



August 28, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1414-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS 1414-P-- Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates; Proposed Rule

Dear Administrator Frizzera:

On behalf of the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), and the American Society for Gastrointestinal Endoscopy (ASGE), representing over 16,000 physicians specializing in digestive diseases, we are pleased to provide these comments with respect to CMS' proposed changes to the Ambulatory Surgical Center (ASC) payment system for CY 2010.

We also would like to take this opportunity to endorse and express support for the comments and recommendations submitted by ACG in a separate comment letter.

BACKGROUND

The ASC is an important part of current GI practice, providing a safe, patient friendly and cost effective environment for the provision of medical services, such as colorectal cancer screening, for patients of all ages. The majority of ASCs used by gastroenterologists are single specialty centers. According to data from the Ambulatory Surgical Center Association, more than 1200 Medicare certified ASCs provide at least 80 percent of their services in the GI field. That is more than 20 percent of all Medicare certified centers, and GI endoscopy is the most common set of procedures provided to Medicare beneficiaries in the ASC. Because of their focus, and the

difficulties involved in changing the single specialty ASC structure, these facilities are uniquely sensitive to changes in Medicare payments.

Since the beginning of the transition to a new payment system in 2007, our societies have repeatedly expressed concern that the Centers for Medicare and Medicaid Services' (CMS) new ASC payment system would pay for endoscopic services at a rate below their cost. According to data from a number of surveys of the costs in single specialty GI centers, payment rates are now equal to or below the cost of care. The proposed rule does not reverse that trend, but rather accelerates it. The imposition of new conditions of coverage will add to the costs for all ASCs, and the proposed rule does not appear to take these added expenses into consideration.

COST PER CASE

The most useful measure of costs is the analysis of the cost per case. ASCs use this measurement because it captures all services, including multiple procedures, provided to patients from the time they enter the ASC until the time they leave. ASGE has collected data from GI ASCs to analyze the impact of the CMS proposed rules.

Using the Endoscopic Operations Survey, ASGE collected 2008 GI physician practice cost data from 61 practices and found that the mean cost per case in a GI ASC in 2008 ranged from \$375 to \$395 per case.

The 2008 Medicare ASC rate for diagnostic colonoscopy was \$370.60. Based on the mean cost per case value ranging from \$375 to \$395, many GI ASCs have already begun to lose money when performing procedures on Medicare beneficiaries.

If the ASC rate were tied to the HOPD rate at 70% in 2008, payment would approximate the mean cost per case, assuming no profit to the ASC. Some return on investment is necessary, however, if an ASC is going to be able to replace equipment, maintain competitive salaries or engage in quality improvement activities. Analysts consider a 5-10% return on investment to be appropriate.

The 2009 ASC rate for this service declined to \$353.47, while in the same year CMS implemented new Conditions for Coverage, including quality measurement, infection control standards, and advanced patient notices about physician ownership. Each of these conditions will result in some additional costs for ASCs. To generate cost estimates for these mandates, ASGE reviewed the practice management literature and interviewed several ASC practice managers. ASGE also examined the impact of future e-prescribing and health information technology requirements.

For 2010, incorporating our assumptions about CMS's new coverage mandates and technology requirements as outlined above, a conservative estimate for the ASC cost per case would range on average from \$440 to \$460. Based on the proposed 2010 HOPD rate of \$614.11 and a modest profit margin of approximately 5 percent or less, the ASC rate should be at least 75% of the HOPD rate.

This proposed rule only exacerbates that situation with a further proposed reduction of at least five percent in payments for GI endoscopy. **This continuing decline will inevitably lead to a migration of Medicare patients requiring gastrointestinal procedures back to the hospital, increasing the cost to the patient and to the Medicare program.** In many communities, hospital endoscopy units are already very busy, and will not be able to easily accommodate new patients. Forcing Medicare patients to endure longer waits and increased costs for essential services, like screening for colorectal cancer, is a disservice to the beneficiaries the agency is obligated to serve. Increasing the costs of care by refusing to adequately reimburse in a more economical setting, is a disservice to the taxpayers who support a substantial portion of the Medicare program, particularly Part B, the source of ASC payments.

