September 4, 2012

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1589-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via online submission at www.regulations.gov

Re: CMS-1589-P – Medicare Program; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2013 Payment Rates

Dear Acting Administrator Tavenner:

Please accept the following comments regarding the payment and quality issues related to ambulatory surgery centers (ASCs) in the proposed rule for CY2013 payments (77 Fed. Reg. 45061*, Et. Seq*., July 30, 2012). These comments are submitted by the Ambulatory Surgery Center Association (ASCA), the voice of the ASC industry. The Association members include single- and multi-specialty ASCs, physician-owned ASCs, joint ventures between hospitals and physicians, joint ventures between physicians and management companies, professional societies and accrediting bodies. Participating ASCs range from the very small to the very large and are located in all 50 states.

We appreciate the diligent work of your staff to review and evaluate the proposed changes to the ASC payment system in 2013. However, after another year of stagnant growth in the industry, a persistent exit of ASCs that have been bought and converted to hospital outpatient departments and a growing number of physicians being employed to practice in higher-priced modalities, we urge you to act expeditiously to promote the expanded use of the ASC setting. Since the inception of the Medicare benefit in 1982, ASCs have steadily expanded the role they play in meeting the surgical needs of Medicare beneficiaries. However, a multi-year period of flat growth in the number of centers and the Medicare procedure volume relative to the growth prior to implementation of the new payment system indicates that the outflow of procedures to this lower-priced setting have unnecessarily slowed.

We are extremely pleased that this fall ASCs will have the opportunity to report to CMS on several important indicators of clinical processes and outcomes of care. With this data, we believe CMS and consumers will have even stronger evidence of the high-quality care provided in this setting. We appreciate all that the agency has done to begin implementing this new system, and we are working diligently to ensure robust participation.

I. Summary of Major Comments

A failure to address key design elements of the ASC payment system has led to a lack of confidence in the Medicare program as a reliable business partner, advocate of competition and transparency and steward of taxpayer dollars among ASCs. The ASC setting is an economical site of service for millions of

Medicare beneficiaries each year, but industry capacity is limited and future growth is uncertain. Growth of this industry is necessary to support the bending of the cost curve and to ensure that patients have access to low-priced, high-quality outpatient surgical services.

The Secretary has the tools and authority to adjust policies within the ASC payment system to ensure a level playing field for outpatient surgical services, encourage competition and evaluate the quality of care provided across settings. In the sections that follow, we describe policy changes that will encourage the migration of services to lower-priced modalities and maximize participation of ASCs in the Medicare quality reporting program. Simple changes to the update factor, transparency in decisions about procedure list changes and alignment of overall payment system policies with the outpatient PPS will be a strong signal of stability to the market. Key areas of focus include the following issues:

- CMS should ramp up its educational and training activities to encourage full participation in the ASC quality reporting program. The ASC industry is large and fragmented, and the agency should play a leading role with the assistance of ASCA and the ASC Quality Collaboration (ASC QC) to build awareness of the new program. Looking ahead, CMS should focus development efforts on new measures that will help consumers meaningfully evaluate the quality of services under the facility's control. Importantly, this should include measures of patient experience.

- CMS should adopt the hospital market basket as the measure of ASC cost increases, rather than using the Consumer Price Index for Urban Consumers (CPI-U). There is broad agreement that the CPI-U measures inflation in a basket of consumer goods atypical of what ASCs purchase. The delay, expense and burden of developing an alternative index will not result in a measure more appropriate to the ASC setting than the hospital market basket used to update the outpatient payment system. Aligning the outpatient update and productivity factors across the two settings will help minimize the silos around settings of care that are inconsistent with the Secretary's desire to harmonize payments.

- CMS should use a single wage index for ASC and outpatient hospital payments to improve consistency between the payment systems and limit variation in price at the local level. As CMS and Congress consider the recommendations of the Institute of Medicine (IOM) to improve the hospital wage index, many of which include eliminating special policies that raise the wage index above the pre-floor, pre-reclassification rate, the agency should seek a common wage index to apply to outpatient surgical services.

- CMS should encourage the migration of device-intensive procedures to the less expensive ASC setting by establishing a reasonable device-intensive threshold.

- CMS should revise its process for recognizing new procedures in the ASC setting to provide full transparency to the public about any safety concerns with services excluded from the ASC setting.

II. Overview of Market Reactions

We observe several troubling trends across the industry that indicate an imbalance between the overarching goals of the Medicare program to ensure patient access to care and set payments at a level sufficient to ensure that access. Below, we discuss trends in the following areas:

- Entry and exit of ASCs in the market

- Growth and diversification of the procedures performed in ASCs
- Trends in Medicare spending on ASC services

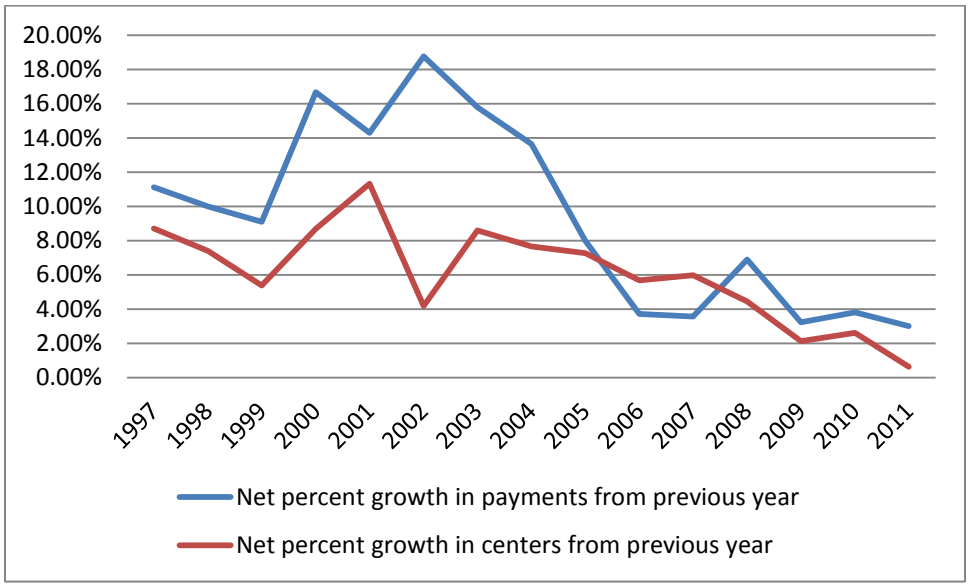
A. Entry and exit of ASCs in the market

As we have described in previous comment letters, the policies CMS uses to establish and update the ASC payment system have resulted in a growing delta between the rates paid for the same services under the ASC and hospital outpatient department (HOPD) prospective payment systems. Although much of the divergence resulted from a statutorily-mandated, six-year payment freeze for ASC rates, persistent failure to address this issue has eroded the once healthy growth of the ASC setting that enabled the migration of procedures from the hospital into ambulatory settings.

In our comments last year, we noted that 2009 had marked an all-time low in new center growth, but as shown in Figure 1, 2011 has set a new low. The outpatient surgery *market* continues to grow, but we believe much of this new growth is emerging as newly created or expanded outpatient departments. Several years ago this expansion was reflected in the growing ASC market, but now, new volume is being added in the more expensive modality. This should be alarming to the agency and the taxpayers who support the Medicare program.

The number of open and operating ASC facilities increased by 0.6% between 2010 and 2011, the lowest increase over the previous year since MedPAC began tracking this statistic in 1997. After peaking in the early 2000s, the growth rate of both ASC facilities and ASC payments have decreased dramatically, with both growth rates falling to new minimums since 1997. The rate of ASC facility openings decreased as well: 189 new ASC facilities opened in 2010, but only 153 ASC facilities opened in 2011.

Figure 1 2011 marked the slowest growth rate for new center growth and payments



Several members of Congress have written to the agency to express similar concerns with the payment system and resulting migration of some procedures back to the hospital. We understand that both CMS and the Office of the Inspector General are investigating these issues, and expect

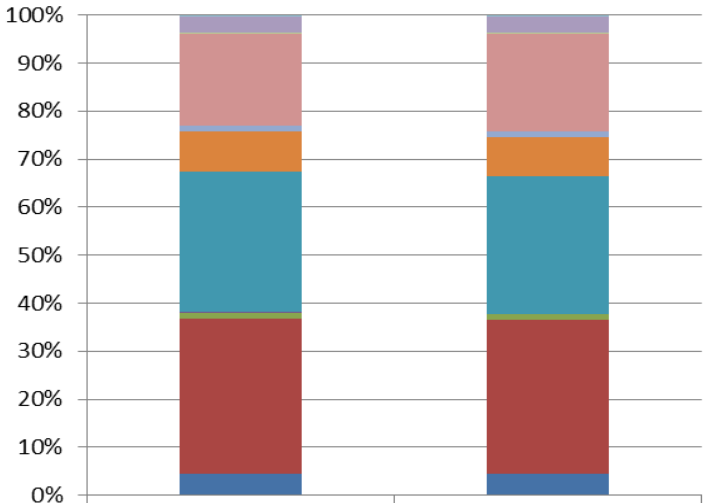
that their findings will create an even greater imperative to stabilize the ASC payment system. The current trend is bad for consumers who face fewer choices and/or higher prices, and it is bad for the Medicare program and the taxpayers who support it. However, we believe CMS actions to stop the continued divergence of the rates could halt, if not reverse, this trend.

Changes at the center level are also apparent, with those remaining in the market showing only modest growth. An analysis of facilities open and operating in both 2010 and 2011, using data provided in the ASC Limited Data Set published with the proposed rules for 2012 and 2013, shows that facilities open in both years had volume growth of approximately 3%. However, this increase in volume was offset by a decrease in payment.

