September 2, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1613-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via online submission at www.regulations.gov

Re: CMS-1613-P – Medicare Program; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2015 Payment Rates

Dear Administrator Tavenner:

The Ambulatory Surgery Center Association (ASCA), on behalf of the nearly 5,400 Medicare-certified ambulatory surgical centers (ASCs) nationwide, submits these comments in response to the calendar year (CY) 2015 proposed ASC payment rule (79 Fed. Reg. 134, July 14, 2014). ASCs offer patients a high-quality, convenient and lower-cost choice for their care. An analysis by researchers at the University of California-Berkeley found ASCs saved the Medicare program and its beneficiaries $7.5 billion during the four-year period from 2008 to 2011.[1] The Berkeley researchers project that ASCs have the potential to save Medicare an additional $57.6 billion over the next decade *if* policymakers take steps to encourage the use of these innovative healthcare facilities within the Medicare system.

The U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) also found that substantial savings can be achieved when procedures are performed in ASCs; our facilities saved Medicare almost $7 billion and saved beneficiaries an additional $2 billion during CYs 2007 through 2011, and have the potential for even greater savings in the future.[2] Another study published earlier this year in the prestigious journal *Health Affairs* found that ASCs save money and increase efficiency for Medicare and patients while providing the same high quality care as hospital outpatient departments (HOPDs), but the authors warn, that "recent [Medicare] reimbursement changes have lowered payments to ASCs, which reduces the incentives to start or expand these facilities."[3]

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[1] University of California-Berkeley Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, *Medicare Cost Savings Tied to Ambulatory Surgery Centers*, September 2013.
[2] U.S. Department of Health and Human Services. Office of Inspector General. Washington: Government Printing Office, April 2014. (A-05-12-00020)
[3] Munnich, Elizabeth L. and Stephen T. Parente. "Returns to Specialization: Evidence from the Outpatient Surgery Market." *Health Affairs*, April 2014.

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ASCs play an integral role in health care delivery and have a long record of providing high quality and efficient care to Medicare beneficiaries. As you know, the ASC community was an early proponent of the Medicare ASC quality reporting program, and we believe that it will demonstrate that ASCs provide quality care equal to or greater than that of other settings. Last year was the first full year of data reporting under this program, and we look forward to a full reporting on our indicators of clinical processes and outcomes of care.

As referenced in the research mentioned above, ASCs have achieved cost savings and produced high-quality outcomes for the Medicare program and its beneficiaries in spite of CMS policies that systematically disadvantage ASCs. While we appreciate the efforts of your staff to apply the design fundamentals of Medicare's prospective payment system, an overly-rigid interpretation of the law has resulted in great divergence between ASC and hospital outpatient prospective payment system (OPPS)[4] rates.

Summary of Major Comments

As rates between OPPS and ASC payments have diverged since 2008, migration of services from the hospital into the ASC has slowed or reversed. Indeed, a failure to pay competitive rates to ASCs to encourage a shift in site of service comes at a high price to the Medicare program, the taxpayers who fund it, and the beneficiaries who needlessly incur higher out-of-pocket expenses. Low-complexity surgical care in too many markets continues to be predominantly provided in HOPDs.

Advances in medical technology and patient safety are creating an ever-growing list of procedures appropriate for ambulatory settings and have expanded the types of patients who can be safely treated outside the hospital. Despite these advances, however, we have observed low entry into the ASC industry over the past several years and slow or negative growth in Medicare volume for some common ASC procedures.

One suggested solution to this problem is site neutral payments. Congress, the Medicare Payment Advisory Commission (MedPAC) and CMS have been exploring the concept of site-neutral payments for some procedures common in our setting. While this is a conversation worthy of additional dialogue, policymakers must ensure that the unit of payment is the same between settings. Unfortunately, the divergent payment policies CMS continues to use for ASCs and HOPDs make the path to a common unit of service difficult. In the sections that follow, we describe policy changes to better align the OPPS and ASC payment systems. These proposals will improve the likelihood of further migration of services into the lower-priced ASC setting and ensure access to ASC services for Medicare beneficiaries. Our comments will focus on the following key issues.

- CMS must replace the Consumer Price Index for All Urban Consumers (CPI-U) as the update mechanism for ASC payments. The CPI-U measures inflation in a basket of consumer goods atypical of what ASCs purchase. Further, the Affordable Care Act (ACA)

[4] Throughout this letter we use OPPS to refer to the payment system and HOPD to refer to the site of service/type of facility.

requires CMS to reduce the update by a measure of productivity gains, which inappropriately subjects ASCs to two productivity adjustments: improvements reflected in the price of consumer purchased goods and the additional ACA-mandated reduction.

- CMS should mirror any changes to the APCs adopted in the OPPS in a manner that preserves the alignment between the payment systems and ensures accurate payment for services within the ASC. The agency should engage stakeholders in discussions of how to implement those changes given the proposed differences in how services are reported and paid.

- CMS should implement further policy changes for setting payments for device-intensive procedures to encourage migration of services into the less-expensive ASC setting. ASCA recognizes CMS' proposed policy change as a strong step in the right direction, and thanks CMS for acknowledging the need to reevaluate how device-intensive rates are set.

- CMS should discard the current policy of limiting ASCs to being reimbursed for only a subset of the procedures that it reimburses HOPDs. While ASCA commends CMS for proposing the addition of ten new spine codes to the ASC-payable list, CMS should migrate many more procedures to our setting.

Overview of ASC market developments

Medicare's payment policies contribute to the slowed industry growth as evidenced by the lack of Medicare volume migration to the lower-priced ASC setting. We are alarmed to report that CMS data shows that HOPD market share of some common ASC procedures is growing—a counterintuitive market response to the rates in both settings.

