights, has shown through its projections of the hospital market basket that hospital costs are increasing faster than the general economy. Quite appropriately, 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.

The construction of the input price indices makes obvious the inability of the CPI-U to predict ASC cost growth. Both the CPI-U and market basket assign weights to categories of goods and services based on how much money is being spent on a variety of predetermined items. However, the CPI-U looks at all urban consumers and the market basket analyzes hospital spending—embedding in the two payment systems two entirely different proxies for inflation. Further, CMS uses different proxies for price increases for most of the categories of goods and services in the market basket. Each index also has one major component driving the size of the increase – in the market basket, spending on wages and benefits represent nearly 60% of the weight of the index. On the other hand, the CPI-U is dominated by inflation in the housing sector (42% of its weight).

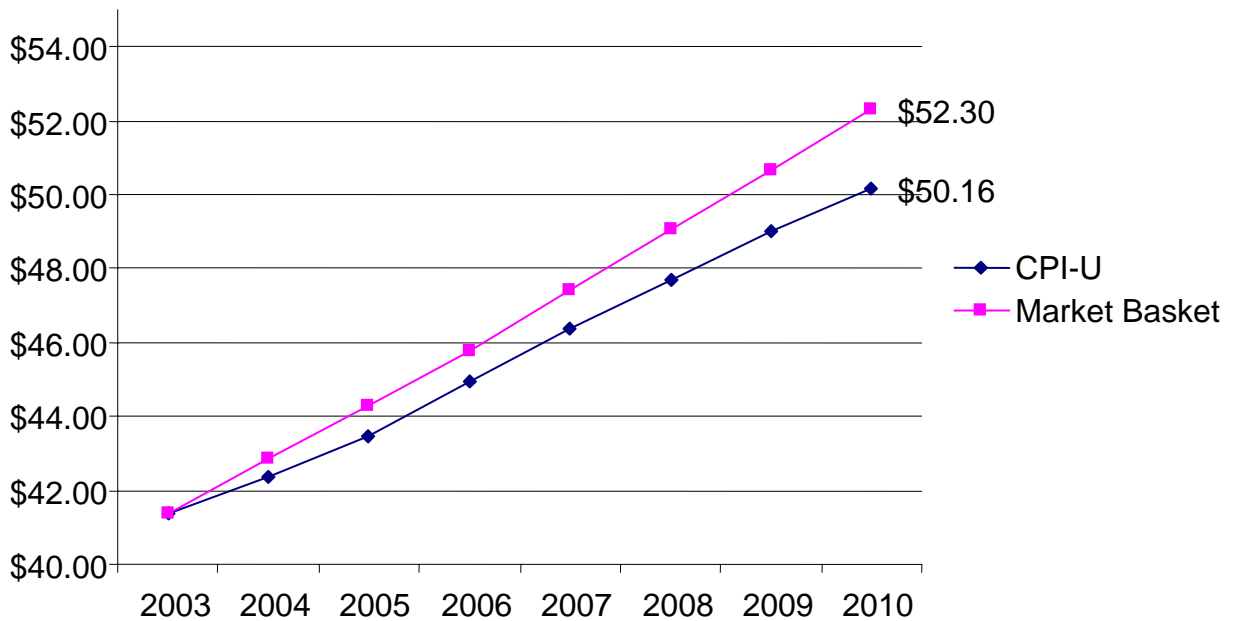
In the few instances in which CMS uses the same proxy to measure inflation, the proxies have dramatically different weights. For example, the market basket has assigned a combined weight of 2.84 to food products (Food-direct purchase and Food-away from home); meaning that out of every hundred dollars the hospital spends, \$2.84 cents of it is spent on food. The CPI-U, on the other hand, assigns a weight of 14.914 to all food and beverages. The disparity in weights illustrates the inherently different cost pressures between the typical U.S. household and the hospital sector. Such a discrepancy reveals how unlikely it is that the CPI-U is representative of ASC costs.

Using the CPI-U for ASC updates will widen the gap between ASC and OPSS payments. The OPSS uses the hospital market basket for updates, and it has been a half a point higher, on average, than the CPI-U for the past several years. ASCs are purchasing a basket of goods and services more similar to a U.S. hospital than a typical household. While these differences in inflation factors seem small, the cumulative effect is a widening gap between ASC and OPSS payments.

⁶ CPI-U obtained from the BLS: <http://www.bls.gov/cpi/>

⁷ See Greenlees, J.S. "A Bureau of Labor Statistics Perspective on Bias in the Consumer Price Index" (2005); Hausman & Leibtag "CPI Bias from Supercenters: Does the BLS Know that Wal-Mart Exists?" (2004); and Hausman "Sources of Bias and Solutions to Bias in the Consumer Price Index" (2003).

Figure 5. Differences between indices accumulate over time



The figure above illustrates the difference in growth between the CPI-U and the market basket as it relates to ASC payments. If ASCs began receiving a payment in 2003 based on market basket updates, by 2010 the payment would be four percent higher than a payment adjusted to reflect CPI-U growth. Using the CPI-U to update ASC payments drives a difference in the conversion factor between the OPPS and the ASC that is unrelated to the actual cost of performing procedures.

As we look forward to 2010 when ASC payments will be updated for inflation, we urge the agency to adopt the hospital market basket as the ASC inflation index. Not doing so will widen the differential in the conversion factors for ASC and OPPS payments, far exceeding the so-called budget neutral relationship established for the 2008 payment system. This difference cannot be explained by real differences in the growth of the cost of goods and services furnished by ASCs and HOPDs and should not be perpetuated by policies the agency has the administrative authority to correct.

III. ASC wage index

We urge CMS to adjust ASC payments using the wage index values published in the Tables 4A and 4B of the inpatient hospital PPS rule and applied to hospital outpatient payments. CMS should also apply the out-commuting adjustment to ASCs in qualifying counties, as it does for non-PPS hospitals. Using the pre-floor, pre-reclassification wage index for ASCs is inconsistent with the concept of ASC payments as subordinate to the OPPS rates.

We have consistently argued that only the conversion factor should drive variation between ASC and hospital payments. There should be a fixed relationship between the rates paid to ASCs and hospitals in all geographic areas after application of the wage index.

A. Regulatory decisions related to application of the wage index

All of the adjustments to the hospital wage index discussed below are established under section 1886(d) of the Social Security Act, the inpatient hospital section of the statute. No analogous adjustments are provided under the outpatient hospital payment section of the Act, section 1833(t). When CMS proposed rules to implement a prospective payment system for hospital outpatient services in 1998, the agency (then the Health Care Financing Administration) discussed their options for applying an adjustment for geographic variation in local input prices. The agency argued for using the hospital wage index, rather than another type of geographic adjustor because of the nature of the outpatient department as a unit of the hospital.⁸

“We decided that using the hospital inpatient PPS wage index as the source of an adjustment factor for geographic wage differences for the hospital outpatient department PPS was both reasonable and logical, given the inseparable, subordinate status of the outpatient department within the hospital overall.”

The question of whether to use the wage index reflecting the IPPS adjustments such as the floor policies was then addressed. The agency argued that outpatient staffing costs were likely reflected in the inpatient hospital cost reports because of the rotation of employees throughout the facility. Although ASCs are not subordinate units of a hospital, the services they provide require similar labor costs to attract workers equally qualified for hospital employment. For example, qualified nurses for the operating room are critical to providing quality care in any surgical setting.

Since implementation of the OPPTS, CMS has adopted the pre-floor, pre-reclassified (PFPR) wage index for all other prospective payment systems. CMS justifiably asserts that the occupational mix of professionals and the services they provide in systems like home health and skilled nursing facilities are likely to vary from that of hospitals. Further, there is no linkage between their payment systems that may affect the selection of a site of service based on beneficiary cost sharing or other factors that would be exacerbated by wage index differentials.