In implementing the new payment system, CMS suggested that the market—and more importantly, individual centers—would diversify their surgical offerings in response to the new payment system. In analyzing center-level data for 2010 and 2011, we see little evidence of either trend occurring. First, the presence of ASCs in which 75% of their services are in a single specialty grew by about 4% between 2010 and 2011. This shift towards specialization helped the ASC facilities increase their average number of allowed services, as ASC facilities in all specialties but gastroenterology and pulmonology experienced an average increase in volume per facility. However, GI facilities experienced a slight average decrease in Medicare volume and a more than 5% decrease in payment.

B. Growth and diversification of the procedures performed in ASCs

Figure 2 Diversification among specialties remains limited



	2010 Allowed Services	2011 Allowed Services
VA	23,019	22,615
UR	212,021	217,774
PU	3,210	3,000
PM	1,211,613	1,296,256
OT	72,511	75,551
OR	517,636	520,153
OP	1,835,630	1,812,766
OB	14,369	14,104
GS	73,829	75,912
GI	2,017,047	2,033,637
DR	278,322	277,560

Overall, the ASC market has been stagnant or worsening over the past several years. Volume of allowed surgical services in the ASC setting increased by 3.02% between CY2010 and CY2011,the lowest increase from the previous year since implementation of the new payment system. After removing outliers, a paired combinations test showed that each individual procedure was actually statistically less likely to be performed in 2011 than in 2010.

In the recent past, diversification of procedures had been slow, but evident. However, the diversification halted completely in 2011. For instance, in 2008, the 25 most frequently performed procedures accounted for 75% of the volume. In 2009, this increased to 28 procedures that accounted for 75% of the volume, and again increased in 2010 to 31 procedures. However, in 2011, the

number of procedures that accounted for 75% of the overall volume stayed steady at 31, meaning that ASCs stopped performing new types of procedures at increasing rates. Further, diversification did not change greatly by assigned specialty of procedure. Between 2010 and 2011, the percent of procedures performed in a particular specialty did not increase or decrease more than 1%, demonstrating that there was no change in the general types of procedures performed.

C. Trends in Medicare spending on ASC services

Like the change in volume, payments to ASCs only increased by 3%, the lowest increase from the previous year since MedPAC's tracking of the data began in 1997. Total spending dropped for eight of the ten most commonly performed ASC procedures, for a total reduction of $72 million to those eight procedures. The total Medicare spent on the 100 most commonly performed procedures, which account for about 85% of the total volume, actually decreased by 1.38%. After removing outliers, a paired combinations test showed that payments for each individual procedure were not statistically likely to increase between 2010 and 2011.

Figure 3 Medicare spending changed little from 2010-2011

HCPCS	Short Descriptor	ASC Spend 2010	ASC Spend 2011	Difference
66984	Cataract surg w/iol, 1 stage	$1,101,590,000	$1,070,320,000	-$31,270,000
43239	Upper GI endoscopy, biopsy	$166,900,000	$157,730,000	-$9,170,000
45380	Colonoscopy and biopsy	$138,930,000	$137,440,000	-$1,490,000
45385	Lesion removal colonoscopy	$90,130,000	$88,330,000	-$1,800,000
45378	Diagnostic colonoscopy	$105,050,000	$85,150,000	-$19,890,000
66982	Cataract surgery, complex	$79,710,000	$81,280,000	$1,570,000
64483	Inj foramen epidural l/s	$66,130,000	$69,800,000	$3,670,000
62311	Inject spine l/s (cd)	$68,370,000	$67,620,000	-$750,000
66821	After cataract laser surgery	$60,710,000	$55,140,000	-$5,570,000
15823	Revision of upper eyelid	$41,160,000	$39,280,000	-$1,880,000
	Total	**$1,918,680,000**	**$1,852,100,000**	**-$66,580,000**
	Eight Decreasing	**$1,772,840,000**	**$1,701,020,000**	**-$71,810,000**

The majority of payments are categorized into the major procedure codes, and there is no sign that this will diversify. In 2010, 95% of the total payments were to procedures with A2 or G2 payment indicators. The 2011 percentage remained exactly flat, with 95% of total payments still being allocated to procedures with A2 or G2 indicators.

III. Quality reporting

The ASC industry has advocated for CMS to adopt a quality reporting program for ASCs for many years, and we appreciate the diligent and thoughtful work of the CMS staff to construct this proposal with input from the industry. Working with the ASC QC, we have advanced six measures of facility processes or outcomes that apply broadly to the industry and should give consumers meaningful information about the centers where they may seek services. We are proud of this work, and believe it will contribute to the industry's ability to demonstrate its value to patients and payors. We applaud the

agency's inclusion of the five ASC QC measures that have been endorsed by the National Quality Forum (NQF).

Today, about 1200 ASCs, or 20% of the industry, participate in the voluntary collection of the ASC QC measures and report that information in the aggregate to consumers via the internet. We hope that, with CMS bringing its resources to collect and report data, we will soon achieve full participation of the entire industry in the quality reporting program. The comments we offer to this proposal are constructed with the goals of ensuring maximum participation, offering meaningful information to consumers and purchasers, applying broadly to the diverse participants in the ASC industry and achieving the agency's priorities of improving outcomes, quality, safety, efficiency and patient satisfaction. We are committed to moving toward a value-based purchasing program and are advancing legislation in Congress to give the Secretary authority to implement a pay-for-performance system for ASCs.

As we have commented previously, we remain very concerned about the overall awareness of the Medicare ASC QRP in the ASC community as a whole. We are pleased to learn that CMS has initiated outreach to all Medicare certified ASCs, and urge the agency to communicate about its outreach efforts with the Association so that we may reinforce these efforts. We seek the agency's ongoing assistance in facilitating opportunities to educate providers about the upcoming requirements and providing technical assistance to facilities struggling to participate. We stand ready to offer our assistance in meeting those educational needs, and have already done significant outreach with ASCs across the country about the proposed requirements. For example, we recently mailed an extensive quality reporting "tool kit" to every Medicare-certified ASC (regardless of membership in ASCA) to assist them in complying with the program.

Looking ahead, we urge the agency to build measures to evaluate the total ASC experience. The proposed measures will touch on many CMS priority areas; however, they do not capture patients' experiences in the ASC setting or focus on areas in which ASCs specialize. We urge CMS to work with the industry, particularly the ASC QC, to develop and seek NQF endorsement of a broad range of measures appropriate to the ASC setting, but which are not redundant of physician quality measures. We believe a group of measures to evaluate patient experience are a critical next step and an essential component of a value-based purchasing program.

We also encourage CMS to leave open a process for ASCs to provide data to CMS in the future through registry-based or electronic health record (EHR) reporting. The ASC community is exploring the potential to develop a registry for quality reporting. It would be beneficial in exploring alternative data collection mechanisms to be clear that CMS will facilitate reporting on ASC quality measures through a registry or EHR system. As those systems and capabilities mature, we urge CMS to allow data to be reported through other platforms.

For detailed comments on the quality reporting program, we have attached under Appendix 1 the recommendations of the ASC QC, which we endorse.

A. Flexibility and responsiveness

CMS has stipulated that any ASC failing to meet the quality reporting criteria will suffer a two percentage point reduction to their annual market basket update. We appreciate the agency's initial plans to recognize centers as having met their obligations to the Medicare ASC QRP by

successfully reporting the quality measures on 50% of their claims for the 2014 and 2015 updates. We welcome CMS's flexibility towards ASCs as they continue to familiarize themselves with the new quality reporting standards.

We also appreciate that CMS has provided forums for ASCs to address situations where quality requirements were not met. In particular, CMS is allowing ASCs to submit a reconsideration request by March 17 of the next payment year so that it may avoid the two percentage point penalty, and is also allowing a waiver granting ASCs that have suffered an "extraordinary circumstance" an extension to submit their quality reporting data. We encourage CMS to continue to be both fair and flexible during the quality data collection process to ensure that the most current and accurate information can be submitted.

B. Measures in use and under development

CMS has established that the following five claims-based measures would be used for CY2014 payment determination: Patient Burns (NQF #0263), Patient Falls (NQF #0266), Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267), Hospital Transfer/Admission (NQF #0265) and Prophylactic Intravenous Antibiotic Timing (NQF #0264). Additionally, the following two structural measures will also be used to calculate the CY2015 payments: Safe Surgery Checklist Use and ASC Facility Volume Data on Selected ASC Surgical Procedures. Finally, for CY2016 payment determination, CMS will add an eighth measure, Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431). These measures are a good first step toward a robust quality reporting program.

We support the inclusion of these measures in the Medicare ASC QRP, especially those that have been NQF-endorsed. Moreover, we believe that these measures would be appropriate for all outpatient surgical facilities. We encourage CMS to use these criteria to judge other outpatient surgical facilities, as well as ASCs. In doing so, CMS can ensure that different facilities will have comparable facility-level information for use by Medicare beneficiaries, creating greater transparency within the health care system and assistance to beneficiaries in making more informed decisions.

Looking ahead, we believe CMS should follow several basic principles when considering additional measures for the Medicare ASC QRP. These guidelines, consistent with the principles articulated by the ASC QC, will ensure broad acceptance of the measures within the ASC community and utility for the public and other decision-makers.

1. Measures should reflect aspects of patient care that are within the sphere of influence of the facility itself. Measures of physician performance should be included in the physician quality reporting system, and CMS should seek to avoid redundant reporting of those measures through the Medicare ASC QRP.
2. Measures should be selected which empower consumers to make informed decisions about their surgical needs. CMS should strive to eliminate reporting burdens that do not result in meaningful decision-making tools.
3. CMS should focus on measures that have been endorsed by the NQF, a process to ensure the measures have been thoroughly vetted and will be broadly accepted by the ASC community.