Table 1 ASCs have not gained Medicare market share

	HOPD Market Share	
HCPCS	2013	2008
66984	32%	36%
43239	53%	53%
45380	50%	52%
45385	51%	54%
64483	31%	35%
66821	20%	21%
62311	44%	36%
45378	59%	58%

When CMS implemented the revised ASC payment system in 2008, the agency anticipated a significant shift in the site of service from the HOPD to the ASC. Table 1 depicts the top 8 ASC services by volume (based on 2013 data), and serves as a stark sign that not only has very little market share moved out of the higher-priced HOPD in the last 6 years, but that hospitals are actually growing their share of some of these services. While there are certainly cases in which a screening colonoscopy (HCPCS 45378) needs to be performed in the hospital – in emergent cases and for patients with high comorbidities – it is troubling that the HOPD market share on this routine procedure has increased since 2008. In 2014, Medicare will pay over $105 million more – just for this code – when a standard screening colonoscopy is performed in the HOPD instead of an ASC. The slow or non-existent migration rate of Medicare services to the ASC setting is a clear signal that Medicare's reimbursement policies have not resulted in competition and a shifting of site of service.

Any case volume growth in ASCs can be attributed to the diversification of services away from Medicare cases. Industry-wide statistics are not available, but some of the largest ASC

management companies have been moving volume away from Medicare to ensure the viability of many centers. According to the filings of one publicly-traded company, the Medicare share of its payer mix has plummeted from approximately 35 percent in 2008 to 25 percent last year.

This disturbing trend is an indicator of the payment issues that may be leading many owners to either consider sale to their local hospitals/health system or to close, resulting in a continued movement of care to more expensive sites of service.

In addition, ASCA is extremely concerned that migration in the wrong direction may be exacerbated by CMS' electronic health record (EHR) technology policies. Unlike hospitals and physician practices, ASCs were not included in the Health Information Technology for Economic and Clinical Health Act (HITECH), which was enacted as part of the American Recovery Reinvestment Act (ARRA) of 2009. It is therefore unreasonable to expect ASCs to be equipped with an interoperable EHR system at the same pace as hospital and physician practices.

Even though ASCs were not contemplated in HITECH, CMS guidance requires surgeries and procedures performed at ASCs to count toward a physician's total in determining whether the physician meets the statute's "meaningful use" requirements – defined as having at least 50 percent of patient encounters at a location(s) equipped with a certified EHR. By including ASC patient encounters in the denominator of the 50 percent threshold calculation, physicians will be at significant risk of not having a sufficient number of encounters in a setting equipped with a certified EHR, resulting in unjust penalties. Faced with the possibility of penalties, some physicians may choose to treat more patients at an HOPD with a certified EHR, where the costs are substantially higher to Medicare and its beneficiaries.

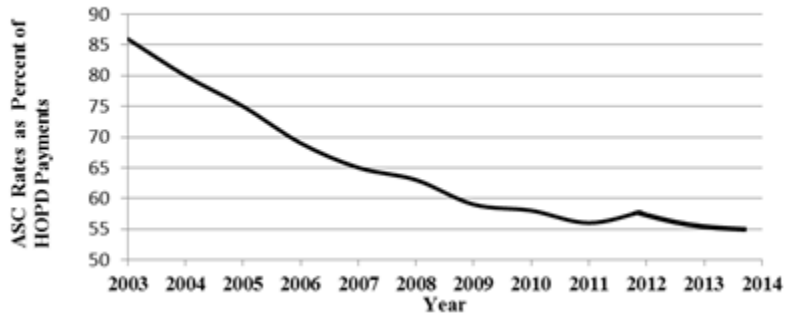
CMS needs to quickly reevaluate its policies to stop this migration of volume to higher-cost settings.

CMS should align ASC and OPPS payment policies

ASC update factor should be the hospital market basket

The most glaring example of the lack of alignment between ASC and OPPS payment policies is the continued use of different inflation update factors. While the ASC update is based on the CPI-U, the HOPD update is based on the inpatient hospital market basket, which has historically been higher than the CPI-U. Figure 1 illustrates how the use of different update factors has led to a growing disparity in reimbursement rates. Whereas ASCs were reimbursed over 85 percent of HOPDs rates just a decade ago, our facilities are currently reimbursed 55 percent of HOPD rates for performing the same procedures.

Figure 1 Growing Disparity between ASC and HOPD Payments



CMS inaction under the 2015 proposed rule will cause this divergence between ASC and HOPD payment updates to widen. We urge CMS to adopt the same measure to update both the ASC and HOPD payment systems to minimize further divergence, prevent the trend of ASCs being purchased by hospitals and, ultimately, reduce costs to the Medicare program.

We continue to argue that using the CPI-U to update payments for ASCs is unsuitable and does not accurately represent the changing costs borne by facilities. The ASC payment system is one of the last CMS payment systems to be tied to the CPI-U (the other being the ambulance fee schedule); other payment systems use indices derived from the basket of goods actually purchased by those providers. Our concerns, which we have discussed in previous comments to the agency, include:

- The CPI-U is an output price index that measures the cost of goods purchased by typical consumers.
- 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. 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.

Therefore, we continue to urge the agency to align ASC payment updates with the OPPS payment updates by using the inpatient hospital market basket for both settings. Doing so will stabilize the payment differential without creating any additional burden on ASCs or CMS staff.

However, while ASCA maintains that the best policy would be to update ASCs based on the hospital market basket to provide consistency with the OPPS, there are various alternatives within the CPI-U that CMS could explore that more accurately reflect the economic climate in the ASC environment. For instance, CMS could use subsets of the CPI-U (medical care, medical care services, and outpatient services) that are consistent with the services being provided in the ASC setting.

CMS should apply the hospital wage index to ASCs

The use of different wage indices is also of concern. The wage index was created by the Social Security Act to adjust reimbursement for regional differences in wages. The purpose of the wage index adjustment is to achieve regional purchasing power parity and equalize payments

according to variation in wage rates or cost of labor. Congress has historically adjusted the wage index for inpatient hospital services in order to address certain flaws in the index that failed to capture anomalies in local markets. These adjustments have been extended to HOPDs as well, but have failed to reach ASCs.

