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November 6, 2006

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

Re: CMS-1506-P Medicare Program; XVIII Proposed Revised Ambulatory Surgical Center (ASC) Payment System for Implementation January 1, 2008

Dear Administrator Norwalk:

The American Society for Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rules revising payment and coverage policies for ambulatory surgical centers (ASC) for 2008.

The more than 9,000 members of ASGE specialize in the use of endoscopy to diagnose and treat gastrointestinal diseases and conditions. Many of ASGE's members provide these services in single and multi-specialty ASCs.

ASCs have been very successful in providing Medicare with a safe, less costly setting for surgical services compared to hospitals. As medical technology and surgical technique have improved, the number of ASCs has grown. In 2005 more than 4,500 ASCs were certified by Medicare. Gastroenterology is the largest surgical specialty in ASCs, representing 25 percent of all surgical cases performed in these facilities. Its proportion of Medicare volume is even higher, totaling approximately one third of all ASC cases paid for by Medicare. About 650 of all Medicare certified ASCs are single specialty GI endoscopy centers. For all ASCs, including endoscopy centers, Medicare represents 30 percent of total revenue. Therefore, the new payment system can have a significant impact on all ASCs, particularly on single specialty facilities.

The growth of ASCs has provided Medicare and program beneficiaries substantial and measurable cost savings. According to data from FASA, in 2004 Medicare saved $1.15 billion because services were performed in ASCs rather than in the hospital. Beneficiary coinsurance was reduced by over $200 million because their out of pocket costs are less in the ASC than in the hospital. Therefore, it is critical that CMS fully and carefully consider the impact of any proposed changes to the

ASC payment system in order not to jeopardize this valuable program and the cost savings that are provided.

Private health plans increasingly recognize the advantages of the ASC and frequently provide physicians incentives to move cases out of the hospital and into an ASC. We recognize that the statutory framework of the Medicare program offers does not provide CMS with the same flexibility available to private payers. However, within the Medicare structure, it is critical that CMS makes certain that the new ASC system continues to provide the appropriate incentives for ASCs to deliver cost effective surgical services to Medicare beneficiaries. As noted below, we are firmly convinced that the ability of ASC's to continue to provide GI endoscopy services will be severely jeopardized under the proposed rule.

There is no question that the current payment system for ASCs is out of date. The coverage rules reflect a standard of medical care that no longer exists and the relationship between the cost of services and payments is badly frayed. CMS has the opportunity to design a system that will encourage the appropriate migration of services out of the expensive hospital setting while assuring that services already performed in the ASC continue to be provided there.

The proposed rule, however, fails to rise to this opportunity.

IMPACT ON GI ENDOSCOPY

In 2004 ASGE sponsored a study of 70 ambulatory surgical centers, including 66 single specialty endoscopy centers, and determined that the average cost of a patient visit was $314.00 (2003 data) (Attachment A). Adjusted for inflation using the hospital outpatient prospective payment system (HOPPS) market basket, the cost of the same visit in 2008 would be $372.03. However, under the proposed rule, reimbursement for commonly performed GI procedures would fall well short of that amount by the time the transition period ends, with an average payment of $338.12.

A more recent study (2005 data) of 45 endoscopy centers (Endoscopy Intellimarker, VMG Health and InforMed Healthcare Media, 2006) found a mean cost per endoscopic procedure of $414.00. Adjusting for inflation, it is clear that the 2008 proposed rates would be below actual costs. A recently concluded analysis by the Lewin Group reached a similar conclusion (Attachment B).

The purpose of this latter study was to see how the actual costs would match up with the proposed CMS ASC payments at full implementation in 2009. According to this Lewin data, in 2007 Medicare ASC payment will be about 11% higher than actual costs for GI procedures, but in 2008 under the proposed rule, payments would drop at least 4% below actual costs. With full implementation in 2009, ASC rates for GI endoscopy would be at least 22% below actual costs.

All of these analyses examine only the actual costs of performing the procedure. There is no allowance for profit or return on investment.

While there is some variation in mean cost among these studies, ASGE believes that it is a function of the different samples used and the methods for calculating costs. In any event, all of the studies demonstrate the fundamental problem with the CMS proposed rule. The data from the ASGE study also show that smaller and newer ASCs have higher costs than larger, more mature facilities. Any error in calculating rates will impact those centers most heavily. These newer, smaller providers make up more than two thirds of the single specialty GI ASCs, so the impact on the delivery of these services will be especially severe. These rates are certain to discourage the construction of new single specialty

ASCs, which are essential to meet the demand for Medicare's colorectal cancer screening benefit, as well as the other GI needs of an ever increasing beneficiary population.

The result of sustained underpayment for all GI endoscopy in the ASC will be a significant shift of services out of the ASC, most likely into the HOPD. This will increase program costs, as well as costs to beneficiaries. For example, using 2004 Medicare data compiled by FASA, the total reimbursement for GI endoscopy in the ASC was $654 million. Using the assumption that only 25 percent of current GI endoscopy volume moved back to the OPD because of inadequate payment, we estimate that the added cost to the Medicare program would be in the $100 million range taking into account growth in volume of ASC services. ASGE considers a 25% reverse migration factor to be very conservative, given the magnitude of the reimbursement reductions that GI endoscopy would experience under the proposed rule.

CMS also makes no effort to take into account the different cost structures of multispecialty and single specialty centers. The multispecialty facility can cost shift and more readily add new services whose reimbursement rates might be more attractive. These are not options for most single specialty facilities. A GI endoscopy center is not equipped to begin to provide specialized ophthalmology or orthopedic surgical services, and the costs of converting existing space to another use can be significant. To add new procedure rooms, assuming that space was available, would cost between $750,000-$1 million per room. This is simply not feasible for many practices. Even if cost were not a factor, many states prohibit single specialty ASCs from adding services outside the specialty for which they have been licensed. Thus, the future of the single specialty facility is in serious jeopardy. At the same time, we see no possibility that large multi specialty centers will be interested in adding GI endoscopy services at the proposed rates. Even if they were willing to, there is no data to suggest that multispecialty facility can equal the efficiency and cost effectiveness of the single specialty GI endoscopy center.

The only appropriate response by the centers faced with inadequate Medicare rates is to schedule Medicare patients at the HOPD, effectively closing off the ASC alternative. Such a circumstance could be a great disservice to the program and beneficiaries. Not only will CMS and beneficiaries pay more for the same services, but the waiting time for services will likely increase because few hospitals could quickly absorb the volume of procedures that would migrate to them. In this connection, we would anticipate an adverse effect on the availability of colorectal cancer screening which we know is of concern to CMS and the Congress.

LINKAGE BETWEEN HOPD AND ASC COSTS/RATES

ASGE has a fundamental concern with using a single proportion of the HOPPS payment rate as a measure of the costs of providing ASC services and does not think that CMS has developed adequate data to validate this assumption. Most hospitals provide a much wider range of surgical services than a typical ASC and can afford to have a mix of winning and losing services as long as the overall costs are adequately covered. By comparison, the limited service array in multi specialty and single specialty ASCs makes it extremely difficult to offset losses in high volume procedures with gains in other services, which may not have equivalent volume. As noted, the single specialty facility is particularly vulnerable to payment reductions in core services.

The HOPPS APC weights are largely based on median charges converted to costs and are based on all hospital outpatient services, not just surgical services. Before making the presumption that APC payments are an appropriate standard for determining both absolute and relative ASC cost weights, we think additional analyses of relative hospital and ASC costs are needed. As far as we know, none of

these analyses have been undertaken. Prior to making sweeping changes in ASC payment based only on a single budget neutrality calculation, we think it incumbent on CMS to have firm data on the differences between hospital and ASC costs and the magnitude of these differences. ASGE accepts the fact that hospitals operating 7 days a week, 24 hours a day, have somewhat higher overhead than a freestanding ASC. However, the direct costs for providing an endoscopy service including clinical labor, equipment, and supplies as well as the costs of setting up an endoscopy suite should be similar if not identical in both settings. Thus, for GI endoscopy services, we are convinced that whatever the cost differential is between hospitals and ASCs, it is substantially less than 38 percent of the HOPPS rate.

A recent study conducted by RAND for the Medicare Payment Advisory Commission (MedPAC) further strengthens this argument. This study looked at whether or not certain settings were more likely to have patients with characteristics that might drive up costs. It also looked at relative quality in these settings, based on risk adjusted rates of adverse outcomes following the procedures. Colonoscopy, a common ASC procedure, was one of the services examined in the study. RAND found little difference in quality between ASCs and HOPDs, with minimal numbers of adverse events in both settings. RAND also did not find that any single setting had consistently higher rates of those patient characteristics that would be expected to increase costs. This strongly suggests that the cost per procedure in ASC and HOPD are very similar and does not justify a significant differential in payment in one setting versus another.

ASGE believes that the evidence does not support a large difference in payment between the HOPD and the ASC for the same service.

BUDGET NEUTRALITY

The fundamental flaw in the proposed rule is the calculation of budget neutrality. We understand that CMS is bound by the statutory restriction; however, we believe that the calculation (simply a rate comparison) is too simplistic. The alternative calculation, measuring reasonable assumptions of migration, is a more appropriate standard, although the specific way that CMS conducted it needs to be reconsidered.

CMS limited its analysis to the migration of new procedures, but migration of underrepresented services already on the ASC list is very likely if the rate structure is adequate and should be considered in the calculation. For example, CMS could look at procedures for which the payment in the ASC would increase by at least 10% over current levels and add them to the list of services that will experience the estimated 25% migration to the ASC. The measure of migration should be the total universe of covered procedures not a small percentage of the services.

At least two independent analyses have examined CMS's calculations of the alternative budget neutrality methodology and determined that there are errors in the way the agency conducted them. These studies have suggested that simply correcting the calculation errors could reach a budget neutrality figure between 71% and 73% of the HOPD rate. These analyses are continuing in order to refine the conclusions and explore the migration issues more thoroughly. Once complete, the full information can be provided to the agency. However, the fact that this initial review led to an increase from 62% to more than 70% strongly suggests that CMS needs to revisit its alternative budget neutrality calculation and further refine the effort. An even higher budget neutrality number is the likely result of more thorough research and analysis. Making this effort is well worth the effort it would take. Only that way, we believe, will the agency be able to establish reasonable rates for ASC services while staying within the current statutory guidance.

If the goal of the new payment system is to encourage the migration of services out of the expensive hospital setting into the ASC, while not creating reverse migration of the services (gastroenterology, pain management and ophthalmology) that currently make up the bulk of Medicare payments to the ASC, then CMS will have to undertake a much more thorough review of the impact of migration than it has previously done. The simple rate comparison that leads to budget neutrality only when the ASC rate is set at 62% of HOPD will not lead to a sound policy.

ASGE believes that CMS also needs to consider the erosion of the ASC pool of dollars that has occurred since 2003, with the freeze in the update and the cap on payments at the APC level. HOPD rates have increased every year, creating an ever growing disparity between the two settings. If CMS wants to maintain a truly viable ASC sector, the budget neutrality calculation must take this problem into account.

UPDATE

CMS has discretion to select any method for updating the ASC rates. The use of CPI is a default measure and does not prevent the agency from adopting another method. ASGE recommends that CMS use the market basket that is used for the HOPPS. As previously noted, there is great similarity in costs and the market basket better reflects cost increases in medical settings than does the CPI. Use of the same update factor also assures that the relationships between HOPD and ASC rates remain more constant. Since CPI traditionally is less than the market basket, continued use of CPI to update the ASC rates will only increase the discrepancies between the two systems. This defeats the goal of trying to align the economic incentives across all sites of service.

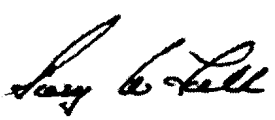
TRANSITION

CMS proposes a very limited transition, essentially one year of mixed rates in 2008 with adoption of the new rates in 2009. No matter how CMS handles other issues in the proposed rule, ASGE recommends that a four-year transition be adopted. This has been standard practice in other substantial payment changes and the scope of changes considered for the ASC demands nothing less. The law of unintended consequences is always at work and a longer transition will give CMS and the ASC community the time to determine if mid course corrections are warranted before significant harm can occur.
The goal should be to have a successful transition to a new payment system, not necessarily a fast one, which would leave no time for any adjustments or Congressional action that might be required.

ASGE appreciates the opportunity to provide these comments and looks forward to working with the agency to implement a successful new payment and coverage system for ASCs.

Please direct any inquiries to ASGE's Washington Representative, Randy Fenninger (202-833-0007).

Sincerely,



Gary W. Falk, MD, FASGE
President

Attachment A-1

ASC Cost Survey

Name

Address

Volume of endoscopy procedures in 2003 _____

Expenses in 2003—see definitions attached

1- Clinical staff costs _____

2- Administrative and management staff costs _____

3- Clinical equipment _____

4- Clinical supplies _____

5- All other expenses _____

6- Total (should equal sum of lines 1-5) _____

Explanation of Cost Elements

Item 1—Include salaries and fringe benefits paid to clinical personnel including nurses and technicians. Fringe benefits include employment taxes, health insurance, pension and 401 contributions, etc. paid by employer. Exclude any salaries paid to employee physicians which are billed for as professional fees.

Item 2—Include salaries and fringe benefits paid to administrative and management personnel including billing staff, secretaries, receptionists, administrators, cleaning staff, etc. If any of these services are contacted out to, for example, a billing service, include the fees paid in lieu of a salary amount. If the physician owner is compensated for administrative/management services as opposed to a distribution of profits, such costs should be included here.

Item 3—Include the allowable depreciation on all clinical equipment such as endoscopes, imaging equipment, examination tables, etc. If some equipment is leased instead of purchased, include the lease payments in lieu of depreciation.

Item 4—Include the amount paid for disposable clinical supplies such as catheters, saline, gauze, needles, gowns, etc.

Item 5- All other expenses including depreciation or lease payments for facility and office equipment, interest, insurance, office supplies, accounting and legal expenses, property taxes, utilities, etc. Essentially include any expense not included in 1-4 above. However, insurance write-offs or bad debts should not be included as an expense.

A-2.

MARC Associates
AEC Survey

Summary of Response Data

Certification and GI Endoscopy

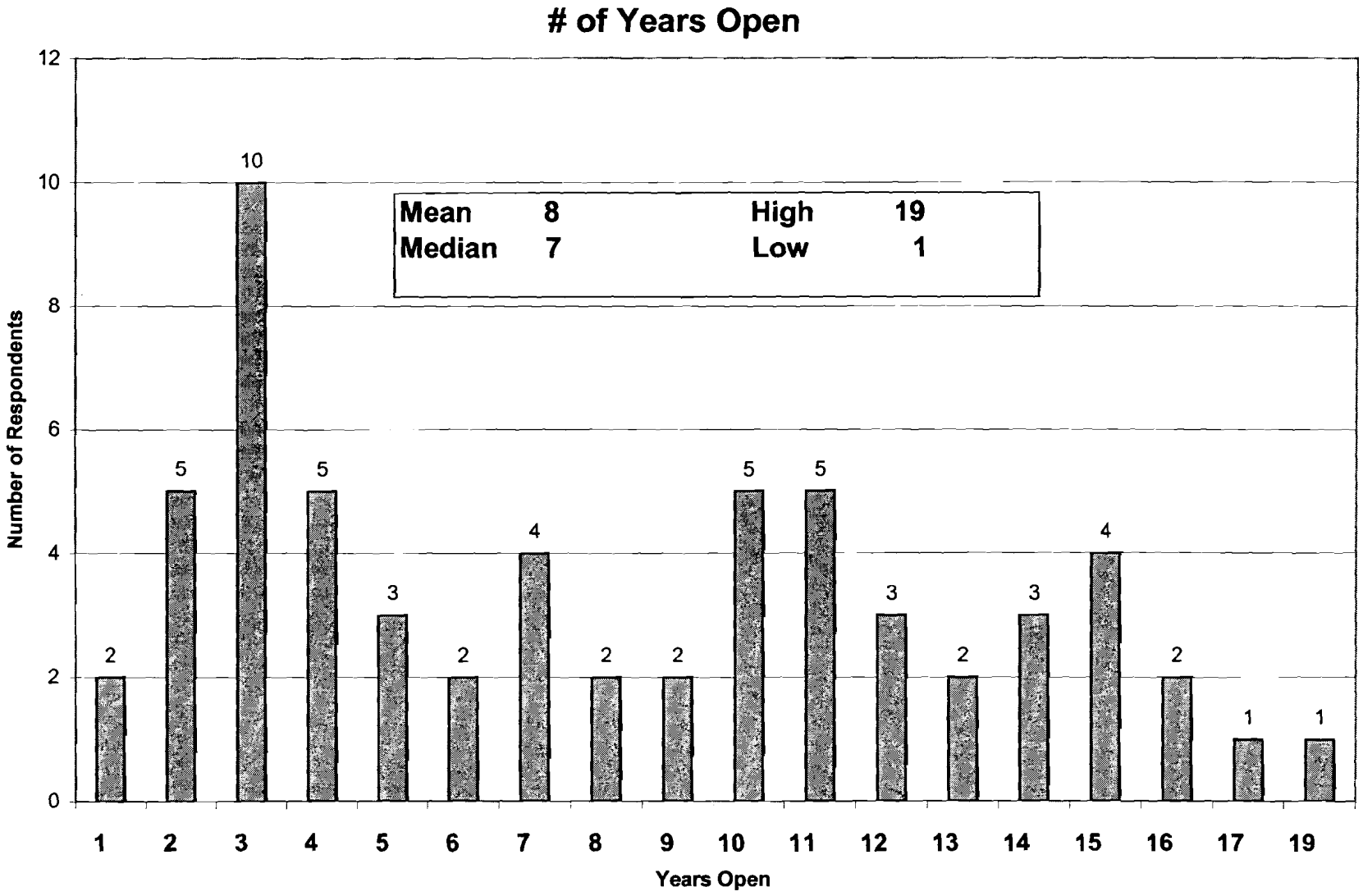
Number certified

Q1 Response		%
N	2	2.8%
Y	70	97.2%
	72	100.0%

Number perform only GI endoscopy

Q2 Response		%
N	7	9.6%
Y	66	90.4%
	73	100.0%

Years Open


# of Years Open
Mean 8
Median 7
High 19
Low 1
Number of Respondents
0
2
4
6
8
10
12
2
5
10
5
3
2
4
2
2
5
5
3
2
3
4
2
1
1
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 19
Years Open

Procedure Rooms

# of Rooms	Respondents	%
0	2	3.2%
1	8	12.7%
2	24	38.1%
3	16	25.4%
4	9	14.3%
5	-	0.0%
> 5	4	6.3%
	63	100.0%

Total Patient Visits

Low	High	Number	%
-	500	1	1.6%
501	2000	4	6.3%
2,001	3000	9	14.3%
3,001	5000	18	28.6%
5,001	7000	16	25.4%
7,001	8000	5	7.9%
>8,000		5	7.9%
		58	92.1%

Median	**4,731**
Mean	**5,145**

High	**11,540**
Low	**501**

Patient Visits / Medicare

% of Patient Visits are Traditional Medicare

Low	High	Number	%
0	20	8	13.3%
20	40	35	58.3%
40	60	12	20.0%
60	80	5	8.3%
80	100	-	0.0%
Average	**31.5%**	**60**	

Median	**1,542**
Mean	**1,741**

High	**3,940**
Low	**120**

Patient Visits / Medicare HMO

% of Patient Visits are Medicare HMO

Low	High	Number	%
None		31	53.4%
0	1	7	12.1%
1	5	3	5.2%
5	10	8	13.8%
10	20	5	8.6%
> 20		4	6.9%
Average	3.7%	58	

Median	**347**
Mean	**803**

High	**1,014**
Low	**7**

Total Procedures and Mix

	Total # of Procedures
High	12,880
Low	501
Median	5,424
Mean	5,339

EGD Services	Mean
EGD Mcare	533
EGD HMO	67
EGD Comm	887
EGD Mcaid	84
Total EGD Services	1,571

Colon Services	Mean
Colon Mcare	1,157
Colon HMO	172
Colon Comm	2,074
Colon Mcaid	102
Total Colon Services	3,505

Other Services	Mean
Other Mcare	129
Other HMO	7
Other Comm	121
Other Mcaid	20
Total Other Services	277

Expenses Analyses

	Expenses - Staff Costs	Expenses - Admin Costs	Expenses - Equip Costs	Expenses - Supplies Costs	Expenses - Other Costs	Expenses - Total Expenses
Total All	33,564,799	13,680,145	9,656,567	12,557,182	21,817,383	90,725,459
High	1,335,797	840,638	1,298,821	724,644	1,978,489	4,715,251
Low	84,959	2,251	18,793	20,620	29,061	204,577
Median	525,000	221,927	139,603	178,664	289,000	1,450,330
Mean	568,895	235,865	163,671	212,834	369,786	1,537,720
% of Total Expense Mean	37.0%	15.3%	10.6%	13.8%	24.0%	100.0%

	Expenses Per Visit
High[1]	623
Low	123
Median	309
Mean	314

Note 1 : Excluded one outlier $2,590 expenses per visit.