MIGRATION OF SERVICES

Our societies have made the point about migration since the first proposed rule in 2007, but CMS has not incorporated this issue in its analysis. However, a 2009 study shows that 75% of the growth in the volume of GI procedures in ASCs from 2000-2007 resulted from migration of these procedures from the hospital to the ASC. If Medicare reimbursement for these services continues to lag far behind the true costs of care, it is predictable that these cases will begin to go back to the hospital.

This study also found no statistical evidence that ASCs cause an increase in utilization of common Medicare procedures like colonoscopies and cataract surgery.

The report further finds that growth in factors completely external to the ASC industry, such as the increasing number of Medicare beneficiaries, disease prevalence, increased prevention, expanded insurance coverage, and new technologies help explain the total trend. Much of the growth in ASC spending has also been in procedures whose volume increases are relatively slow. For example, the volume growth in GI endoscopy has declined significantly in all settings in recent years.

We believe that this new study should be incorporated in CMS' analysis of the ASC rate system. The results allow CMS to think very differently about its current payment structure. Since CMS currently has almost complete discretion in the design of the ASC payment system, these new data should be the basis of a substantial revision in the way the fee schedule is structured.

BUDGET NEUTRALITY

Our societies disagree with the agency's interpretation of the 2003 budget neutrality requirement. The law speaks only to budget neutrality in the first year (2008) of implementation of a new fee structure. We do not believe the agency is obligated to maintain budget neutrality in ASC payments beyond that point. In fact, such a standard works against Medicare's own interest in paying less money for better quality, efficient medical care.

We believe this new information on migration can allow CMS to incorporate this element into any budget neutrality calculation and provide a greater degree of flexibility and program growth than is possible under the current definitions.

Migration analysis can also be used to establish a link between HOPD and ASC rates of 75% in a budget neutral fashion, thus encouraging continued migration of services into the less expensive environment.

Figure 1 – ASC Payment Savings Projection - Assumptions

Assumptions:

- Estimated 2010 ASC Payments \$3.4 Billion
- Proposed 2010 conversion factor \$41.625
- Estimated units of services \$3.4 B/\$41.625 equals 81,681,681
- Assume 10 percent growth in ASC units each year
- No inflation in ASC or OPD Rate
- ASC payments equal 58 percent of OPD payment
- Equivalent OPD CF = \$41.65/.58= \$71.81 - \$41.625/.58 equals \$71.77
- 75 percent of OPD CF equals \$53.83

Projection:

	81,681,681 units	89,849,849 units	98,834,834 units	108,718,317 units	119,590,149 units	131,549,163 units	144,704,080 units	
	Base Yr	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
ASC Payments	\$3.4 B	\$3.74 B	\$4.38 B	\$5.09 B	\$5.87 B	\$6.73 B	\$7.67 B	
OPD Equiv Payments	\$5.86 B	\$6.45 B	\$7.09 B	\$7.8 B	\$8.58 B	\$9.44 B	\$10.38 B	
ASC Savings	\$2.486 B	\$2.71 B	2.71 B	\$2.71 B	\$2.71 B	\$2.71 B	2.71 B	
Incremental Savings*		\$246 M	\$246 M	\$246 M	\$246 M	\$246 M	\$246 M	
New CF**	\$41.63	\$41.63	\$44.37 (+\$2.74)	\$46.85 (+\$2.48)	\$49.11 (+\$2.26)	\$51.16 (+\$2.05)	\$53.03 (+\$1.87)	capped at \$53.83

Notes:

- *ASC volume growth X OPD CF-ASC CF
- ** current CF + incremental savings/total frequency