ASCs and hospitals compete in the same local markets and provide many of the same services. For this reason, HOPDs and ASCs require similar staff. Despite these similarities, CMS continues to apply a different wage index to ASCs than it applies to hospitals, further exacerbating the gap between the OPPS and ASC payment rates. We believe CMS should address these inconsistencies by applying the same wage index adjustments to both ASCs and hospitals, thereby aligning payment systems and providing similar payment for similar services.

The Office of Management and Budget has used 2010 Census data to change the current core based statistical areas (CBSA) delineations, which will be phased in next year. In some areas, the new delineations will reduce the wage index value. In those counties that will be impacted, CMS is proposing to phase in the decrease by blending the 2014 and 2015 rates, and then applying the new rates in 2016. We support the policy of consistency between the ASC and OPPS wage index and appreciate that CMS has proposed to phase in the changes over the next two years, as they have done in other settings. Sudden, unforeseen wage index changes can cause significant disruptions in payments to ASCs and it is imperative that they are allowed adequate time to properly adapt to these changes.

CMS should apply comprehensive APC changes to the ASC setting

For CY 2015, the proposed rule would implement a change initially proposed last year to combine multiple payments into comprehensive APCs in the OPPS. These new codes create bundles of services, primarily focused around the former "device-intensive" codes that present a challenge and an opportunity for HOPDs. If HOPDs successfully manage services and supplies within the bundle, their margins on those procedures will improve. However, those HOPDs with higher-than-average costs for delivering services will lose under this policy. New incentives will likely cause shifts in relative cost and frequency of the comprehensive codes and the codes within the bundle in the OPPS, and the effects of these shifts will be transferred to ASCs through the application of OPPS-derived relative weights to ASC codes and through the application of the scaler that adjusts the total ASC weighting system to remove the effect of higher weights on total ASC payments.

Through weighting and scaling, the new comprehensive APCs for the OPPS will cause more volatility in the ASC payment rates from which they are derived. We urge CMS to investigate the impact of comprehensive APCs on ASC payments and to alleviate unintended consequences, especially if they result in increased divergence in payment rates across the two settings.

CMS should ensure packaging policies do not disproportionately affect ASCs

CMS currently pays HOPDs and ASCs separately for services that are integral to a primary service. For CY 2015, CMS is proposing to conditionally package ancillary services assigned to APCs with a geometric mean cost of $100 or less (prior to applying the conditional packaging status indicator to the services within these APCs), as a criterion to establish an initial set of

conditionally packaged ancillary service APCs. Conditional packaging means that if these ancillary services are furnished by themselves, CMS will continue to make separate payment for the service. Since ASC reimbursement rates are already substantially lower than HOPD rates, the fear with any packaging policy is that, by packaging these codes and not providing adequate reimbursement for all of the procedures being performed, this will simply be another CMS policy that sends more services back to the higher-priced HOPD.

While several packaging policy changes led to historic numbers of packaged codes last year, the expansion of the packaging policy will once again create problems for the ASC community this year. There are 244 ancillary and surgical codes that are separately payable in 2014 procedures but are proposed to be packaged and no longer separately payable in 2015.

When CMS bundles procedures that were previously paid for separately in the ASC setting, the packaging assumes that the secondary procedures are not always performed in combination with the primary service and, thereby, ascribes only part of the cost to the OPPS payment. Currently, Medicare is paying ASCs approximately 55 percent of the hospital rate for the same service. The concern is that when packaged the payment for the secondary services will drop even further, causing another disparity between ASC and OPPS payments and discouraging the movement of volume to ASCs. Moving forward, CMS should work to ensure that any packaging policies are not structured to disproportionately impact the already lower-cost provider.

Proposed device-intensive policy encourages migration of services to the ASC setting

CMS currently 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 currently defined as those procedures for which the cost of the device represents 50 percent of the mean cost of the procedure in the HOPD. For example, if an HOPD is reimbursed $1,000 to perform a procedure and the device costs represent $600 of the $1000 payment, the procedure is considered device-intensive when performed in the ASC setting. In this example, the ASC would receive the same $600 that the HOPD receives to cover the device cost and another $220 to cover the facility's other overhead expenses (the result of applying the ASC's discounted conversion factor, or 55 percent of the remaining $400 of the HOPD rate). The total ASC payment would be $820 compared to the HOPD payment of $1,000.

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. In the example above, if the device costs the hospital $499, the ASC would receive no added reimbursement for the device and only $550 to perform the procedure, meaning the ASC would receive just $51 for the facility's costs for that patient encounter. The obvious result is that most ASCs will choose not to perform such procedures. The current methodology stifles migration from the hospital outpatient setting and increases costs to beneficiaries and taxpayers.

ASCA applauds CMS for reevaluating this policy and making recommendations that could lead to the migration of volume to the lower-cost ASC setting. Under this proposal, CMS would define ASC device-intensive procedures as those procedures that are assigned to any Ambulatory

Payment Classification (APC) (not only an APC formerly designated device-dependent) with a device offset percentage greater than 40 percent based on the standard OPPS APC rate setting methodology.

ASCA has identified 163 codes with high device costs that are performed in the HOPD setting but are not typically performed in ASCs due to the payment challenges that derive from current policy: while the cost of the device for these codes is greater than 50 percent of the total ASC cost for these procedures in the ASC setting, it does not meet the 50 percent threshold in the HOPD setting, and therefore the facility would not be reimbursed for the device.

According to our analysis, CMS' proposal to drop the threshold to 40 percent would make it economically feasible for 48 of these 163 procedures to be performed more frequently in ASCs. Based on 2012 volume data and 2014 payment rates, even a 10 percent migration of volume to the ASC setting on just these 48 codes would result in almost $15.5 million savings to Medicare. While we support CMS' proposal to change the device-intensive payment policy from 50 percent to 40 percent, we recommend further adjustments to allow even more procedures to migrate to the lower cost ASC setting.