Unlike post-acute care providers, CMS noted in the August 23, 2006 ASC-OPPTS proposed rule that there is a “significant overlap between surgical procedures furnished in hospital outpatient setting and those performed in ASCs. Currently, of the 150 highest volume surgical procedures furnished in the hospital outpatient departments, more than

⁸ Health Care Financing Administration, Department of Health and Human Services. 1998. Medicare Program; Prospective Payment System for Hospital Outpatient Services; Proposed Rules. *Federal Register* 63, No. 173: 47551-48036.

half (80) are also among the highest volume procedures performed in ASCs.” In order to provide a similar mix of services, ASCs must employ a similar mix of employees. In any geographic labor market, ASCs are directly competing with the hospital for the registered nurses and other professionals necessary to operate the centers. Consequently, they should be paid using an equitable adjustment for geographic differences in costs.

B. Adjustments denied to ASCs and the impact on payments

CMS 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, CMS applies several adjustments to the wage index to address market-specific or provider-specific competition for labor. These policy adjustments should be applicable to the ASC payment system, and 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 an 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 an MSA in which they are not physically located.

When CMS applies these policies, the agency creates a higher wage index for hospital outpatient services delivered in the same geographic area as ASC services in many parts of the country. These policies keep the hospital payments higher than they would be if the hospital wage index relied solely upon the wage and hour data of providers in their geographic core based statistical area (CBSA).

In the Fiscal Year (FY) 2009 rule for the hospital inpatient PPS, CMS adopted several changes to the way the hospital wage index is calculated. Most notably, the agency is phasing in a state-level budget neutrality adjustment for the imputed and rural floor adjustments. For states with urban area wage indices affected by these policies, the state-level adjustment lowered the state’s wage index values. In Vermont, for example, the state-level budget neutrality calculation actually lowered the hospital wage index below the PFPR index value.

In all but a few instances, the adjustments applied to the hospital index result in a wage index value for a particular area that is higher than the pre-floor, pre-reclassified wage index used in the ASC payment system and have a substantial impact on the difference in payment between the ASC and hospital outpatient department. Below is an illustration of

how these policies affect payments for services in certain markets where ASCs and hospitals compete for labor.

Table 4. Proposed CY 2009 payment for laproscopic cholecystectomy (CPT 47562)

Policy adjustment	Geographic area	Wage Index		Payment		Ratio of ASC:HOPD	
		Hospital	ASC	Hospital	ASC	Wage Index	Payment
Rural Floor	Madera, CA	1.1822	0.7944	\$3,739.94	\$1,679.78	67%	45%
Budget neutrality	Vermont	0.9275	1.0086	\$2,914.32	\$1,880.30	109%	65%
Imputed floor	Vineland-Millville-Bridgeton, NJ	1.1221	1.0373	\$3,270.07	\$1,907.70	92%	58%
Out-commuting	Monroe County, PA*	0.9512	0.8371	\$2,957.65	\$1,719.76	88%	58%

* Reflects application of out-commuting adjustment of 0.117 to rural PA index

Source: Values from the inpatient and outpatient proposed rules, reflecting a fully-implemented state-level budget neutrality adjustment

The different wage index values between ASCs and their neighboring hospital outpatient departments can create differentials in payments for the same outpatient surgical procedure in excess of 45 percent. These differences do not, however, reflect real differences in the cost of treating a patient in the ASC versus the hospital outpatient department. Using the hospital wage index will largely mitigate these market-level anomalies.

Finally, we understand CMS is developing recommendations for broad reform of the wage index as required under Section 106 of the Tax Relief and Health Care Act of 2006 (TRHCA). The ASC community looks forward to the results of RAND's research and CMS's subsequent proposals. Given the extended transition period that will be necessary for CMS to implement the broad wage index reforms called for in the TRHCA, we urge CMS to move quickly to align the ASC and hospital outpatient department wage indices in the interim.

IV. Coverage and payment issues

A. Overview of procedure list issues

ASCs have afforded significant savings to the Medicare program and its beneficiaries over the last several decades while delivering high quality services. We continue to believe that CMS's ASC-specific standards are unnecessarily duplicative of the process already in place for approving services for HOPD coverage. 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 a separate process and different language to determine the exclusions for the two settings. 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. If

a procedure is approved for payment in the HOPD, but not the ASC, the agency should articulate its rationale for not including the service on the list of ASC procedures.

Although CMS has made great strides in expanding the list of ASC-covered surgical procedures, we urge improvement in the following arenas:

- ***Transparency in decision-making.*** CMS should reveal its rationale for excluding any service not on OPPS inpatient-only list from ASC coverage. CMS maintains criteria for excluding services from the ASC, but does not reveal to the public the reasons for exclusion of any particular procedure.
- ***Consideration of items removed from inpatient-only list.*** As part of the process of annually reviewing the status of procedures on the inpatient-only list, CMS should consider any service removed from the inpatient-only list for coverage in the ASC. If a procedure is approved for the hospital outpatient department, but not the ASC, the agency should articulate its rationale for not including the service on the list of ASC procedures.
- ***Addition of procedures to the ASC list.*** CMS should cover additional procedures that would not be excluded based on current ASC criteria.
- ***Coverage of unlisted procedures.*** CMS should implement a payment option for certain unlisted procedures in ASCs to parallel the HOPD option for such procedures.
- ***Preservation of ASC procedures bundled into codes outside the surgical CPT range.*** The application of the OPPS packaging policies should not have the inappropriate affect of excluding procedural services from the ASC when the service otherwise meets CMS's coverage criteria.
- ***Treatment of office-based procedures.*** CMS should not finalize new designations of procedures as office-based. These designations erode the relationship between the ASC and OPPS payment systems and are unnecessary to limit migration of procedures.
- ***Treatment of procedures with fixed device costs.*** CMS should pay for services designated as device-intensive at the fully-implemented payment rates beginning in 2009. Migration of these services out of the HOPD to the less expensive ASC has been stifled by payment policy. In all services with fixed device costs, CMS's policies should institute policies to shield this portion of the payment from the wage index and the ASC conversion factor.

B. Transparency in decision-making

CMS has made great strides in expanding the number of procedures on the ASC list, but we believe that some procedures continue to be inappropriately excluded from payment in the ASC. The lack of transparency in the agency's application of the exclusion criteria impairs our ability to respond with evidence directly addressing the agency's concerns. We urge CMS to publish in this final rule (and in subsequent proposals) an addendum identifying which of the criteria triggers the agency's decision not to add the procedure to the list of covered ASC services.

The agency provided some indications of their concerns in publishing Addendum EE to the final rule last year⁹, but provided no comparable data for the proposed CY 2009 rule. We note that the version of this file currently on the agency's website is different than the one originally published on the internet with the final rule. The original file used four codes to describe the reason for exclusion:

- E5 – Not covered by Medicare
- C5 – Inpatient only
- U5 – Unlisted code
- X5 – Safety/overnight stay

These indicators are not present on the file currently on the website.

We urge the agency to expand on their previous efforts to describe reasons for exclusion. In order for physicians and ASCs to provide evidence to CMS that a procedure can be safely performed in an ASC, we must know why it is excluded. CMS should expand the reason codes above to identify which specific standard(s) listed below and incorporated under §416.166(c) result in the exclusion of a procedure.