In Addendum 1 attached to this letter, the ASC QC has described measures that they are currently considering, including normothermia, venous thromboembolism and hospital admission following discharge from an outpatient surgical facility. As mentioned above, we are enthusiastic about developing measures of patient satisfaction. We are encouraged by recent efforts that CMS has undertaken to advance the development of an ASC CAHPS. We stand ready to provide assistance as needed.

IV. ASC Inflation Update

CMS has again proposed to update ASC payments by a measure of inflation in the Consumer Price Index for Urban Consumers (CPI-U), a measure we have argued is irreparably flawed for purposes of the ASC payment system. Recognizing the limitations of the CPI-U, CMS has requested comment on the feasibility of collecting information to establish an ASC-specific market basket. Given the heterogeneity of the centers comprising the ASC industry, we do not believe an ASC market basket will provide a more accurate reflection of ASC cost growth, nor does an ASC-specific market basket would not lead to better alignment between the settings of outpatient surgical care. While the CMS Innovation Center is advancing projects like ACOs and bundled payments that seek to tear down the silos between types of providers, maintenance of two separate update factors perpetuates the very site of service selection biases the Innovation Center seeks to eliminate.

A. Market basket background

CMS input price indices, or market baskets, are intended to measure the pure price change of inputs used by a provider in supplying health care services by using price data from the Bureau of Labor Statistics (BLS). To develop a market basket, CMS must create two components: cost weights and price proxies. Cost weights measure the mix (intensity), quantity and prices of inputs used by a provider while the price proxies measure only the price change of the category being measured. CMS primarily uses price data from BLS for the majority of price proxies.

Medicare cost reports are the primary data source for CMS construction of cost weights. These data are supplied directly to CMS from providers and are the most current and complete data available for use in developing the weights. However, for physicians who use the Medicare Economic Index, CMS does not require cost data to establish an update factor. As described below, CMS also lacks cost weights for the hospital outpatient department. Other data sources, such as the Bureau of the Census' Business Expenditure Survey and the Bureau of Economic Analysis' Benchmark Input-Output tables, are also used as secondary sources to derive weights for detailed categories.

Data for the price proxies, the second component of market basket construction, come primarily from BLS data and includes producer price indexes (PPIs), consumer price indexes (CPIs), and employment cost indexes (ECIs). Producer price indexes measure changes in the prices producers (e.g. health care providers) receive for their output. We concur with CMS that PPIs are the preferable price proxies for goods and services that facilities purchase as inputs since these facilities generally make purchases in the wholesale market. On the other hand, CPIs measure changes in the prices of final goods and services purchased by the typical consumer, which reflect productivity improvements by the provider. Finally, ECIs measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. They are fixed weight indexes that only

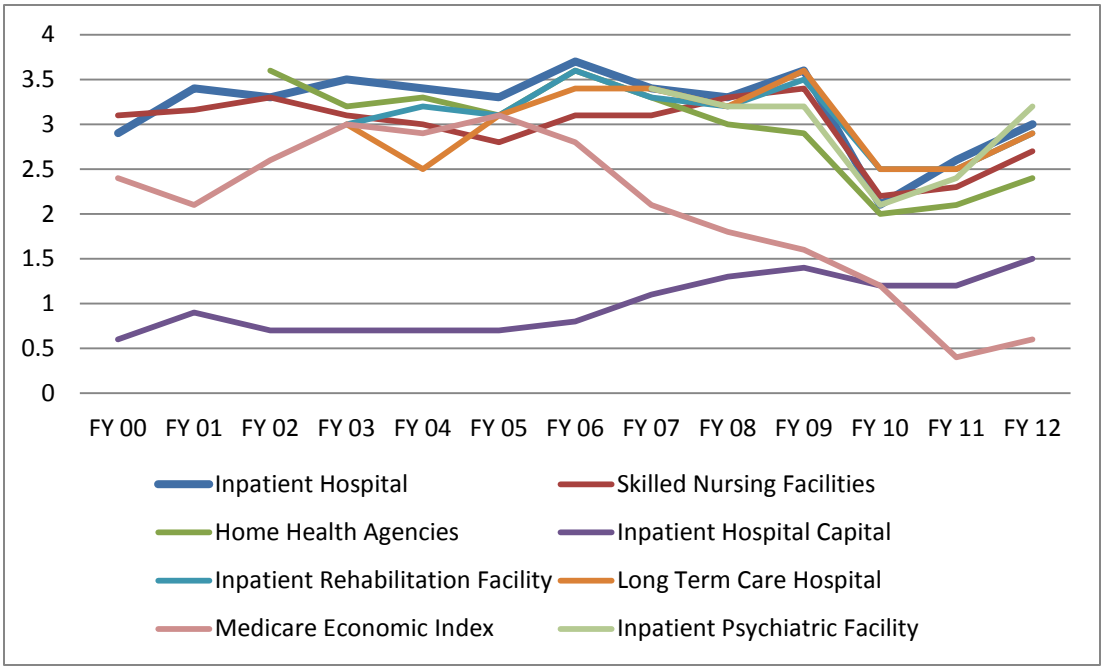
measure changes in wages and benefits per hour and are not affected by changes in occupational mix.

1. Past agency actions to collect cost data have been unproductive

CMS has expressed interest in collecting information from ASCs to establish an ASC-specific market basket. Specifically, CMS has requested feedback on the type of cost information that would be feasible to collect from ASCs in the future to determine if an alternative update or an ASC-specific update would be a better proxy for ASC cost inflation than the CPI-U. This request is similar to a request in the calendar year 2010 proposed rule (74 CFR 35391) in which CMS solicited information on the feasibility of ASCs submitting cost information, including whether to collect that data from a sample or the entire universe of ASCs, the burden of the collection, the potential for accurate information to be reported and other issues of interest. In expressing opposition to cost report collection in 2009, the ASC industry concerns included the new administrative burden, a lack of necessity given that the ASC payment rates are based on the relative costliness of procedures in the hospital outpatient department, a belief that updates should track with changes in the OPPS and a concern that data collection activities not tied to payment have historically resulted in submission of unreliable data.

We maintain these concerns. First and most importantly, ASC and HOPD relative payment rates are determined by the relative costliness of procedures performed in the HOPD. We have consistently endorsed this position. In implementing the revised ASC payment system, CMS created an ASC conversion factor that was budget neutral and intended to reflect the relative costliness of services between the ASC and HOPD. The delta between the ASC and HOPD conversion factor should be consistent from year-to-year, meaning that both systems are updated using a single inflation factor. An ASC-specific market basket moves no closer to the full alignment of the parallel payment systems than any other factor EXCEPT application of the update applied to the OPPS. Sector-specific indexes, as seen below in Figure 4, can be higher or lower than the inpatient operating market basket, which promises only to perpetuate a varying delta between ASC and HOPD rates.

Figure 4 Sector-specific market basket indices



Consistent with our views in 2009 when we commented on the last CMS solicitation for cost-reporting input, requiring cost reporting for ASCs represents a difficult and unnecessary administrative burden for both the ASC industry and CMS. As evidenced by past efforts by MedPAC to analyze ASC cost data provided to the GAO, there is significant variation in the cost weights among ASCs with different specialties. Creating a single set of cost weights representative of the industry mean would relate to few, if any, ASCs as most centers are specialized and would have a cost structure specific to the handful of high-volume procedures they provide. As such, an ASC-specific index would likely use different weights and price proxies from the CPI-U, but the cost weights may be no more accurate for any given center. Given the heterogeneity of the ASC sector, CMS should seek to align the ASC update factor with the updates applied to the OPPS. The hospital outpatient mix of services most closely mirrors the services provided in the ASC, and using the same update factor reduces one major source of payment variation that can influence site of service or capital budgeting decisions about whether to construct an HOPD or ASC to accommodate the future increase in cases that can be performed on an outpatient basis.

Third, we remain concerned that a data collection activity solely for the purposes of establishing an ASC market basket will result in the reporting of erroneous data. As CMS and MedPAC have observed in other sectors, portions of cost reports or other data collection instruments not directly tied to receipt of payment are often populated by data that is unusable. We urge CMS to avoid investing in a costly and unproductive data collection effort.

2. CMS should not delay action on the update factor

The absence of ASC cost data should not be a deterrent to CMS adopting the hospital market basket for the ASC setting. The agency can leverage the availability of a good proxy, the hospital market basket, without a prolonged search for a perfect measure of ASC costs. As described above, we do not believe that a perfect measure is possible given the heterogeneity of the industry, nor is it the appropriate policy objective given the alignment of the ASC and HOPD payment systems.

In the past, CMS has chosen to use the best available proxy when no direct measure of a setting's cost weights and price proxies are available. By the agency's own description, the hospital operating market basket is an imperfect measure of HOPD costs. In a description of the market basket indexes[1], CMS states that although the Office of the Actuary has "researched the feasibility of creating separate market baskets, we have not done so at this time because we have not been able to separate the cost categories developed from the Medicare Cost Reports separately into inpatient and outpatient services. There is also no secondary data source available to develop detailed weights for inpatient and outpatient services." By the agency's own statements, it appears that CMS questions whether the inpatient hospital market basket is appropriately capturing the input prices of the outpatient department. As hospitals have grown and diversified, including the operation of many remote outpatient departments that do not provide the full spectrum of outpatient and emergency department services, it is unlikely that the outpatient and inpatient hospital cost structures are truly similar.