Specifically, CMS should establish the threshold at 50 percent of the "unadjusted" ASC payment rate (relative weight * conversion factor). This threshold mirrors the current policy for establishing device-intensive services and pass-thru payments under the OPPS, and since ASCs are not included in the new comprehensive APCs, this is the policy that should be referenced. Using the example above, if the device costs the hospital $499 the ASC would now receive $499 for the device and $275.55 (55 percent of the remaining $501) for a total payment of $774.55. This would save Medicare over $225 per procedure every time a beneficiary chooses the ASC for their device-intensive surgery. In addition, 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.

If CMS prefers to continue to determine device-intensive status based on HOPD rates, lowering the proposed 40 percent threshold to 30 percent would achieve similar savings to our proposal above. Appendix 1 illustrates the potential savings CMS could achieve by making it economically feasible for ASCs to perform procedures that are currently being performed in high volume in the HOPD setting. As this chart only includes the highest volume HOPD device-intensive codes, it represents only a portion of the savings that may be achieved by lowering the threshold to 30 percent.

It is important to note that we used the 2014 payment rates when producing the analysis for this section, instead of projecting the savings based on 2015 rates, because there are a number of codes which have dramatic and unexplained shifts in payment rates in the proposed rule. There is a reasonable chance that these shifts may be caused by an error or unintended consequence of CMS' methodology when implementing the comprehensive APCs. Since the rates are intended to be set in a neutral manner, this shouldn't adjust aggregate payments, but may cause a number of differences at the code (and provider) level.

One particular area where we have identified a concern with CMS' calculations is in the treatment of the device-dependent APC rates for the OPPS, which are then used to calculate ASC rates. CMS appears to have combined two different sets of weights. For APCs that are not device-dependent, CMS applied the weights calculated in the OPPS to all of the data. However, the device intensive codes were calculated based solely on the subset of claims used for comprehensive APCs. This mixing of universes for calculation of the weights may be what is leading to these strange shifts in weights. We encourage CMS to reevaluate these calculations.

Changes to the list of ASC covered procedures

There are currently 359 CPT codes for which Medicare reimburses HOPDs but not ASCs. These procedures are designated as Surgical Procedures Excluded from Payment in ASCs but are not included on the inpatient-only list. If the determination is made to remove a procedure from the inpatient only list, we strongly recommend that it should also be eligible for payment in the ASC setting. ASCs are subject to a rigid set of survey and certification standards designed to ensure patient safety. The 2008 overhaul of the ASC Conditions for Coverage enhanced these standards to further safeguard patient safety.

Appendix 2 highlights 26 procedures with high Medicare volume (which we are defining as 1,000 services or more a year) in the HOPD setting that surgeons are routinely performing in ASCs for commercial payer cases but for which Medicare does not reimburse in the ASC setting. In a survey conducted by ASCA, surgeons who operate in ASCs identified procedures that are currently being paid for by commercial payers but not Medicare. These procedures – including many of the high volume procedures in Appendix 2 – are found in Appendix 3, and are codes for which physicians report positive outcomes when performed on non-Medicare patients in the ASC setting. Physicians also indicate there are no safety concerns that should bar a procedure from being added to the ASC list of covered procedures that can be performed on Medicare beneficiaries.

In addition, 60 of the 359 codes for which Medicare reimburses HOPDs but not ASCs are unlisted codes. Commercial payers commonly provide ASCs the flexibility they need to use unlisted CPT codes to report procedures. This is a practice CMS permits for HOPDs but not for ASCs, and is yet another example of an area where CMS could make a change and derive savings for both the Medicare program and its beneficiaries.

ASCs are often on the cutting edge of new treatments, as acknowledged by the discussion of ASCs involved in investigational device trials as discussed in XII(C)(1)(d) of the proposed rule, "Proposed Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices." With technological advances increasingly driving procedures from the inpatient to the outpatient setting, we urge the agency to leverage the high-quality and cost-effective care that ASCs provide by reforming its current policy of unnecessarily limiting the types of outpatient surgical procedures ASCs are allowed to perform.

Recognizing that eliminating the distinction between the ASC and HOPD approved codes may be too large a step for CMS to take this late in the rulemaking process, CMS could simply add all

of the procedures listed in Appendix 3 to the ASC-approved list, and allow patients and the Medicare system to realize substantial savings in 2015 and beyond.

Proposed addition of ten spine codes

We are grateful that CMS has identified ten spine codes for addition to the ASC list in 2015. ASCs have been performing the 10 proposed spine procedures for years on commercial patients of all ages, and there is substantial evidence in medical literature that these procedures can be safely performed in the outpatient setting, including in the ASC. However, there are meaningful issues that need to be addressed in the rule to assure that ASCs can be properly reimbursed for these procedures, specifically with the anterior cervical discectomy and fusion (ACDF and PLF) codes (22551, 22612 and 22614).

Based upon the clinical indications of the patient, an ACDF can be performed with the insertion of a cage (22851) and require instrumentation such as screws, plates and hardware (22845) and may be performed with or without an allograft (20930-20931). In addition, lumbar fusions (PLF codes 22612 (1-level) and 22614 (2-level)) may also require insertion of a cage, instrumentation and allografts. These cases commonly also encompass a combination of procedures including, but not limited to: 22552, 22851, 22842-22845 and 20930-20936. As of 2014, many of these codes are considered add-on codes and bundled into the payment rates of the primary procedure. If these additional codes are not reimbursed, it will not be financially feasible for an ASC to perform ACDFs (22551) and PLFs (22612, 22614) on Medicare patients. The cost of the instrumentation and cages alone exceeds the reimbursement rates established on the current HOPD rate schedule. While we appreciate the efforts made to approve new spine codes, CMS will not see volume migrate out of the inpatient setting without adding all codes that could be included in the case.