- 1) Generally results in extensive blood loss
- 2) Requires major or prolonged invasion of body cavities
- 3) Directly involves major blood vessels
- 4) Is generally emergent or life-threatening in nature
- 5) Commonly requires systemic thrombolytic therapy
- 6) Typically requires active medical monitoring and care at midnight following the procedure

For example, we believe the following procedures meet CMS's criteria for inclusion on the ASC List. We would appreciate more information from CMS as to why these procedures continue to be excluded from payment. These procedures are provided to non-Medicare patients on an outpatient basis in ASCs and we feel beneficiaries should be offered the same opportunity.

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 90 minutes of operating time and do not require a patient to stay past midnight.

64448, 64449 Injection of anesthetic agent (nerve block) for femoral nerve or lumbar plexus, with continuous infusion by catheter Continuous peripheral nerve blocks are already being performed on a regular basis for non-Medicare patients in the ASC setting. An indwelling catheter is positioned in a manner to provide drug delivery to the femoral

⁹ 1392 FC, Addendum EE, internet only.

nerve or lumbar plexus. An infusion pump is connected to the catheter, providing a continuous flow of anesthetic to the site at the desired rate. These procedures are used to address situations in which more prolonged postoperative pain management is needed. They are safely done in the ASC setting and do not require an overnight stay.

C. Consideration of items removed from the OPPS inpatient-only list

CMS should, as part of its annual review of the inpatient-only list, consider which services being proposed for removal from that list are appropriate for coverage in both the HOPD and ASC settings. When such services are not proposed for ASC coverage, the specific criterion or criteria that led to that decision should be explicitly stated.

In CY 2009, CMS proposes to allow HOPDs to perform 10 procedures that had been previously restricted to hospital inpatient care. Many of these procedures meet CMS's ASC list criteria and we ask CMS to include them on the ASC list of procedures or provide more information on why they were excluded from coverage in the final rule.

For example, 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 addition, we disagree that 0184T should be classified as inpatient-only. This Category III CPT code was implemented on January 1, 2008. Transanal endoscopic microsurgery is a minimally invasive procedure for the excision of precancerous lesions or 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 covered in the ASC setting. When this is removed from the inpatient-only list, we recommend it should be payable in the ASC setting.

D. Additions to the ASC list for CY 2009

We commend CMS for reviewing annually the addition of procedures to the ASC list. We applaud the agency's addition of nine procedures to the ASC list for CY 2009 and concur with their assessment that these can be safely performed in an ASC without the need for an overnight stay. Several of the undersigned companies are already performing these procedures on their non-Medicare patients and look forward to making the ASC an option for Medicare beneficiaries.

We are concerned that the agency's secondary, separate approval process for ASC services continues to result in exclusion of procedures that can be safely performed in an ASC. Of the procedures eligible for OPSS payment, CMS declined to add to the ASC list any of the services proposed for removal from the inpatient only list, 213 HCPCS which the agency reported unspecified safety concerns last year and an additional 78 HCPCS representing unlisted procedures. Many of these exclusions unnecessarily restrict Medicare beneficiaries' choice to the hospital outpatient department.

We note that many procedures excluded from the ASC list 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 paid under that APC are eligible for ASC payment. For example, the table below shows all the HCPCS that comprise APC 0075 Level V Endoscopy Upper Airway.

Table 5. HCPCS codes in 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	Larynsco w/tumr exc + scope	A2	
31545	Remove vc lesion w/scope	A2	
31546	Remove vc lesion scope/graft	A2	
31560	Laryngoscop w/arytenoidectom	A2	
31561	Larynsco, remve cart + scop	A2	
31571	Laryngoscop w/vc inj + scope	A2	
31576	Laryngoscopy with biopsy	A2	
31578	Removal of larynx lesion	A2	

Most of the services in this APC were on the ASC list in 2007; however, CMS continued to exclude 3 procedures in 2008, citing safety concerns. We were pleased to see that the agency was convinced of the safety of HCPC 31293 and has proposed its addition in 2009, but believe the agency should also add the two closely related procedures, HCPCs 31292 and 31294. CPT code 31292 describes a less extensive service than 31293; the former describes decompression of either the medial or inferior orbital wall, while the latter includes decompression of both the medial and inferior orbital walls.

Examples of CMS excluding some, but not all, of the services covered under an APC appear elsewhere in the payment system. We encourage CMS to add other services in APCs with homogeneous clinical characteristics and resource use in 2009. The chart and description below provide one such example. While all of the other services in the APC are covered, CMS excludes one closely related procedure from the ASC – forcing physicians to keep these services in the hospital outpatient department. The other procedures in the APC were added to the ASC list in 2008.

Table 6. HCPCS codes in APC 0423, Level II Percutaneous Abdominal and Biliary Procedures

HCPCS Code	Short Descriptor	Proposed CY 2009 ASC Payment Indicator	CY 2008 Exclusion Code (CMS 1392-FC)
32998	Perq rf ablate tx, pul tumor	G2	
47382	Percut ablate liver rf	G2	
50592	Perc rf ablate renal tumor	G2	
50593	Perc cryo ablate renal tum		X5

In APC 0423, Level II Percutaneous Abdominal and Biliary Procedures, percutaneous cryoablation (CPT 50593) is very similar to percutaneous radiofrequency ablation, CPT code 50592, which CMS already covers in the ASC setting. Depending on patient factors, anesthesia for these procedures ranges from moderate sedation to general anesthesia. Both procedures employ a minimally invasive percutaneous approach through small skin incisions with imaging guidance to localize the target lesion. With cryoablation, destruction of the renal tumor is accomplished through freezing, as compared to destruction with heating in radiofrequency ablation. An overnight stay is not required for recovery.

We see a similar pattern of excluding one or two services in the case of unlisted codes as well.

E. Coverage of unlisted procedures

In some ASCs, physicians utilize new, more efficient and effective approaches to surgical procedures; however, this can mean that the service is not described by a particular CPT code. For example, an endoscopic approach to cyclophotocoagulation was developed several years ago. Initially, per specific guidance from the AMA, the CPT code for

traditional cyclophotocoagulation could not be appropriately used to describe the endoscopic approach and the use of the unlisted code (in this case CPT 66999) was necessary. Ultimately a specific CPT code (CPT 66711) was created for reporting of endoscopic cyclophotocoagulation in 2005, and the code was included for ASC coverage.

The use of an innovative approach or use of a new technology to perform a procedure otherwise reimbursed by Medicare should not result in noncoverage of that service. HOPDs can receive reimbursement under OPPS using an “unlisted” procedure code to identify otherwise unclassified procedures by CPT subsection. CMS should implement a parallel structure in the ASC payment system: When all the specific codes in a subsection of CPT are eligible for ASC payment under the revised payment system, the associated “unlisted” code should also be eligible for payment of an ASC facility fee.

We do not think it is necessary to exclude all unlisted codes from payment of an ASC facility fee in order to address potential safety risks. There are many subsections of the CPT manual for which CMS has determined that all the specific CPT codes within the clinical group are safely performed in the ASC setting. When this is the case, we submit that the unlisted codes for such sections would not pose a safety risk. 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 would not pose a safety risk. Similarly, all the specific codes in the posterior segment subsection of the ophthalmic section of the CPT are currently classified as ASC list procedures or physician office procedures. Given this, we do not believe that an unlisted procedure on the posterior segment of the eye would pose a safety risk.

In addition to the CPT manual, CMS’s construction of the APCs provides a similar roadmap to identifying unlisted procedures that can be safely performed in an ASC. In the example below, we show all the procedures covered by APC 0232, Level I Anterior

Segment Eye Procedures. Because the APCs are constructed by grouping services together that are homogeneous in terms of clinical characteristics and resource use, most of the procedures in this APC are on the ASC list. In fact, two of the services in this APC are designated as office-based. We see no reason why an unlisted code in this APC could not be reimbursed when necessary to report a procedure for which a specific CPT is unavailable.