In addition, the market basket update applied to hospital inpatient operating and the OPPS rates does not include capital costs, as the inpatient PPS makes a separate capital payment for which CMS

[1] Source, CMS website: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/downloads/info.pdf, accessed 08/09/2012.

maintains a separate capital market basket. The capital market basket, as seen in Figure 4, has grown significantly slower than the inpatient operating PPS market basket. As such, the hospital market basket is overcompensating hospital outpatient departments for cost growth, as the OPPS payment implicitly includes capital costs, but 100 percent of their update is based on the faster growing operating cost structure.

Given the imperfection of the hospital operating market basket as applied to the outpatient PPS, the continued reliance on the CPI-U for the ASC setting is counterintuitive. CMS has rationalized their use of the hospital operating market basket as the best available measure of costs in the outpatient setting. Based on the agency's description of the tradeoffs between input price proxies and output price proxies, it makes sense that the 'best available' alternative for the ASC setting remains the hospital market basket. In the agency's own description of the tradeoffs between measures, CMS describes the principles of building an appropriate update factor:

> *PPIs are the preferable price proxies for goods and services that facilities purchase as inputs since these facilities generally make purchases in the wholesale market. Consumer Price Indexes (CPIs) measure changes in the prices of final goods and services purchased by the typical consumer. We use CPIs only if an appropriate PPI is not available, or if the expenditure more closely resembles a retail rather than wholesale purchase.*[2]

We are extremely frustrated by the agency's intransigence in refusing to move ASCs to the hospital market basket, since it at least reflects producer price inputs, measures health care delivery-related costs and is used by the other setting of care that is providing a significantly similar mix of outpatient surgeries. We urge the agency not to waste precious resources collecting ASC cost data when a reasonable measure of input prices is readily available.

3. CPI-U is an inappropriate update mechanism for the ASC setting

We maintain that continuing to use the CPI-U to update payments for ASCs is unsuitable and does not fairly represent the costs borne by the industry. An output price index, the CPI-U measures the cost of goods purchased by typical consumers. As a result, the prices measured in the basket of goods comprising the index reflect the types and weights of categories typical of an American household, rather than an outpatient surgical provider. A comparison of the weights placed on goods in the CPI-U with the weights on goods in the OPPS market basket reveals this dichotomy between consumer and hospital spending. For example, in December 2011 households allocated approximately 41% of spending on housing payments and just over 5% to utilities. In contrast, the current OPPS allocates no weight to housing and only 2% to utilities. Likewise, about 60% of hospital spending is dedicated to wages and benefits, a cost not typically borne by consumers.

In other words, the market basket that adjusts HOPD payments more closely reflects the cost structure of ASCs than does the basket of goods implied by the CPI-U. Rather than using the CPI-U to adjust the ASC payment rates, CMS ought to apply an adaptation of the hospital market basket to make adjustments for inflation. While ASCs may not have precisely the same cost structure as an HOPD, it is certain to be a more appropriate measurement than that of a typical consumer. This view was articulated in a 2011 report from MedPAC to Congress, which stated, in reference to the CPI:

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[2] *Ibid.*

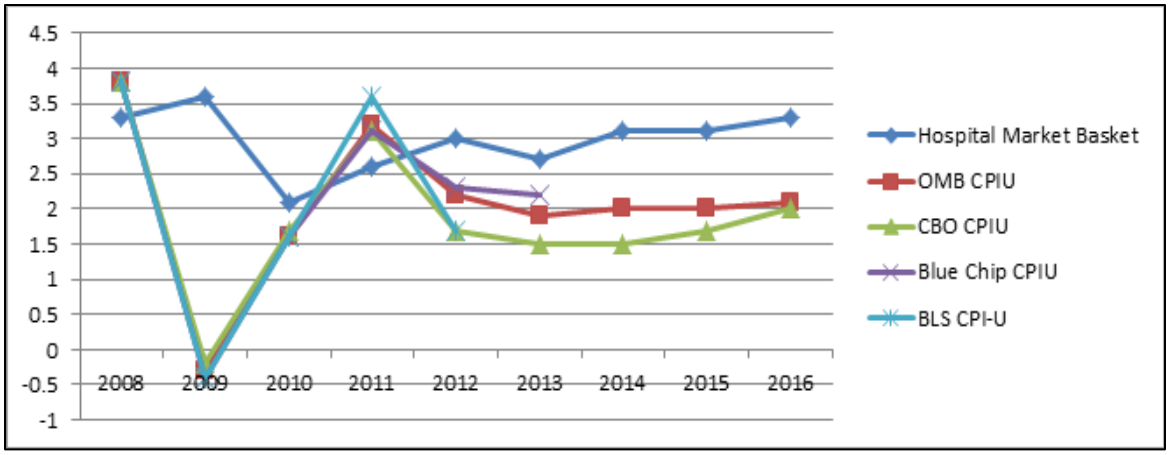
"The weight of each item is based on spending for that item by a sample of urban consumers during the survey period. Although ASCs probably use some of these items, their share of spending on each item is likely very different from the CPI-U weight."[3]

As we have seen over the past several years of economic turmoil, the prices for these goods are extremely sensitive, leaving ASCs with a highly volatile update factor that is difficult to predict accurately.[4] As a result, we urge CMS to align ASC payment updates with the OPPS Market Basket.

a) The use of the CPI-U remains a volatile and unpredictable measure of inflation for ASCs

Major government and independent forecasters show significant variation in their estimates of the CPI-U. Particularly during the current economic uncertainty, projections of the CPI-U have varied substantially and shown significant volatility. Figure 5 illustrates that all of the major government and private sector forecasters show significant variation in their estimates of the CPI-U. Figure 5 also provides insight into how divergent the OPPS and ASC payment systems are when one is updated using the market basket and the other is updated using the CPI-U. No matter which predictor of the CPI-U CMS uses, the rates paid under two systems will inappropriately drift further apart in future years.

Figure 5 Projections of the CPI-U vary widely and remain lower than the hospital market basket



	2008	2009	2010	2011	2012	2013	2014	2015	2016
Hospital Market Basket	3.3	3.6	2.1	2.6	3.0	2.7	3.1	3.1	3.3
OMB CPIU	3.8	-0.3	1.6	3.2	2.2	1.9	2.0	2.0	2.1
CBO CPIU	3.8	-0.2	1.7	3.1	1.7	1.5	1.5	1.7	2.0
Blue Chip CPIU	3.8	-0.4	1.6	3.1	2.3	2.2			
BLS CPI-U	3.8	-0.4	1.6	3.6	1.7				

[3] See MedPAC. "Report to the Congress: Medicare payment Policy" Chap. 5 pgs. 128-130

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

Moreover, as can be seen in Figure 5, the hospital market basket rate is typically higher than the different measures for the CPI-U, a trend which will continue in 2013. CMS has given a 3.0% upward adjustment of the OPPS market basket, while the CPI-U adjustment is only 2.2%. After accounting for the 0.9 percentage point reductions in mandated productivity adjustments, the OPPS payment update will be 2.1% while the ASC rate will be 1.3%[5]—indicating that the disparity remains. Adopting the hospital market basket for the ASC update would minimize the divergence in 2013 and prevent the update from causing a further deviation when the productivity adjustment is applied to both settings.

Given the failure of the 2011 update to accurately reflect real inflation by more than 2%, we urge the agency to use its authority to adopt an alternative update to ensure continued beneficiary access to ASCs. Absent these changes, we will continue to see behavior in the marketplace that results in services remaining—or returning to—higher-priced settings of care.

b) Multifactor Productivity Adjustments for ASCs

PPACA mandated that the annual payment update for ASCs be further adjusted by the multifactor productivity (MFP) rate, which is required by statute to equal the ten-year rolling average of the economy-wide, private, non-farm MFP rate. The MFP adjustment is designed to limit the amount provider output prices can be raised by subjecting the updates to adjustments for economy-wide productivity gains. MedPAC recommended this approach as a means of controlling overall health care spending growth, using MFP as an incentive for providers to increase output efficiency despite rising input costs. We maintain our assertions from previous comments that MFP is an inappropriate measure of ASC productivity. Further, the timeframe for MFP measurement is likely to put ASCs at an even greater payment disadvantage relative to HOPDs.

c) The MFP adjustment highlights the inappropriateness of the CPI-U as a measure of ASC payment updates

As previously discussed, payment adjustments for ASCs are determined by the CPI-U, which is already an output price index that accounts for productivity gains. Thus, we see no reason to hold ASCs accountable to a second productivity adjustment. CMS actuaries have voiced concerns regarding the ability of providers to achieve productivity improvements consistent with the general economy over time. Their analysis stated that, "some Medicare payment systems (such as payments for ambulatory surgical centers and lab tests) are updated by the CPI, which is already an output price index. These updates will also be reduced by economy-wide multifactor productivity gains under the new law, essentially requiring that these providers and suppliers achieve twice the rate of economy-wide multifactor productivity increases to break even."[6] CMS has the authority to correct this inequity by establishing an alternative update based on an input price index, and we urge the agency to make that correction immediately. ASCs have already been penalized once by the application of MFP to the 2013 CPI-U update, and there is no reason to perpetuate this flawed policy.

[5] http://www.gpo.gov/fdsys/pkg/FR-2012-07-30/html/2012-16813.htm
[6] http://www.cms.gov/ReportsTrustFunds/Downloads/2011TRAlternativeScenario.pdf

d) The multifactor productivity adjustment should be uniform across providers

The rolling average of MFP must be calculated for the ten-year period ending with the applicable fiscal year, calendar year, cost reporting period or other annual period.[7] Since ASC payments are already determined by the timeframe of the CPI-U, MFP rates for ASCs will be calculated for a calendar year. Alternatively, CMS proposes to apply a MFP payment adjustment to HOPDs aligned with the federal fiscal year, despite the fact that the HOPD payment system operates on a calendar year basis. Based on the proposed calendar year and final fiscal year estimates of MFP, this discrepancy will result in two separate productivity adjustments, adding an additional divergence between the ASC and HOPD updates that favors the latter. Consistency in the timeframe that the MFP is calculated would eliminate this disparity and align the HOPD productivity adjustment with the calendar year estimate of expected gains. As long as MFP applies to the ASC update the agency should, at a minimum, apply a single productivity factor to providers on the basis of their calendar- or fiscal-year payment system as directed by the statute.