Another issue regarding the reimbursement of spine codes is the assignment of APC weight and rates. Appendix 4 shows the HOPD-reported costs for spine codes that CMS published on January 1, 2014. As indicated, all of the spine codes are assigned to APC 0208, but there are apparent reporting errors in the cost data. For example, the lumbar fusion shows the minimum cost reported for a 22612 is $270.60 and the maximum cost is $55,222, and the ACDF has a minimum cost of $1,689.75 and a maximum cost of $38,033. It is impossible to perform a lumbar fusion (22612) without hardware and devices, the cost of which far exceed $270.60.

These higher-cost cervical and lumbar fusions are incorrectly assigned to the same APC group as the laminectomy codes due to faulty cost reports. We suspect this is the primary factor impacting the low frequency of these services provided in the HOPD setting, which will also be the case in the ASC setting unless changes are made. As you can see in Appendix 4, the cervical and lumbar fusion volume reported by HOPDs is nominal compared to the laminectomy/laminotomy volume (63001-63056). We urge CMS to evaluate the cost of services further, and reassign the APC and weight to afford a higher value and enable ASCs to provide these services.

Changes to the Quality Reporting Program

We appreciate the work the agency has done to implement the ASC quality reporting program (ASCQRP), and are pleased that 98 percent of ASCs successfully reported during 2012. We

understand there was drop off in successful reporting in 2013 when centers were first required to submit web-based data for measures ASC-6 and ASC-7 via QualityNet. There were several barriers to reporting via QualityNet, including a delay in the availability of the site. ASCA was disappointed CMS did not provide relief for those ASCs who clearly want to participate in the ASCQRP by reporting on claims but failed to report via QualityNet. ASCA requests CMS allow a one-year reprieve from penalties for centers who failed to report via QualityNet in 2013.

The ASC community has coalesced behind a group of stakeholders who came together nearly a decade ago to develop, test, and seek endorsement of measures specific to the ASC setting. This group, the ASC Quality Collaboration (ASC QC), has prepared and submitted detailed comments on the specific measures proposed for adoption in the ASCQRP. We endorse those comments and have included them under Appendix 5.

Last year, CMS proposed an August 15, 2015 deadline by which ASCs must submit 2014-2015 influenza season data through CDC's National Healthcare Safety Network (NHSN) system, which aligns with the submission deadline for the ASCQR Program structural measures entered via QualityNet. The agency did not finalize the August 15, 2015 deadline, and this year, proposed a deadline of May 15 of the year in which the influenza season ends, which would align the ASC submission deadline with the deadline used in the hospital inpatient and outpatient programs.

While we recognize August 15 is not consistent with the deadline for other quality reporting programs that enter data for the influenza vaccination measure, we support the August date. Although in its infancy, the ASCQR Program is already complex, featuring different data collection time frames, data submission deadlines and data submission methodologies. We believe any steps that can be taken to simplify and streamline program requirements would help reduce the burden of compliance with the already numerous requirements. If the agency desires a consistent data submission deadline across settings, we believe it should also consider the August 15 date for the other quality reporting programs.

ASCA appreciates CMS' proposal to make *ASC-11: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)* voluntary for the CY 2016 reporting period and subsequent years. This measure was widely opposed by stakeholder groups, based primarily on its lack of feasibility, and we appreciate that CMS has acknowledged "that it may be operationally difficult at this time for ASCs to collect and report this measure." It is our belief that the number of ASCs that might voluntarily report this measure will be very small. Given that the measure is challenging and expensive for ASCs to implement, we anticipate that voluntarily participation will be much lower than that of physicians (only 215 of the more than 7,300 cataract physicians reported it in 2013).

However, if any ASCs do report measure data for ASC-11, CMS contractors would still have to perform all of the tasks necessary to develop and maintain the means to collect and publicly report the information. We question the value of this effort and do not believe it would have any appreciable impact on ASC performance or provide enough consumer information to warrant the effort. Therefore, we recommend the removal of the measure from the program.

CMS has proposed to adopt one new claims-based measure into the ASCQR Program for the CY 2017 payment determination and subsequent years, a measure titled *Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy*.

We do not support the inclusion of this measure in the ASCQR Program due to significant problems with the measure's validity, reliability and usability, all of which are discussed in great detail in the ASC Quality Collaboration's comments. Looking ahead, we encourage CMS to only include measures in the ASCQR Program that truly measure aspects of surgical visits over which the facility has control and that allow ASCs and patients to evaluate the quality of the facility.

Conclusion

CMS must ensure Medicare beneficiaries have access to the high-quality, lower-cost care ASCs provide. The recommendations in this comment letter highlight several areas in which CMS can facilitate movement of outpatient procedures to the ASC setting in a fiscally responsible manner.

The current regulatory framework that governs ASC payments is based on an outdated perspective of the ASC delivery model. The modern ASC serves an integral role in the healthcare delivery system, and we implore CMS to update its policies to encourage these providers to continue to serve Medicare patients. We appreciate the opportunity to provide feedback on the agency's work and are happy to discuss any of these issues further.

Please contact Kara Newbury at knewbury@ascassociation.org or (703) 836-8808 if you have any questions or need additional information.

Sincerely,

William Prentice
Chief Executive Officer

Appendix 1

DEVICE-INTENSIVE PROCEDURES (WITH DEVICE COST >50% OF UNADJUSTED ASC RATE (AND LESS THAN 50% OPPS MEDIAN COST) WITH 2012 HOPD DISCOUNT VOLUME OVER 1,000)