Table 7. HCPCS codes in APC 0232, Level I Anterior Segment Eye Procedures

HCPCS Code	Short Descriptor	Proposed CY 2009 ASC Payment Indicator	CY 2008 Exclusion Code (CMS 1392-FC)
65286	Repair of eye wound	P2	
65820	Relieve inner eye pressure	A2	
66030	Injection treatment of eye	A2	
66500	Incision of iris	A2	

66505	Incision of iris	A2	
66625	Removal of iris	A2	
66820	Incision, secondary cataract	G2	
66830	Removal of lens lesion	A2	
66999	Eye surgery procedure		U5
68100	Biopsy of eyelid lining	P3	
76510	Ophth us, b & quant a	Z3	
0124T	Conjunctival drug placement		

F. Procedures bundled into services outside of the CPT surgical code range

The revised payment system implemented in January incorporated many changes which we supported to ensure an appropriate linkage between ASC and OPSS payment policies. However, CMS’s packaging policies for certain services exclude some procedures from the ASC setting that are clinically appropriate. For many years, ASCs were accustomed to working with an all-inclusive payment bundle. Like CMS, we believe bundling can encourage efficiencies. However, the agency’s bundling policies in the outpatient PPS are inappropriately restricting access to services that would otherwise be eligible for ASC coverage.

We urge the agency to reconsider this policy and allow ASCs to be paid for services outside the CPT surgical range when an ASC-eligible service is reported on the same claim and is integral to that procedure.

The application of the OPSS packaging policies should not have the inappropriate affect of excluding procedural services from the ASC when the service 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 OPSS, 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.

CMS’s packaging of an “ASC-eligible” procedure into a non-covered code (e.g. outside CPT 10000-69999) under the outpatient PPS means that the procedure will likely remain in the hospital outpatient department rather than migrate to a less expensive site of care. CMS’s policies should permit ASC payment for both the traditional forms of surgery as well as other invasive procedures appropriate to the outpatient surgical setting.

G. Procedures designated as office-based

CMS designates certain services as office-based and caps ASC payments for those services at the nonfacility practice expense RVU payment available to physicians. Over

350 HCPCS were capped in CY2008; CMS proposes to cap several additional HCPCS in CY 2009. We urge CMS to revise its policies as follows:

- Raise the threshold for designating a service as "office-based."
- Use multiple years of data to determine whether a procedure meets the threshold and revisit the threshold over time.
- Recognize the HOPD median cost data for procedures as the best proxy for relative ASC costs and limit the reduction in payment to ASC services designated as office-based.

We have argued in the past that this policy would inappropriately force some services to remain in the higher-priced HOPD. While physicians routinely perform these procedures on Medicare beneficiaries in the office setting, certain beneficiaries may require the additional infrastructure and safeguards of an ASC to maximize the probability of a good clinical outcome. Even when a procedure is frequently performed in an office there are circumstances when the office is an inappropriate or unavailable setting. These circumstances typically revolve around patient-specific factors and/or co-morbidities causing situations in which, for example, the patient cannot lie still, mental status or language barriers limit the ability to cooperate, anxiety issues cannot be addressed in the office setting, greater sterility is needed, or the surgical site cannot be anesthetized in the office. In other cases, specialized equipment is not available in the office or additional staff requirements preclude the office setting. Unless ASCs are an eligible alternative site of service in such instances, these procedures will have to be performed in a more costly hospital-based setting.

CMS proposed to designate several additional procedures as office-based for CY 2009. In the absence of data from the first year under the new payment system, we see no justification for additional temporary or permanent designations of procedures as office-based. As we will address below, we further urge CMS not to finalize the new designations of procedures as office-based in order to limit the exposure of the ASC payment system to the vulnerabilities of the physician fee schedule. Further, CMS provided no publicly-accessible data to validate the agency's assertions that the procedures proposed for temporary or permanent assignment as office-based were commonly performed in the office in 2007.

CMS indicated its policy on the utilization threshold for considering whether a procedure is "commonly performed in physicians' offices" in the Final Rule for CY 2008:

We generally interpret "office based" or "commonly performed in a physician's office" to mean a surgical procedure that the most recent BESS data available indicate is performed more than 50 percent of the time in the physician's office setting. (72 FR 42509)

However, we note that the regulation did not codify the 50 percent threshold in section 416.171(d) where the concept of "commonly performed" is introduced:

"...[F]or any covered surgical procedure under §416.166 **that CMS determines is commonly performed in physicians' offices** or for any covered ancillary radiology service, the national unadjusted ASC payment rates for these procedures and services will be the lesser of the amount determined under paragraph (a) of this section or the amount calculated at the nonfacility practice expense relative value units under §414.22(b)(5)(i)(B) of this subchapter multiplied by the conversion factor described in §414.20(a)(3) of this subchapter."¹⁰ (emphasis added)

We agree with the agency's decision to not codify 50 percent as the cutoff for this designation in the regulatory text and believe that the Secretary has flexibility in applying this rule. We offer the following observations to demonstrate why the threshold is too low and the data is too volatile to make designations using one year of data.

Finally, as more procedures are designated as office-based, the linkage between the ASC and OPSS rate-setting methodology will be eroded and relative weight scaling based upon changes in the median cost of hospital outpatient procedures will be further confounded.

The 50 percent threshold is too low, and the data is too volatile. Evidence suggests that the payment cap policy is conceptually flawed because it cannot account for regional variations in practice patterns that determine whether a procedure is commonly performed in a physician's office, nor can a permanent designation as a capped service reflect the variations in practice patterns over time. In the revised ASC system, CMS attempted to establish payments for certain ASC services using the setting where the service was most frequently performed as the basis for the selection of the payment system upon which to base the ASC rate¹¹. The construction of this threshold solely on one year's worth of volumes fails to capture changes in subsequent years. This national average policy ignores dynamic variations occurring at the local level.

As many researchers have demonstrated, practice patterns vary significantly across geographic areas.^{12,13,14} In the case of site of service selection, some of the variation is driven by state law and regulation of the types of procedures that can be performed in various settings, by both certificate of need requirements that have affected the supply of

¹⁰ §416.172(d), "Determination of payment rates for ASC services: Limitation on payment rates for office-based surgical procedures and covered ancillary services." 42 CFR Ch. IV (10-1-07 Edition), CMS.

¹¹ Federal Register / Vol. 72, No. 148 / Thursday, August 2, 2007 / Rules & Regulations / 42509

¹² Wennberg JE et al. "Tracking the Care of Patients with Severe Chronic Illness." Executive Summary, The Dartmouth Atlas of Health Care, April 2008.

¹³ Tedeschi PJ, Wolfe RA, Griffith JR. "Micro-area variation in hospital use." *Health Serv Res.* 1990 Feb;24(6):729-40.

¹⁴ Wennberg JE et al. "The Dartmouth Atlas of Health Care in the United States, 1998." Report, American Hospital Assoc. 1998.

different provider types, and by investment decisions that affect the supply of ASCs or the technological sophistication of physician office practices, among other factors.

One weakness of CMS's approach to capping payments is their reliance on national averages to gauge practice patterns. The national average volume fails to capture wide variation at the sub-national level. In other words, though a procedure may be performed 50 percent of the time across the country *on average*, in fact, in many places it is rarely performed in a physician's office. The table below includes seven procedures which, at a national level, are performed in physician offices about 50 percent of the time (though they are not capped due to an exception to the rule). However, in some states the physician office is only used two or three percent of the time. The same procedures are performed in a physicians' office almost all the time in other states. This state-level variation illustrates the weakness inherent in using a national average to try to capture practice patterns and to shape the site of service choices for physicians.