4. Conclusion

The ASC industry has demonstrated its ability to achieve higher levels of efficiency relative to HOPDs, and CMS captures those savings by paying ASCs more than 40 percent less than HOPDs. CMS research suggests that hospitals, in response to changes in the PPS, may have already accomplished many achievable gains[8], and we believe ASCs have been even more successful in doing so, but are similarly constrained in their ability to achieve ongoing productivity gains. We acknowledge that introducing the productivity adjustment will incite providers to control spending and eliminate waste - a welcome and necessary improvement to the health care system – but we are adamant in our belief that requiring providers to maintain continuous efficiency gains year after year will eventually become unmanageable and damaging to the ASC care delivery model and our patients, particularly if ASCs remain tethered to the CPI-U for inflation updates.

V. The ASC Wage Index and Geographic Variation

A. Application of the Hospital Wage Index to ASCs

The Medicare wage index was created to account for geographic differences in the cost of labor in healthcare. Congress has historically adjusted the wage index for inpatient hospital services in order to address certain flaws in the index that failed to address anomalies in local markets. These adjustments have traditionally been applied to outpatient hospitals as well, under the agency's reasoning that outpatient settings are subordinate to the hospital. Nevertheless, when the new ASC payment system was established in 2008, CMS chose not to extend the adjusted hospital wage index to ASCs.

ASCs and hospitals compete in local markets for the same operating room nurses, infection control officers, coding and billing professionals and administrative staff. In essence, the similarity between the services that each provides ensures that they will require similar staffing needs. Yet despite

[7] http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf
[8] http://www.cms.gov/ReportsTrustFunds/Downloads/2011TRAlternativeScenario.pdf

these similarities, CMS continues to apply a different wage index to ASCs than it does to hospitals. This deviation is a product of policy rather than market forces, and has resulted in a significant gap between the OPPS and ASC payment rates in markets where the hospital benefits from additional policy adjustments not applicable to the pre-floor, pre-reclassification index. CMS should end this imbalance by applying the same wage index adjustments to both ASCs and hospitals. More broadly, this move is consistent with other agency actions to align payment systems that cut across sites of care to provide similar payment for similar services.

B. Accuracy of the Hospital Wage Index

In July 2012, the Institute of Medicine (IOM) released a report detailing its recommendations on geographic adjustments made to the payment rates used to reimburse physicians and hospitals. Market misclassifications, misdirected policy adjustments and the use of poor data were highlighted as specific problems impeding the accuracy of the hospital wage index. In the report, the committee recommended the removal of several provisions in the OPPS and IPPS that adjust the hospital wage index in situations when access to care may be threatened. [9] The IOM concluded that adjusting for special provisions causes the wage index to be inaccurate, and that rather than using the index as a policy tool, the methodology used to tabulate it should be redesigned. The committee recommended a number of alternatives to more effectively and appropriately achieve payment redistribution, including:

- Using commuter data to "smooth" the differences between indexes in adjacent market areas where people often commute across borders to go to work.
- Eliminating the wage index adjustment known as "the state rural floor," thereby allowing the wage index of an urban area in a state to fall below the state-wide rural floor.
- Eliminating the frontier status that gives qualifying states an index floor of 1.00. This would affect North Dakota, South Dakota, Nevada, Wyoming and Montana.

We would add that not only do these artificial adjustments to the OPPS make the hospital wage index inaccurate, they also distort the real difference in the costs between treating patients in a hospital versus an ASC. In particular, the rural floor and frontier status adjustments currently increase payments to hospitals, but not to ASCs, as they are not eligible for these benefits.

The IOM also recommended that the hospital wage index should be computed using the Bureau of Labor Statistics (BLS) Occupational Employment Statistics wage data rather than the current CMS hospital data. MedPAC has also advocated that the CMS should utilize BLS data rather than CMS hospital data to calculate the hospital wage index.[10] Currently, the data CMS uses to compute the hospital wage index consists only of hospital workers, but as MedPAC pointed out, this may not be the most accurate representation of hospital wages. For example, hospitals may choose to pay above the market rate of labor in order to enhance productivity, quality or patient satisfaction. CMS data that only takes hospital labor payments into account overestimates the true value of labor for hospitals. The BLS data, in contrast, includes workers throughout the health care industry, thus making it a more precise measurement of the true price of labor in health care.

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[9] IOM (Institute of Medicine). 2012. *Geographic Adjustment in Medicare payment: Phase II: Implications for access, quality, and efficiency*. Washington, DC: The Academies Press

[10] MedPAC. 2007. *Potential Refinements to Medicare's Wage Indexes for Hospitals and Other Sectors*.

As the agency considers the recommendations from the IOM, MedPAC and others, we encourage CMS to focus on reforms that will minimize distortions in payments for similar services within a market, based on the type of facility and applicable geographic adjustment factor. The changes could be highly redistributive of payments, and such changes should be considered carefully and phased in to minimize disruptions to existing businesses.

VI. CMS should encourage the migration of device intensive procedures to the less expensive ASC setting by establishing a reasonable device intensive threshold.

CMS generally pays for ASC procedures that have high, fixed device costs using one of two payment methodologies. The first class of procedures is classified as "device intensive codes", which is defined as those procedures for which the cost of the device represents 50% of the reimbursed amount to perform the procedure in the hospital outpatient department. For all other ASC services that have device costs, the conversion factor is applied to the entire relative weight for the service, effectively discounting the payment for the device by more than 40 percent over what is paid to the hospital outpatient department.

This policy does not take into account that ASCs are currently reimbursed only 56% of what an HOPD is paid for similar procedures. Because of the payment differential, the cost of the device can be up to 88% of the reimbursement that an ASC would receive for performing the procedure, thereby making it highly unlikely that an ASC would perform these procedures.

We recommend two adjustments to CMS's policies to improve the likelihood that these procedures will migrate from the HOPD to the lower cost ASC setting. First, CMS should not adjust the device portion of the payment by the wage index. This is consistent with the agency's policy for separately payable drugs and biologics. In addition, CMS should not apply the ASC conversion factor to the device-related portion of the payment for all procedures for which CMS can establish a median device cost, regardless of whether they are designated as device dependent under the OPPS. We recommend that CMS establish a threshold at 50 percent of the "unadjusted" ASC payment rate (relative weight * conversion factor). This threshold mirrors the policy for establishing device dependent services and pass-thru payments under the OPPS.

Currently, there are 271 procedures that would qualify as ASC device intensive procedures under this new definition, over half of which are orthopedic in nature. While these 271 codes accounted for about 150,000 ASC services from 2008 to 2010, the vast majority of these services are still performed in the HOPD at a much higher cost to the Medicare program.

Clearly, the 271 ASC device intensive procedures are being negatively affected by the current payment rates. For procedures that were on the ASC list prior to 2008 and transitioned to the fully-implemented rates, volume of the device-intensive services declined in the early part of the transition, where payments arguably failed to cover the cost of the device and service portion. As the transition

progressed, payment improved for device-intensive services that had previously been on the ASC list (and for which the device was previously paid separately), and the percent change in volume was significant. ASC procedures that are categorized as device intensive under OPPS standards increase in percent of volume in each year, while procedures that qualify as ASC device intensive procedures under the above methodology decrease in percent of volume each year.

Change in ASC Volume for Device Intensive (and similar) Procedures			
Payment Indicator	Number of Procedures	Percent Change in Volume from 2008 to 2009	Percent Change in Volume from 2009 to 2010
H8 to J8	25	-24.72%	32.84%
J8	39	23.48%	24.46%
ASC Potential Device Intensive	271	-14.35%	-0.86%

VII. Changes to the list of ASC covered procedures

We support the proposal to add an additional sixteen procedures to the list of ASC covered procedures. Under the proposal beginning in 2013, Medicare beneficiaries will have a less expensive option for these procedures. However, even with these proposed additions the list of ASC covered procedures is not reflective of all that ASCs could safely do. Instead, CMS's current policy of limiting the types of surgical procedures ASCs can perform on Medicare patients unnecessarily costs the Medicare system money and should be reformed.

Every time a procedure is performed in a Hospital Outpatient Department (HOPD) rather than an ASC, it costs the Medicare system significantly more money. Currently, the government and Medicare beneficiaries pay HOPDs 73 percent more to provide the same set of procedures. Many payers, including Medicare, have recognized the cost saving benefits of ASCs, yet Medicare has lagged behind other payers in fully leveraging the ability of ASCs to reduce costs.

For over 350 procedures, Medicare patients are not allowed to choose the less costly ASC setting because Medicare does not pay ASCs for performing these procedures. These patients are forced to seek treatment at the more expensive, and often less convenient, hospital setting simply because CMS is not fully taking advantage of what ASCs offer: a safe and efficient place for outpatient care.

ASCs are a safe place for Medicare beneficiaries to receive care. ASCs are subject to a rigid set of standards designed to ensure patient safety. These standards were enhanced to further safeguard patient safety in 2008. Additionally, studies have documented that ASCs have comparable or superior outcomes as compared to hospital outpatient departments. For example, a recent study of over 150,000 colonoscopies concluded that there was no difference in the rate of adverse events between beneficiaries that were treated at ASCs versus those treated at an HOPD. The clinical similarity between ASCs and HOPDs is further underscored by the growing trend of hospitals purchasing existing ASCs and reclassifying them as HOPDs.