Figure 2 – ASC Payment Savings Projection - Detailed

ASC Payment Savings Calculation								
	Base Year	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Volume Growth								
Number of Units	81,681,681	89,849,849	98,834,834	108,718,317	119,590,149	131,549,164	144,704,080	159,174,489
Incremental OP Volume		8,168,168	8,984,985	9,883,483	10,871,832	11,959,015	13,154,916	14,470,408
Growth		10%	10%	10%	10%	10%	10%	10%
ASC								
Base Conversion Factor	\$ 41.63	\$ 41.63	\$ 41.63	\$ 41.63	\$ 41.63	\$ 41.63	\$ 41.63	\$ 41.63
Increase in CF		0.0%	6.6%	5.6%	4.8%	4.2%	3.7%	1.5%
Annual Addition to ASC CF	\$ -	\$ 2.74	\$ 2.48	\$ 2.26	\$ 2.05	\$ 1.87	\$ 0.80	\$ 0.80
Cum Addition to ASC CF	\$ -	\$ 2.74	\$ 5.22	\$ 7.48	\$ 9.53	\$ 11.40	\$ 12.20	\$ 12.20
Total ASC CF	\$ 41.63	\$ 41.63	\$ 44.37	\$ 46.85	\$ 49.11	\$ 51.16	\$ 53.03	\$ 53.83
Total Payment if ASC	\$ 3,399,999,972	\$ 3,739,999,969	\$ 4,384,807,411	\$ 5,092,909,579	\$ 5,872,474,274	\$ 6,729,397,488	\$ 7,672,933,867	\$ 8,567,590,283
Incremental Payment if ASC		\$ 339,999,997	\$ 398,618,856	\$ 462,991,780	\$ 533,861,298	\$ 611,763,408	\$ 697,539,442	\$ 778,871,844
HOPD								
ASC % of HOPD	58.0%	58.0%	61.8%	65.3%	68.4%	71.3%	73.9%	75.0%
HOPD Conversion Factor	71.77	71.77	71.77	71.77	71.77	71.77	71.77	71.77
Total Payment if HOPD	\$ 5,862,068,917	\$ 6,448,275,808	\$ 7,093,103,389	\$ 7,802,413,728	\$ 8,582,655,101	\$ 9,440,920,611	\$ 10,385,012,672	\$ 11,423,513,939
Incremental Payment if HOPD		\$ 586,206,892	\$ 644,827,581	\$ 709,310,339	\$ 780,241,373	\$ 858,265,510	\$ 944,092,061	\$ 1,038,501,267
Savings								
Incremental Savings		\$ 246,206,894	\$ 246,208,725	\$ 246,318,559	\$ 246,380,075	\$ 246,502,102	\$ 246,552,619	\$ 259,629,423

Legend

Assumptions
Calculations

RECOMMENDATIONS

Fixed Relationship Between HOPD and ASC Payments

ACG, AGA and ASGE believe that CMS must set a fixed relationship between the HOPD payment and the ASC payment, and that the relationship should be 75% of HOPD. This rate would correct the current problems faced by GI centers and would also create the right incentives for enhanced migration of other surgical services out of the expensive hospital setting and into the less costly ASC. Such a fixed rate acknowledges that the procedure costs are similar in both settings, with the difference in payment attributable to the more complex overhead structure of the hospital. This would also simplify the annual rate setting for the ASC and make the fee schedule more transparent for all parties.

A fixed relationship also eliminates the need for secondary rescaling, which is a destructive process for ASC payments, leading to an increasing disconnect between the payment in the hospital outpatient setting and the ASC.

Under the HOPPS system, CMS assures that changes in the hospital relative weights are budget neutral in the aggregate. Since the hospital relative weights have already been scaled to preserve budget neutrality within the HOPPS system, increases in the HOPPS relative weights for services on the ASC list reflect actual increases in the costs for performing these services relative to other services. There is no reason to believe that these cost increases in hospital costs are not equally applicable to ASCs. However, the application of the scaling adjustment to ASCs suggests inappropriately that these increases in relative weights do not reflect legitimate increases in ASC costs and further lessens any logical link in the relationship of hospital and ASC payments for the same set of services. That link between hospital and ASC payments which was tenuous at best at the start of the ASC system will be virtually destroyed over time with the application of the scaling factor each year and the differential update measures.