Table 8. State level variation in proportion of total volume of procedures performed in physician offices, CY 2006

% of Total Volume (2006)	HCPCS Codes						
	66821	64475	64472	52214	36589	15240	11043
Highest	MN (41%)	ND/SD (63%)	OK (74%)	RI (90%)	RI (89%)	VT (92%)	AK (91%)
75th Percentile	VA (18%)	IN (31%)	CT (29%)	AK (67%)	NH (71%)	WI (53%)	OK (76%)
50th Percentile (Median)	IN (16%)	TX (24%)	SC (17%)	MO (52%)	NJ (61%)	WY (43%)	ID (60%)
25th Percentile	AL (12%)	AK (15%)	KY (7%)	OK (30%)	AZ (51%)	HI/Guam (36%)	MN (49%)
Lowest	NV (2%)	NM (3%)	DE (1%)	NY (10%)	WY (20%)	FL (14%)	GA (27%)

Note: Total volume is the sum of volume in ASC, HOPD, and Physicians' Offices

These state level variations underscore that the payment cap might not be an effective tool to shape practice patterns because many factors influence the site selection for surgery. The number of ASCs is quite low in many of the states represented above, including Kentucky, Wyoming, and New Mexico. This might suggest that a procedure clinically appropriate for the office would be performed predominantly in that setting in states with few ASCs. However, we do not see this pattern emerge consistently, and in fact the HOPD is the predominant site of service in these regions. This suggests that these procedures are instead remaining in the hospital outpatient department at the higher OPSS rate either because they are too complex to perform in the office or the

combination of the geographic adjustments and MPFS RVUs understates the cost of the procedure and sets a prohibitively low rate for ASCs.

If service selection were predominately motivated by the price differential between the ASC and physician office rates, office volume should be very low for procedures for which the ASC rate exceeded the office rate by a wide margin. Instead, the chart above shows that the proportion of these procedures performed in the ASC varies widely from state to state, and not in relationship to the differences in payment rates.

Table 9. National payment rates for ASC and physician office procedures, CY 2006

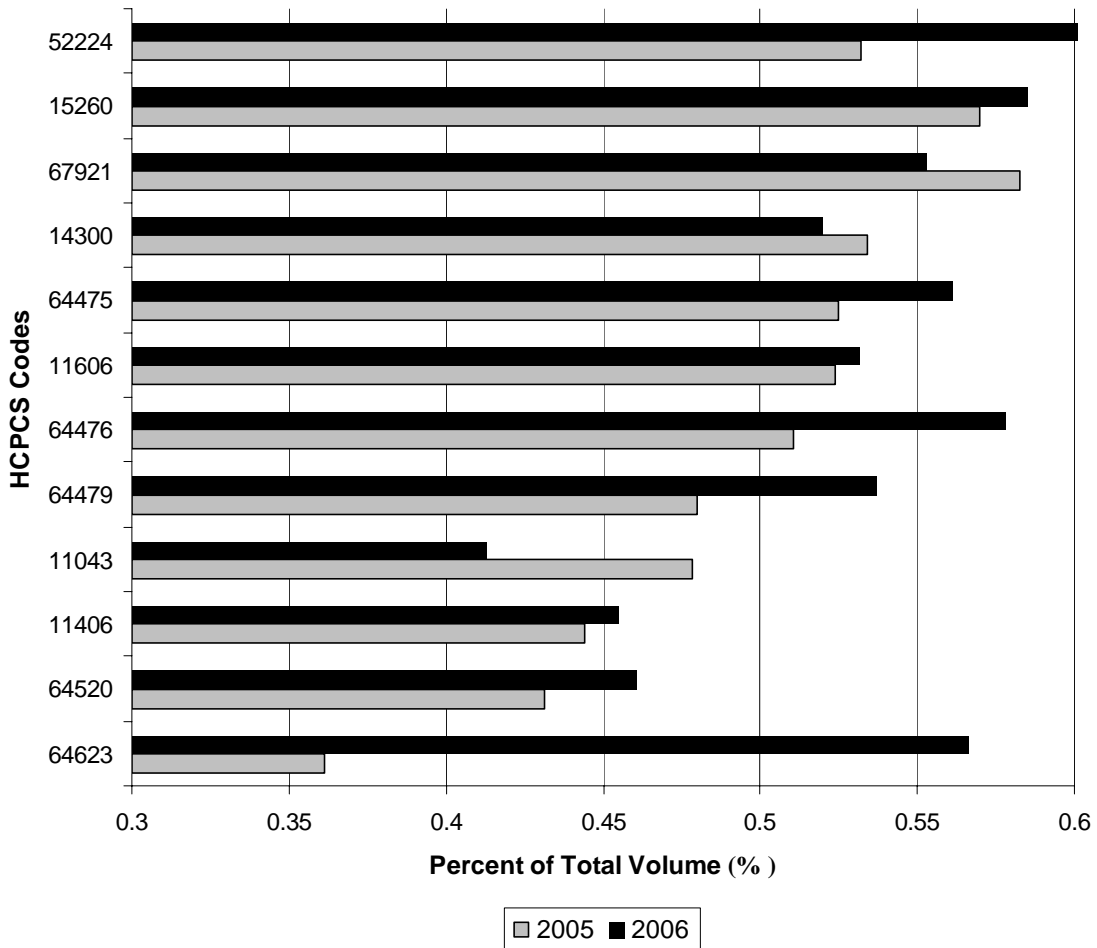
Site of Service	HCPCS Codes						
	66821	64475	64472	52214	36589	15240	11043
	After cataract laser surgery	Inj paravertebral l/s	Inj paravertebral c/t add-on	Cystoscopy and treatment	Removal tunneled cv cath	Skin full grft face/gen it/hf	Debride tissue/muscle
ASC	\$446	\$333	\$333	\$446	\$333	\$510	\$446
Physician office	\$155	\$261	\$89	\$1,448	\$85	\$387	\$128

Note: Physician office payments are based on MPFS nonfacility PE RVU

If CMS were to cap these procedures, as they have for services newly added to the list, taxpayers and the Medicare beneficiaries seeking these services would fail to capitalize on the savings available in the ASC. For existing capped services, the office-based payment is likely impeding the migration of services from the hospital to the less expensive ASC because the physician rate is too low for services requiring the sterile, technologically advanced setting afforded by ASCs. The addition of new procedures to the capped list could threaten to stall the migration of these procedures out of the HOPD.

A second weakness of the capping policy is its failure to recognize fluctuations in practice patterns over time. By examining the information in the graph below, it is evident that even with only two years of data, the change in proportion of total volume for a procedure performed in physician offices is quite volatile. The year-to-year variation implies that a permanent cap ignores common year-to-year changes.

Figure 6. Physician office volume varied substantially between 2005 and 2006 for many services close to the 50 percent threshold



The volatility in site of service discussed above may be explained by other causes which likewise suggest that an inflexible threshold is inappropriate. By their very nature, site of service volume criteria are arbitrary. Past site of service volume criteria have proven problematic, primarily because their static nature has clashed with the dynamic and constantly evolving landscape of outpatient surgical care. The results of applying previous site of service criteria have been unsatisfactory. In the case of the current site of service criterion limiting ASC payment for services performed 50% or more in the physician office, CMS fails to recognize the variation in practice patterns across the country, the varying sophistication of physician offices, and the adverse effect on beneficiaries' out-of-pocket costs.