Expense Analyses (Cont'd)

		Years Open		
	Expenses Per Visit	10 or more	4-10 years	Less than 4
High	623	366	437	623
Low	123	123	204	179
Median	309	252	316	375
Mean	314	268	329	369

Expenses Per Procedure	
High	799
Low	112
Median	273
Mean	296

Expense Analyses (Cont'd)

Total Expenses by Size

Rooms	N	High	Low	Median	Mean
1 - 2	29	2,993,575	204,577	953,610	1,112,220
2 -3	17	2,821,703	749,839	1,483,085	1,587,263
4	9	2,998,748	1,672,281	1,927,987	2,057,284
6	3	3,392,602	2,100,000	2,100,000	2,530,867
7	1	4,715,251	4,715,251	4,715,251	4,715,251
All	59	4,715,251	204,577	1,450,330	1,537,720

Average Expenses by Size (Per Visit)

Rooms	N	High	Low	Median	Mean
1 - 2	29	464	123	316	316
2 -3	17	529	199	293	306
4	9	437	231	273	296
6	3	448	207	207	287
7	1	623	623	623	623
All	59	623	123	309	314

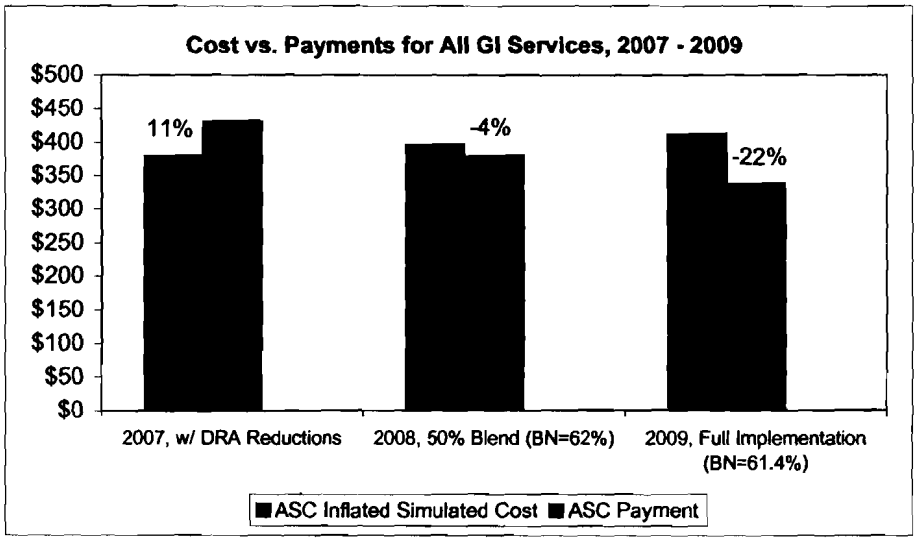
# of Visits by Size

Rooms	N	High	Low	Median	Mean
1 - 2	29	11,540	501	3,596	3,650
2 -3	17	7,711	2,267	5,705	5,520
4	9	9,083	4,793	6,861	6,988
6	3	10,143	7,568	10,143	9,285
7	1	7,573	7,573	7,573	7,573
All	59	11,540	501	4,731	5,145

Migration and Cost Analysis at 65% Budget Neutrality:
CMS Presentation

Attachment B

	ASC Inflated Simulated Cost	ASC Payment	Margin
2007, w/ DRA Reductions	$380.89	$430.20	11%
2008, 50% Blend (BN=62%)	$396.13	$379.30	-4%
2009, Full Implementation (BN=61.4%)	$411.98	$338.12	-22%



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CI8

November 6, 2006

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

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

Dear Ms. Norwalk:

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

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

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

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

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

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

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

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

Sincerely,

Rick Pollack
Executive Vice President

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

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

ASC PAYABLE PROCEDURES

Proposed Payable Procedures

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 1

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

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

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

ASC RATE-SETTING AND CONVERSION FACTOR

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

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

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

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

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

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

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

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

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

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[1] Fleisher LA, *et al.* "Inpatient Hospital Admission and Death after Outpatient Surgery in Elderly Patients: Important of Patient and System Characteristics and Location of Care." *Arch. Surg.* 2004;139:67-72.
[2] Fleisher LA, *et al.* "A Novel Index of Elevated Risk of Inpatient Hospital Admission Immediately Following Outpatient Surgery." Manuscript submitted for publication.
[3] DHHS, Office of Inspector General. *Quality Oversight of Ambulatory Surgical Centers.* February 2002.
[4] Seeley RR, Stephens TD, and Tate P. *Essentials of Anatomy & Physiology, 6th Edition.* McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.
[5] Seeley RR, Stephens TD, and Tate P. *Essentials of Anatomy & Physiology, 6th Edition.* McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.
[6] American College of Surgeons' *Advanced Trauma Life Support* (ATLS).
[7] Akopian G and Katz SG. "Peripheral Angioplasty with Same-day Discharge in Patients with Intermittent Claudication." *J Vasc Surg.* 2006;44:115-8.
[8] Young N, *et al.* "Complications with Outpatient Angiography and Interventional Procedures. *Cardiovasc Intervent Radiol.*" 2002; 25:123-126.
[9] Waugh JR, Sacharias N. "Arteriographic Complications in the DSA Era." *Radiology.* 1992; 182:243-246.
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[11] Gray BH, *et al.* "Complex Endovascular Treatment for Critical Limb Ischemia in Poor Surgical Candidates: A Pilot Study." *J Endovasc Ther.* 2002; 9:599-604.
[12] Fleisher LA, *et al.* "Inpatient Hospital Admission and Death after Outpatient Surgery in Elderly Patients: Important of Patient and System Characteristics and Location of Care." *Arch. Surg.* 2004;139:67-72.
[13] Ibid.
[14] http://www.nlm.nih.gov/medlineplus/ency/article/003102.htm. Note, however, that different authorities utilize different levels or ranges for defining morbid obesity.
[15] Starnes BW, *et al.* "Totally Percutaneous Aortic Aneurysm Repair: Experience and Prudence." *J Vasc Surg.* 2006; 43:270-6.
[16] http://www.asahq.org/clinical/physicalstatus.htm.
[17] Kruse JR, Cragg AH. "Safety of Short Stay Observations after Peripheral Vascular Intervention." *J Vasc Interv Radiol.* 2000; 11:45-49.
[18] Fleisher LA, *et al.* "Inpatient Hospital Admission and Death after Outpatient Surgery in Elderly Patients: Important of Patient and System Characteristics and Location of Care." *Arch. Surg.* 2004;139:67-72.
[19] Fleisher LA, *et al.* "A Novel Index of Elevated Risk of Inpatient Hospital Admission Immediately Following Outpatient Surgery." Manuscript submitted for publication.
[20] MedPAC Report to the Congress: Medicare Payment Policy, March 2004.

Boston Scientific

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November 6, 2006

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Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Washington, DC 20201

RE: Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Update to the Ambulatory Surgical Center Covered Procedures List

Dear Ms. Norwalk:

Boston Scientific Corporation (Boston Scientific) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed changes to the 2008 Ambulatory Surgery Center (ASC) payment system described in: Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year (CY) 2007 Payment Rates (CMS-1506-P, Federal Register, Vol. 71, No. 163, August 23, 2006).

As the world's largest company dedicated to developing, manufacturing, and marketing of less-invasive therapies, Boston Scientific supplies medical devices and technologies to the following medical specialty areas:

- Cardiac Rhythm Management;
- Cardiovascular;
- Endosurgery; and
- Neuromodulation.

Executive Summary

Boston Scientific appreciates CMS' efforts to reform the ASC payment system. Completely revamping the payment system to base it on hospital outpatient payment rates and greatly expanding the list of procedures eligible for payment is an important milestone in the Medicare program, one which will have far-reaching consequences for the care provided to Medicare patients.

With the proposed expansion of the Medicare Covered Procedure List in 2008, even more intensive procedures could be allowed in ASCs. The procedures that CMS proposed to allow in ASCs in 2008 generally have excellent safety profiles when performed in hospitals. However, all procedures have some inherent risk of complications. The critical issue that must be addressed as CMS reforms the ASC payment system is whether or not the possible complications associated with these newly proposed ASC procedures can be appropriately and adequately managed in the ASC setting. We applaud the

commitment to patient safety that CMS demonstrated in its decisions regarding changes in covered ASC procedures for 2007.

We urge CMS to continue to demonstrate its commitment to patient safety by thoroughly vetting procedures based on patient safety to ensure that only appropriate procedures are furnished in the ASC setting. We believe that patients and physicians should have the flexibility to determine the appropriate site of care. However, we also believe that CMS should adopt a deliberative and cautious approach at the outset of this system to ensure the highest standards of quality care for Medicare patients.

Boston Scientific's comments focus on the following key areas:

I. Refining clinical definitions and expanding exclusion criteria
II. Establishing consistent patient safety standards
III. Implementing quality reporting measures on processes & ASC clinical outcomes; and
IV. Recommended changes to ASC payment methodology.

I. Refining Clinical Definitions and Expanding Exclusion Criteria

Refining Clinical Definitions
In its March, 2004 Report to Congress, MedPAC stated that if Medicare moves from an inclusive to an exclusionary "list" of procedures, "[t]he burden would be on CMS to demonstrate that the ASC is an inappropriate setting for a given surgical procedure," and that "if CMS does not keep this list up to date, ASCs could begin performing services that are unsafe in that setting."[1] For these reasons, at this important transition point in the ASC payment system it is critical to carefully and fully refine each exclusion criteria to avoid confusion, make compliance easier, and ensure that procedures are not either inappropriately added to or excluded from the ASC Covered Procedures List.

In its proposed rule, CMS offers a series of exclusion criteria to be applied to surgical procedures. The AMA defines surgical procedures as any procedure described within the range of CPT Category I codes between 10000-69999. While we do not recommend expanding that definition outside this range, we agree that there may be certain HCPCS "G" codes (e.g., G0104 and G0105, screening colonoscopies) that may be appropriately performed in the ASC setting that describe procedures that would otherwise reside in the 10000-69999 code range. **Boston Scientific supports the CMS proposal to keep the current definition of a surgical procedure outlined by the AMA and currently recognized by CMS.**

We agree in principle with many of the exclusion criteria. However, we have specific suggestions for refining and strengthening certain definitions as well as recommendations for additional exclusion criteria that should be implemented to ensure patient safety and high quality care. The following are listed in order of importance:

a) **Refine Major Blood Vessel Definition**-

We urge CMS to adopt a modified version of the definition of major blood vessels provided by Seeley, Stephens and Tate in their medical textbook, Essentials of Anatomy & Physiology, 6th

[1] Medicare Payment Advisory Commission (MedPAC). Report to the Congress: Medicare Payment Policy. March, 2004, page 199.

Edition[2], which is used in many medical schools throughout the United States and abroad, as its standard for determining whether a procedure should be added to the ASC list.

To develop a suggested definition of "Major Blood Vessel," Boston Scientific conducted research in peer-reviewed literature to determine whether a standard definition exists. The most widely accepted list of major blood vessels found in our research is provided by the Seeley text. This list includes not only the heart and the aorta, but also vessels providing primary blood supply to major limbs and organs including the legs and the kidneys.[3]

Boston Scientific recognizes that some of the vessels described as major blood vessels by Seeley, *et al.* are already intervened upon in the ASC setting. To avoid major changes to the existing approved procedures list, CMS could, for example, modify the Seeley, Stephens, and Tate definition by allowing exceptions for those procedures are already being performed in the ASC. By adopting a modified version of the Seeley definition, CMS will not affect any of the procedures currently covered in the ASC, but will take an important step towards insuring the safety and wellbeing of Medicare beneficiaries as the list is expanded. Please refer to Appendix A for more detail on our proposed modified version of the Seeley, *et al.* definition of "Major Blood Vessel."

b) **Expand the "Prolonged Invasion of Major Body Cavity Definition" to Include Major Blood Vessels and Keep Current Time Thresholds**

We recommend that CMS maintain the 90-minute and 4-hour thresholds for excluding procedures from ASCs, and that CMS expand the "major body cavity" criteria to include major blood vessels in keeping with the definition proposed earlier.

CMS has proposed eliminating the criteria stating that procedures involving 90 minutes or more of operative time or 4 hours or more of recovery time should be excluded from ASCs. However, CMS has not provided any clinical evidence supporting the elimination of these time requirements, nor has the Agency proposed a more detailed definition of "prolonged" invasion. Therefore, until CMS offers a more appropriate definition of "prolonged" supported by clinical data or until the Agency can provide data to support elimination of this criterion, we ask that CMS maintain the 90-minute and 4-hour thresholds. Moreover, because prolonged invasion of major blood vessels can also lead to increased clinical risk, Boston Scientific asks that the definition of "Major Body Cavity" be expanded to include major blood vessels.

c) **Refine Extensive Blood Loss Definition- Boston Scientific proposes that CMS adopt the American College of Surgeons' definition of extensive blood loss. (The loss of ≥15% of total blood volume during the routine performance of the procedure, excluding any peri-procedural complications).[4]**

The loss of <15% of total blood volume typically results in no change in vital signs, and fluid resuscitation is not usually necessary. Boston Scientific assumes that few, if any, of the procedures currently allowed or proposed to be allowed in ASCs will involve extensive blood loss. We suggest

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[2] Seeley RR, Stephens TD, and Tate P. Essentials of Anatomy & Physiology, 6th Edition. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.
[3] *Ibid.*
[4] American College of Surgeons' Advanced Trauma Life Support (ATLS) as defined at http://en.wikipedia.org/wiki/Hemorrhage .

that CMS work with relevant medical specialty societies when there is a question of the amount of blood loss associated with a procedure being considered for the ASC.

d) **Adopt and Implement a Femoral Access Exclusion**

CMS should exclude procedures requiring femoral access from ASCs. As CMS expands its ASC coverage list, some additional procedures are likely to be more intensive and more risky to patients. Therefore, strengthening the exclusionary criteria is critical to ensure the continued safety of Medicare beneficiaries. The first such exclusion proposed by Boston Scientific is procedures involving femoral access.

These procedures, while generally extremely safe, can be associated with significant complications such as bleeding at the puncture site, even when performed in hospital settings. For example, one review of complications associated with lower extremity endovascular revascularization (LER), which is conducted via femoral access, found that approximately 7.3% of LER associated with procedure-related bleeding complications.[5]

When complications that require hospital-based management arise in a physician office or ASC setting, patients must be transported to a hospital for further management while maintaining open femoral access. While ASCs certified as Medicare providers are required to have transfer agreements in place, the transfers themselves significantly increase the risk of infection, perforation, and hemorrhage. Therefore, procedures requiring femoral access should be excluded from ASCs.

e) **Adopt a Lytic Therapy Exclusion**

Procedures that may require lytic therapy should be excluded from ASCs.

When physicians perform peripheral vascular procedures, in particular, they often do not know the nature of the lesion or blockage before they begin the procedure. Lesions that appear to be stenoses on ultrasound can actually be total occlusions when viewed using angiography. Moreover, in the process of peripheral interventions, it is possible to dislodge plaque or blood clots resulting in total occlusions. In one study of 181 lesions in 166 vessels, 55% of lesions were either occluded or stenosed and occluded.[6]

Regardless of the type of occlusion, lytic therapy is often required to break up or "soften" the occlusion so that the intervention can be performed successfully at an acceptable level of risk. Lytic therapy is administered on an inpatient basis via catheter at the site of the occlusion for 24-48 hours prior to the intervention. Therefore, if a physician undertakes a peripheral vascular procedure such as peripheral angioplasty or stenting in an ASC and then discovers or causes an occlusion, the patient must be transferred to a hospital for lytic therapy while maintaining open femoral access. The same risk of infection, perforation and hemorrhage described for the femoral access exclusion necessitates that when a procedure may result in the need for lytic therapy, it should be excluded from ASCs and from physician offices.

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[5] Nowygrod R, *et al.* Trends, complications, and mortality in peripheral vascular surgery. *J Vasc Surg.* 2006;43:205-61.

[6] Akopian G and Katz SG. Peripheral angioplasty with same-day discharge in patients with intermittent claudication. *J Vasc Surg.* 2006;44:115-8.

f) **Adopt Patient-Specific Exclusion Criteria Based on Obesity, Comorbidities**

CMS should exclude patients with morbid obesity or other specific comorbidities from ASCs.

In addition to the procedure-related exclusion criteria either already in place or recommended for ASCs, Boston Scientific believes it is appropriate for CMS to implement some patient-specific exclusion criteria. Specifically, patients who are diagnosed as morbidly obese or who have the following comorbidities that place them at higher risk for peri-procedural complications should not have procedures in ASCs:

- Poorly controlled diabetes;
- Uncontrolled hypertension;
- Significant renal insufficiency;
- Cardio-pulmonary failure; and
- Coagulopathy.[7,8]

Boston Scientific recognizes that, unlike the procedure-specific exclusion criteria, it may be more difficult to define and apply these co-morbidity exclusions from ASCs. However, Medicare has set a precedent for excluding patients with specific comorbidites from access to certain procedures with its National Coverage Determinations (NCDs) for Carotid Artery Stenting (CAS) and Lung Volume Reduction Surgery (LVRS). Medicare can work with appropriate physician specialty societies or patient advocacy groups and consult peer-reviewed literature to establish the appropriate co-morbidity exclusions.

The exclusion criteria can be enforced through the audit process, just as it is for CAS and LVRS. While it is highly likely that physicians already consider these comorbidities when deciding on site of service for their patients, codifying these patient-specific exclusions as part of the ASC final rule will result in a more consistently appropriate site of service selection for Medicare beneficiaries.

g) **Strengthen the Inpatient Exclusion by Changing it to a 50% Inpatient Exclusion**

CMS should lower its threshold for excluding procedures from the ASC to exclude any procedure that is done 50% or more in the inpatient setting.

CMS proposed to exclude any CPT code that has 80% or greater inpatient utilization from ASC payment, using 2005 BESS data. We support CMS' concept of applying a percentage of inpatient utilization as a threshold for ASC payment exclusion. However, we urge CMS to lower that threshold to any procedure that is done 50% or more in the inpatient setting. This would ensure that procedures done the majority of time (>50%) in the inpatient setting would be excluded from ASC payment.

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[7] Kruse JR, Cragg AH. Safety of short stay observations after peripheral vascular intervention. J Vasc Interv Radiol. 2000; 11:45-49.