HCPCS	Short Descriptor	ASC Volume 2012	HOPD Volume 2012	ASC Pay Rate 2014	Device Cost %	Device Cost	New ASC Rate	Additional ASC Medicare Spend/Year	Medicare Savings/Year (10% Migration)
Total								$14,399,465.96	**$28,024,421.98**
66180	Implant eye shunt	6,591	5,326	$1,677.90	55.14%	$925.18	$2,188.65	$3,366,372.00	$452,026.84
36561	Insert tunneled cv cath	5,931	88,351	$1,296.22	51.75%	$670.85	$1,673.16	$2,235,600.00	$5,948,543.00
28750	Fusion of big toe joint	2,184	5,075	$2,689.89	68.53%	$1,843.51	$3,653.48	$2,104,470.00	$617,026.13
57288	Repair bladder defect	2,004	21,188	$1,971.53	67.70%	$1,334.77	$2,671.18	$1,402,105.00	$1,902,082.38
51715	Endoscopic injection/implant	1,717	5,826	$1,400.62	63.74%	$892.72	$1,875.35	$815,115.10	$384,555.47
35476	Repair venous blockage	958	91,408	$1,262.40	93.00%	$1,174.05	$3,109.98	$1,769,981.00	$11,886,979.00
62350	Implant spinal canal cath	772	3,882	$1,886.87	51.10%	$964.24	$2,430.63	$419,779.40	$382,386.38
37765	Stab phleb veins xtr 10-20	398	2,715	$346.05	55.88%	$193.37	$1,357.26	$402,463.20	$212,265.78
26531	Revise knuckle with implant	360	1,570	$2,562.62	77.44%	$1,984.52	$3,572.31	$363,489.20	$167,452.72
28740	Fusion of foot bones	341	1,674	$2,689.89	68.53%	$1,843.51	$3,653.48	$328,582.60	$203,527.42
28300	Incision of heel bone	271	1,341	$2,689.89	68.53%	$1,843.51	$3,653.48	$261,131.60	$163,040.78
28730	Fusion of foot bones	261	1,342	$2,689.89	68.53%	$1,843.51	$3,653.48	$251,495.70	$163,162.36
36558	Insert tunneled cv cath	220	30,056	$1,062.84	61.19%	$650.31	$1,412.19	$76,857.70	$1,538,226.63
28725	Fusion of foot bones	183	1,603	$2,689.89	68.53%	$1,843.51	$3,653.48	$176,336.10	$194,895.14
36571	Insert picvad cath	183	4,679	$1,062.84	61.19%	$650.31	$1,412.19	$63,931.63	$239,465.08
35475	Repair arterial blockage	156	14,205	$1,337.62	87.77%	$1,174.05	$3,109.98	$276,488.00	$1,847,262.25
36581	Replace tunneled cv cath	130	14,878	$1,062.84	61.19%	$650.31	$1,412.19	$45,415.91	$761,436.50
57265	Extensive repair of vagina	32	1,901	$1,971.53	67.70%	$1,334.77	$2,671.18	$22,388.90	$170,655.97
33241	Remove pulse generator	19	4,296	$1,280.34	55.70%	$713.16	$1,672.96	$7,459.85	$276,978.72
36595	Mech remov tunneled cv cath	10	1,373	$449.58	144.65%	$650.31	$1,412.19	$9,626.13	$70,268.34
37200	Transcatheter biopsy	1	2,262	$1,296.22	51.75%	$670.85	$1,673.16	$376.93	$152,297.13
37233	Tibper revasc w/ather add-on	0	1,047	$5,037.90	81.03%	$4,081.98	$7,095.45	$0.00	$211,939.33
33234	Removal of pacemaker system	0	1,209	$1,280.34	55.70%	$713.16	$1,672.96	$0.00	$77,948.63

Appendix 2

HIGH VOLUME (>1,000) PROCEDURES IN THE HOPD SETTING WHICH ARE NOT COVERED BY MEDICARE IN THE ASC SETTING

HCPCS	Short Descriptor	Rate	2013 Volume
19307	Mast mod rad	$ 4,150.16	6,329
23470	Reconstruct shoulder joint	$ 10,359.54	1,387
28805	Amputation thru metatarsal	$ 1,755.81	1,113
31600	Incision of windpipe	$ 1,946.88	1,317
32551	Insertion of chest tube	$ 492.77	1,309
33244	Remove eltrd transven	$ 2,079.89	1,908
35471	Repair arterial blockage	$ 4,334.22	3,341
35903	Excision graft extremity	$ 2,442.89	2,183
37191	Ins endovas vena cava filtr	$ 2,517.04	7,311
37193	Rem endovas vena cava filter	$ 2,517.04	3,575
39400	Mediastinoscopy incl biopsy	$ 3,004.03	4,645
43280	Laparoscopy fundoplasty	$ 5,454.40	2,618
43281	Lap paraesophag hern repair	$ 5,454.40	3,103
43770	Lap place gastr adj device	$ 5,454.40	1,316
44180	Lap enterolysis	$ 3,790.53	3,149
44970	Laparoscopy appendectomy	$ 3,790.53	6,625
57120	Closure of vagina	$ 4,365.85	2,273
57282	Colpopexy extraperitoneal	$ 4,365.85	6,785
57283	Colpopexy intraperitoneal	$ 4,365.85	2,823
57425	Laparoscopy surg colpopexy	$ 3,790.53	5,698
58260	Vaginal hysterectomy	$ 4,365.85	4,409

58262	Vag hyst including t/o	$ 4,365.85	1,905
58573	Tlh w/t/o uterus over 250 g	$ 3,790.53	1,010
60252	Removal of thyroid	$ 3,720.28	1,077
60260	Repeat thyroid surgery	$ 3,720.28	1,250
60271	Removal of thyroid	$ 3,720.28	1,247

Appendix 3

PROCEDURES PROPOSED FOR COVERAGE BY MEDICARE FOR THE ASC SETTING WHICH ASCS PERFORM ON NON-MEDICARE PATIENTS WITH STELLAR OUTCOMES