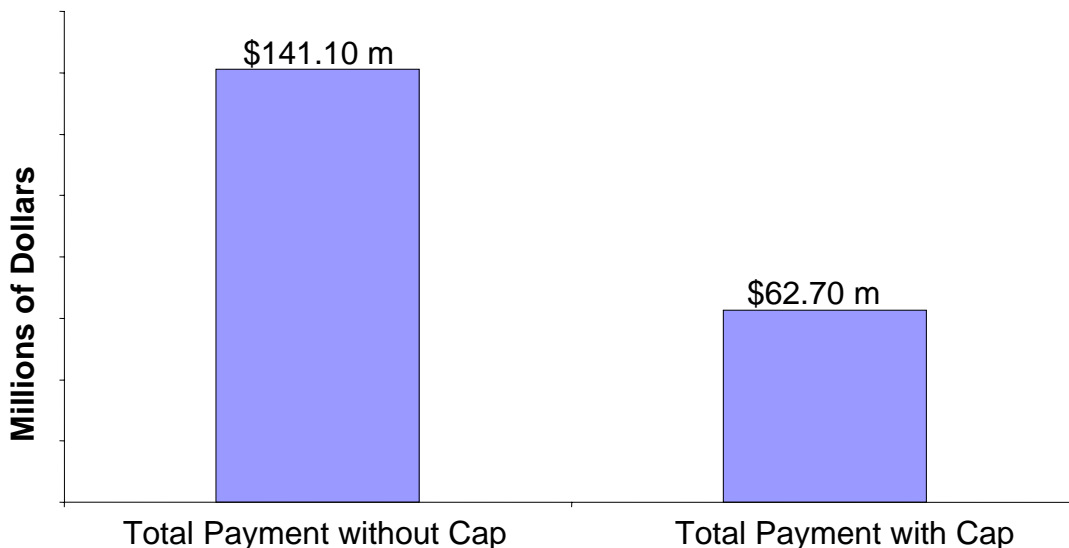
A third weakness of the capping policy is that it relies on site of service data that can be unreliable. The data CMS relies upon to make the determination of office-based status is questionable. Relying on Part B claims data when determining the frequency with which procedures are performed in various settings is not a sound approach. The OIG has documented significant error rates in place of service reporting – suggesting that using

these data to set payment caps could erroneously assign procedures to office-based status. Significant error rates (80% and higher in some cases) for selected services have been reported (OIG Report Numbers A-02-04-01010, A-05-04-00025, A-06-04-00046). Given the probability of significant flaws in the data CMS proposes to use to determine site of service, the criterion has questionable validity.

The OPPS median cost data is the best proxy for ASC costs. CMS uses the Medicare physician fee schedule to set the payment rate for almost 400 procedures on the ASC list. The figure below illustrates the substantial impact of the capping policy on total ASC payments. We recognize that CMS did not propose to change how office based procedures are paid, but urge the agency to consider several factors in future rulemaking. Addressing these issues will help ensure the integrity of the ASC relative weights over the life of the payment system.

Using CMS's assumptions, we estimate that ASCs would provide over \$60 million in CY 2008 in procedures capped at the nonfacility RVU rate. These procedures range in payment from \$3 to \$1,553. OPPS payments for the same set of procedures range from \$21 to \$2,865. The ASC payments are steeply discounted from the OPPS payment rates, resulting in a savings to the government of about \$80 million that is not captured in the recalibration.

Figure 7. Capping ASC payments at physician fee schedule rates substantially reduces total ASC payments



Note: We applied CMS's assumptions to estimate 2008 volume for all the procedures capped at the physician payment rates. The uncapped rate is equal to the OPPS weight by procedure by the 2008 ASC conversion factor. The capped rate is equal to the MPFS rate by procedure.

First, as we discussed in the section on relative weights, the 2006 GAO report on ASCs concluded that the median cost of most ASC services was strongly correlated to the median cost of HOPD services. In fact, GAO noted that 45 percent of all the procedures they reviewed fell within a 0.10 point range of the ASC-to-APC median cost ratio, and 33 percent of procedures fell within a 0.10 point range of the OPSS-to-APC median cost ratio. Given the absence of cost data from the ASC and physician office setting, GAO further concluded that the hospital data was the best source of relative weight information because it is updated annually.

Finally, CMS is deriving an ASC relative weight from the payment rates under the physician fee schedule. This means that the ASC weight for office-based procedures is subject to fluctuation in both the PE RVU value and the physician conversion factor. As we saw in the weeks leading up to the release of the proposed rates for CY 2009 payments, the ASC relative weight for office-based procedures could drop dramatically based solely on the Congress' response to the flawed SGR formula. This volatility in the ASC relative weight is inappropriate to the payment system and unnecessary given the availability of the OPSS median cost data and the agency's wide latitude in determining how the ASC payment system is structured.

We urge the agency to address the problems created by basing payment for many ASC services on the physician fee schedule in a future rulemaking. GAO demonstrated that the HOPD relative weights are the most appropriate proxy for the cost of ASC services, and the linkage to OPSS should be maintained for as many ASC services as possible. In the interim, CMS should not finalize the new designations of procedures as office-based.

If CMS's concerns about migration result in the continued application of the payment cap on office-based procedures, the agency should apply more flexibility to the determination of a procedure as office-based. First, the threshold should be set higher, as state-level variation suggests that a national number fails to represent many local practice patterns. Second, a procedure should not be designated as office-based *until* it has met the higher threshold level for multiple years and the designation should be revisited over time to determine whether practice patterns have changed. Lastly, CMS should seek to limit the number of services it designates as office-based in order to maintain the strongest linkage to the OPSS relative weights.

We urge CMS to reconsider applying the office-based payment cap to any of the procedures being proposed to be office-based for the first time in 2009 and carefully examine any new procedures created before the release of the final rule. In the Final Rule for 2008, CMS added the newly created CPT 68816, Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation to the ASC list with a temporary payment indicator of P3. The code previously used to identify this procedure, CPT code 68815 was not performed 50 percent or more of the time in the physician office setting based on 2006 claims data. In our experience, this procedure almost always requires general anesthesia. The resulting low rate is inadequate to cover

the cost of the balloon and other expenses incurred by the ASC. We believe that the payment indicator for this code should be changed to G2.

Another example is the newly created CPT code 21073, Manipulation of temporomandibular joint(s), therapeutic, requiring an anesthesia service (i.e., general or monitored anesthesia care), which was assigned a temporary payment indicator of P3. In this case, there is no existing claims data that would allow CMS to determine the service is performed in the physician office setting the majority of the time as it is not analogous to a previously existing code. As the procedure requires anesthesia services, we do not believe that physicians' offices will be the primary site of this service. In this case, we believe a payment indicator of G2 is appropriate.

J. Treatment of procedures with fixed costs for devices and implants

CMS generally pays for ASC procedures that have high, fixed costs for devices and implants using one of four payment methodologies indicated by payment indicator codes H8, J8, A2, and G2. We are concerned that payments using the agency's current methodology are often insufficient to encourage ASCs to provide services with significant fixed costs, mitigating the amount of migration from the hospital outpatient setting that can save beneficiaries and taxpayers significant dollars.

Device-dependent APCs should be treated as device-intensive in the ASC. In the OPPS, CMS 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. Each year, CMS collects data from hospitals on the costs of the implanted devices from the claims for services and calculates a median cost using claims that contained appropriate device codes, did not have token charges, and did not contain the modifier "FB" to identify a procedure was performed using an item provided without cost (or where a credit was received for a replaced device). The services are then grouped into APCs that are homogeneous with regard to clinical characteristics and resource use. 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 the HOPD.