[8] Starnes BW, *et al.* Totally percutaneous aortic aneurysm repair: Experience and prudence. *J Vasc Surg.* 2006; 43:270-6.

h) **Maintain Time-based Exclusions**

As previously described, we believe that the current standards of 90 minutes of operating or anesthesia time or 4 hours of recovery time should be maintained and would recommend no change to this criterion.

i) **Link the Overnight Stay Exclusion to the Inpatient Percentage Exclusion–**

Because of variations in the way "overnight stay" is defined, CMS should defer to the inpatient percentage (revised to be 50% or more) for exclusion from payment in an ASC setting.

We agree in principle with applying an overnight stay as a criterion for exclusion from payment but have concerns about the amount of data available that measures this variable. Due to variations in the way "overnight stay" is defined, CMS should defer to the inpatient percentage (revised to be 50% or more) for exclusion from payment in an ASC setting. Using this as exclusion criterion should, in theory, encompass CPT codes on the "overnight" list.

Procedural Complications and Additional Procedure Exclusions

As noted above, the procedures that CMS proposed to allow in ASCs in 2008 generally have excellent safety profiles when performed in hospitals. However, all procedures have some inherent risk of complications, and while these complications are low in frequency, the ability of these procedures to be adequately handled in an ASC needs to be carefully considered.

One of the primary examples of the increased intensity and risk associated with newly proposed additions to the ASC list are peripheral vascular interventions. Clearly, these procedures are generally extremely safe when performed by skilled operators in appropriate sites of care. However, despite their excellent overall safety profile, peripheral vascular procedures are associated with some risk of adverse events. Therefore, CMS should not allow procedures in ASCs which have complications that cannot be adequately addressed without transfer to a hospital.

In our review of the literature on peripheral vascular procedures, for example, we found that, while infrequent, there can be complications associated with the peripheral vascular procedures proposed for addition to the ASC list (CPT codes 35473, 35474, 35476, and 35492) (including infection, dissection, amputation and even death. These complications, which primarily stem from the need for femoral puncture to gain access to the target vessel(s), are usually relatively easily managed in hospitals. If such complications arise in a physician office or ASC setting, the patient would be required to be transported to a hospital for further management while maintaining open femoral access. Maintaining an open femoral puncture during transport raises the risk of dissection, hemorrhage and infection.

In a recent study of 112 interventions in 97 patients, 9 (8%) outpatient procedures resulted in admission, including one patient with a major puncture site hematoma requiring blood transfusion and two patients with minor hematomas at the puncture site.[9] In another study of 197 interventional procedures, 177 of which were balloon dilatations, there were 68 complications (35%), including five patients (2.5%) who had significant problems requiring admission and active therapy.[10] Waugh and Sacharias described a

[9] Akopian G and Katz SG. Peripheral angioplasty with same-day discharge in patients with intermittent claudication. *J Vasc Surg.* 2006;44:115-8.
[10] Young N, *et al.* Complications with outpatient angiography and interventional procedures. *Cardiovasc Intervent Radiol.* 2002; 25:123-126.

significant complication rate of 3.6% among patients undergoing peripheral interventional procedures (63% of which were balloon angioplasty procedures).[11]

Occlusion is also commonly found in, or may be a complication of, peripheral vascular interventions including venous PTA and transcatheter placement of intravascular stents. In one study of 181 lesions in 166 vessels, 55% of lesions were either occluded or stenosed and occluded.[12] In another study of 23 patients with critical limb ischemia, patients typically presented with combined stenoses and occlusions in 15 (60%) limbs, stenoses alone in 4 (16%), and occlusions alone in 6 (24%).[13] As previously discussed, transfer of these patients to a hospital for lytic therapy involves movement of the patient in non-sterile environments, increasing the risk of infection.

In the 2007 ASC final rule, CMS recognized some of the safety concerns associated the management of complications that may occur with certain peripheral vascular procedures. The Agency stated that, "[o]ur medical advisors reconsidered our proposal to add CPT codes 37205 and 37206 to the ASC list and determined that it would be in the best interests of Medicare beneficiaries to continue to deny payment for them in ASC facilities," and "we will not be adding CPT code 35475 for arterial angioplasties to the ASC list, and we are not finalizing our proposal to add CPT code 35476 for venous angioplasties to the ASC list because of safety concerns due to the broad array of vessel angioplasties that could be reported with the two codes."[14] **Boston Scientific applauds CMS on this decision, and encourages the Agency to maintain this position in CY 2008 and to exclude all peripheral vascular procedures, particularly 35473, 35474 and 35492 (PTA, iliac; PTA, femoral-popliteal; and peripheral atherectomy, iliac) from the list of procedures allowed in the ASC.**

While these safety issues justify Boston Scientific's request for CMS to refine the definitions and expand the exclusion criteria, we recognize the importance of assessing the impact of these requested changes to the ASC system as a whole. To assess this impact, Boston Scientific compared the current list of approved procedures and the proposed list against the new exclusion criteria and definitions. We found that the implementation of the refined definitions and additional exclusion criteria would have little or no impact on the list of procedures currently allowed in ASCs, however it would exclude a subset of CPT codes from being added to the 2008 ASC List of Approved Procedures (please refer to Appendix B).

Appendix B is a list of procedures of interest to Boston Scientific. These codes should be excluded from the ASC Covered Procedures List not only because they do not meet Medicare's current and proposed criteria for coverage, but also because in some situations they may result in adverse events that require hospital-level infrastructure to effectively manage complications.

G0297 Example in Proposed Rule

Boston Scientific would like to bring to CMS' attention a potential discrepancy on page 49637 in the proposed ASC 2008 rule. CMS suggested that HCPCS code G0297 (Insertion of single chamber pacing cardioverter defibrillator pulse generator) represented a procedure that, "could be safely and appropriately performed in an ASC" setting. Because no ICD procedures were included in the ASC-approved list,

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[11] Waugh JR, Sacharias N. Arteriographic complications in the DSA era. *Radiology*. 1992; 182:243-246.
[12] Krankenberg H, et al. Percutaneous Transluminal Angioplasty of Infrapopliteal Arteries in Patients with Intermittent Claudication: Acute and One-Year Results. *Catheter Cardiovasc Interv*. 2005; 64:12–17.
[13] Gray BH, *et al.* Complex Endovascular Treatment for Critical Limb Ischemia in Poor Surgical Candidates: A Pilot Study. *J Endovasc Ther*. 2002; 9:599-604.
[14] Department of Health and Human Services, Centers for Medicare & Medicaid Services. Medicare Program; CY 2007 Update to the Ambulatory Surgical Center Covered Procedures List; [CMS-1506-FC]. 42 CFR Parts 410, 416, 419, 421, 485, and 488.

Boston Scientific believes CMS inadvertently provided this example as a procedure that could be performed in the ASC.

A defibrillation threshold test (DFT) is often performed on patients who receive an ICD. ICD implant procedures and DFT testing require a large medical professional team including an implanting physician such as an electrophysiologist or surgeon, a healthcare professional in charge of anesthesia, a scrub nurse, a circulating nurse, and a representative of the company that manufacturers the device[15]. Most importantly, the "equipment and team should be ready to rescue the patient in the event the device does not defibrillate the patient."[16] Since an ASC does not typically have access to such lifesaving equipment and additional resources, an ASC setting is not appropriate for procedure G0297 or any other related ICD procedure where DFT testing could possibly occur.

While BSC believes this example was a discrepancy, we would like to reiterate that we do not support placing G0297 or any other ICD related procedure in an ASC setting because of the safety concerns discussed above.

BSC Recommended Action:

- Exclude all procedures listed in Appendix B from the list of procedures allowed in the ASC.
- Do not allow G0297 or any other ICD-related procedures in ASCs.

II. Establishing Consistent Patient Safety Standards

Medicare's interest in both safety and quality is reflected in recent initiatives for both inpatient and outpatient care.[17] However, despite suggestions from MedPAC and the Office of the Inspector General (OIG) to implement quality standards for ASCs, Medicare has not proposed safety and quality standards for ASCs that are consistent with those in hospitals.[18,19] The majority of procedures proposed for payment when performed in ASCs have excellent safety records. The safety concern described here and elsewhere relates more to ASCs' abilities to manage complications that may arise, however rarely, and to achieve the same clinical outcomes for both procedures and complication management as are seen in outpatient hospital settings. Therefore, we urge CMS to implement patient safety standards for ASCs.

The need for more consistent ASC safety standards is further demonstrated by the significant variability of state licensing requirements and accreditation standards. In a report by the American Hospital Association (AHA), only 43 of 50 states even require ASCs to be licensed whereas all states require hospitals to be licensed.[20] The AHA report also suggests that "states' ability to oversee ASCs on behalf of Medicare is eroding because of the growth in ASCs and states' limited resources. Of state-surveyed ASCs, one-third (872) had not undergone a recertification survey in over five years."[21] According to the OIG, "CMS gives little oversight to ASC surveys and accreditation, and CMS does not make findings readily available to the public as it does for hospitals and other types of providers."[22] Few states have

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[15] Nuts and Bolts of ICD Therapy, Chapter 5, Implant Procedures. Tom Kenny, 2006.
[16] Nuts and Bolts of ICD Therapy, Chapter 5, Implant Procedures. Tom Kenny, 2006.
[17] http://www.cms.hhs.gov/HospitalQualityInits/ .
[18] MedPAC. March 2005 Report to Congress. Page 154.
[19] DHHS, Office of Inspector General. Quality Oversight of Ambulatory Surgical Centers. February, 2002.
[20] American Hospital Association. The Migration of Care to Non-hospital Settings: Have Regulatory Structures Kept Pace with Changes in Care Delivery? *TrendWatch*. July, 2006.
[21] *Ibid.*
[22] *Ibid.*

restrictions on the procedures that can be performed in ASCs, and few states regulate infection control practices or equipment requirements.[23]

Examples of Safety Standards That Should Be Considered

From a safety perspective, hospitals are required to have experienced nurses or physicians supervising operating rooms; ASCs are not. Although Medicare requires hospitals to document history and physical examination for every patient prior to surgery, there is no similar requirement for ASCs.[24] Hospitals are also required to have infection control processes in place, whereas ASCs are not consistently required to do so. Moreover, the Medicare Conditions for Coverage (CfCs) for ASCs state that all ASCs must have procedures for the immediate transfer of patients needing hospitalization after an ASC procedure and that "such situations should not be infrequent."[25,26] However, "infrequent" is not defined in the CfCs, and the availability of transport services does not eliminate the risks of infection, dissection and perforation associated moving patients who have undergone procedures in ASCs, particularly those that are catheter-based. Because CMS does not have a consistent method to track transfer rates, CMS (nor patients and physicians) cannot confirm whether a given ASC's rate of complications requiring transfer is infrequent or not.

Safety standards should also require that patients being considered for a procedure in an ASC be evaluated for their level of surgical risk, and that that evaluation be documented in patients' ASC medical record. One approach to evaluate and manage surgical risk is to use the American Society of Anesthesiologists' (ASA's) Physical Status Classification System.[27] The ASA classifies patients' conditions according to the following, six-point system:

- P1. Normal healthy patient.
- P2. Patient with mild systemic disease.
- P3. Patient with severe systemic disease.
- P4. Patient with severe systemic disease that is life-threatening.
- P5. Moribund (dying) patient who is not expected to survive without an operation.
- P6. Brain-dead patient whose organs are being removed for donation.

Safety standards should more fully address whether appropriate process steps have been taken to provide treatment at the level of the general standard of care for the indicated condition. For instance, ASCs, like hospitals, should be required to capture whether proper medications were given at admission, whether the patient has been appropriately evaluated for anesthesia risk, and whether there is a comprehensive history and physical documented in patients' records.

Implementing and Enforcing Safety Standards

The ASC CfCs offer one way for CMS to implement more consistent safety standards in ASCs across states and to create a more level "playing field" in terms of safety across sites of care. On April 24, 2006, CMS announced in the Federal Register that it would be revising the CfCs for ASCs for the first time

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[23] *Ibid.*
[24] http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalStarterSet200512.pdf .
[25] 42 CFR §416.41.
[26] DHHS, Centers for Medicare and Medicaid Services. State Operations Manual, Appendix L: Guidance to Surveyors: Ambulatory Surgical Services (Rev. 1, 05-21-04).
[27] American Society of Anesthesiologists. ASA Physical Status Classification System. http://www.asahq.org/clinical/physicalstatus.htm .

since 1982 and publishing a proposed rule in the Fall of 2006.[28] As yet, the proposed revisions to the CfCs have not been released.

Working with professional specialty societies, for example, CMS could update CfCs to specify which patient classes are eligible for coverage in the ASC and which are not (for example, P1-P2 are allowed in ASCs, where as P3-P6 are not).

In addition to establishing consistent safety standards across sites of care, CMS must also reexamine safety standards and ASC CfCs are enforced across the country. Currently, there is no uniform enforcement of safety standards for ASCs. The enforcement of CfCs is conducted at the state level where there is significant differentiation individual states' interpretation of the CfCs. The current CfCs cover some aspects of safety, however they are not well-defined and ASCs are largely self-monitoring through their governing bodies. Therefore, there is not consistent enforcement of the CfCs across states. As the intensity of procedures performed in ASCs increases, the need for better defined, more consistent, and strongly enforced safety standards and CfCs also grows.

BSC Recommended Action:

- Establish safety standards that are both relevant to ASCs and consistent with the safety standards in place for other sites of care (particularly hospital outpatient departments);
- Refine the ASC CfCs, and consider using them as a mechanism to implement and enforce consistent safety standards for ASCs; and
- Implement stronger and more consistent enforcement of CfCs and ultimately of ASC safety standards.

III. Implementing Quality Reporting Measures on Processes & ASC Clinical Outcomes

CMS should develop and implement safety and quality measures relevant to ASCs that are similar to those used for hospitals. Given the significant interest CMS and all stakeholders have in gaining insights to the quality of care associated with contemporary clinical practice, it is essential that clinical process and outcomes information be captured to inform decision-making. For example, hospitals must report specific clinical process information that ASCs are not required to report, such as surgical infection prevention (SIP) via prophylactic antibiotic administration (for a full list of the hospital quality measures required by Medicare, please refer to Appendix C).[29] Although these measures are currently process-oriented, CMS has indicated that it is going to be evaluating hospital outcomes measures in the near future.

Unfortunately, the patchwork of quality reporting "systems" are not as comprehensive or as stringent for ASCs compared to hospitals, skilled nursing facilities, and other settings.[30] In addition, inconsistent regulation and reporting standards by states provide no clear pathway to understanding the outcomes in this site of service. Therefore, Medicare cannot track processes or outcomes in ASCs. Moreover, there is currently no way to assess the safety of procedures in ASCs and to tie infections and complications stemming from procedures performed in ASCs back to the ASC.

CMS should model the effort for implementing ASC quality reporting standards on the Ambulatory Care Quality Alliance (AQA) and the Hospital Quality Alliance (HQA) efforts for hospitals. Another possible

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[28] Department of Health and Human Services. Semiannual Regulatory Agenda. Federal Register. April 24, 2006; 71 (78): 22544.

[29] *Ibid.*

[30] American Hospital Association. The Migration of Care to Non-hospital Settings: Have Regulatory Structures Kept Pace with Changes in Care Delivery? *TrendWatch*. July, 2006.

starting point for ASC measures is the Surgical Care Improvement Project (SCIP). ASC measures should address both care processes and outcomes so that stakeholders can make educated decisions about site of care. For example, process measures should be implemented to review whether proper medications were given at admission and whether the patient was evaluated for anesthesia risk. Clinical outcomes including rates of infection and the number of cases requiring transfer to hospitals due to complications should also be captured. Until such measures are in place, Medicare cannot insure that the well-being of its beneficiaries treated in ASCs is appropriately protected.

BSC Recommended Action

- CMS should implement consistent ASC quality reporting measures on both care processes and clinical outcomes.

IV. Recommended Changes to ASC Payment Methodology

Accurate Payments

BSC supports accurate payment rates in all payment systems, including the reformed ASC system. We urge CMS to establish ASC rates that reflect the cost of providing services in the ASC setting. In addition, below we offer specific recommendations with improve the accuracy of payment rates in the ASC.

Charge Compression Adjustment

BSC has supported an adjustment for charge compression in Medicare's inpatient and outpatient prospective payment systems. We commend CMS for undertaking the charge compression study as stated in the FY 2008 Inpatient Prospective Payment System final rule. In our comments to CMS on the CY 2007 Outpatient Prospective Payment System proposed rule, we have urged CMS to adjust OPPS rates based on the findings of the charge compression study. We urge CMS to use OPPS rates that have been adjusted for charge compression when setting ASC rates if CMS finalizes its current ASC proposal (basing ASC rates on a percentage of the OPPS rates). We urge CMS to initiate a charge compression study in the ASC setting and implement its findings expeditiously if the final ASC payment system is not based on OPPS rates.

Account for Costs of Implantable Devices Paid Under the DMEPOS Fee Schedule in the New ASC Payment System

a. **For current ASC procedures involving prosthetic implants and implantable DME devices, continue to pay separately for these devices under the DMEPOS fee schedule and only apply a reduction to the facility portion of the total payment.** While procedural cost efficiencies can be realized in the ASC setting versus the hospital outpatient setting because of lower ASC infrastructure and staffing costs, no cost efficiencies exist across settings for high-cost implantable devices. One example of a similar Medicare payment policy is the separate reimbursement outpatient departments and ASCs receive for corneal transplants. CMS decided to exclude the cost of corneal tissue and preparation (V2785) from the base APC rate (APC 0244 = $2.336) and allow payment to be made based on acquisition cost. (We are not recommending payment based on acquisition cost, but, rather to continue making separate device payments based on the DMEPOS fee schedule.) The average Medicare allowed charge in 2005 for V2785 was $2,166. CMS is proposing to continue this policy in the ASC setting for 2008, thereby allowing full payment for the cost of the corneal tissue and a reduced payment for the facility costs in ASCs. The reduced ASC facility payment being proposed is $1,506, or 64% of the base OPPS APC rate (0.64 x $2,336). A similar policy is used in paying for new technology intraocular lenses (NTIOLs).

We believe the same type of policy should be implemented for ASC procedures that involve implantable devices and that are currently paid on the DMEPOS fee schedule. These procedures include implantation of neurostimulators (APCs 0040 and 0222), cochlear implants (APC 0259), breast prosthetics, various joint implants, ocular and ossicular implants, aqueous shunts, etc. According to 2005 Medicare ASC claims data; the total allowed charges for corneal tissue ($13.5M) accounted for almost half of the total allowed charges that CMS paid under the DMEPOS fee schedule to ASCs. The next largest category of implantable devices was neurostimulators with total allowed charges of $8.6M. The total amount of dollars allowed by CMS in 2005 for separately payable DMEPOS was only approximately 1% of total dollars allowed in ASCs. Therefore, adjusting the proposed ASC payments to more appropriately account for the cost of these devices would have a minimal effect on the budget-neutral conversion factor. However, the impact on payment -- and patient access -- for these device-intensive procedures such as neurostimulators, would be significant.

One method to calculate the facility proportion, or, non-device portion of the payment is to use the device percentages that CMS already calculated for device-intensive APCs. The device percentages can be used to back-out the device costs from the HOPD APC payment to derive the facility payment. Then, reductions for budget-neutrality can be applied to the facility portion only. Table 1 below provides an example of this calculation.