Commercial payers have recognized the value proposition of ASCs and pay for many additional types of procedures beyond the limited list CMS deems appropriate. With technological advances increasingly driving procedures from the inpatient setting to the outpatient setting, we urge the agency to leverage the high-quality and cost-effective care that ASCs are capable of providing by reforming its current policy of unnecessarily limiting the types of outpatient surgical procedures ASCs are allowed to perform.

Commercial payers also commonly provide ASCs the needed flexibility of using unlisted CPT codes to report procedures, which is a practice CMS permits for HOPDs but not ASCs.

Clearly, if CMS adds procedures to the list of ASC covered services, the Medicare system would benefit from a shift in service to the lower-price setting. In a survey conducted by ASCA, ASCs identified procedures, included as Appendix 2 to this letter, that are currently commonly being paid for by commercial payers but not Medicare. ASCs report positive outcomes when they perform these procedures on non-Medicare patients and indicate that the procedures would not raise any of the specific safety concerns that would bar a procedure from being added to the ASC list of covered procedures.

A. CMS's current process of determining ASC-eligible procedures lacks transparency

One of the primary problems with the process that CMS uses to add procedures to the list of ASC covered procedures is that it completely lacks transparency, stunting dialog between the agency and the ASC community and impeding the agency's ability to add procedures to the ASC list of covered procedures based on sound, outcomes-based evidence.

The ASC list of covered procedures is defined by an "exclusionary list." That is, ASCs should be allowed to perform any surgical procedure that is not designated as an "inpatient only procedure" unless CMS has explicitly determined that the procedure would raise one or more specific safety concerns found at 42CFR §416.166. CMS, however, has never provided specific justification for why it excludes a particular procedure from the list.

This opaque decision making prevents the ASC community from addressing any concerns that the agency is using to exclude procedures from the list of ASC covered procedures. In many instances, clinical experts from the ASC setting believe that procedures would not violate any of the agency's exclusionary criteria. Absent the agency revealing its rationale, we are unable to provide additional information to rebut the agency's concerns.

As we have repeatedly done in the past, we urge the agency to bring transparency to its decision making and disclose the specific reason(s) that a procedure has been excluded from the list of ASC covered procedures.

This could be accomplished by simply including an appendix of the procedures that Medicare pays HOPDs for performing, but are excluded from the list of ASC covered procedures, that contains a code corresponding to which of the following six specific reason(s) reasons for exclusion the agency is relying to keep the procedure off the ASC list of covered procedures.

1) Generally results in extensive blood loss

2) Requires major or prolonged invasion of body cavities

3) Directly involves major blood vessels

4) Is generally emergent or life-threatening in nature

5) Commonly requires systemic thrombolytic therapy

6) Typically requires active medical monitoring and care at midnight following the procedure

In addition, we urge the agency to disclose the clinical evidence upon which the reason(s) for exclusion is based. Such transparency will foster a constructive dialog as CMS evaluates additions to the ASC list of covered procedures.

B. CMS should add to the ASC list both procedures removed from the inpatient-only list

ASCA supports the proposed removal of CPT 22856 - total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical - And CPT 27447 (arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty) from the inpatient-only list. Several studies have shown that these procedures can be safely and effectively performed in the outpatient setting.

However, CMS should treat ASCs and HOPDs equitably by adding the two procedures to the list of ASC covered procedures beginning in 2013. Alternatively, the agency should explicitly articulate the evidence it is relying on to determine that the procedures are inappropriate for the ASC setting but should be allowed in the clinically comparable HOPD setting.

C. CMS should also provide a payment for ASCs that use non-highly enriched uranium (non HEU) derived Techetium-99 (Tc-99m)

CMS proposes an additional payment of $10 per use for facilities that use the Technetium-99 (Tc-99m) radioisotope produced by non HEU (non-highly enriched uranium) beginning in 2013. However, CMS proposes no parallel payment policy to increase the payment for the use of non-HEU radioisotopes by ASCs. We encourage CMS to align the policies between the two settings and make the additional $10 per dose of Tc-99m radioisotope produced by non-HEU methods available in the ASC setting, as well.

D. We support the switch from median to geometric mean cost for calculation of APC relative weights

In CY2013, CMS has proposed to calculate the relative payment weights in the OPPS by using geometric mean cost of services within an APC, instead of median costs. While median costs have been used since the inception of the OPPS, as CMS notes, the use of geometric mean costs will more accurately model costs. We appreciate the agency's consideration of the policy impact on ASCs and support the switch to the geometric mean.

VIII. Summary

We appreciate the agency's consideration of our comments. CMS can take positive steps to improve the ASC payment system and we urge CMS to address the many sources of variation between the ASC and outpatient hospital payment systems, starting first with the update factor. CMS can also positively affect the participation of ASCs in the upcoming quality reporting program by enhancing their education and outreach activities. We appreciate the steps the agency has taken to date and stand ready to provide additional information and assistance as needed.

For additional information, please contact Steve Miller, Director of Government and Public Affairs at smiller@ascassociation.org or 703.836.8808.

Sincerely,

William Prentice
Chief Executive Officer
Ambulatory Surgery Center Association

ASC Quality Collaboration

September 4, 2012

VIA ELECTRONIC SUBMISSION

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1589-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1589-P; Proposed Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

Dear Acting Administrator Tavenner:

On behalf of the ASC Quality Collaboration (ASC QC), a cooperative effort of organizations and companies interested in ensuring ambulatory surgical center (ASC) quality data is appropriately developed and reported, please accept the following comments regarding CMS-1589-P, Section XVI. Requirements for Ambulatory Surgical Center Quality Reporting (ASCQR) Program (77 FR 45061, July 30, 2012) and the recently released ASC Quality Reporting Specifications Manual, Version 1.0a. The ASC QC's stakeholders include ASC corporations, ASC industry associations, physician and nursing professional societies, and accrediting bodies with an interest in ASCs. Please see Appendix A for a list of the ASC QC's participating organizations.

The ASC QC strongly advocates quality reporting. This commitment is reflected in the steps we have taken independently to facilitate quality reporting by ASCs – all without federal incentive or penalty. This includes developing six ASC facility-level quality measures and securing the endorsement of the National Quality Forum (NQF) for each, as well as developing and publishing a quarterly public report of ASC quality data that is freely available online. These quarterly reports are made possible through the voluntary efforts of participants in the ASC QC and may be accessed at the ASC QC's website at: **http://www.ascquality.org/qualityreport.html**. Over 1300 centers, representing more than 20 percent of all Medicare certified ASCs, participated in the most recent report.

We recognize the significant effort the agency has invested in preparing for the implementation of the ASC Quality Reporting Program (ASC QRP). We are grateful to see the

measures we developed included in the program and appreciate the consideration the agency has given to our feedback on implementing a quality reporting system for ASCs. We are pleased to have this opportunity to offer additional insights and recommendations.

I. Educational Materials Regarding the Medicare ASC Quality Reporting Program

In our recent comments to the agency regarding CMS-1588-P, we expressed deep concern regarding the level of awareness surrounding the Medicare ASC QRP in the ASC community as a whole. We are therefore pleased to learn that FMQAI, the CMS support contractor for the ASC QRP, recently sent an educational mailing via FedEx to all Medicare-certified ASCs. This type of direct communication is essential to achieving high levels of initial participation in the program and maximizing the number of ASCs that achieve, or exceed, the minimum threshold for successful reporting. While we were pleased by this direct outreach, we were disappointed that the mailing did not mention the educational webinars regarding the ASC QRP that are scheduled for September 26, 2012. This was certainly a missed opportunity. We urge CMS to take steps to make the webinar available to ASCs that may not become aware of this educational opportunity in time to register and attend. At a minimum, the webinar should be recorded, then posted on both the QualityNet and CMS websites for later viewing.

We are pleased to see the agency has created a page specific to the ASC QRP under the Quality Initiatives section of the cms.gov website. We encourage the agency to continue to expand the resources available at this ASC Quality Reporting webpage, as many in the industry will look to this as a primary source of definitive program information.

We look forward to providing commentary and feedback as CMS continues to expand the ASC QRP resources through additional postings on the QualityNet and CMS websites. We would be happy to provide feedback on these materials prior to their publication.

II. Principles Used in the Selection of Measures for the ASC Quality Reporting Program

A. CMS Principles

CMS has outlined a set of general principles the agency has applied in the selection of measures for inclusion in its other quality reporting programs. While generally sound, we offer the following thoughts on selected items.

The ASC QC supports the alignment of measures across public reporting and payment systems to the extent possible. We believe that the four claims-based outcome measures CMS has adopted under the ASC QRP could be applied to other surgical providers, and encourage CMS to take steps to include these measures in other quality reporting programs. Applying the same facility-level quality measures to all settings offering outpatient surgery expands the comparative data available to Medicare beneficiaries and would represent an important step toward full transparency.

We agree it is important to develop quality reporting programs within the context of national priorities. However, we are concerned by the lack of ASC stakeholder input into the

partnerships that establish priorities and measure applications. ASCs perform approximately 40 percent of *all* surgeries and procedures in the United States – over 22 million each year. Yet there is no direct representation of the industry on either the National Priorities Partnership (NPP) or the Measure Application Partnership (MAP). We believe HHS and CMS should include ASC representation in both partnerships to improve the effectiveness of these entities in formulating priorities for outpatient settings and coordinating efforts across inpatient and outpatient settings.