Unfortunately, many of the procedures that CMS identifies as device-dependent are not likewise treated as device-intensive on the ASC list. In the table below, we show a sample of the services on the ASC list and the impact of CMS's various payment status indicators on the resulting payment differential between the ASC and HOPD. As a result of applying the conversion factor to the entire payment in the case of the A2 and G2 codes, payments are too low for these services to be viable in the ASC. For services identified as device dependent, but going through the transition, the resulting payment rate is also too low.

An example of a procedure the ASC community would view as device-dependent and device-intensive which is not classified as such under the CY 2009 proposals is CPT code

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69714, which describes the surgical placement of an auditory osseointegrated device (also known as a bone-anchored hearing aid, or BAHA). Currently, the BAHA device has pass-through status, and is separately billed using HCPCS code L8690. With the expiration of that status in 2009, the costs associated with L8690, which include all internal and external components of the device, are to be packaged into the payment for the surgical procedure. ASC costs for these components are \$5,565.00 (Cochlear Americas). The proposed CY OPSS reimbursement is \$7,919.42, of which slightly more than 70% would therefore be accounted for by the device itself.

Even worse, proposed CY 2009 ASC reimbursement of \$3,086.15 is inadequate to cover the device costs alone, and therefore does not come close to approximating the total cost of performing this surgery, which in turn eliminates the service as an option in the ASC setting.

Table 10. Payments for many ASC procedures fail to recognize device costs

APC	HCPCS Code/ APC	APC & HCPCS Short Descriptor	OPPS Payment Rate	ASC Payment Rate	ASC Payment Indicator	Ratio of ASC to OPPS payment
0083		Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty	\$ 3,170.43			
	35473	Repair arterial blockage		\$ 1,948.18	G2	0.61
	35476	Repair venous blockage		\$ 1,948.18	G2	0.61
	G0392	AV fistula or graft arterial		\$ 1,627.05	A2	0.51
	G0393	AV fistula or graft venous		\$ 1,627.05	A2	0.51
0040		Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve	\$ 4,231.11			
	63650	Implant neuroelectrodes		\$ 3,157.73	H8	0.75
	64555	Implant neuroelectrodes		\$ 3,512.75	J8	0.83
	64560	Implant neuroelectrodes		\$ 3,512.75	J8	0.83
	64561	Implant neuroelectrodes		\$ 3,188.94	H8	0.75
	64565	Implant neuroelectrodes		\$ 3,512.75	J8	0.83
0623		Level III Vascular Access Procedures	\$ 1,942.11			
	36260	Insertion of infusion pump		\$ 845.40	A2	0.44
	36560	Insert tunneled cv cath		\$ 845.40	A2	0.44
	36561	Insert tunneled cv cath		\$ 845.40	A2	0.44
	36563	Insert tunneled cv cath		\$ 845.40	A2	0.44
	36565	Insert tunneled cv cath		\$ 845.40	A2	0.44
	36566	Insert tunneled cv cath		\$ 845.40	A2	0.44
	36582	Replace tunneled cv cath		\$ 845.40	A2	0.44
	36583	Replace tunneled cv cath		\$ 845.40	A2	0.44
	36640	Insertion catheter, artery		\$ 759.09	A2	0.39
	37200	Transcatheter biopsy		\$ 1,193.39	G2	0.61
	37203	Transcatheter retrieval		\$ 1,193.39	G2	0.61
0202		Level VII Female Reproductive Procedures	\$ 2,865.67			
	57220	Revision of urethra		\$ 1,129.16	A2	0.39
	57265	Extensive repair of vagina		\$ 1,365.67	A2	0.48
	57288	Repair bladder defect		\$ 1,230.10	A2	0.43
	57556	Remove cervix, repair bowel		\$ 1,230.10	A2	0.43
	58356	Endometrial cryoablation		\$ 1,552.77	P3	0.54
	58565	Hysteroscopy, sterilization		\$ 1,533.42	A2	0.54
0115		Cannula/Access Device Procedures	\$ 2,005.59			
	35761	Exploration of artery/vein		\$ 1,232.40	G2	0.61
	36800	Insertion of cannula		\$ 864.90	A2	0.43
	36810	Insertion of cannula		\$ 864.90	A2	0.43
	36815	Insertion of cannula		\$ 864.90	A2	0.43
	36835	Artery to vein shunt		\$ 923.42	A2	0.46
	36861	Cannula declotting		\$ 864.90	A2	0.43
	49419	Insrt abdom cath for chemotx		\$ 778.59	A2	0.39

The placement of an APC on the device-dependent list in the OPPS means that a significant portion of the procedure cost is *not* influenced by factors such as the cost of labor. If an ASC-approved procedure appears on the device-dependent list under the OPPS, it should likewise be protected from the full application of the ASC conversion factor to account for the fixed cost of the device or implant.

Transitional policies for related services with fixed costs for devices and implants.

We appreciate that the transitional policies implemented by CMS are mitigating payment reductions for certain procedures with historical rates higher than the product of the OPPS relative weight multiplied by the ASC conversion factor. For services with significant device costs, ASCs simply cannot afford to perform the procedures during the transition in which no compensation for the device cost is made. For example, CPT code 26535 requires implantation of a prosthetic joint. The proposed CY 2009 reimbursement is \$1416.56. However, ASC costs for the device alone are \$1433, exclusive of shipping and handling (Ascension® PIP PyroCarbon Total Joint, Ascension Orthopedics). This procedure will not be economically feasible in the ASC setting until full transition in 2011. Without reimbursement that covers the costs of devices, these procedures will not move to the ASC and thus no savings will occur. Previous experience with these services in the ASC setting supports this contention.

Application of the wage index. The acquisition of devices and implants 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. CMS should not adjust the device or implant-related portion of the payment by the Medicare wage index. 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. In markets where the wage index is low, CMS is underpaying for the cost of the item; likewise, the agency is likely paying too much in markets where the wage index is above 1.0.

CMS has the data available to implement such a policy. For services with device costs, CMS requires the hospital outpatient setting to report the device cost on their claims. CMS uses claims with devices to calculate the APC median costs, and could also use them to determine what portion of the ASC payment should be excluded from wage index adjustment. For ASC services designated as device-intensive, CMS could apply the wage index to the same portion of the payment adjusted by the ASC conversion factor (e.g., those services with H8 and J8 payment indicators). This proposal is consistent with the agency's policy to adjust for labor-related differences only the portion of the payment related to the service provided by the ASC. For other services with device costs included in the calculation of the APC median cost, CMS could determine the amount of the payment attributable to the median device cost and apply the wage index to the remainder of the payment. CMS should not adjust the portion of the payment attributable to the device by the ASC conversion factor.

We recommend several adjustments to CMS's policies to improve the likelihood that these procedures will migrate from the HOPD to the lower cost ASC setting. First, CMS should not adjust the portion of the payment attributable to the device or implant by the wage index. This is consistent with the agency's policy for separately payable drugs and biologics. Second, CMS should treat as device-intensive all ASC services on the OPPTS list of device-dependent APCs. A similar process for procedures with high costs for implants like tissues should likewise be established. Further, CMS should move to the fully-implemented payment weight in CY 2009 for procedures that require implants. Finally, CMS should not apply the ASC conversion factor to the device-related portion of the payment for all procedures for which CMS can establish a median device cost.

V. APC panel representation

As the ASC payment system uses the same APC assignments as the OPPTS, the ASC industry should have input on the APC group and payment weights. We urge CMS to include a designated ASC representative on the Advisory Panel on Ambulatory Payment Classification Groups (the APC Panel). As recommended earlier in our comments, we believe CMS should concurrently review procedures proposed for removal from the OPPTS 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.