HCPCS Code	Short Descriptor
19307	Mast mod rad
22851	Apply spine prosth device
22856	Cerv artific diskectomy
23470	Reconstruct shoulder joint
28805	Amputation thru metatarsal
31600	Incision of windpipe
32551	Insertion of chest tube
33244	Remove eltrd transven
35471	Repair arterial blockage
35903	Excision graft extremity
37191	Ins endovas vena cava filtr
37193	Rem endovas vena cava filter
39400	Mediastinoscopy incl biopsy
43280	Laparoscopy fundoplasty
43281	Lap paraesophag hern repair
43770	Lap place gastr adj device
44180	Lap enterolysis
44970	Laparoscopy appendectomy
54332	Revise penis/urethra
54336	Revise penis/urethra
54535	Extensive testis surgery
54650	Orchiopexy (Fowler-Stephens)
57120	Closure of vagina
57282	Colpopexy extraperitoneal
57283	Colpopexy intraperitoneal
57310	Repair urethrovaginal lesion
57425	Laparoscopy surg colpopexy
58260	Vaginal hysterectomy
58262	Vag hyst including t/o
58543	Lsh uterus above 250 g
58544	Lsh w/t/o uterus above 250 g
58553	Laparo-vag hyst complex
58554	Laparo-vag hyst w/t/o compl
58573	Tlh w/t/o uterus over 250 g
60252	Removal of thyroid

60260	Repeat thyroid surgery
60271	Removal of thyroid
63011	Removal of spinal lamina
63012	Removal of spinal lamina
63015	Removal of spinal lamina
63016	Removal of spinal lamina
63017	Removal of spinal lamina
63035	Spinal disk surgery add-on
63040	Laminotomy single cervical
63048	Remove spinal lamina add-on
63057	Decompress spine cord add-on
63075	Neck spine disk surgery
63076	Neck spine disk surgery

Appendix 4

COSTS FOR HOSPITAL OUTPATIENT SERVICES, BY HCPCS CODE FOR CY 2014
(BASED ON CLAIMS FOR SERVICES PROVIDED JANUARY 1 – DECEMEBER 31, 2012)

HCPCS	Description	APC	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Median Cost	Geometric Mean Cost
22551	Neck spine fuse&remov bel c2	0208	$4,003.31	285	506	$1,689.75	$38,033.98	$8,750.51	$8,742.93
22554	Neck spine fusion	0208	$4,003.31	46	92	$1,033.49	$48,911.46	$8,090.43	$6,615.49
22612	Lumbar spine fusion	0208	$4,003.31	51	195	$270.60	$55,222.47	$9,984.43	$8,893.05
22856	Cerv artific diskectomy	0208	$4,003.31	4	4	$6,670.01	$36,974.19	$10,505.62	$12,819.37
63001	Remove spine lamina 1/2 crvl	0208	$4,003.31	49	75	$2,149.02	$11,768.37	$4,193.97	$4,509.50
63003	Remove spine lamina 1/2 thrc	0208	$4,003.31	29	85	$1,390.98	$39,387.82	$4,407.07	$4,628.97
63005	Remove spine lamina 1/2 lmbr	0208	$4,003.31	817	1232	$1,039.67	$15,306.55	$3,984.85	$4,047.26
63012	Remove lamina/facets lumbar	0208	$4,003.31	51	71	$1,123.38	$19,336.45	$4,263.89	$4,742.65
63015	Remove spine lamina >2 crvcl	0208	$4,003.31	32	57	$2,398.01	$7,767.13	$4,170.56	$4,131.70
63016	Remove spine lamina >2 thrc	0208	$4,003.31	3	6	$3,548.43	$7,009.20	$5,108.90	$5,027.41
63017	Remove spine lamina >2 lmbr	0208	$4,003.31	141	212	$2,210.85	$9,889.67	$4,488.90	$4,420.55
63020	Neck spine disk surgery	0208	$4,003.31	349	477	$1,451.09	$9,598.96	$4,227.43	$4,111.91
63030	Low back disk surgery	0208	$4,003.31	12639	18088	$1,151.35	$13,158.90	$3,760.04	$3,822.71
63040	Laminotomy single cervical	0208	$4,003.31	7	12	$2,706.00	$7,608.26	$3,683.43	$4,040.86
63042	Laminotomy single lumbar	0208	$4,003.31	724	1060	$1,443.70	$10,672.60	$3,723.18	$3,794.32
63045	Remove spine lamina 1 crvl	0208	$4,003.31	424	578	$1,549.59	$13,433.98	$4,487.30	$4,471.20
63046	Remove spine lamina 1 thrc	0208	$4,003.31	98	210	$1,392.71	$10,849.99	$4,301.01	$4,242.24
63047	Remove spine lamina 1 lmbr	0208	$4,003.31	8574	11618	$1,285.09	$13,125.82	$4,018.69	$4,088.00
63055	Decompress spinal cord thrc	0208	$4,003.31	17	20	$2,943.09	$8,521.63	$4,588.61	$4,632.40
63056	Decompress spinal cord lmbr	0208	$4,003.31	740	990	$1,157.44	$11,249.16	$3,641.20	$3,816.26
63064	Decompress spinal cord thrc	0208	$4,003.31	2	2	$2,554.19	$6,643.81	$4,599.00	$4,119.41
63075	Neck spine disk surgery	0208	$4,003.31	43	77	$1,934.99	$17,445.59	$4,200.10	$4,698.20

Appendix 5

COMMENTS SUBMITTED BY THE ASC QUALITY COLLABORATION AND SUPPORTED BY THE ASCA

ASC Quality Collaboration

September 2, 2014

VIA ELECTRONIC SUBMISSION

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1613-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1613-P; Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated with Submitted Data

Dear 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-1613-P (79 FR 40916, July 14, 2014), Section XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. 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 these organizations, which represent over 1,500 ASCs.

The ASC QC's strong commitment to advancement of quality is reflected in the steps we have taken independently to facilitate quality reporting by ASCs – all without federal incentive or penalty. This includes having developed six ASC facility-level quality measures and secured the endorsement of the National Quality Forum (NQF) for each, as well as continuing to publish 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.

We appreciate the ongoing effort the agency has devoted to the ASC Quality Reporting (ASCQR) Program and are pleased to have this opportunity to offer insights and recommendations regarding the agency's recent proposals for the ASCQR Program.