Table 1 – Example Calculation of ASC Payments for Neurostimulator APCs

APC	A 2007 HOPD Payment	B Device %	C Facility % (100% - B)	D Facility Payment ((A x C) x 64%)	E Typical* DMEPOS Device Payments	F Total 2009 BSC Proposed Payment (D+E)
0040 – implant percutaneous lead	$3,477	54%	46%	$1,202	$2,190	$3,392
0222 – implant neurostimulator (non-rechargeable)	$11,164	78%	22%	$1,572	$6,876	$8,448

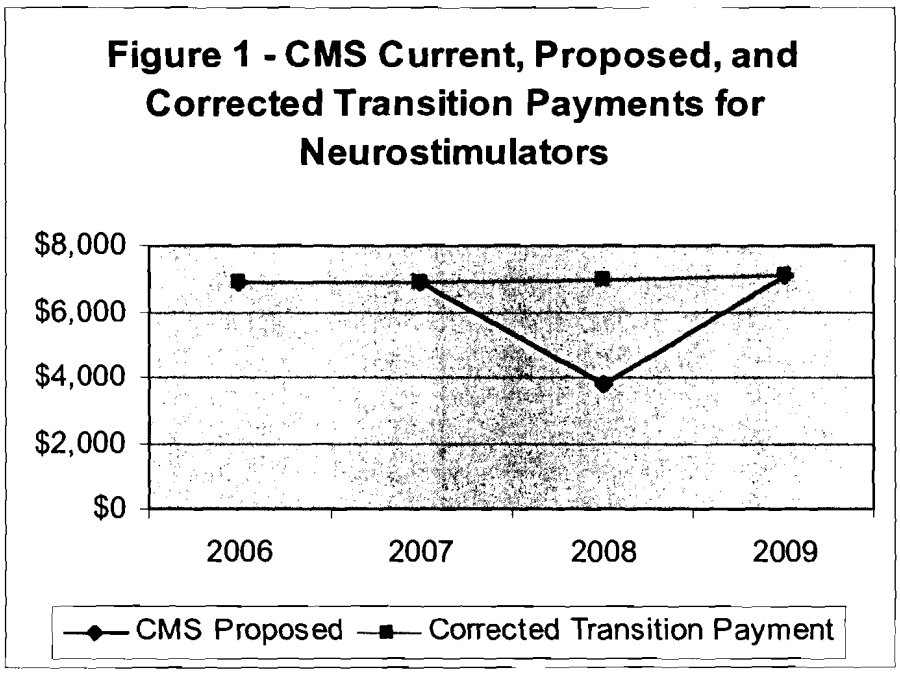
* Note that device payments per procedure will vary if payments continue to be made based on the DMEPOS fee schedule. This could result in total ASC APC payments that may be higher or lower than the OPPS APC payment. DMEPOS device payments derived from BSC analysis of Medicare 2005 ASC claims data (allowed charges) for neurostimulator devices.

If CMS does not implement the proposed recommendation to maintain separate payment for implantable devices currently paid under the DMEPOS fee schedule, then two (2) technical errors described below should be corrected.

b. **Correct error in ASC conversion factor calculation by incorporating claims for implantable devices that are currently paid separately under the DMEPOS fee schedule.** We believe that CMS made a technical error when setting the proposed ASC conversion factors for 2008 and 2009 by omitting costs associated with devices that are currently paid separately under the DMEPOS fee schedule in the ASC setting (examples include implantable neurostimulators and implantable infusion pumps). CMS explains its method for computing the budget neutral conversion factor in the Proposed Rule. This explanation does not incorporate claims for implantable devices paid under the DMEPOS fee schedule (identified by HCPCS codes) in the method. CMS also published the claims

data it used to calculate the budget-neutral APC conversion factor on its website (www.cms.hhs.gov/ASCPayment/Downloads/SupportingData.zip) and there is no claims volume for implantable devices that are currently paid separately in ASCs under the DMEPOS fee schedule. Although these claims do not comprise a significant portion of the total ASC dollar volume, they should be included in the ASC conversion factor calculation for completeness and accuracy.

c. **Correct error in setting 2008 transition payments for procedures involving implantable devices that are currently paid separately under the DMEPOS fee schedule.** As described below, CMS erred by not including implantable device payments when setting the base payment rate for implantable neurostimulators and other similar procedures. As demonstrated in Figure 1, this error causes an unintended effect on the 2008 transitional payments in which the proposed payment dramatically decreases in 2008 and then, just as dramatically, increases in 2009. Transitional payments are intended to be a way to mitigate the effects of payment policy changes. This error does not provide for a smooth transition to 2009 payments for procedures that include separately payable implantable devices.



Some procedures performed in ASCs involve implantable devices that are currently paid separately under the DMEPOS fee schedule. When an ASC bills for one of these procedures, it bills the CPT-4 procedure code as well as the device HCPCS code. Medicare then pays the procedural "base rate" for the appropriate ASC group as well as the DMEPOS fee schedule amount for the implantable device. Examples include implantation of a neurostimulator (CPT 63685) and neurostimulator electrodes (CPT 63650) for chronic intractable pain. Most of the ASC reimbursement for such procedures under the current payment system is associated with the actual implantable devices paid under the DMEPOS fee schedule. **The proposed 2008 transition payment for these procedures only incorporated the current ASC base rate of $446 in the transition payment calculation. We believe CMS erred by omitting the current separate device payment from the calculation.** Table 2 below illustrates this example for implanting dual-array, non-rechargeable neurostimulators.

Table 2 – ASC Payments for Dual-Array Non-Rechargeable Neurostimulator Implantation Procedures if Transition Payments Corrected

	Current ASC Payment	CMS 2008 Proposed ASC Payment	[2] *2008 Corrected ASC Transition Payment*	CMS 2009 Proposed ASC Payment
63685 – Implant neurostimulator (dual array non-rechargeable)				
ASC Group 2	$446	APC 0222	*APC 0222*	APC 0222
L8688 (dual-array non-rechargeable neurostimulator)	$6,014[1]			
L8681 (patient programmer)	$862[1]			
TOTAL Payment (sum of devices + ASC base rate)	**$6,876**	**$3,758 (50% x $446 + 50% x $7,070)**	***$6,973 (50% x $6,876 + 50% x $7,070)***	**$7,070**
63650 – Implant 1 percutaneous lead (average of 6 electrodes/lead)				
ASC Group 2	$446	APC 0040	*APC 0040*	APC 0040
L8680 ($365*6)	$2,190[1]			
TOTAL Payment (sum of devices + ASC base rate)	**$2,636**	**$1,342**	***$2,437***	**$2,238**

[1] Payments vary by geographic region. Data based on BSC analysis of 2005 Medicare allowed charges using E codes billed to report non-rechargable neurostimular devices.
[2] Transition payment corrections would not be necessary if DMEPOS continues to be paid separately.

CMS should be aware that the example in Table 2 illustrates the payment for implanting a typical dual array, non-rechargeable neurostimulator. In 2006, CMS determined that ***rechargeable neurostimulators*** represent a substantial clinical improvement over non-rechargeable neurostimulators and created a transitional pass-through payment for procedures performed in the hospital outpatient department setting. Hospitals receive the base APC payment for APC 0222 plus an additional payment for the new technology. Boston Scientific will be working with CMS to request a separate APC for rechargeable neurostimulators so that the value of this technology continues to be recognized in both Medicare's hospital outpatient department and ASC reimbursement systems.

If CMS does not adopt our recommendation to use the DMEPOS fee schedule to account for implantables devices, CMS should use actual, detailed Medicare ASC claims data rather than the modeling approach that CMS employed to compute the conversion factor and transitional payment rates. CMS used ASC procedure volume multiplied by ASC group base rates to derive the total ASC dollar volume. As noted, in using this approach, CMS did not include claims for separately payable DMEPOS devices. Because various types of devices using different HCPCS codes and different DMEPOS fee schedule amounts may be billed with certain procedures, the best way to compute the budget-neutral conversion factor and the "current" ASC payment used in the 2008 transitional payment calculation may be to use real claims data.

BSC Recommended Action:

- Continue to use the DMEPOS fee schedule for implantable devices currently provided in ASCs, and apply budget-neutral adjustments to the facility or non-device portion of the payment.
- If CMS does not implement this payment proposal, we urge CMS to correct conversion factor calculations and 2008 transitional payments to ensure DMEPOS fee schedule costs are recognized.

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Thank you for the opportunity to comment on the proposed 2008 ASC changes. Given the magnitude of the changes contemplated and resulting impact on Medicare patient care, we urge CMS to consider patient safety as the overarching principle determining the appropriateness of ASC-payable procedures. We welcome the opportunity to discuss our responses to CMS' proposal.

Please contact me at (508) 652-7492 or parashar.patel@bsci.com or Scott Reid, Director of Health Policy and Payment, at (202) 637-8021 or reids@bsci.com if you have any questions.

Sincerely,

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cc: Herb Kuhn, Center for Medicare Management
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Appendix A

Recommended Clarification to Existing Criteria

1. "Major Blood Vessels"
   Boston Scientific advocates the adoption of the definition of "major blood vessel" advanced by Seeley, Stephens and Tate in their medical textbook, Essentials of Anatomy & Physiology, 6th Edition.[31] This list includes not only the heart and the aorta, but also includes vessels providing primary blood supply to major limbs and organs including the legs and the kidneys.[32]

   Please note that because procedures involving some of the vessels defined as "major" by Seeley, *et al.* are already performed safely in ASCs (e.g., thrombectomy, percutaneous, arteriovenous fistula), we have omitted these vessels from the list. As a result, the following vessels would be included in the definition of "Major Blood Vessels" and procedures involving these vessels would be excluded from the ASC:

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

[31] Seeley RR, Stephens TD, and Tate P. Essentials of Anatomy & Physiology, 6th Edition. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.
[32] Seeley RR, Stephens TD, and Tate P. Essentials of Anatomy & Physiology, 6th Edition. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.

- Superior and inferior vena cava

- Veins of the Head and Neck
  - Internal jugular vein
  - Vertebral vein
- Veins of Abdomen and Pelvis
  - Hepatic veins
  - Renal veins
  - Gonadal veins
  - Right and left common iliac veins
- Veins of Lower Limb
  - Anterior and posterior tibial veins
- Hepatic Portal System
  - Hepatic portal vein
  - Mesenteric veins
  - Gastric veins
  - Cystic vein[33]

[33] Seeley RR, Stephens TD, and Tate P. Essentials of Anatomy & Physiology, 6th Edition. McGraw-Hill. 2007: Chapter 13, Blood Vessels and Circulation.

Appendix B- List of CPT Codes for Exclusion from 2008 ASC Payment*

CPT Code	Short Descriptor	Major Blood Vessel	Prolonged Invasion**	Femoral access	Lytic Therapy	Inpatient ≥50%
33206	Insertion of heart pacemaker	Y				Y
33214	Upgrade of pacemaker system	Y	Y			Y
33215	Reposition pacing-defib lead	Y				Y
33216	Insert lead pace-defib, one	Y	Y			Y
33217	Insert lead pace-defib, dual	Y	Y			Y
33218	Repair lead pace-defib, once	Y	Y			Y
33220	Repair lead pace-defib, dual	Y	Y			Y
33222	Revise pocket, pacemaker		Y			Y
33223	Revise pocket, paceing-defib		Y			Y
33224	Insert pacing lead & connect	Y	Y			Y
33225	L ventric pacing lead add-on	Y	Y			Y
33226	Reposition L ventric lead	Y	Y			Y
33234	Removal of pacemaker system	Y	Y			Y
35473	Repair arterial blockage	Y	Y	Y	Y	Y
35474	Repair arterial blockage	Y	Y	Y	Y	Y
35475	Repair arterial blockage (non-dialysis)	Y	Y	Y	Y	
35476	Repair venous blockage (non-dialysis)	Y	Y	Y	Y	
35492	Artherectomy, perc.	Y	Y	Y	Y	Y
35761	Exploration of artery/vein	Y		Y	Y	Y
37205	Transcath IV stent, perc.	Y	Y	Y	Y	Y
37206	Transcath IV stent/perc addl	Y	Y	Y	Y	Y
37250	IV US first vessel add-on	Y		Y	Y	Y
37251	IV US each add vessel add-on	Y		Y	Y	Y
37650	Revision of major vein	Y		Y	Y	Y
G0297	Insrt 1 chamb dfib pulse generator	Y				Y

* Extensive blood loss and overnight stay not included in this table as it does not always apply to the procedures listed or the information is unavailable. As previously noted, CMS should consult with relevant specialty societies to determine the amount of blood loss typically associated with procedures it is considering adding to the ASC list, and the Agency should defer to the 50% inpatient threshold rather than rely on inconsistent overnight stay data.

**Source: For all codes except 35473, 35474, 35476, 35492, 37205, and 37206: 2005 Physician and Clinical Staff Time (CMS). For 35743, 35474, 35476, 35492, 37205, and 37206, source is 2006 Total Physician Time as published as part of CMS' 5-year review of RVU assignments.

Appendix C: Medicare Hospital Quality Measures[34]

The Hospital Quality Alliance (HQA) Ten Measure "Starter Set"

Performance Measures	Measure Description – for additional information including inclusions and exclusions click on the Performance Measure
AMI - Aspirin at Arrival	Acute myocardial infarction (AMI) patients without aspirin contraindications who received aspirin within 24 hours before or after hospital arrival.
AMI - Aspirin Prescribed at Discharge	Acute myocardial infarction (AMI) patients without aspirin contraindications who are prescribed aspirin at hospital discharge.
AMI – ACEI or ARB for LVSD	Acute myocardial infarction (AMI) patients with left ventricular systolic dysfunction (LVSD) and without angiotensin converting enzyme inhibitor (ACEI) and angiotensin receptor blocker (ARB) contraindications who are prescribed either an ACEI or ARB at hospital discharge.*
AMI - Beta Blocker at Arrival	Acute myocardial infarction (AMI) patients without beta blocker contraindications who received a beta blocker within 24 hours after hospital arrival.
AMI - Beta Blocker at Discharge	Acute myocardial infarction (AMI) patients without beta blocker contraindications who are prescribed a beta blocker at hospital discharge.
HF-LVF Assessment	Heart failure patients with documentation in the hospital record that left ventricular function (LVF) were assessed before arrival, during hospitalization, or planned for after discharge.
HF-ACEI or ARB for LVSD	Heart failure patients with left ventricular systolic dysfunction (LVSD) and without angiotensin converting enzyme inhibitor (ACEI) and angiotensin receptor blocker (ARB) contraindications who are prescribed either an ACEI or ARB at hospital discharge.*
PNE-Initial Antibiotic Timing	Pneumonia patients who receive their first dose of antibiotics within 4 hours after arrival at the hospital.
PNE- Pneumococcal Vaccination	Pneumonia patients age 65 and older who were screened for pneumococcal vaccine status and were administered the vaccine prior to discharge, if indicated.
PNE-Oxygenation Assessment	Pneumonia patients who had an assessment of arterial oxygenation by arterial blood gas measurement or pulse oximetry within 24 hours prior to or after arrival at the hospital.

*Measure revised to incorporate ARBs, per joint agreement of the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission on Accreditation of Health Care Organizations (JCAHO) issued on November 15, 2004. Page last updated November 22, 2005

[34] http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalStarterSet200512.pdf .

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AMBULATORY SURGERY CENTER RULE

November 6, 2006

Leslie Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1506-P
P.O. Box 8014
Baltimore, Maryland 21244-8014

Re: Medicare Program: Ambulatory Surgery Centers PPS Proposed Rule

Dear Ms. Norwalk:

The American College of Gastroenterology is pleased to provide these comments with respect to the proposed rule issued August 23, 2006, by the Centers for Medicare and Medicaid Services' (CMS), on revisions to the payment policies relating to the Ambulatory Surgery Centers PPS Proposed Rule (to begin Calendar Year 2008) and other related topics.

INTRODUCTION

The American College of Gastroenterology (ACG) is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers nearly 10,000 physicians among its membership. While the majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists and other specialists who focus on the various aspects of treating digestive diseases and conditions. The College focuses its activities on clinical gastroenterology, i.e., the issues confronting the gastrointestinal specialist in treating patients. The primary activities of the College have been and continue to be educational.

A significant number of physicians practicing gastroenterology perform most of their GI procedures, including life-saving colorectal cancer screenings, in GI ambulatory surgery centers (ASCs). In some cases, the physicians have an ownership interest in those ASCs. In other cases, the physicians may not have an ownership interest, but the centers provide the most accessible, convenient, reliable, and cost-effective location in which to perform their endoscopies.

It is exceedingly important for CMS to recognize that the vast majority of the ASCs where GI procedures are performed are single specialty ASCs, dedicated solely to GI. GI ASCs are not profoundly a corporate environment or multi-specialty in nature. CMS's proposal to change the ASC payment system would visit tremendous damage upon GI ASCs and this damage will not be spread across a diversified

corporate portfolio, or among winners and losers in a multi-specialty ASC format. If CMS reduces the margin in GI ASCs by roughly negative -22% for Medicare patients, as the proposed rule stipulates, the losses will stay right in the GI ASC. Those ASCs will be forced to lay off support staff, go out of business, and profoundly limit access to Medicare beneficiaries solely because of the draconian, survival-threatening, economic imperatives CMS plans to impose on them.

Overview

ACG wishes to express our grave concerns with CMS's recent proposal to change the way the agency pays ambulatory surgery centers for their services, via facility fee payments.

Physicians in the clinical practice of gastroenterology see a large number of Medicare patients. Treatment for a substantial percentage of these patients includes performing screening colonoscopies for those who are at average risk or high risk for colorectal cancer, as well as surveillance colonoscopies for those who already have been identified as having either polyps, or who have had cancerous lesions excised previously. Additionally, we see a very significant number of patients with other conditions: GI bleeding, inflammatory bowel disease, gastroesophageal reflux disease (GERD), and/or Barrett's esophagus. Patients with these diseases require ready access to an appropriate, safe, and cost-efficient site for GI endoscopy if we are to maximize our ability to treat them.

On August 23, 2006, the CMS issued a proposed rule setting forth a draft policy scheduled for implementation on January 1, 2008, for a new prospective payment system for ASCs, required by the Medicare Modernization Act (MMA) of 2003. Major features of the proposed rule include but are not limited to: the addition of 14 surgical procedures in 2007; a new payment system that pegs procedure payments to approximately 62% of the hospital outpatient department amount to be fully phased in by 2009; and a larger expansion of procedures approved to be performed in an ASC. This proposed rule would reduce the ASC payment for GI services by a remarkable 25-30%. The effect of cutting ASC payment rates by 25-30% will prove completely draconian, especially since they would be on top of the existing cuts of nearly -40% to Medicare physician fees for colorectal cancer screening colonoscopies since 1998.

There are ten major aspects of the CMS proposal the effects of which need to be better understood by CMS, as well as by Members of Congress:

I. CMS's definition of budget neutrality fundamentally undercuts the fairness of the rule and diminishes the prospect for survival of many ASCs if the CMS proposal is implemented.

CMS's proposal has interpreted the MMA 2003 provision to mean that it must take the single pot of funds that were expended on ASC services in 2003 to pay for all costs associated with reform of the ASC payment system, which would also include the total

costs of expanding the ASC list of approved services. That is not the construction required by the MMA, as we will demonstrate below. CMS has presented an "alternative" which does contemplate the possible role for migration, and this can certainly be interpreted to indicate that the agency recognizes that there is a solid legal argument that a broader view of budget neutrality is justified.

We believe that the broader view of budget neutrality which allows a full incorporation of potential savings from case migration is the correct approach. We will endeavor in this section to explain both the legal arguments as to why CMS has the authority already to adopt a broader view of budget neutrality (and we do this at the risk, perhaps, of being a bit redundant if in fact the "alternative" approach demonstrates that CMS already recognizes that there is a sound legal basis for this broader approach), and then through our discussion of migration, underscore why we believe it is essential for CMS to adopt that broader approach.