VI. Quality reporting

At the outset, we want to thank CMS for its ongoing communication with the ASC community to obtain guidance on appropriate quality measures, data collection processes and data reporting mechanisms for outpatient surgical procedures. Beneficiaries will benefit from quality data as they consult with their physicians to choose a site for surgical care. We urge CMS to proceed with the critical work of measuring and reporting quality of care in ASCs.

The ASC industry is committed to quality reporting efforts and believes beneficiaries should have access to national quality information. Since the industry's inception, ASCs have been benchmarking and collecting quality data to demonstrate the quality outpatient surgical care they provide. As a result of our commitment to the development of national facility-level ASC quality measures and national quality reporting efforts, the industry formed the ASC Quality Collaboration in 2006. Since that time, the ASC Quality Collaboration has developed and pushed forward five measures. These five measures have been endorsed by the NQF.

The ASC Coalition supports the five measures created by the ASC Quality Collaboration as they are quality measures that reflect processes or outcomes of care that are

attributable to the facility itself and for which the facility can reasonably be held accountable. In addition, the measures are applicable to all facilities offering ambulatory surgery, allowing consumers to compare quality among providers offering the same services. For many of the most common outpatient surgical services, Medicare beneficiaries have choices as to where to have that procedure. By having access to the same quality information across settings, beneficiaries will be able to make more informed decisions regarding their surgical care.

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. More specifics on these measures are included in the comments being submitted by the ASC Quality Collaboration.

As CMS moves forward with evaluating data collection and reporting, we reiterate our earlier concerns of the potential data collection burden. After careful evaluation of alternative data collection methods, and taking into account the characteristics and resources of the typical ASC, we find the administrative claims approach to be the most practical, feasible and economical solution for ASCs.

We look forward to consulting with CMS as the public reporting mechanism is developed to provide clear, fair, and comparable quality information. CMS should engage stakeholders as soon as possible in the design of the ASC quality reporting system. 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.

Given all parties' eagerness to move forward with the quality agenda, we urge CMS to proceed with the critical work of measuring and reporting quality of care in ASCs. We continue to believe Medicare beneficiaries need to have provider quality information to support their surgery choices – and the ASC industry is eager to make this information available sooner rather than later. We look forward to participating in CMS's program-wide efforts to provide consumers with information about the quality and effectiveness of care.

We reference the comments of the ASC Quality Collaboration to underscore our unified support for quality reporting and to expand on several technical issues in this area.

* * * * *

We appreciate the agency's consideration of our comments on behalf of the ASC community. Although these comments address a number of discrete issues, there is one message the Coalition wants to emphasize. The application of the secondary scaling of the relative weights in the ASC is the single greatest threat to the payment system in 2009 and beyond. We urge the agency to suspend application of this policy until the concerns discussed above can be addressed. Overall, we urge the agency to recognize the importance of maintaining an ASC payment system that is:

Fair. As we have discussed, ASCs operate much under the same conditions as hospital outpatient units. As a result, there is no reason that services should be subject to the application of different inflation updates or different wage index adjustment policies. CMS should use its broad authority to minimize discrepancies between the two payment systems.

Transparent. We recognize that CMS has crafted discrepancies between the ASC and HOPD payment systems for a variety of reasons; CMS should articulate clear, rational reasons to the industry if it chooses to leave those disparities in place.

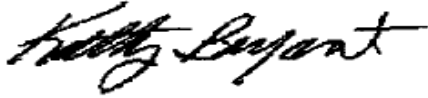
Viable. As proposed, the combined effect of the relative weight rescaling and the ASC conversion factor result in payments less than the aggregate dollars anticipated by the legislation. This is particularly problematic for more than 50% of the ASCs that are single-specialty providers unable to diversify the mix of their services. The policies implemented by CMS should establish reasonable payment rates and ensure that physicians and their patients can make decisions about the site of outpatient surgery exclusively on the basis of clinical appropriateness.

Patient-centered. Above all else, the changes that we have proposed are not only beneficial for ASCs and their patients, but are requested with the patients' best interests in mind. By improving ASCs' ability to operate efficiently and effectively on an administrative level, we can better assure access to the high quality care available to patients in ASCs.

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

Kerry N. Weems
August 26, 2008
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Sincerely,



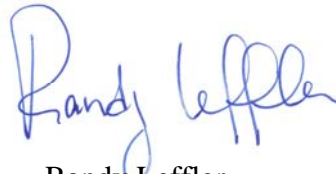
ASC Association
Kathy Bryant
President



Nueterra Healthcare
John Schario
Chief Executive Officer



AmSurg Corp.
Christopher A. Holden
President & Chief Executive Officer



Randy Leffler
Ohio Association of Ambulatory
Surgery Centers
Executive Director



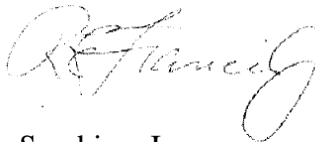
David Shapiro, M.D.
Florida Society of Ambulatory Surgery
Centers



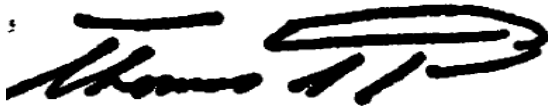
Surgical Care Affiliates
Andrew P. Hayek
President & Chief Executive Officer



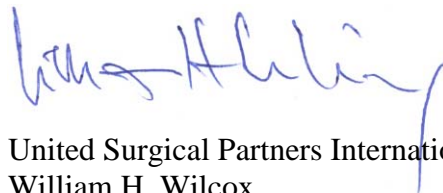
National Surgical Care
Richard D. Pence
President & Chief Operating Officer



Symbion, Inc.
Richard Francis
Chairman & Chief Executive Officer



NovaMed, Inc.
Thomas Hall
Chairman, President & Chief Executive
Officer



United Surgical Partners International
William H. Wilcox
President & Chief Executive Officer

APPENDIX A

**PREVIOUSLY PROPOSED ADJUSTMENTS TO CMS ALTERNATIVE
 BUDGET NEUTRALITY CALCULATION**

Proposed Adjustments to CMS Alternative Budget Neutrality Calculation		
Starting Point	62.90	CMS's Calculation (This includes migration of HOPD at 25% for new procedures and migration from physician offices at 15% for new procedures.)
Change 1	+0.11	To accurately reflect ASC payment rates for procedures capped at HOPD rate if no new payment system in 2008
Subtotal	=63.01	
Change 2	+ 0.41	To include in the 2007 device costs that were paid to ASCs in addition to facility fees.
Subtotal	=63.42	
Change 3	+ 3.11	Net savings of reducing movement from physician offices; CMS assumed 15%; Coalition reduced to 2%
Subtotal	=66.53	
Change 4	+ 0.43	Correction to exclude beneficiary copayments for procedures subject to the physician office limit
Subtotal	=66.96	
Change 5	+1.04	Adjust for variable co-insurance in hospital by using total payment rates or by applying 20% co-insurance discount to all 2007 services in formula.
Subtotal	=68.00	
Change 6	+ 5.57	Net savings of positive migration from HOPDs for procedure on the ASC list. Assume that for every 10% increase in reimbursement rate, 1.5% of HOPD volume moves subject to maximum of 25% of HOPD volume or 25% increase in ASC volume if more than 4,600 procedures are performed in ASCs annually.
Subtotal	=73.57	
Change 7	-0.51	Net cost for negative migration from ASC to HOPD. Assume that for every 10% decrease in ASC reimbursement, 1.5% of ASC volume moves from ASC to HOPD.
Total	=73.06	Final conversion percentage after seven changes made to original CMS alternative model