There is over a 40 percent differential in payments for 2009 and this will grow over time. Inevitably this is going to lead to reluctance on the part of some ASCs, particularly those providing services taking major reductions in payment, to continue to offer these services to Medicare patients. The result will be that these services will be forced back to the hospital setting at dramatically higher payment rates. Eroding payments for ASC services so they return to the hospital is directly contrary to the need to manage Medicare resources more carefully. Scaling also negatively impacts those surgical services that CMS once indicated would see payment increases under the new ASC rate structure. The use of scaling will discourage the movement of services out of the HOPD into a more cost effective setting and will increase overall program costs. For the sake of the beneficiaries and for the Medicare program, we hope that this does not occur. We strongly urge CMS to reconsider the application of rescaling in calculating ASC payment rates.

Annual Inflationary Update

Under the law, the ASC conversion factor has been frozen through 2009. In the final rule published August 2, 2007, CMS indicated it was adopting a policy of updating the ASC

conversion factor using the CPI-U to adjust ASC payment rates for inflation. This would apply for years beginning with CY 2010. We are requesting CMS revisits their initial decision to use the CPI-U as the basis for adjusting the ASC payment for inflation. It is our strong recommendation that the hospital market basket is a much more appropriate measure of ASC cost inflation than an index measuring changes in the costs of goods and services purchased by consumers. The market basket is used to adjust the hospital outpatient prospective payment system, and reflects the same types of operating costs faced by ASCs. This is especially true given new conditions for coverage requirements for ASCs that are not only costly and otherwise unfunded, but approximate the complexity of the hospital outpatient department. This recommendation is universally endorsed by the ASC industry and CMS has complete discretion to adopt a market basket approach. The rationale advanced for maintaining CPI-U as the ASC inflation factor is contrary to the way CMS calculates annual updates for virtually every other provider that is reimbursed by Medicare. In short, there is no justification for maintaining this policy.

The hospital market basket is a much more appropriate measure of ASC cost inflation. First of all, it is necessary if the ASC payment system is to remain tied to payments under the hospital outpatient prospective payment system (HOPPS). In addition, ASC payment for an individual procedure is based directly on the weights assigned to surgical services under HOPPS. Secondly, the hospital market basket measures changes in the costs of goods and services purchased by hospitals. The goods and services purchased by ASCs are very similar. Whether an endoscopy is performed in a hospital outpatient department or an ASC, very similar supplies, equipment and labor are used to perform the service. When there are inflationary increases in medical supplies or nursing personnel purchased by hospitals, ASCs experience precisely the same cost increases. For these reasons, we recommend that for 2010 and beyond, CMS modify their earlier decision and use the hospital market basket for ASCs in lieu of the CPI-U which has no relationship to measuring changes in the costs of goods and services purchased by a health care facility.

Quality Measures

The Medicare Payment Advisory Commission (MedPAC) has recommended that Congress require ASCs to submit quality data. CMS already has authority to require reporting in ASCs just as it does in the HOPD. ASGE, ACG and AGA are supportive of initiatives to improve the quality of care in all settings including ASCs. We recommend, however, that the major issues we have identified in the payment system be fixed before imposing new requirements on ASCs. At that point, we would welcome the opportunity to review and comment on a proposal setting out specific quality measures for ASCs. It will be important that the quality measures be applicable to ASCs since some of the hospital quality measures are clearly not appropriate. In addition, since some ASCs specialize in particular types of procedures such as gastroenterology or pain management, we would ask CMS to ensure that all facilities have the opportunity to participate in quality reporting with specialty-specific measures.