The unfairness of this CMS approach is demonstrated by two factors. First, there is no explicit evidence Congress intended for CMS to add a significant number of additional services to the ASC list and still pay for all of those additional services out of a single pot of funds which had originally excluded all of those new services. Second, CMS has not recognized that migration of cases from one site to another, a shift that is already ongoing to a limited degree, from the more expensive HOPD to the less expensive ASC, saves Medicare a great deal of money. Savings or expenditures from resulting changes in patterns due to the proposed rule should be included in the budget neutrality definition. Current migration patterns, from the HOPD to the ASC, result in more expenditures each year from the ASC pot, and correspondingly fewer expenditures from the HOPD pot.

Congress not only would want to encourage this tendency, but would want it counted. CMS cannot fairly and legitimately put on its blinders to exclude from the budget neutrality equation all the savings in terms of relatively fewer services being done at the HOPD level. Those savings belong in the same budget neutrality calculation. CMS should be looking at budget neutrality, not just in the ASC pot of funds, but across the entire outpatient system, so that savings from the ASC pot are computed into the overall savings and budget neutrality picture.

We developed the attached projected "fact sheet" which demonstrates the sizeable savings which are excluded, based on just a few procedures, by CMS' refusal to count savings from the relative reduced number of services in the HOPD which occur as a result of the ongoing migration for cases from the HOPD to the ASC (Attachment 1).

The agency's concept of budget neutrality in this proposal is incorrect and unfair for multiple reasons. First and foremost, the agency proposes to increase markedly the number of procedures, from a variety of different specialties, that are performed in the ambulatory surgery center. By markedly raising reimbursement for vascular, orthopedic and urologic services, much larger numbers of these services will be performed in ASCs. But in computing budget neutrality, CMS appears to believe that exactly the same pool of dollars should fully cover the new payments. When the ASC list is expanded, millions of

procedures that once were performed in other settings (HOPD, physician office) will be reimbursed under the ASC payment policy. Congress could never have intended that CMS would secure twice as many services for the same number of dollars. Under this interpretation, every new service that is added to the ASC list will force the facility fee payment for a GI endoscopy performed in an ASC that much lower, as will each procedure that migrates from the HOPD to the ASC. This approach is unfair, unsubstantiated, and bad health policy.

For every single case that moves from the HOPD to the ASC under this expansion of the ASC approved list, the Medicare program will save money because at the current rates, ASC payments are always lower than, or at least never greater than, the facility fee that CMS pays to HOPDs. If the pool of dollars for ASC payments remains fixed despite a large increase in the number of cases done in the ASC (because of expansions to the ASC list), then the pool of dollars paid out to HOPDs will decline, because fewer cases are likely to be performed there. So, the only rational accurate approach to budget neutrality is to consider the impact on the total pool of both ASC facility fee payments and HOPD facility fee payments. In summary, the agency needs to expand its definition of what payment "pots" comprise budget neutrality for ASCs: (1) you cannot expect the same pool of funds to cover all costs when the expansion of the ASC approved list will likely result in millions of additional cases moving to the ASC; and (2) CMS must take into account, and not ignore, the savings that are generated in HOPD payments because of the cases that will move from the HOPD to the ASC.

Legal Issues Relating to the CMS Interpretation of Budget Neutrality

CMS has already received an extensive and well-documented legal opinion which demonstrates that the agency has the legislative authority and precedent to adhere to the clear intent of MMA 2003, and take a broad and aggregate view of budget neutrality across the outpatient payment system. We have attached a copy of that document to these comments, and we have extracted below some of the key findings of that opinion, which concludes that the CMS' current view of budget neutrality is neither what the law requires, nor what Congress intended when it passed MMA in 2003 (Attachment 2).

"To achieve the policy goals set forth above, however, it is essential that the budget neutrality provisions in MMA be interpreted and applied to include cost savings that will be realized from the inevitable shift of services currently performed in HOPDs to lower cost ASCs following implementation of the new payment system. (Legal Opinion, Attachment #2, , final para, on p. 1)

"As technology and practice protocols have advanced, ASCs can now safely perform many procedures that are currently not covered by the Medicare program when performed in an ASC. Therefore, these procedures continue to be provided in HOPDs, in most cases at greater cost to the Medicare program, as well as to beneficiaries. Under the statute, Medicare beneficiaries pay a 20% copayment for all services received in ASCs. However, under the statute, beneficiary copayments for HOPD services can be as high as

40%, and, according to the Medicare Payment Advisory Commission (MedPAC), in 2004 were as high as 34%.. (Legal Opinion, Attachment #2, , second para, on p. 2)

"If HHS develops an ASC payment system that substantially underpays ASCs relative to HOPDs, market forces will work to keep procedures in the hospital setting. The end result will be continued barriers to effective competition and reduced access for Medicare beneficiaries. . (Legal Opinion, Attachment #2, , final para, on p. 2)

"Section 626 of MMA directs the Secretary to consider the budgetary baseline impacts of the revised ASC payment system. Specifically, that section provides that:

"(ii) In the year the system described in clause (i) is implemented [i.e., the revised ASC payment system], *such system shall be designed to result in the same **aggregate** amount of expenditures for **such services** as would be made if this subparagraph did not apply, as estimated by the Secretary."* (Emphasis added.). . (Legal Opinion, Attachment #2, , second para, on p. 3)

"The key to interpreting this budget neutrality provision is the underlined phrase. Looking only at the statutory text, the most logical reading of the term "such services" is that it relates to "such system" referenced in parallel form earlier in the same sentence, thus meaning the services covered by the new ASC payment system. With that established, "aggregate" expenditures then refers, by its plain meaning, to "total" or "overall" Medicare expenditures for the services covered by the new system. In other words, under this provision, budget neutrality is to be measured by reference to the impact the new ASC payment system will have on overall Medicare expenditures for the total package of services covered by the system. Thus, if, as we anticipate, the new payment system will expand coverage to include additional procedures not currently on the Medicare ASC list, the budget impact is to be evaluated to include any savings that will be achieved through the performance of those procedures in ASCs, rather than in HOPDs. . (Legal Opinion, Attachment #2, , third para, on p. 3)

"Unfortunately, CMS has at least initially selected the alternative way to measure budget neutrality by referencing ASC payments only – that is, the new payment system could not result in overall ASC expenditures being greater than they would be without the new system. The problem with such an approach is that if CMS significantly broadens the list of covered ASC procedures, as Secretary Leavitt indicated is the plan (in a December 2005 letter to Senator Mike Crapo), ASCs will be able to perform hundreds of additional procedures for Medicare beneficiaries that currently are performed only in HOPDs. Thus, budget-neutrality, if applied to avoid any aggregate increase in ASC payments, would necessitate drastic, across-the-board reductions in payments for all ASC services to a level that would not be sustainable for the ASC community. Many ASCs could be forced to discontinue providing Medicare services, thus reducing patient choice and

harming beneficial competition for outpatient surgery. . (Legal Opinion, Attachment #2, , final para, on p. 3)

"Fortunately, the statute does not compel this result. By its plain language, Section 626 calls for budget neutrality to be measured by reference to the new ASC payment system, and that system's impact on "aggregate" Medicare expenditures for all of the services it covers, "as estimated by the Secretary." . (Legal Opinion, Attachment #2, , first para, on p. 4)

"In short, the MMA should be read in the context of Congress' goal to modernize Medicare, improve patient choice, and lower the cost of services, including outpatient surgery, to the program and its beneficiaries. The Secretary's own Inspector General noted that the majority of procedures currently performed in ASCs and HOPDs can be performed at a lower cost in the ASC setting. A revised ASC payment system that ensures reasonable reimbursement rates will reduce the costs of those outpatient procedures to Medicare, thus fulfilling the intention of Congress when it sought to modernize payments for ASCs. Moreover, improved patient access to ASC services will result in lower out-of-pocket costs for beneficiaries. ASC copayments are 20% of the service's cost; copayments for the same service in the HOPD can be as high as 34%. . (Legal Opinion, Attachment #2, , first full para, on p. 5)

"The MMA was designed to modernize Medicare, lower cost, and improve patient choice through increased competition. Thus, the proper lens through which a revised ASC payment system should be viewed involves lowering the cost of outpatient surgery. (Legal Opinion, Attachment #2, , second full para, on p. 5)

"Congress enacted the MMA to modernize Medicare, improve patient choice, and lower costs. Outpatient surgery is recognized as a valuable, high quality service for Medicare beneficiaries. Congress acted upon the opportunity to modernize and lower the cost of outpatient surgical services by encouraging competition between sites of services for such services, namely, ASCs and HOPDs. The Secretary should adhere to Congress' intent by designing a payment system that improves patient choice and lowers program costs, by improving and enhancing access to outpatient surgical services in ASCs, and by applying the budget neutrality provision in a broad and dynamic way – consistent with these policy goals and the language of the statute – that recognizes the new payment system's effects not just on payments to ASCs, but also its overall cost savings to the Medicare program." (Legal Opinion, Attachment #2, , final para, on p.9)

The budget neutrality adjustment is too narrow. CMS interpretation of budget neutrality under the 2003 MMA provision does not yield rational results or sound outcomes for the health system. CMS would apply budget neutrality to each individual site of service such as the ASC, HOPD, or office setting. Because of the steady shift in procedural services from the HOPD to the ASC, the ASC budget must fund an increasing number of services while the HOPD budget funds fewer services.

It would be more appropriate for budget neutrality to be applied across all three sites of service because there will be savings to the Medicare system for each case that moves from the more expensive HOPD to the ASC. Currently, CMS does *not* count those savings in the CMS budget neutrality equation because these will be attributed to the excluded HOPD sector, and not within the narrowly described ASC sector. ACG believes, under a payment structure created using this broader view of budget neutrality, many cases would migrate from the HOPD to the less expensive ASC, thereby creating savings in Medicare. The correct analysis for CMS is to see budget neutrality in terms of the entire outpatient payment system, including both ASC and HOPD. Any reductions to the facility fee for GI procedures and screening colonoscopies will simply exacerbate already low payment rates for these services. Again, if these CMS proposed ASC changes are implemented, it will reduce access to GI procedures, including colon cancer screenings, in the ASC setting.

II. CMS Migration Analysis Is Understated and Far Too Limited

CMS must recognize that significant migration will occur because changing the ASC price structure will trigger major shifts in whether procedures are performed in the HOPD or the ASC.

The second flaw in the agency's analysis is its failure to seriously consider the potentially enormous impact of case migration under its proposal. There is currently approximately a 50 point spread between the biggest potential loser (GI) and the biggest potential winner (orthopedics) in light of CMS's proposed rule to bring ALL subspecialty procedures to a single percentage level, 62% of the HOPD payment. If GI is to take a cut in the range of 25-30%, it is inappropriate for CMS not to factor into its analysis the inevitable impact this will have in reducing the number of GI Medicare patients who will receive their procedures in the GI ASC. Likewise, it is equally naïve for CMS to think that, if orthopedics is going to get a payment boost in the range of 25%, it does not need to factor into its analysis the inevitable impact this will have in increasing the number of orthopedic Medicare patients who will receive their procedures in the orthopedic ASC. As is noted below, positive migration of cases from HOPD to ASC in orthopedics may be mitigated somewhat as long as CMS continues to refuse to provide for the pass-through, and Medicare reimbursement of device and similar costs that are now reimbursed in the HOPD, but not in the ASC.

CMS provides an exceedingly simplistic alternative analysis on migration which the agency purports to apply to only the 14 procedures being added to the ASC list. This is merely the tip of the iceberg—the real dollar shifts are going to occur with respect to the many more procedures that are, and have been, on the ASC-approved list--ones which have developed a natural pattern of volume in the respective ASC and HOPD settings. In its very limited alternative analysis, CMS simply plugs in its own convenient ballpark numbers and says, "oh, it works out to be a wash." That absolutely will not be the case when one looks at the shifts that will occur in the large number of procedures across all specialties that have been on the ASC list.

Orthopedics, which currently represents about 13% of the ASC payment pool, is likely to experience some positive case migration, likely some more cases being done in the ASC if the rule were adopted. But CMS has not included a critical component of parity with HOPD, the ability to receive reimbursement for pass-through costs and devices, in this proposal. As long as this situation prevails, the shift in orthopedics from HOPD to ASC will be muted and modest. Conversely, GI and ophthalmology represent over 70% of the current ASC payment pool; with major reductions in payment to both specialties, much deeper for GI than for ophthalmology, clearly there is not going to be any positive migration of cases from HOPD to ASC in these fields. Being paid less, there is no reason for these specialties not to shift more commercial cases to fill their ASCs, thereby costing Medicare very significant amounts of money.

CMS's analysis is deficient as: (1) the agency has not factored this case migration for services already n the ASC list AT ALL into the computation of budget neutrality, despite huge potential swings in total Medicare outlays; and (2) the agency has completely failed to even consider this huge economic variable which argues compellingly against the agency's proposal to bring all specialties to a single payment level, as a fixed percentage of HOPD payments.

ACG joined with a coalition of other interested parties in commissioning an in-depth study conducted by the Lewin Group into the potential impact of this critical, but heretofore ignored, case migration. We anticipate Lewin's being able to brief the agency on its findings, and you will find attached to these comments some key summaries demonstrating the potential huge impact of case migration. (Attachment 3)

a. CMS must recognize "negative migration" because deep cuts in GI and pain management facility fees will result in significant numbers of cases migrating from ASCs to HOPDs, which will increase Medicare costs.

As noted above, the alternative analysis that CMS has proferred regarding the 14 new procedures, is spectacularly deficient in giving significant credence to this compelling economic factor. The agency has completely glossed over or ignored a critical case migration component that it is the agency's duty, as the steward of the Medicare fund, to evaluate, namely, the entire topic of negative case migration.

If the proposed rule is enacted, it is inevitable that GI ASCs will react to the huge cut in Medicare payment (Attachment 4). Their reaction, according to data we have collected, will almost certainly fall into a mixture of two behaviors. We should start by clarifying that GI physicians will almost certainly continue to treat Medicare physicians in their practices. When these patients need a colonoscopy or other endoscopic procedure, the question arises whether, in the face of the very strong economic imperatives this proposed rule would generate, GI physicians will be able to perform these procedures themselves in their ASCs, or refer them for a procedure by another physician (within the

original gastroenterologist's practice, or beyond) who would provide that service in the hospital outpatient department.

Expressing the alternative response to this question in broad general terms, on the one hand, GI physicians could shift their Medicare patients from the ASC back to the HOPD, with each and every case where this happens resulting in higher cost to the Medicare program. Alternately, some GI physicians find doing procedures in the hospital outpatient department so inefficient, in terms of travel time, uncontrolled waits in the HOPD and other factors that those physicians may simply decide that they cannot themselves perform the procedures on Medicare patients, and refer them to another physician who does perform procedures in the hospital outpatient department (HOPD).

The extent of this latter reaction will probably depend on the commercial volume. If every Medicare procedure under this proposed rule loses substantial amounts of money for the ASC because the actual costs exceed the Medicare payment, GI ASCs (and other losing specialties like pain management and ophthalmology) can be expected to populate their ASC scheduling first and foremost with as many commercial pay patients as possible. If there are gaps, weeks when commercial demand falls short of capacity in the ASC, these centers ***may*** proceed to schedule a modest number of Medicare patients. So, negative migration, ignored entirely by the agency, leaves two unhappy outcomes in GI and elsewhere: (1) CMS will expend significantly more money on each and every case where doctors choose to transfer procedures for their Medicare patients back to the HOPD; and (2) with respect to a potentially large number of doctors who simply will not do GI procedures in the HOPD, CMS's policy of huge payment cuts per case in GI (and potentially other losing specialties), ASCs will reduce access and increase waiting time for Medicare patients.

b. 62% is probably not the accurate Budget Neutrality number

The entire ASC community was shocked when CMS, using a narrow definition of budget neutrality, arrived at a budget neutrality number of 62%. As mentioned above, ACG and others have commissioned the Lewin Group to look at the overall case migration situation. Part of the Lewin analysis resulted in their conclusion that there were flaws in CMS' computation of budget neutrality. Even when they accepted all of CMS' assumptions regarding case migration, limitations to the ASC pot only, etc., Lewin still arrived at a budget neutrality figure of approximately 65%. We commend this analysis to the agency in the anticipated briefing by Lewin, and for consideration as part of the rulemaking.

Some interesting factors came to light in September when CMS officials (Ms, Sanow, Dr. Simon, and Ms. Burney) provided a briefing on the ASC rule at the AMA headquarters in Washington. Ms. Sanow revealed that in addition to the "wash" analysis on case migration for the 14 new codes which CMS had provided as an alternative in its rulemaking announcement, the agency had also looked at what the budget neutrality number would be if they did NOT factor in any migration of cases from the physician office to the ASC on the 14 new codes. The result announced by CMS at the AMA

meeting of that analysis was that it would have increased the budget neutrality number but it would still be below 70%. CMS has drawn a very tight net around those fourteen new codes, by providing that the total payment in the ASC cannot exceed what the payment had been in the physician office. So, it is reasonable to believe that given the prohibition on any financial payment difference between physician office and ASC, there is strong basis for excluding any physician office to ASC migration costs. As noted above, CMS has missed the bigger picture, as well as the huge significance of case migration, but it would make sense for the agency to correct its alternative analysis to reflect this "no cost for physician office to ASC migration" conclusion, and raise the budget neutrality number accordingly.

Another issue was raised at that same AMA meeting. Namely, the question was asked, "What would budget neutrality be if the 14 new codes had not been added to the ASC list?" This may seem like the above question stated in a different way, but it brings to bear another major problem with the CMS exceedingly narrow view of budget neutrality. It is inconceivable to us that Congress could have intended in MMA 2003 that CMS should, through additions to the ASC list, load into the ASC pot a sizeable number of additional codes, ***but*** pay for all of those new codes out of the same pool of funds, essentially mandating that every new code added would serve to dictate a corresponding reduction in the payment level for every other procedure already on the ASC list. Even in the CMS' narrow reading, and its unfortunate exclusion of case migration, it needs to separate in concept (and budget neutrality): (a) the reform of the payment system; and (b) the additions to the ASC list. The additions to the list, as constructed by CMS do not really cost Medicare any new money. Those funds are already being expended under the physician fee schedule for these services in the physician office. But CMS insists on driving down budget neutrality by counting these as new expenditures, not for the Medicare program, but simply because of the administrative decision by CMS to shift these payments from the physician fee schedule to the ASC pot. Fairness demands that CMS, at least, interpret the budget neutrality provisions of MMA 2003 as applying only to the payment reform component. No costs for payments on the fourteen (14) new codes should be included in the budget neutrality computation, as these exact dollars have already been counted elsewhere.

III. CMS's fundamental assumption that the HOPD payment system is reasonably aligned to ASC actual costs is incorrect for many GI procedures.