CMS indicates that it "continuously seek[s] to adopt electronic-specified measures so that data can be calculated and submitted via certified EHR technology with minimal burden". We agree that moving toward electronically-specified measures is desirable, but do not believe this is practical for the majority of ASCs in the near term. The use of EHRs in the ASC industry is limited. ASCs were not included in provisions of the American Recovery and Reinvestment Act of 2009 establishing an incentive and penalty program to encourage adoption of health information technology. However, we do strongly encourage CMS to move quickly to allow an EHR reporting option to meet the requirements of the ASC QRP for those ASCs that have implemented EHRs.

Finally, while we support the use of a mix of measure types, we do not believe this should be among the primary considerations for measure selection. We are concerned that a press for measure diversity may lead to the selection of poorly developed measures that have not been adequately tested. For example, the structural measures CMS has selection for inclusion in the ASC QRP – use of a safe surgery checklist and ASC procedure volume – lack carefully developed and tested specifications. Yet their inclusion allows CMS to "check the box" for the structural measure category for the ASC QRP.

B. Additional Principles CMS Should Apply in the Selection of Quality Measures

The ASC QC believes additional considerations should guide CMS in the selection of measures for its quality reporting programs. The following principles are important and should be incorporated into the construct CMS uses: appropriate attribution of accountability, results that are meaningful to the general public, and rigorous measure evaluation and testing prior to implementation. These are described in more detail below.

Selection of quality measures should be guided by appropriate attribution of accountability. Measures selected for use in outpatient surgical facilities should reflect aspects of patient care that are attributable to the facility itself - its staff, equipment, environment of care, and its roles in the delivery of patient care - and for which the facility, by virtue of its specific functions in patient care, may reasonably be held accountable. We do not believe it is appropriate to implement physician-level quality measures for non-physician provider types, such as ASCs.

Measures should generate data that is meaningful to the general public. Appropriately selected quality measures must provide information that can be readily understood by the consumer and that can be used in their evaluation of the quality of care offered by the provider. Measures that do not result in clear and helpful data should not be selected.

Whenever possible, measures should be selected from among those endorsed by the National Quality Forum (NQF) through its national multi-stakeholder consensus approval process. While CMS states that consensus among affected parties can be achieved in other ways – including through the measure development process, through broad acceptance and use of the measure, and through public comment – we do not believe these proxies are always equivalent or entirely satisfactory. These alternatives often lack the rigor that characterizes the NQF measure evaluation process and typically bypass the testing that is so essential to the development of a satisfactory quality measure.

III. Measure Topics for Future Consideration

The ASC QC continues to evaluate and develop other potential outpatient surgery quality measures, examining areas such as normothermia, venous thromboembolism, and hospital admission following discharge from an outpatient surgical facility.

We have had a longstanding interest in the development of a patient experience measure for outpatient surgical facilities similar to CAHPS survey tools currently in existence for other providers. We developed a draft survey instrument several years ago, but do not have the resources to complete the necessary testing. We are pleased that CMS has issued a procurement for an ASC CAHPS, and look forward to actively participating in the project.

We are also planning to participate in the Agency for Healthcare Research and Quality's (AHRQ) project that would develop a Surgical Unit-based Safety Program in Ambulatory Surgery (SUSP-AS) to further reduce surgical site infections and other surgical complications. We look forward to providing input regarding several aspects of the project, including the surgical safety checklist and the survey that would assess the culture of safety.

IV. Process for Making Updates to Measures

In its other quality reporting programs, CMS has adopted a subregulatory process for making updates to the measures adopted for each program. We agree that when a national consensus building entity (such as the NQF) updates the specifications for a measure adopted under the ASC QRP that CMS should update its specifications accordingly. These NQF updates typically occur as a result of a measure maintenance process that occurs every several years, although there is an ad hoc process for annual updates. We believe CMS should also look to specification changes made by measure developers/stewards, as these changes can occur any time a change in evidence, consensus standards or other factors merits an update.

For measures that are not endorsed by a national consensus building entity, CMS currently determines when changes are needed, in part, through an internal measure maintenance process involving Technical Expert Panels. We believe relevant ASC clinical and operational expertise should be brought to bear in the review and update of any measures CMS adopts for the ASC QRP that are not endorsed by a national consensus building entity. CMS should ensure the Technical Expert Panel used in its internal, subregulatory maintenance process for such ASC measures includes substantial representation from the ASC industry.

V. Form, Manner and Timing for Claims-Based Measures for Payment Determination for CY 2015 and Subsequent Years

A. Data Completeness Requirements for Payment Determinations for CY 2015 and Subsequent Years

We support the agency's proposal to determine data completeness for claims-based measures for the CY 2015 and subsequent payment determination years by comparing the number of Medicare claims (including Medicare secondary payer claims) meeting measure specifications that contain the appropriate quality data codes (QDCs) with the number of Medicare claims that would meet measure specifications, but did not have the appropriate QDCs on the submitted claims. With the exception of the inclusion of Medicare secondary payor claims, this is the same method CMS will use to determine data completeness for the CY 2014 payment determination.

B. Data Collection and Processing Period for Payment Determinations for CY 2015 and Subsequent Years

CMS proposes that, in order to be included in the quality reporting data used for the CY 2015 payment determination, claims for services furnished between January 1, 2013 and December 31, 2013 be paid by the administrative contractor by April 30, 2014. As the agency knows, ASCs have up to one year to submit claims for services rendered. We understand the agency's need for lead-time in order to process and analyze quality data, make payment determinations, and supply payment information to administrative contractors, but continue to believe that the proposed period for the collection of claims data is too abbreviated to capture all pertinent data, especially for the outcome measures.

We believe that as the agency gains experience with ASC quality data analysis, and the determination and implementation of any payment adjustments over time, it should seek ways to push the date by which claims must be processed back as close to the one-year mark as possible. For example, for the CY 2016 payment determination, the deadline for claims for services furnished between January 1, 2014 and December 31, 2014 should be pushed back to June 30, 2015, allowing for the capture of as many claims as possible.

VI. ASC Quality Reporting Specifications Manual Version 1.0a

We appreciate the agency's willingness to accept feedback regarding its specification manual for the ASC QRP. We are pleased to see several significant improvements in Version 1.0a, but encourage CMS to make additional changes to improve the clarity and usefulness of the manual as soon as possible.

In addition, there is essential information regarding successful claims-based reporting that has not been included in the manual. We note that for its other quality reporting programs, CMS has used a separate implementation guide to convey this type of information. While the enclosure in the FMQAI letter mentioned above was helpful, we believe CMS should include

this information in the specifications manual, or, if this is not feasible, prepare an ASC implementation guide explaining the mechanics of claims-based reporting and the use of the QualityNet website. ASCs should not have to search through a list of FAQs to try to piece together this essential information. If this information is incorporated into a separate implementation guide, that guide should be posted online at both the QualityNet website and the CMS website.

A. Claims-Based Reporting for Medicare Secondary Payer Patients

Although CMS issued the G-codes for the ASC QRP with the April 2012 HCPCS release, private payers will not have the HCPCS data files for use until January 1, 2013. As a result, private payer claims with QDCs received prior to January 1, 2013, can be rejected for having invalid codes. Recognizing this, CMS determined that only claims where Medicare is the primary payer would be used in the calculation of data completeness for the CY 2014 payment determination. Claims where Medicare is the secondary payer will not be included.

The current specifications manual indicates that data for claims-based measures are to be reported for all Medicare Part B fee-for-service patients, including Medicare Secondary Payer (MSP) patients. To avoid confusion, we believe it is essential CMS clarify the finalized status of MSP claims by explicitly stating that MSP claims will not be included for the October 1, 2012 through December 31, 2012 reporting period. This statement should be included in the "Data Collection and Submission" discussion on page 4 of the manual. This information should also be explicitly stated in the "Reporting Period" section for each of the claims-based measures. This type of information should also be included in the suggested implementation guide referenced above.

B. Instructions for the Use of QDCs G8907 and G8916

CMS has included a page of information regarding the use of QDCs 8907 and G8916 on page 5 of the specifications manual. For those who are not well acquainted with the measures and their corresponding codes, this section of the manual is confusing. More explanatory context is needed for this information to be as helpful as possible. First-time users are likely to be confused by the references to measure numbers without their corresponding titles, by statements that reference outcome measures without stating what those outcome measures are, and by references to "four of the five claims-based outcomes measures" (there are only four claims-based outcome measures).

Users are also likely to be confused by seemingly contradictory statements regarding the use of G8918. In one sentence the manual states, "CMS requires all facilities to report on the ASC-5 measure for all Medicare fee-for-service patients, *even if there is no indication for or order for perioperative antibiotics* (G8918)" (emphasis added). In the very next sentence the manual states, "IMPORTANT: *For surgical patients with an order for prophylactic antibiotics,* information on the fifth measure, Prophylactic IV Antibiotic Timing, will be reported separately" (emphasis added).

C. Prophylactic Intravenous (IV) Antibiotic Timing (ASC-5)

The ASC QC developed five of the measures that have been adopted for claims-based reporting. For each of the four claims-based outcome measures, CMS has included a statement following the "Clinical Recommendation Statements" that directs the user to the ASC QC website for additional information: "Additional information and resources, such as sample data collection forms and frequently asked questions (FAQs) about the measures, can be found on the ASC Quality Collaboration website at **www.ascquality.org**." We believe it would be helpful to include the same statement in the specifications for this process measure.