Cost Reporting

MedPAC has also recommended that ASCs be required to submit cost data. ACG, AGA and ASGE believe that this would not be necessary if CMS adopts a fixed and adequate relationship between the HOPD and ASC rates. The HOPD rates are based on millions of claims and there is a close tie between the procedure costs in both settings. We should be able to rely on that database, with no further burden on ASCs.

The difficulties of cost reporting in ASCs are many. First, many of the ASCs are small and lack the personnel to perform the reporting. Second, because the types of services (single specialty, multispecialty) vary widely, the cost structures are quite different among the different types of ASCs. Third, CMS' previous efforts to collect cost data on a periodic basis were not successful for a variety of reasons. We are not aware of any changes that have taken place that would improve that record. Fourth, the type of information that CMS might need to calculate costs for payment purposes are not likely to be maintained by the ASC in the format needed by the agency. As a result, the opportunity for confusion and error would be high.

CONCLUSION

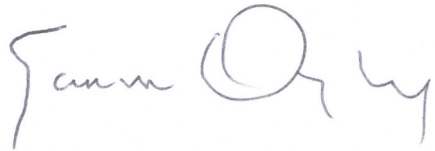
The issues raised in these comments have been raised by our societies and other organizations since the beginning of the new ASC payment schedule. In the case of the GI single specialty ASC, we fear there may be misconceptions about the structure, function and regulation of single specialty GI endoscopy centers. As in the past, we remain eager to meet with CMS representative to further discuss any differences in opinion, especially regarding single-specialty facilities and their cost structures. CMS has suggested that ASCs experiencing a decline in revenue in one area simply expand services in another area. This may be an option for multispecialty centers, but ignores the fact that state licensure and certificate of need regulations often define a limit on the services that a GI ASC can provide. The simple fact is that these facilities are usually unable to transform into another type of ASC.

We believe that the proposed rule will accelerate the movement of Medicare patients back into the HOPD, increase costs, decrease patient satisfaction, and delay or deny needed medical services, including life-saving colorectal cancer screening. These results are not necessary since CMS has ample authority to make decisions that will preserve the endoscopic ASC as a viable choice for the Medicare beneficiary.

The ASC has been one of the most positive developments in the delivery of services to Medicare beneficiaries in the last 20 years. We are deeply concerned that CMS, when given the opportunity to devise a new payment system for ASCs, continues to make policy choices that clearly undermine the ability of ASCs to serve Medicare beneficiaries. Given strong patient preference for these centers, and the compelling need to manage Medicare expenses more effectively, it is extremely difficult to understand why the agency has chosen this direction. Congress has granted CMS broad authority to establish a new and better payment system for all services provided in the ASC. We hope that CMS will utilize its authority in a way that enhances the ability of ASCs to provide services to Medicare beneficiaries.

Thank you for the opportunity to offer these comments.

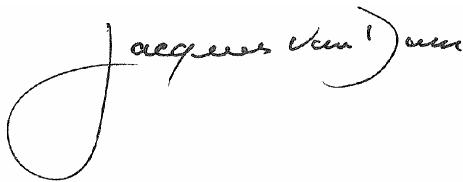
Sincerely,

A handwritten signature in black ink that reads "Eamonn M.M. Quigley". The signature is fluid and cursive, with the first name "Eamonn" written in a larger, more prominent script.

Eamonn M.M. Quigley, M.D., FACP
President, American College of Gastroenterology

A handwritten signature in blue ink that reads "Robert Sandler". The signature is cursive and stylized, with the first name "Robert" written in a larger, more prominent script.

Robert Sandler, M.D. PhD, AGAF
Chair, American Gastroenterological Association

A handwritten signature in black ink that reads "Jacques Van Dam". The signature is cursive and stylized, with the first name "Jacques" written in a larger, more prominent script.

Jacques Van Dam, M.D., PhD, FASGE
President, American Society for Gastrointestinal Endoscopy