The CMS proposal for a single HOPD to ASC payment conversion factor assumes that the costs of most procedures bear a comparable relationship to the relative payment structure in the HOPD payment system. This is not true for many GI procedures.

a. HOPD cost data, as reported by hospitals do not bear out CMS' implicit assumption that costs for GI ASCs bear a comparative relationship with payments in HOPD

However, there are some contrary indications. In fact, a study of hospital costs, derived form HOPD costs and payment data [Attachment 5], shows that among eighteen 40000 series GI CPT codes, four codes [45378 (diagnostic colonoscopy), 43239 (EGD with

biopsy), 43247 and 43450 (two much lower volume codes)] had HOPD payments in excess of the hospital's reported costs, while for the remaining fourteen GI procedures Medicare payments were less than the hospital's reported costs. Based on this-- 77% of GI cases have a negative margin when paid at 100% of the HOPD facility fee payment rate. This disparity will be exacerbated if the proposal to reduce payment for all GI procedures performed in ASCs to 62% of the HOPD payment is implemented as is..

b. Lewin Data on ASC Costs

Lewin has reached a similar conclusion based on an independent analysis of costs for GI procedures performed in ASCs. The purpose was to see how the actual costs would match up with the proposed CMS ASC payments at full implementation of the proposal in 2009. According to this Lewin data, in 2007, Medicare ASC payments will be about 11% higher than actual costs for GI procedures, but in 2008 under the proposed rule, GI payments would drop to around 7% below costs. In 2009, with full CMS ASC payment reform implementation, GI ASC payments would drop dramatically to 22% below actual costs. (Attachment 6)

Further validation of the Lewin cost analysis is the 2003 American Society for Gastrointestinal Endoscopy (ASGE) cost study which determined that costs for GI procedures in an ASC were in the range of $320, With inflation increases, as well as the higher costs of sedation medications, a current day projected cost is in the range of $390 per case. The Lewin information shows costs at $400.50 for 2007, increasing to $416.52 for 2008, and again to $433.18 in 2009. Compare these costs to the dismal projected payment of $349.62 per GI case upon full implementation of the CMS proposal in 2009, for a loss on each case of $83.56.

More broadly, Lewin's data indicating the **negative –22%** in GI, such losses do not reflect any arguable fairness in the envisioned new system. Some have suggested that CMS use cost data, and instead of finding a single percentage of HOPD, focus on a single target profit margin by adjusting the payment structure to reflect the necessary spread between actual payments and actual costs to attain that net profit margin percentage parity. CMS may be reluctant to venture into the arena of profit, but the disconnect between the agency's proposed new payment system and actual costs in GI is so broad and distorted that the agency clearly MUST evolve to a modified or alternate approach for GI ASCs. Fairness demands it.

c. GAO data should NOT be considered in this rulemaking unless it is released to the public, and public comment on it permitted before the end of the comment period. CMS should not utilize information that was in its possession but not shared with the public for comment.

We are compelled to comment on the legal status of the long-overdue GAO report. The GAO report, which Congress directed be published by January 1, 2005, was not published in a timely manner that would have allowed it to be considered by all stakeholders in this rule-making. CMS issued its proposed rule without the benefit of the

GAO report, and welcomed comments on that proposal without anyone having the benefit of seeing any GAO cost analysis. If the agency wanted to factor the GAO report into its analysis of these questions, and into this ASC rulemaking, CMS could have deferred publishing this proposal until after a final GAO report was released to the public. CMS chose to proceed without the GAO report and we believe is now bound to exclude that report completely from all consideration in this rulemaking.

We have been informed that within the final three weeks of the comment period, GAO shared with CMS a "draft"of its report for agency review and input. While GAO made provision for a very small number of people outside CMS to see this draft proposal, we have not seen it (in fact, despite our request to GAO, we have affirmatively been denied access to review it), do not know its contents, and so cannot factor it into our response to the CMS proposal. We believe at this juncture, CMS should be constrained from considering the GAO report in any way in this proposed rulemaking. CMS cannot have the benefit of information in an NPRM, under the Administrative Procedure Act, that is not made available to all stakeholders and interested parties. Legally, the agency has only two choices: (1) eliminate the GAO report entirely from all consideration in this ASC payment reform rulemaking, since this information is not available to the public now, or at any time during the comment period; OR (2) withdraw the current proposed rule, await the dissemination of the GAO report for public availability, and then publish an entirely new rulemaking proposal so that right of public comment is not compromised by the lack of availability of the final GAO report.

The cost data, referenced under item (b) above, argues quite compellingly in favor of some specific intervention to address the GI disparity. In the face of this cost data, and with CMS's unsubstantiated presumption that the costs of GI ASCs bears a comparable relationship to the GI HOPD payment system having been soundly disproven with actual data, we think the agency must invoke a higher percentage payment for GI. Essentially, we are advocating a bi-level approach. Time is short, and we have pressed our efforts with Lewin to identify a bi-level structure that would make for either no loss, or the smallest possible loss to GI, while still maintaining all other specialties at roughly the budget neutral level. While this work is still ongoing, we believe a bi-level approach will fall somewhere in the range of 81% for GI and 65% for all other specialties. **This would still mean a reduction for GI, while avoiding the precipitous decline that the data demonstrates would uniquely drive GI *only* into *huge* negative margins of negative – 22% or more. Such a plan could be budget neutral if CMS adopts the broader view of budget neutrality across the entire Medicare outpatient system as envisioned and authorized by Congress in MMA 2003, and outlined in #I above.**

IV. The proposal to bring all ASCs to a single percentage of HOPD generates too many big winners and losers. A bi-level approach will better reflect actual costs AND can assure the best outcome in Medicare savings by reducing potential profound negative migration among the big losers

Initially, virtually the entire ASC community (except GI and perhaps pain management) thought that moving all specialties to a single percentage of HOPD was the fair and

correct approach. Many had also hoped that a combination of a stop loss provision and long phase-in could save GI from huge immediate losses. But over time, the CBO estimate on the Herger-Crapo bill showed that the cost of this was fairly high. Therefore, the legislative approach to ASC reform stalled. In our discussions with Lewin, we have asked them to evaluate the merit of a bi-level payment structure, that would avoid the huge "winners and losers" implicit in moving across what was a 48 point spread between GI (where estimates of current payment as percentage of HOPD range from 89% to 83.4%) and orthopedics currently at 36% of the HOPD payment.

CMS indeed had a suitable model to examine for at least some of the issues it faces related to ASC payment reform. The **Herger-Crapo bill (H.R. 4042/S. 1884)** misses the mark although it targets a more reasonable ASC payment structure, and is certainly preferable and more realistic than the current CMS proposal. **It too insists on moving all medical services, those currently reimbursed at 34% of HOPD to those currently reimbursed at 89% of HOPD, a spread of 55%, to a single level as a percentage of HOPD payments, creating profound winners and losers, instead of moving to at least two different levels to help narrow both the losers and the winners.**

If CMS is bound to peg ASC payments at a percentage of HOPD, it must adopt a bi-level approach. The first level would consist of GI ASCs, both because of the huge negative margins (estimated at **negative –22%**), and because of the delicate impact on an already underutilized Medicare colorectal cancer screening benefit. The first level should be at a higher tier of payment, close to the current 89% GI now receives but at least no lower than 81%. If not, data show GI procedures moving into a huge negative margin that would limit Medicare access in multiple ways, including, as noted below, pushing perhaps 20% of GI ASCs out of business. A second, lower tier as the facility fee percentage should be established for ASCs in other specialties which are not involved in life-saving preventive services like colorectal cancer screening tests (Attachment 7).

V. Specific deficiencies with percentages and proposals

The uniform discount rate of 62% is too low. The payment threshold proposed by CMS is an unusually low number, both compared to the 89% currently paid by CMS for GI services, and in light of the fact that ASCs are smaller, have less purchasing power and therefore are at a cost disadvantage vis-a-vis hospitals. **This is too drastic a drop for any small business to absorb, and will likely result in reduced access by Medicare beneficiaries to life-saving colorectal cancer screening tests commonly performed in ASCs.** The Crapo-Herger legislation acknowledged these concerns, and provided a combination of hold harmless/stop loss provisions along with a longer phase-in period to prevent sharp reductions in payment, severe disruption of these small businesses and their employees, and resulting declines in access. For these reasons, we urge CMS to modify the rule to adopt a two-tiered structure. **One level would apply for GI services, projected at somewhere around 81% or modestly higher, and a second level, projected at 65% of the hospital outpatient rate, would apply to all other services provided in the ASC setting.**

The list expansion needs refinement. The expansion of procedures eligible for Medicare payment in ASCs in 2008, while an improvement over current law, does not go far enough. The proposed list expansion remains restrictive, does not provide true site neutrality with the hospital setting and thus does not offer beneficiaries and their physicians a true choice with respect to accessing outpatient surgical care.

If ASC payment is to be linked to HOPD payment there needs to be comparability. Clearly, an essential reform that is not addressed in the CMS rule is that the cost for devices used during procedures performed in the ASC must be reimbursed (they are currently reimbursed in the hospital, but not in the ASC). **This change would generate savings by opening ASCs to many services currently performed only in the more expensive HOPD setting solely because device costs cannot be fully absorbed by the ASC.** CMS needs to create some greater measure of parity between the HOPD and ASC setting. Specifically, CMS must revise this rule to permit the payment in the ASC to include, in additional to the facility fee itself, the cost of devices and other pass-through items. The current discrepancy, where these devices and pass-through items are paid in addition to the facility fee in the HOPD but not the ASC, is unfair, and is a major reason why many cases that could be cost-effectively and safely done in the ASC are not done there.

Finally, while we do not think that the current proposal by CMS linking ASC payments to a percentage of HOPD payments is a sound one, we do believe that it is essential that facility fee payments in both the ASC and HOPD settings be updated, using the same factors and formula. ASCs, like hospitals, should be updated based on the hospital market basket rather than the urban Consumer Price Index. Using the hospital market basket for annual updates as to both ASC and HOPD facility fees would achieve parity and transparency in the market. The hospital market basket is almost certainly a better indicator than CPI of inflation costs in providing medical and surgical services. Unifying the criteria for inflation updates around the hospital market basket approach would help assure that decisions regarding where services are to be provided continue to be made on the basis of what is best for the patient, and not be skewed by economic considerations.

VI. ACG survey of ASCs

We have commented above on key factors relating to GI ASCs. Among these are the expectation of a strong negative case migration from GI ASCs to HOPDs if this proposed rule were adopted, the prospect for longer waiting times and increased pressures on GI ASC access for Medicare patients, and difficulty in maintaining ASC operations will result. In addition, one very likely negative public health ramification of the adoption of this proposal is reduced utilization of the Medicare colorectal cancer screening benefit, with likely reduction in early detection, and higher total costs, both financially and in lost lives, for cancers diagnosed at more advanced stages. ACG is not making these conclusions ab initio (as CMS seems to do with its conclusion that the HOPD payment system somehow accurately reflected relative costs by specialty). Rather, ACG compiled data from GI ASCs on the likely effects adoption of this proposed rule would have. ACG initiated a survey of 105 randomly-selected GI ASCs to try to gauge anticipated actions

and expected responses by these stakeholders in the event that the CMS proposed rule is enacted with the resulting reduction in dollars paid to GI ASCs for services provided to Medicare beneficiaries. A total of 38 responses were received to this survey. The entire survey profile is attached to these comments (Attachment 8). Some of the key findings from this survey, which are shared for illustrative purposes only, are as follows.

The phenomenon of reverse migration was confirmed, but the relationship is not a linear one. With cuts of 5%, only 3.6% of GI ASCs would start refusing to see Medicare patients. When the cuts increased to between 11-20%, a total of roughly 19% of GI physicians say when their Medicare patients require colonoscopy or other endoscopic procedure, they likely are not going to continue to perform those procedures themselves in their ASCs, at least not as consistently. When the ASC payment cuts increased above the **negative -20%** mark, a full one-third of GI physicians surveyed said they would not be able to continue to perform the procedures on their Medicare patients themselves, at least not within their ASCs.

-90% of respondents said Medicare patients definitely would always wait longer than they currently do if the CMS ASC payment reform proposal were adopted.

-93% said that enactment of this proposed rule, and the resulting payment reduction, would increase the likelihood of their recommending to Medicare patients who desire to have procedures done in the ASC that they should instead have these done in the HOPD (no reference in this question to whether GI physicians would be willing to go to the HOPD themselves to perform these procedures there).

-17.9% of GI ASCs said that they would expect their ASCs to close completely if the CMS ASC payment rule were implemented as proposed. 79.3% said they expected enactment of this rule would result in fewer employees at their ASC, and 69% said there would also be a reduction in the average compensation for ASC employees. Only 7.1% said they thought this proposed rule's enactment would result in an increase in the total number of hours per week that their ASC would see patients, discounting in strong terms any concept of a behavioral offset for the dramatically reduced per patient payment this rule would portend for GI.

VII. CMS Policy will force many ASCs out of business and others to close to Medicare patients, creating an access dilemma, and more broadly eliminating a cost-effective center for health care

CMS seems to be ignoring both the stated priorities of the current Administration as well as the lessons of cost management in the private sector. President Bush and Administration officials are on record, on multiple occasions, stating that ASCs are a more cost-effective environment than the hospital to receive key medical services. When private sector insurers have sought to reduce total health care costs, they have actively sought to encourage patients to receive their services in the ambulatory surgery center, instead of in the hospital outpatient department. One recent example is Blue Cross of California's announcement that it will pay a 5% premium to physicians for every GI

endoscopy that is performed in the ASC, rather than in the HOPD. This CMS proposal, which would always pay more to HOPDs and always pay less to ASCs, is directly antithetical to the direction adopted by the private sector insurers.

The results of CMS's proposed policies would be to drive a substantial number of ASCs out of business.17.9% of GI ASCs said they would expect to close their doors completely and go out of business if the proposed CMS rulemaking were enacted. If CMS, contrary to both the White House and most Congressional health policymakers, thinks that fewer sources of care and fewer choices for patients represent sound health policy, the agency is certainly using its power in the health marketplace to move in that direction. If CMS wants to eliminate the lower cost centers for quality care, and force more cases into the higher cost hospital centers, it has crafted a policy to accomplish this. If CMS thinks that creating an access crisis for its beneficiaries is necessary to balance the country's health care budget, it has found a policy that will indeed reduce access to critically needed medical and preventive services for Medicare beneficiaries. At the levels of the **negative –25%** in GI, CMS can cut Medicare beneficiary access to GI services by a full one-third. But frankly, we think that these are all results that CMS should want to avoid, not embrace. If CMS thinks more competition, more centers for high quality, lower cost health care, and more choice and access for Medicare beneficiaries are components that should drive the Nation's health policy, then CMS should follow what private sector health planners and insurers are doing. CMS should scrap, or radically change this proposed rule so that Medicare begins providing dollar parity in costs between ASCs and HOPD, and encourage, not penalize those in the business of providing safe, convenient and cost-effective patient care in the ASC setting.

VIII. Volume threshold for ASC services and small business issues for potential closing of ASCs with volumes below the threshold of 3,500 annual cases

A recent Deutschebank analysis was released which provides insights into the minimum number of cases that an ASC would have to perform per year in order to survive under a payment structure such as CMS proposes. Deutschebank analysts concluded that any ASC that provides fewer that 3,500 procedures per year will be put out of business—the data from the ACG survey, while a small sample, indicates that fully 20% or one-fifth of GI ASCs will go out of business based on the volume criteria. In that same survey, 18% of GI ASCs stated that imposition of the draft CMS ASC rule would cause them to go out of business. Clearly, by either of these measures, this CMS proposal would have a profound and disproportionately negative effect on small business ASCs across the country, and may well require study by the Small Business Administration before it can be enacted.

IX. What will happen to GI under the current proposal, Harm to GI as well as the public health consequences, Including Damage to the Colorectal Cancer Screening Benefit, Resultant Loss of Lives from Failure of Early Detection and Resultant Higher Medicare Costs for Patients Whose Colorectal Cancers Are Diagnosed at More Advanced Stages

Damage to the colorectal cancer screening benefit, resultant loss of lives from failure of early detection and resultant higher Medicare costs for patients whose colorectal cancers are diagnosed at more advanced stages are the results that can be expected under this proposed rule. Both the GAO and CMS itself have stated that the Medicare colorectal cancer screening benefit is underutilized. MEDPAC repeatedly has endorsed the concept that medical procedures and services should be site neutral. On its face, a proposal such as this one seems counterproductive. It institutionalizes the concept of paying significantly more to the hospital than to the ASC, and which will likely pose distinct and difficult challenges to providing GI screening colonoscopies and other GI endoscopic procedures, because Medicare's payment level will drop so precipitously that these ASCs can no longer meet their expenses and render a reasonable return on investment, seems counterproductive.

While timely screening could reduce mortality by 90% from colorectal cancer, utilization of the benefit will continue to lag, perhaps irreversibly if these additional cuts are implemented by CMS.

In the gastroenterology area, CMS's proposed policy virtually assures results inimical to the public health. Today, when a GI procedure, such as a screening colonoscopy, is performed in an ASC, that ASC receives a facility fee which on average amounts to 89% of the facility fee CMS pays to the HOPD if that same procedure is performed there. We need to provide a bit of background relating to the effectiveness of the Medicare colorectal cancer screening benefit. Congress did the right thing in 1997 when it enacted the Medicare colorectal cancer screening benefit, and again in 2000 when it added the average risk colonoscopy benefit, and again in 2005 when it waived the deductible for this important screening service. Sadly, and whether intentionally or inadvertently, CMS has diminished utilization of that benefit. Since 1997, CMS has cut the physician fee schedule payment for screening/diagnostic colonoscopies by almost 40%, from a little over $300, to the current level of under $200, and trending downward. No other Medicare service has been cut this much over this period. The new ASC proposal would further diminish prospects for Medicare beneficiaries to receive a colorectal cancer screeing colonoscopy. In terms of the specialty that would be hurt the most by the current proposal, once again, CMS has placed gastroenterology and colonoscopies for colorectal cancer screening in its cross hairs, as by far the biggest potential loser, with the prospect of cuts from 89% of the HOPD payment to 62%.

It is clear and relatively easy to predict what will happen if this CMS proposal is adopted

in anything close to its current form:

For Patients:

Utilization of the Medicare colorectal cancer screening benefit, under this proposed rule will decline still further, and cancers will go undetected. In life and death terms, many Medicare beneficiaries will die unnecessarily because the access to sites where colonoscopies can be performed will be reduced as GI ASCs close. Waiting times for screening will increase, and the overall rate of CRC screening will plummet farther.

For the Medicare System:

Medicare facility fee payments for GI services will increase, rather than decrease. Having dealt a death-blow to many GI ASCs by draconian reductions in payment, the access of Medicare beneficiaries to GI ASCs will be markedly reduced. CRC screening colonoscopies will be reduced, but the volume of diagnostic colonoscopies and endoscopies will not decline.

With fewer ASCs, a larger proportion of all GI procedures will need to be performed in the HOPD, where the facility fees CMS pays will be higher.

So, the inevitable result of this proposed CMS action, if implemented, will be: (a) total Medicare costs for GI facility fees will rise (although the per unit facility fee for decreased number of these performed in the ASC may well decline); (b) available access by Medicare beneficiaries for life-saving GI screening colonoscopies, other GI diagnostic and therapeutic colonoscopies and other endoscopic procedures will decline; and (c) the number of Medicare beneficiaries who will die unnecessarily from colorectal cancer will increase as screening rates decline. These cancer patients, detected at later stages, will incur increased Medicare expenditures for colorectal cancer end-stage treatment accordingly.

CMS may face a choice between which of two ways it wishes to lose money: (1) negative migration of cases from the ASC to the HOPD if GI private practice doctors are willing to go to the hospital to do the cases; or (2) reduced access for Medicare beneficiaries, later detection of many colorectal cancers with higher downstream care costs

If CMS maintains its current posture on this rule and pursues a policy that ensures big losers, like GI and huge winners, like orthopedics, the agency will almost certainly face something of a Hobson's choice between two devastating results. The Medicare budget will sustain significant financial losses in direct proportion to the percentage of physicians, who, when faced with ASC payment cuts in the range of 25-30%, choose to refer their Medicare patients to have their GI procedures performed in the hospital outpatient department. This will trigger negative migration. E ach and every case shifted from the ASC to the HOPD will cost Medicare more money. This result is a very bad

one, but even worse outcomes will await if a substantial number of GI doctors decide, with every single Medicare ASC procedure costing the practice approximately $83,-- i.e. the amount by which 2009 costs will exceed Medicare payment for each and every case--that if they cannot afford to see Medicare patients and do their procedures in the ASC, they will not indulge the further inefficiencies of seeing those patients in the HOPD, but rather simply stop being a physician who does any, or many GI procedures on Medicare patients. This behavior, the only viable alternative to shifting Medicare cases back to the HOPD, would trigger greatly reduced access for Medicare beneficiaries, with the inevitable results of later detection of many colorectal cancers, increased colorectal cancer fatalities among Medicare beneficiaries, and higher resulting downstream costs as patients with cancers detected at later stages require more cost-intensive care.