D. Safe Surgery Checklist Use (ASC-6)

In our comments to the agency regarding CMS-1588-P, we noted that Version 1.0 of the Specifications Manual for the Safe Surgery Checklist Use measure indicated ASCs were to report whether a safe surgery checklist based on accepted standards of practice was used "*at any time during the designated period*" (emphasis added). This was a change from the agency's previous statement finalizing the measure in CMS-1525-FC, which indicated "an ASC would report whether their facility employed a safe surgery checklist that covered each of the three critical perioperative periods *for the entire calendar year of 2012*" (emphasis added). CMS staff advised that it was the agency's intent to measure use of a safe surgery checklist at any time during the performance period. We note that Version 1.0a of the manual now indicates that ASCs are to report whether a safe surgery checklist based on accepted standards of practice was used "*during the designated period*" (emphasis added), a change which deletes the phrase "at any time".

We are pleased CMS has confirmed that, for the initial year of data collection, an ASC may answer "Yes" if the checklist is used at any time during calendar year 2012. In subsequent years the checklist must be utilized for the entire year in order to answer affirmatively. This incremental implementation is a fair approach given that many ASCs are just now becoming aware of ASC QRP requirements. Given that this information is essential to correct interpretation and reporting for this measure, we believe it must be included in the specifications manual itself, not just in a list of questions and answers on the QualityNet website. We urge the agency to ensure the specifications manual is updated timely to include this information.

E. ASC Facility Volume on Selected ASC Surgical Procedures (ASC-7)

CMS finalized the structural measure ASC Facility Volume Data on Selected ASC Surgical Procedures for the CY 2015 payment determination. When originally proposed, this measure was poorly specified. Although improvements were made in Version 1.0 of the Specifications Manual, we noted in comments to the agency regarding CMS-1588-P that there were still many pertinent details lacking. We hoped to see further clarification in this revision of the manual, but none are apparent. We believe it is essential for CMS to take steps to offer the necessary clarification as soon as possible.

As we noted in the past, the measure specifications are not sufficiently detailed to allow consistent preparation of procedure counts across different ASCs. There are several questions CMS should address in order to ensure consistent data preparation and reporting. For example,

are aggregate procedure counts to be prepared for the nine categories alone, or are aggregate counts to be prepared for the thirty-four (34) subcategories, or both? In preparing the aggregate counts, are secondary procedures to be counted in addition to the primary procedure? How are bilateral procedures or those performed on multiple spinal levels to be counted? How should ASCs count cases that are cancelled or otherwise discontinued after the patient has been admitted? These types of questions should be addressed as soon as possible to allow ASCs to prepare for data reporting.

VII. Additional Considerations

CMS has stated its intent to issue proposals pertaining to other aspects of the ASC QRP in future rulemaking. We offer the following comments regarding selected topics as the agency develops these additional proposals and refines existing policies.

A. Exemptions for Low Volume or No Volume

Case mix across ASCs is very diverse. As a result, situations arise when selected measures are not applicable to the case mix of an individual ASC. In circumstances where a measure would never, or very rarely, apply to an ASC, CMS should create appropriate low volume or no volume exemptions to reduce provider burden. Measure ASC-5, Prophylactic Intravenous (IV) Antibiotic Timing, is an example of a measure that does not apply to all ASCs. Single-specialty ASCs that provide gastrointestinal endoscopies do not administer IV prophylaxis for the prevention of surgical site infection (SSI). Many single-specialty ophthalmic ASCs administer topical, rather than IV, antibiotics for SSI prevention.

CMS has determined that it will not offer an exemption for this measure. The collection of this data in centers that do not administer IV antibiotic prophylaxis does not generate any information that can be used in performance improvement or to inform consumer decision-making. As a result, this policy imposes unnecessary burden for ASCs that do not administer prophylactic IV antibiotics for SSI. We strongly recommend CMS reconsider the issue of exemptions for this measure. ASCs that do not administer IV antibiotic prophylaxis for SSI could claim an exemption through their QualityNet account.

B. Alternative Reporting Mechanisms

The ASC QC remains convinced CMS should allow ASCs to meet the quality data reporting requirements under the ASC QRP using registry-based reporting as an alternative to the other mechanisms CMS has outlined for ASC use through CY 2016. We note that CMS has provided physicians with several data reporting options under PQRS and believe this flexibility should be extended to ASCs as well.

The ASC QC has a strong interest is developing an ASC-specific registry. It would be very helpful to our progress if CMS would provide some guidance as to whether or not registry-based reporting will be an option for ASCs in the future. It is our intent that the registry would collect data from participating ASCs on a broad variety of quality measures, including measures

CMS has adopted under the ASC QRP. We anticipate this registry would collect quality measure data for all patients, regardless of payment source.

While we do not have a definitive timeline for our registry development project at this time, we are aware of other registries already in operation. Examples include the GIQuIC and Ophthalmic Patient Outcomes Database registries, which may currently be used to satisfy PQRS reporting requirements. We believe these registries are potential avenues for ASC registry-based reporting if this alternative becomes available under the ASC QRP.

In addition to a registry-based reporting option, ASCs should also have the option of submitting quality data to CMS through an EHR-based reporting mechanism. While the use of EHRs in the ASC industry is limited at this time, there are centers that have implemented this technology and could benefit from this option. Absent an indication from CMS that it will accept EHR-based reporting, there is little incentive for EHR vendors to incorporate ASC measures into their products.

C. Publication of ASC Quality Reporting Program Data

The ASC QC supports transparency and welcomes a fair presentation of ASC quality data that could assist consumers in making informed health care decisions. Consumers should be able to access this information on websites that are organized to allow easy comparisons across facilities that offer outpatient surgical services, while also protecting the rights of providers by assuring that the information made available is correct, current, and clearly presented.

ASCs should have an opportunity to preview any data before they are made public. In conjunction with the preview materials, CMS should provide contact information for program content areas experts that ASCs can contact to ask questions or raise concerns with any information prior to its publication. There should also be a provider narrative section for each provider-specific item presented to the consumer. This narrative box would allow the provider to advise the consumer of any concerns the provider has regarding the reliability or accuracy of the information presented. In addition to reporting quality data, other useful information such as facility accreditation status should be made available to the consumer.

In addition, the site displaying ASC quality data should provide the consumer with basic information regarding each measure, including guidance that would assist the consumer with interpretation of the measure data and its appropriate use in decision-making.

We look forward to the more detailed proposals on the publication of ASC quality program data in later rulemaking. We are particularly interested in the agency's plans for determining the threshold at which data for centers with low Medicare volume should be deemed unreliable, and therefore unsuitable for public reporting.

D. Feedback and Benchmarking

Following the end of each the reporting periods, CMS should provide confidential feedback reports based on the quality measures reported by individual ASCs for services

provided during the reporting period. These reports should address topics such as measure participation, data completeness, QDC submission errors and measure performance detail.

In addition to its use for public reporting purposes, the data collected through the ASC QRP should also be made available to participating ASCs for benchmarking purposes. We urge CMS to develop a process for establishing ASC benchmarks on a measure-by-measure basis. This information would be valuable as individual ASCs assess their performance relative to their peers and determine if performance improvement activities are needed. The Hospital-Specific Reports (HSRs) CMS currently prepares for individual hospitals participating in the Hospital IQR program could serve as a model.

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Thank you for considering these comments. We look forward to continuing our dialogue with the agency regarding the ASC QRP. We would be happy to assist with questions or provide additional information at your request.

Sincerely,

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Appendix A
Current Participants in the Activities of the ASC Quality Collaboration

Accreditation Association for Ambulatory HealthCare
Ambulatory Surgery Foundation
Ambulatory Surgical Centers of America
American College of Surgeons
American Osteopathic Association, Healthcare Facilities Accreditation Program
AmSurg
Association of periOperative Registered Nurses
Florida Society of Ambulatory Surgery Centers
Health Inventures
Hospital Corporation of America, Ambulatory Surgery Division
Nueterra Healthcare
Outpatient Ophthalmic Surgery Society
Surgical Care Affiliates
Symbion
The Joint Commission
United Surgical Partners International

Appendix 2: PROCEDURES THAT ASCs CURRENTLY PERFORM FOR NON-MEDICARE PATIENTS WITH STELLAR OUTCOMES BUT ARE NOT PAID FOR BY MEDICARE WHEN PERFORMED IN AN ASC

HCPCS Code	Short Descriptor
0275T	Minimally invasive lumbar decompressions
21141	Reconstruct midface lefort
21142	Reconstruct midface lefort
22551	Neck spine fuse&remov bel c2
22552	Addl neck spine fusion
22554	Neck spine fusion
22612	Lumbar spine fusion
22845	Insert spine fixation device
22846	Insert spine fixation device
22851	Apply spine prosth device
23470	Reconstruct shoulder joint
27096	Inject sacroiliac joint
27125	Partial hip replacement
27130	Total hip arthroplasty
27415	Osteochondral knee allograft
27447	Total knee arthroplasty
27524	Treat kneecap fracture
27556	Treat knee dislocation
27558	Treat knee dislocation
27702	Reconstruct ankle joint
27703	Reconstruction ankle joint
27715	Revision of lower leg
58571	Tlh w/t/o 250 g or less

HCPCS Code	Short Descriptor
63001	Removal of spinal lamina
63003	Removal of spinal lamina
63005	Removal of spinal lamina
63012	Removal of spinal lamina
63015	Removal of spinal lamina
63017	Removal of spinal lamina
63020	Neck spine disk surgery
63030	Low back disk surgery
63035	Spinal disk surgery add-on
63042	Laminotomy single lumbar
63043	Laminotomy addl cervical
63047	Removal of spinal lamina
63048	Remove spinal lamina add-on
63050	Cervical laminoplasty
63056	Decompress spinal cord
63075	Neck spine disk surgery
63076	Neck spine disk surgery
63081	Removal of vertebral body
63265	Excise intraspinal lesion
63267	Excise intraspinal lesion
63275	Biopsy/excise spinal tumor
63277	Biopsy/excise spinal tumor