X. Additional measures that CMS needs to undertake if this rule is going to proceed: longer phase-in, hold harmless, adoption of a bi-level approach

ACG believes that this CMS proposal for ASC payment reform is seriously ill-conceived and, if adopted, would be disastrous. The agency needs to recognize the realities of this complex field, ones that are not easily assimilated at first glance, as is so clearly evidenced by the agency's initial ASC payment reform proposal. This is not a situation which can be repaired by a few palliatives. Rather, this rulemaking requires a complete re-thinking and new approach, of necessity almost certainly a bi-level one, to help compensate for the "costs exceed payments by –22%" situation in GI, as well as an approach that will expand the definition of budget neutrality, and allow for the powerful economic factors of case migration as part of budget neutrality projection. Such a rulemaking must reflect accurate cost data, and recognize that such data debunks the agency's unsupported presumption that somehow, the costs of GI ASCs bear a comparable relationship to the relative payment structure for GI procedures in the HOPD payment system. ASCs and HOPDs are apples and oranges, not oranges and oranges.. While the agency's total re-thinking is called for, our comments would not be complete unless we mentioned briefly a few additional considerations that could and should be factored into any new agency approach to the task of ASC payment reform.

The transition period is too short. The proposed transition period , essentially a one year phase in of revised rates (the rule proposes a 50/50 rate split between current law and the new amounts in 2008), is drastic and is not sustainable for ASCs. Especially as some surgical specialties confront rate cuts of up to 30% under the proposed rule, a slower transition period, gradually applying a blend of old and new amounts over a four-year period, is necessary for ASCs to prepare for and respond smoothly to the new system.

CMS also needs to adopt a key component of the Herger-Crapo approach, namely, to provide a hold-harmless so that even if the percentage of HOPD payment declines for one or more specialties as a new ASC payment structure is implemented, the losing specialties are assured that their actual dollar payments will not decline. Rather, losers can be held harmless at current payment levels until the calculation of their applicable

percentage of the HOPD payment actually exceeds the number of dollars being paid for that service today.

But clearly, the best prospect to transform this ASC payment reform process so that it does not precipitate huge case migration swings of undetermined consequences, and an extraordinarily damaging degradation of the Medicare health care and access system, is the necessity of adopting a bi-level approach. Obviously, this is the only realistic conclusion to address what would otherwise be extremely devastating losses in GI that would severely handicap the preventive screening fight against colorectal cancer.

Adopting a bi-level approach that pegged GI at about 1.25% of the payment level for other specialty ASCs would substantially diminish GI losses, save Medicare money by minimizing the costs of negative migration of GI cases from ASC to HOPD, and avoid a public health debacle in further undercutting the already seriously underfunded struggle to reduce the lethal toll of colorectal cancer through early screening. Physicians deserve fairness, and Medicare beneficiaries deserve a system that works and saves lives, while being cost efficient. We urge CMS to adopt this bi-level course in evolving this proposal.

a. Conclusion

In conclusion, CMS's proposed changes to the ambulatory surgery center (ASC) payment proposal:

(1) adopts too narrow a view of budget neutrality and does not properly count savings that accrue when services, already approved for ASCs migrate from the HOPD to the ASC. If CMS counted those savings it would allow Medicare ASC payments to be set at a higher, more realistic level. CMS ignores also, under the heading of budget neutrality, the profound cost increases for Medicare attributable to negative migration as big losing specialties predictably shift cases to the higher cost HOPD setting; a costly result that can be avoided only if the final CMS rule is fair and gives relief, most effectively through a bi-level system, to GI and possibly other prospective big losing specialties;

(2) undercuts ASCs, and would cause many of these facilities, which offer a lower cost option, to go out of business. This will cause loss of small business jobs and revenues in most Congressional districts; other ASCs would have to limit access by Medicare beneficiaries;

(3) dramatically reduces the effectivevness of the Medicare preventive colorectal cancer screening benefit, causing unnecessary deaths from colon cancer as patient access is confined to fewer screening sites, and beneficiaries wait longer or simply decide not to be screened. CMS reductions in physician payment for colonoscopies of about

40% since 1998 already have prompted consideration of federal legislative intervention via S. 1010/H.R. 1632, to try to reverse the damage to the screening benefit. If CMS does chop off another 30% from GI ASC facility fees, the colorectal cancer preventive benefit would be damaged even more dramatically.

It is hard to believe that these are the results CMS is seeking; however, the only way to avoid this outcome is to modify the proposed rule to avoid a decrease to the facility fees to GI ASCs. This could alleviate the closure of very significant numbers of GI ASCs, and thus avoid a reduction in access and CRC screening rates. It will also prevent an increase in the number of GI procedures performed in the more costly HOPD setting.

Respectfully submitted,

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Attachments

Attachment 1 –Fact Sheet on Prospective Savings from Case Migration HOPD to ASC
Attachment 2 –Legal Opinion Relating to Budget Neutrality
Attachment 3 –Selected Tables Reflecting Lewin Analysis on Case Migration
Attachment 4 –Lewin Case Migration Analysis Relating to Negative Migrations and Its Costs to the Medicare Program
Attachment 5 –Costs of GI Procedures as Related to HOPD Payment Structure/Amounts
Attachment 6 – Lewin Data on ASC Costs
Attachment 7 –Lewin Table Demonstrating Bi-Level Payments and Amount of Migration Needed to Support Them
Attachment 8 –ACG ASC Survey Results Summary

Attachment 1

Fact Sheet on Prospective Savings from Case Migration HOPD to ASC

Table 1: Payment 75% - With Hold Harmless (code specific migration)

	Specialty	Current ASC	Current APC	New ASC	# cases	Savings per case	Expected Specialty Migration	Total Medicare Savings
43239	GI	$446	480.03	$446	628415	$34	4%	$855,398
62311	Pain/Neurology	$333	357.9	$333	400006	$25	4%	$398,406
45378	GI	$446	509.34	$446	578795	$63	4%	$1,466,435
52000	Urology	$333	412.93	$333	128984	$80	4%	$412,388
64622	Pain/Neurology	$973	1387.71	$1,041	27723	$347	7%	$719,722
15823	Dermatology	$717	1082.84	$812	63684	$271	11%	$1,833,272
66984	Ophthalmology	$333	600.85	$451	2027195	$150	22%	$65,966,885
26055	Orthopedics	$446	930.73	$698	40006	$233	32%	$3,002,655
29881	Orthopedics	$630	1670.39	$1,253	44370	$418	53%	$9,899,563
								$84,554,724

9/5/2006

Legal Opinion on Budget Neutrality

CONSIDERATIONS FOR HHS IN DESIGNING NEW ASC PAYMENT SYSTEM

Congress has given the Department of Health and Human Services (HHS) broad authority to develop a new Medicare payment system for ambulatory surgical centers (ASCs). HHS and the Centers for Medicare and Medicaid Services (CMS) should use this opportunity to accomplish the following policy goals:

- Achieve cost savings for the Medicare program;
- Provide savings to Medicare beneficiaries;
- More closely align payments across the different sites of service for outpatient surgery;
- Promote competition among the providers of outpatient surgical services, especially ASCs and hospital outpatient departments (HOPDs); and
- Encourage increased transparency among Medicare providers, including transparency on price and quality of care.

These goals are fully compatible with the mandate given to HHS in the Medicare Modernization Act of 2003 (MMA), which simply directed the Secretary to develop a "revised" payment system for surgical services furnished in ASCs. While the MMA is short on specifics – other than that the new system be implemented by not later than January 1, 2008 – it does include additional statutory parameters to help guide HHS's development of the revised ASC payment system:

> *First*, MMA requests a Government Accountability Office (GAO) study comparing the relative costs of procedures furnished in ASCs to the relative costs of procedures furnished in HOPDs, as well as recommendations on the appropriateness of using the hospital outpatient prospective payment system (HOPPS) as the basis for the new ASC payment system. Although the GAO report was due by January 1, 2005, the report is not yet complete. Furthermore, it is unclear whether the GAO has compared relative costs between these two settings and/or whether GAO will make recommendations.
>
> *Second*, MMA provides that the revised ASC payment system should be designed to result in the same aggregate amount of expenditures in the first year of the revised ASC payment system that would have been made if HHS had not revised the ASC payment system. In addition, the Deficit Reduction Act of 2005 (DRA) caps payments for certain procedures furnished in ASCs at the HOPD amount for those procedures, beginning January 1, 2007.

These statutory parameters provide HHS broad latitude in developing a revised ASC payment system.

To achieve the policy goals set forth above, however, it is essential that the budget neutrality provisions in MMA be interpreted and applied to include cost savings that will be realized from the inevitable shift of services currently performed in HOPDs to lower cost ASCs following implementation of the new payment system. Otherwise, if budget neutrality is applied only to ASC services, the result will be substantial cuts in ASC reimbursement that will significantly undermine the viability of ASCs serving as an effective competitive alternative to HOPDs.

With that in mind, the remainder of this paper sets forth the case for a broad reading of the budget neutrality requirement in MMA, consistent with (1) the statutory language, (2) the legislative history and context underlying MMA, and (3) other comparable situations, where CMS has applied its budget neutrality obligations in ways that took into account anticipated changes in behavior, like the shift of procedures from HOPDs to ASCs that is likely to occur following implementation of the new ASC payment system.

POLICY GOALS

Achieve savings to the Medicare program and Medicare beneficiaries. As surgical procedures have shifted over time from inpatient to outpatient settings, the costs to the Medicare program for these procedures (by individual procedure) have decreased. However, Part B expenditures in this area have grown. A revised ASC payment system could be used as one tool to reduce the cost of outpatient surgical procedures by allowing ASCs to compete on a more level playing field with HOPDs. When outpatient surgical services are performed in ASCs, the Medicare program and Medicare beneficiaries save money.[1] As technology and practice protocols have advanced, ASCs can now safely perform many procedures that are currently not covered by the Medicare program when performed in an ASC. Therefore, these procedures continue to be provided in HOPDs, in most cases at greater cost to the Medicare program, as well as to beneficiaries. Under the statute, Medicare beneficiaries pay a 20% copayment for all services received in ASCs. However, under the statute, beneficiary copayments for HOPD services can be as high as 40%, and, according to the Medicare Payment Advisory Commission (MedPAC), in 2004 were as high as 34%.

More closely align payments across sites of service delivery and promote competition among providers of outpatient surgical services. CMS has recently observed that many small orthopedic or surgical specialty hospitals "may describe themselves as hospitals rather than ASCs, in part to take advantage of the more favorable payment rates" that apply under HOPPS, as opposed to the current ASC payment system.[2] For the same reason, many procedures that could be performed in ASCs are instead routinely performed in HOPDs because ASC payment rates do not adequately cover facility costs. By reforming the ASC payment system to diminish payment disparities that encourage artificial incentives for the creation of small orthopedic or surgical hospitals and the provision of procedures in HOPDs, CMS will lower costs to the Medicare program while, at the same time, promote healthy competition. However, if HHS develops an ASC payment system that substantially underpays ASCs relative to HOPDs, market forces will work to keep procedures in the hospital setting. The end result will be continued barriers to effective competition and reduced access for Medicare beneficiaries. Without payment parity across sites of service, potential providers of surgical services may be unintentionally encouraged by the Medicare program to invest in building and expanding hospitals, rather than ASCs.

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[1] The HHS Office of Inspector General (OIG) examined the costs of 424 procedures performed in both ASCs and HOPDs and determined that 66% of these procedures were performed in ASCs at a lower reimbursement rate. *Payment Procedures in Outpatient Departments and Ambulatory Surgical Centers*, OEI-05-00-00340, Jan. 2003.

[2] Testimony of Mark B. McClellan, MD, PhD, Administrator, Centers for Medicare & Medicaid Services, Before the House Committee on Energy and Commerce Hearing on Specialty Hospitals: Assessing Their Role in the Delivery of Quality Health Care (May 12, 2005).

Encourage increased transparency among Medicare providers. Equal competition among hospitals and ASCs also should include price transparency, especially with regard to beneficiary co-payment obligations. This would empower beneficiaries to make more informed choices about the cost of the services they receive. CMS also should consider other opportunities to promote transparency in its development of the revised ASC payment system.

THE BUDGET NEUTRALITY PROVISION

Section 626 of MMA directs the Secretary to consider the budgetary baseline impacts of the revised ASC payment system. Specifically, that section provides that:

> *"(ii) In the year the system described in clause (i) is implemented* [i.e., the revised ASC payment system], *such system shall be designed to result in the same **aggregate** amount of expenditures for **such services** as would be made if this subparagraph did not apply, as estimated by the Secretary."* (Emphasis added.)

The key to interpreting this budget neutrality provision is the underlined phrase, particularly the words in bold – that is, what "such services" are covered by this provision and how is their "aggregate" impact to be measured? Looking only at the statutory text, the most logical reading of the term "such services" is that it relates to "such system" referenced in parallel form earlier in the same sentence, thus meaning the services covered by the new ASC payment system. With that established, "aggregate" expenditures then refers, by its plain meaning, to "total" or "overall" Medicare expenditures for the services covered by the new system. In other words, under this provision, budget neutrality is to be measured by reference to the impact the new ASC payment system will have on overall Medicare expenditures for the total package of services covered by the system. Thus, if, as we anticipate, the new payment system will expand coverage to include additional procedures not currently on the Medicare ASC list, the budget impact is to be evaluated to include any savings that will be achieved through the performance of those procedures in ASCs, rather than in HOPDs. The statute recognizes that this is not capable of precise measurement; thus, it only requires that the system be "designed" to achieve this result, "as estimated by the Secretary."

The alternative way to measure budget neutrality would be by reference to ASC payments only – that is, the new payment system could not result in overall ASC expenditures being greater than they would be without the new system.[3] The problem with such an approach is that if CMS significantly broadens the list of covered ASC procedures, as Secretary Leavitt indicated is the plan (in a December 2005 letter to Senator Mike Crapo), ASCs will be able to perform hundreds of additional procedures for Medicare beneficiaries that currently are performed only in HOPDs. Thus, budget-neutrality, if applied to avoid any aggregate increase in ASC payments, would necessitate drastic, across-the-board reductions in payments for all ASC services to a level that would not be sustainable for the ASC community. Many ASCs could be forced to discontinue providing Medicare services, thus reducing patient choice and harming beneficial competition for outpatient surgery.

[3] We presume that even under this alternative interpretation, CMS would make the kinds of routine adjustments for changes in case mix and volume that historically have been applied in assessing budget neutrality.

Fortunately, the statute does not compel this result. By its plain language, Section 626 calls for budget neutrality to be measured by reference to the new ASC payment system, and that system's impact on "aggregate" Medicare expenditures for all of the services it covers, "as estimated by the Secretary." Under traditional canons of statutory construction, that should resolve the issue and define the approach CMS should follow. *See Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002) (if the statutory language is unambiguous, then the inquiry ceases).

If there is doubt in that regard, then the "statutory language must always be read in its proper context." *McCarthy v. Bronson*, 500 U.S. 136, 139 (1991). While statutory interpretation begins with the express language of the statute, "[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *United States Nat'l Bank of Oregon v. Indep. Ins. Agents of America, Inc.*, 508 U.S. 439, 455 (1993) (citations omitted). In this case, we believe the overall object and policy behind MMA further supports application of budget neutrality in a way that accounts for the cost savings to be achieved through the expanded provision of services under the new ASC payment system.

THE MMA SEEKS TO PROMOTE EFFECTIVE COMPETITION

Looking at the "whole law," its "object and policy" requires a broader examination of MMA. The preamble to the law states that one of its purposes is to modernize the Medicare program. "Modernizing" Medicare includes expanding the role of private market forces in the program. Indeed, in MMA, Congress explicitly created an enhanced role for private health plans, disease management companies and private pharmacy benefit managers to compete on a local, regional and national basis to deliver enhanced Medicare benefits, most notably including outpatient prescription drugs. These entities submit bids in open competition free from government interference; health and drug plans must meet certain baseline benefit standards, but are encouraged to compete on cost and quality. These private market forces, and the value of head-to-head, level playing field competition, have served to lower the cost of health care, while at the same time increase the quality of care received by Medicare beneficiaries. Fostering competition is one of the primary tools utilized by Congress in the MMA to achieve cost savings for the Medicare program. In other aspects of the program, Congress has developed competitive bidding programs to produce savings in the areas of durable medical equipment, clinical diagnostic laboratory services, and certain physician-administered outpatient drugs.

The same approach to promoting market competition can be seen in the ASC provisions of MMA. Congress clearly recognized that many surgical procedures that are performed in HOPDs can also be performed in ASCs. Thus, Congress mandated the creation of a new payment system for ASCs and directed GAO to consider the appropriateness of basing that system on HOPPS. Congress's clear intention was to consider an ASC payment system that was similar to the HOPPS, thus providing a more level playing field between similar settings. Congress no doubt hoped this would lead to the migration of procedures from the more-costly HOPD setting to the ASC setting. The collective group of "such services" would include those procedures currently performed only in HOPDs, but that may be performed in ASCs upon implementation of the revised ASC payment system. In other words, the dynamic nature of the HOPD/ASC marketplace should be considered, and we believe the Secretary should approach the budget neutrality provision with the same breadth Congress did when it enacted Section 626,

which is to say with a depth that includes the cost impact of all outpatient surgical services performed across all service lines, not just ASCs.

In short, the MMA should be read in the context of Congress' goal to modernize Medicare, improve patient choice, and lower the cost of services, including outpatient surgery, to the program and its beneficiaries. The Secretary's own Inspector General noted that the majority of procedures currently performed in ASCs and HOPDs can be performed at a lower cost in the ASC setting. A revised ASC payment system that ensures reasonable reimbursement rates will reduce the costs of those outpatient procedures to Medicare, thus fulfilling the intention of Congress when it sought to modernize payments for ASCs. Moreover, improved patient access to ASC services will result in lower out-of-pocket costs for beneficiaries. ASC copayments are 20% of the service's cost; copayments for the same service in the HOPD can be as high as 34%.

The MMA was designed to modernize Medicare, lower cost, and improve patient choice through increased competition. Thus, the proper lens through which a revised ASC payment system should be viewed involves lowering the cost of outpatient surgery. For the majority of surgical procedures, where such services are performed in an ASC setting instead of an HOPD setting, we believe Medicare's costs will be lower; that ASCs can and will provide such services in a safe and more efficient way than other providers.

OTHER APPROACHES INVOLVING BUDGET NEUTRALITY

Numerous statutory and regulatory references to budget neutrality exist in changes to various payment systems instituted by Congress and implemented by HHS over the years. Generally, when CMS prepares to implement payment system reform through the rulemaking process, interpretations tend to lean toward a measure of the same total payment for the same class of providers. Crafting a budget neutral payment system in the instance of ASC payment reform is challenging as this payment system could affect multiple classes of providers (i.e., HOPDs, ASCs and physicians).

In general, CMS considers total payments to providers based upon a particular class of service. For example, when moving from a cost-based system to a prospective payment system, the focus is making changes to payments within that specific system (*e.g.*, inpatient rehabilitation facilities, skilled nursing facilities). Rather than renew or remake a new payment system with new money, budget neutrality provisions tend to force CMS to reconfigure old systems to pay for new ones within the narrow context of services offered by those same providers in the previous year. CMS' conclusions can be driven, however, by how it chooses to define "services" in the context of a particular issue.

Statutory budget neutrality language often includes the narrowing phrases "under this part" or "under this title" to refer to the application of the budget neutral limitation on aggregate spending. Section 626, however, does not include this language. CMS therefore has considerable latitude to define the overall dollar pool broadly in the context of a revised ASC payment system.

What follows is a selected summary of statutory and regulatory approaches to the budget neutrality concept used by CMS in implementing payment system reform. These approaches provide further historical justification for a broad application of budget neutrality with respect to ASC payment reform.

INPATIENT REHABILITATION FACILITY (IRF) PROSPECTIVE PAYMENT SYSTEM

In the IRF PPS final rule, CMS discussed how it would adjust payments in future years in order to facilitate budget neutrality, in part by making changes to the conversion factor, wage adjustments, outlier payments, and relative weights during the transition to the new payment system.[4] CMS discussed the application of budget neutrality in broad terms, recognizing that the new IRF PPS could lead to new practice patterns – an outcome likely under Section 626 as well. Specifically, CMS recognized and discussed the implications of changes in efficiency, site utilization, and behavioral modifications providers would make in adapting to the new payment system. The behavioral offsets of physicians played an important role in this discussion of budget neutrality:

> "*This provision requires the Secretary, in establishing budget neutral rates, to consider the effects of the new payment system on utilization and other factors reflected in the composition of Medicare payments...The purpose of the budget neutrality provision is to pay the same amount under the prospective payment system as would have been paid under the excluded hospital cost-based payment system for a given set of services, but not to pay that same amount for fewer services furnished as a result of the inherent incentives of the new prospective payment system. Thus, our methodology must account for the change in practice patterns due to new incentives in order to maintain a budget neutral payment system. Efficient providers are adept at modifying and adjusting practice patterns to maximize revenues while still maintaining optimum quality of care for the patient. We take this behavior into account in the behavioral offset.*" [5] (Emphasis added.)

We believe that similar behavioral offsets will occur in the presence of a revised ASC payment system. Such behavioral "offsets" will occur as the result of service migration from higher-cost HOPD settings to lower-cost ASCs. If efficient providers determine that higher quality outpatient surgical services can be delivered in ASCs at lower costs to the Medicare program and its beneficiaries, lower aggregate spending for outpatient surgical services may result – an outcome made less likely by a narrow application of budget neutrality that unduly constrains ASC payments. The IRF PPS transition accounted for behavioral changes among efficient providers. As it develops the revised ASC payment system, CMS should similarly take into account the likely migration of services from HOPDs to ASCs, which has the potential to lower "aggregate" Medicare costs.

HOME HEALTH PROSPECTIVE PAYMENT SYSTEM

The creation of the home health prospective payment system also offers an instructive precedent for a broad interpretation of Section 626. The Balanced Budget Act of 1997 mandated the implementation of a prospective payment system for Medicare home health services which

[4] 70 *Fed. Reg.* 41,316 (August 7, 2001).
[5] 66 *Fed. Reg.* 41,366 (August 7, 2001).

would bundle a number of previously separately billed services into a single payment amount. Congress directed that this new system be budget neutral. This required the Secretary to develop a means of incorporating the cost of what previously were separately billed services into a single budget neutrality equation.

> *To determine the budget neutrality adjustment, we use our most current estimate of incurred costs for home health expenditures in FY 2001 under the interim payment system (IPS). Under the President's FY 2001 Budget assumptions, we are projecting this amount to be $11,273 million. This amount includes the medical supplies which were billed separately under IPS but will be bundled under PPS. Our best estimate of what would be spent in FY 2001 on Part B therapies not currently included in the home health benefit but which will be covered by the benefit under the PPS is $109 million. We did not include this in the home health spending for the FY 2001 budget because we had not yet determined it needed to be added to the spending target. We are adding $109 million to the $11,273 million to determine the total spending target for home health PPS spending, $11,382 million.*[6]

This approach allowed the Secretary to take into account the budget effects of services migrating from one payment system to another in order to achieve the congressional objective of budget neutrality without setting payment levels artificially low for home health providers. The Secretary should adopt a similar approach in assessing the budget effects of proposed changes in the ASC payment system that are likely to encourage even greater migration of services across payment settings.

DEMONSTRATION PROJECTS

When it comes to congressionally-mandated or administratively-selected demonstration projects, CMS often makes greater conceptual leaps in applying budget neutrality than it does under statutory mandates for reforming specific payment systems. As an example, when considering the implementation of a congressionally-mandated demonstration program for rural community hospitals to "test the feasibility and advisability of establishing 'rural community hospitals' for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries," the statute mandated that such a program be budget neutral.

But in discussion of the issue in the context of the Final Rule, CMS noted that Section 410A of Public Law 108–173 requires that:

> *"In conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. Generally, when CMS implements a demonstration on a budget neutral basis, the demonstration is budget neutral in*

[6] 65 *Fed. Reg.* 41,186 (July 3, 2000).

> *its own terms; in other words, aggregate payments to the participating providers do not exceed the amount that would be paid to those same providers in the absence of the demonstration. This form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration participants. These reduced expenditures offset increased payments elsewhere under the demonstration, thus ensuring that the demonstration as a whole is budget neutral or yields savings."*[7] (Emphasis added.)

CMS goes on to state that it is well aware of the limitations inherent in such an approach.

> *"However, the small scale of this demonstration, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration could be viable under the usual form of budget neutrality. Specifically, cost-based payments to 15 small rural hospitals is likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these providers. In order to achieve budget neutrality, as we proposed, we are adjusting national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we are applying budget neutrality across the payment system as a whole rather than merely across the participants of this demonstration.* (Emphasis added). *We believe that the language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. This is because the statutory language refers merely to ensuring that "aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration * * * was not implemented," and does not identify the range across which aggregate payments must be held equal."*[8] (Emphasis added.)

Likewise, in reviewing the requirements for budget neutrality in the context of a Chiropractic Demonstration Project, CMS stated that:

> *"The statute requires the Secretary to ensure that the aggregate payments made under the Medicare program do not exceed the amount that would have been paid under the Medicare program in the absence of this demonstration. Ensuring budget neutrality requires that the Secretary develop a strategy for recouping funds*

[7] 69 *Fed. Reg.* 49,183 (August 11, 2004).
[8] *Id.*

should the demonstration result in costs higher than would occur in the absence of the demonstration. We will first determine over the two-year demonstration whether the demonstration was budget neutral. If the demonstration is not budget neutral, we plan to meet the legislative requirements by making adjustments in the national chiropractor fee schedule to recover the costs of the demonstration in excess of the amount estimated to yield budget neutrality. We will assess budget neutrality by determining the change in costs based on a pre-post comparison of costs and the rate of change for specific diagnoses that are treated by chiropractors and physicians in the demonstration sites and control sites. We will not limit our analysis to reviewing only chiropractor claims because the costs of the expanded chiropractor services may have an impact on other Medicare costs."[9] (Emphasis added.)

In this context, CMS appeared to recognize the effect of the demonstration on other Medicare costs and how those costs related specifically to chiropractic care.

Likewise, CMS should construct a revised ASC payment system that contemplates other Medicare cost changes, especially anticipated cost reductions associated with service migration from more costly HOPD settings to less costly ASCs.

CONCLUSION

Congress enacted the MMA to modernize Medicare, improve patient choice, and lower costs. Outpatient surgery is recognized as a valuable, high quality service for Medicare beneficiaries. Congress acted upon the opportunity to modernize and lower the cost of outpatient surgical services by encouraging competition between sites of services for such services, namely, ASCs and HOPDs. The Secretary should adhere to Congress' intent by designing a payment system that improves patient choice and lowers program costs, by improving and enhancing access to outpatient surgical services in ASCs, and by applying the budget neutrality provision in a broad and dynamic way – consistent with these policy goals and the language of the statute – that recognizes the new payment system's effects not just on payments to ASCs, but also its overall cost savings to the Medicare program.

[9] 70 *Fed. Reg.* 4,132 (January 28, 2005).

Attachment 3

Selected Table Reflects Lewin Analysis on Case Migration

Table 3: 84% and 62% @ 65% BN									
	2008 Impact Payment (65% BN)	New Payment	Percent Change	Cases	% of 2008 OPPS cases for ASC services	Additional Procedures (per 100)	Additional Expenditures ($BN)	Total Cost of Migration	2006 pay equivalent
Gastroenterology	84.2	84	-0.4%	0	20.7	-8	0%	0	89
Pain/Neurology	80.5	62	-22.8%	-18	8.2	-151	-2%	6	66
Pulmonary	67.5	62	-7.9%	-5	0.1	0	-1%	0	66
Ophthalmology	66.4	62	-6.3%	-4	46.7	-196	-1%	18	66
Dermatology	63.8	62	-2.5%	-2	2.7	-4	-1%	1	66
Urology	51.9	62	19.7%	10	3.3	34	13%	-16	66
Otolaryngology	40.9	62	51.9%	21	1.7	35	18%	-11	66
General Surgery	40.1	62	55.2%	22	1.9	41	18%	-13	66
Vascular	37.4	62	66.3%	25	0.6	14	19%	-4	66
Orthopedics	36.2	62	71.6%	26	13.8	357	21%	-109	66
OB/GYN	35.9	62	73.1%	26	0.4	9	19%	-3	66
						131	3%	-131	

Migration Analysis 2008 Estimates: 65%
Based on CMS file with Estimated 2008 payments and volume

Table 1: 84% and 65% @ 65% BN									
	2008 Current Payment (65% BN)	New Payment	Percent Change	Cost Shift	65% of 2008 OPPS pay for ASC Services	Total Cost of Procedures per 100	% Assumed to Migration for BN	Total Cost of Migration	2006 pay equivalent
Gastroenterology	84.2	84	0.0%	0	20.7	0	0%	0	89
Pain/Neurology	80.5	65	-19.3%	-16	8.2	-128	-2%	6	69
Pulmonary	67.5	65	-3.7%	-3	0.1	0	-1%	0	69
Ophthalmology	66.4	65	-2.1%	-1	46.7	-64	-1%	16	69
Dermatology	63.8	65	1.9%	1	2.7	3	9%	-9	69
Urology	51.9	65	25.2%	13	3.3	44	33%	-39	69
Otolaryngology	40.9	65	58.8%	24	1.7	40	50%	-29	69
General Surgery	40.1	65	62.3%	25	1.9	47	50%	-33	69
Vascular	37.4	65	73.8%	28	0.6	15	50%	-10	69
Orthopedics	36.2	65	79.4%	29	13.8	395	54%	-260	69
OB/GYN	35.9	65	81.0%	29	0.4	10	50%	-6	69
						363	10%	-363	69

Migration Analysis: 65% Budget Neutrality

Table 1: 65% @ 65% BN; based on survey results									
	2008 Current Payment (65% BN)	New Payment	Percent Change	Cost	% of 2008 OPPS pay for ASC Services	Total Cost of Proposed Leg per 100	Assumed Migration for BN	Total Cost of Migration	2006 pay equivilent
Gastroenterology	84.2	65	-22.4%	-19	20.7	-391	-15%	108	86
Pain/Neurology	80.5	65	-18.8%	-15	8.2	-125	-2%	6	69
Pulmonary	67.5	65	-3.2%	-2	0.1	0	-1%	0	69
Ophthalmology	66.4	65	-1.5%	-1	46.7	-48	-1%	16	69
Dermatology	63.8	65	2.4%	2	2.7	4	3%	-3	69
Urology	51.9	65	25.8%	13	3.3	45	9%	-10	69
Otolaryngology	40.9	65	59.7%	24	1.7	40	12%	-7	69
General Surgery	40.1	65	63.2%	25	1.9	47	12%	-8	69
Vascular	37.4	65	74.7%	28	0.6	16	17%	-3	69
Orthopedics	36.2	65	80.3%	29	13.8	400	20%	-95	69
OB/GYN	35.9	65	81.9%	29	0.4	11	20%	-2	69
						0		0	

Attachment 4

Attachment 5

Hospital Median Costs vs. 2006 Q1 HOPPS Rates

CMS

Hospital Median Costs vs. 2006 Q1 HOPPS Rates

10/16/2006

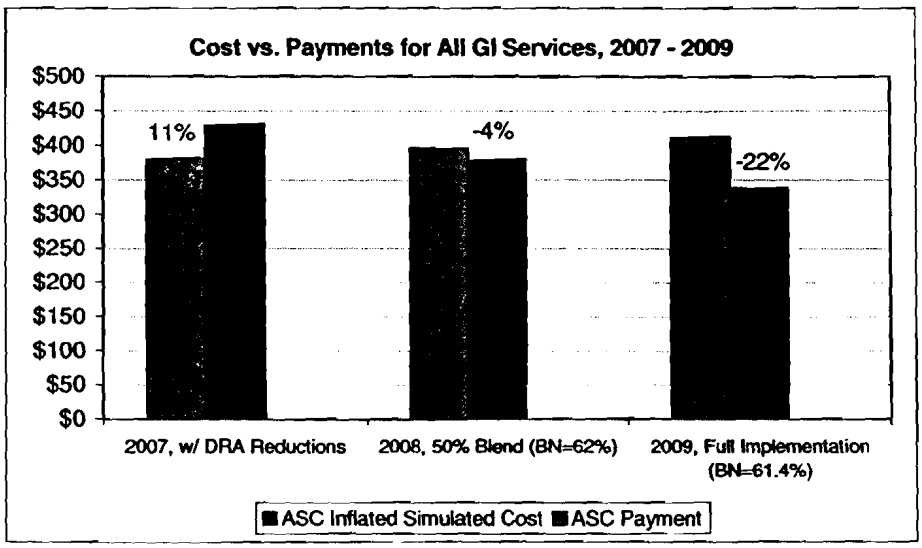
					20	35% 7	65% 13	
Specialty	CPT4	2006 Q1 HOPD Rate (Unadjusted)	CMS Median Cost	Margin	Winner	Loser	Margin %
GI	45378	$509.34	$452.02	$57.32	1	0	12.7%
GI	43239	$480.03	$475.02	$5.01	1	0	1.1%
GI	45385	$509.34	$553.54	($44.20)	0	1	-8.0%
GI	45380	$509.34	$527.62	($18.28)	0	1	-3.5%
GI	43235	$480.03	$395.24	$84.79	1	0	21.5%
GI	45384	$509.34	$577.63	($68.29)	0	1	-11.8%
GI	G0121	$449.56	$449.07	$0.49	1	0	0.1%
GI	G0105	$449.56	$448.88	$0.68	1	0	0.2%
GI	43249	$480.03	$659.50	($179.47)	0	1	-27.2%
GI	45383	$509.34	$578.11	($68.77)	0	1	-11.9%
GI	43248	$480.03	$484.31	($4.28)	0	1	-0.9%
GI	43450	$315.23	$278.16	$37.07	1	0	13.3%
GI	43246	$480.03	$594.78	($114.75)	0	1	-19.3%
GI	43760	$133.15	$149.63	($16.48)	0	1	-11.0%
GI	43262	$1,107.92	$1,357.46	($249.54)	0	1	-18.4%
GI	43259	$480.03	$616.75	($136.72)	0	1	-22.2%
GI	43247	$480.03	$465.41	$14.62	1	0	3.1%
GI	43264	$1,107.92	$1,278.69	($170.77)	0	1	-13.4%
GI	43251	$480.03	$546.56	($66.53)	0	1	-12.2%
GI	45331	$280.21	$336.52	($56.31)	0	1	-16.7%

Lewin Data on ASC Costs

Attachment 6

Cost Analysis: GI Services 2007 - 2009

	ASC Inflated Simulated Cost	ASC Payment	Margin
2007, w/ DRA Reductions	$380.89	$430.20	11%
2008, 50% Blend (BN=62%)	$396.13	$379.30	-4%
2009, Full Implementation (BN=61.4%)	$411.98	$338.12	-22%



A Few Lewin Tables Demonstrating Bi-Level Payments and Amount of Migration Needed to Support Them

Migration Analysis: 65% Budget Neutrality

Table 1: 81% and 65% @ 65% BN									
	2006 Current Payment (65% BN)	New Payment	Percent Change	Cost	% of 2008 OPPS pay for ASC services	Total Cost of Proposed Leg per 100	Assumed Migration for BN	Total Cost of Migration	2006 pay equivilent
Gastroenterology	84.2	81	-4.1%	-3	20.7	-72	-2%	8	86
Pain/Neurology	80.5	65	-19.3%	-16	8.2	-128	-2%	6	69
Pulmonary	67.5	65	-3.7%	-3	0.1	0	-1%	0	69
Ophthalmology	66.4	65	-2.1%	-1	46.7	-64	-1%	16	69
Dermatology	63.8	65	1.9%	1	2.7	3	8%	-8	69
Urology	51.9	65	25.2%	13	3.3	44	36%	-42	69
Otolaryngology	40.9	65	58.8%	24	1.7	40	41%	-24	69
General Surgery	40.1	65	62.3%	25	1.9	47	41%	-27	69
Vascular	37.4	65	73.8%	28	0.6	15	41%	-8	69
Orthopedics	36.2	65	79.4%	29	13.8	395	43%	-207	69
OB/GYN	35.9	65	81.0%	29	0.4	10	43%	-5	69
						291		-291	

Attachment 7

ACG ASC Survery Results Summary

Attachment 8

Am. Coll. of Gastro Survey of GI ASC Physicians

ACG ASC Migration Survey Results: Selected Questions

Question 1: If Medicare drops payments by the indicated percnets, by what perent will your Medicare and commercial payment mix change?		
Payment Reduction	**Change in Medicare Patients**	**Change in Commercial Patients**
-5%	41% expect no change in quantity; 28% will reduce quantity between 1-5%; 20% will reduce quantity between 6-20%	44% expect no change in quantity; 28% will increase quantity between 1-5%; 24% will increase quantity 6-20%
-10%	42% will reduce quantity between 1-10%; 20% will reduce quantity between 11-20%; 4% will eliminate Medicare patients	17% expect no change in quantity; 30% will increase quantity between 1-10%; 41% will increase quantity 11-20%
-15%	14% will reduce quantity between 1-10%; 28% will reduce quantity between 11-20%; 25% will eliminated Medicare patients	12% expect no change in quantity; 36% will increase quantity between 11-30%; 32% will increase quantity over 30%
-20%	19% will reduce quantity between 40-50%; 15% will reduce quantity between 70-90%; 33% will eliminate Medicare patients	12% expect no change in quantity; 20% will increase quantity between 41-50%; 21% will increase quantity over 50%

Question 2: At what payment level will you stop accepting and treating Medicare patients?	
n=28	
Payment Level	Percent of Facilities
0-5%	3.6%
5-10%	3.6%
11-20%	10.7%
21-30%	10.7%
31-40%	3.6%
41-50%	3.6%
51-60%	3.6%
61-70%	7.1%
71-80%	21.4%
81-90%	25.0%
91-100%	7.1%
	100.0%

Question 3: Do you expect the waiting time for Medicare patients between the date it is determined they need a procedure to the date the procedure is performed will be longer, shorter, or about the same once the proposed payment changes take effect?	
n=29	
Response	Percent of Facilities
Longer wait	89.7%
Shorter wait	0.0%
About the same wait time	10.3%
	100.0%

Question 11: Assuming the changes proposed by CMS for Medicare ASC payments are implemented:				
	Yes	No	N=	
a. Do you expect that your ASC would close its business?	18%	82%	28	100.0%
c. Would you expect to increase the total number of hours per week that the ASC treats patients?	7%	93%	27	100.0%
f. Would you expect a reduction in the total number of employees at your ASC?	79%	21%	28	100.0%
h. Would you expect a reduction in the average compensation level (salary and benefits) for the ASC's employees?	68%	32%	28	100.0%