I. Proposed New ASCQR Program Quality Measure for the CY 2017 Payment Determination and Subsequent Years

CMS has proposed to adopt one new claims-based measure into the ASCQR Program for the CY 2017 payment determination and subsequent years, a measure titled *Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy*. The measure concept (but not the measure itself, as it had not been fully developed at the time) received conditional support from the Measure Applications Partnership (MAP) earlier this year. Importantly, this measure is also being proposed for inclusion in the Hospital Outpatient Quality Reporting (OQR) Program. We do not support inclusion in the ASCQR Program due to significant problems with the measure, including its validity, reliability, and usability, which are discussed in detail below.

As CMS is aware, this measure is currently being considered for NQF endorsement and it currently appears that the All-Cause Admissions and Readmissions Standing Committee will identify it as suitable for endorsement. Having reviewed the minutes of the Committee's discussions in their entirety, we are struck by the absence of consideration of key elements of the measure's construction and testing. Though we have commented on several important issues related to this measure, we have not received satisfactory responses from either the measure developer (a CMS contractor) or the Committee. If the measure is endorsed without resolution of these items, we plan to file an appeal with the NQF Board of Directors.

A. Lack of Measure Validity Testing in the Proposed Settings of Implementation

Validity testing for this measure relies primarily on work the developer did in the past related to a different measure for the inpatient setting; this work relied on the use of inpatient hospital claims. For reasons that are unclear, the developer has cited this work with inpatient claims as a basis for the validity of this measure, which is based on outpatient claims.

As CMS is well aware, claims are generated for purposes of reimbursement, and Medicare's inpatient and outpatient payment systems are governed by entirely different sets of rules. These rules have a significant impact on the coded information that is submitted on claim forms.

Inpatient reimbursement is primarily diagnosis driven, and the coding practices surrounding inpatient claim submission reflects this, with a strong emphasis on fully characterizing the patient's diagnoses and comorbid conditions. In contrast, outpatient reimbursement is service driven, and coding practices are focused on accurately describing the services rendered. Diagnosis coding in ASCs is focused on establishing the medical necessity of those services; the ASC billing format does not support the reporting of diagnosis codes that are not explicitly associated with the services provided to the patient during the encounter.

Because this measure relies *entirely* on that coded information for risk adjustment, it is essential to establish that the codes submitted are, *in fact and not in supposition*, reflective of the clinical aspects of care that the measure purports to measure. The developer went to the effort of testing and establishing this for the inpatient measure it developed, but did not evaluate it for this outpatient measure. Why not? Given the different claims structures for inpatient versus outpatient claims, the inpatient results cannot be assumed to apply to the outpatient setting. The sensitivity and specificity of using administrative claims data following outpatient colonoscopy must be determined in order to establish the validity of the measure.

Further, this measure intends to evaluate both Hospital Outpatient Department (HOPD) and ASC performance, but these two settings do not use the same claim format. HOPDs submit claims using the UB-04; ASCs submit claims using the CMS-1500. Among their differences, the two forms vary in the total number of fields available for the submission of diagnosis codes, and in the types of fields associated with diagnosis coding. Without testing, one cannot claim that HOPD results can be fairly and appropriately compared to ASC results.

These issues were brought to the attention of the measure developer and NQF through our comments on the draft report issued by the All-Cause Admissions and Readmissions Standing Committee. The measure developer responded, "CMS will take these points into consideration in field testing and implementing the measure." Yet we see no indication that CMS plans any kind of field-testing at all; rather, the agency is proposing to move directly to implementation. We object in the strongest possible terms to the implementation of an administrative claims-based outpatient measure that has not been validated against outpatient clinical records.

The impact of these differences – outpatient versus inpatient, and HOPD versus ASC - must be systematically assessed to assure the measure results are attributable to differences in quality rather than differences in claims architecture and coding practices. The measure score should be directly validated against outpatient medical records and measure results across settings must be assessed to ensure that any comparisons are valid.

B. The Measure Is Not Valid Due to Systematic Undercounting of HOPD Events

As noted above, the *Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy* measure is also being proposed for inclusion in the Hospital OQR Program. In its

proposals, CMS states the measure is "well-defined and precisely specified for consistent implementation within and between organizations that will allow for comparability." This is not true. Although the measure is likely to do a good job of counting hospital visits following ASC care, it would *systematically undercount hospital visit rates following HOPD care* occurring in the seven-day period following outpatient colonoscopy. As the measure is currently specified, comparisons across the two settings cannot be made on equal footing. The following explains why near-term events following care in the HOPD setting would not be counted accurately using this measure's algorithm.

The NQF's All-Cause Admissions and Readmissions Standing Committee did not evaluate the impact of the use of administrative claims on the validity of the measure results. Yet Medicare's three-day payment window policy has a profound impact on the measure, presenting significant challenges in identifying index HOPD visits, and therefore subsequent "hospital visits" related to HOPD care. The three-day payment window policy requires that outpatient services provided by a hospital, or any Part B entity wholly owned or wholly operated by a hospital, *on the date of a beneficiary's inpatient admission* must be billed with the inpatient stay. In addition, outpatient services provided by a hospital, or any Part B entity wholly owned or wholly operated by the hospital, *on the first, second, and third calendar days preceding the date of a beneficiary's inpatient admission* are also deemed related to the admission, and must be billed with the inpatient stay. Part B entities affected by this policy include hospital outpatient departments, hospital emergency departments and wholly owned physician practices. The three-day payment policy applies to all non-diagnostic services provided during the payment window unless the hospital attests that the services are clinically unrelated. Diagnostic services are always subject to the payment window policy, irrespective of whether they are considered clinically related.

Simply stated, CMS does not permit HOPDs to generate a claim when there is an inpatient admission during the three-day window, except in cases where the service was therapeutic and the hospital attests that the subsequent admission was unrelated. Claims that do not exist cannot be counted. As a result, this measure cannot identify inpatient admissions that may have resulted from colonoscopies performed in the HOPD setting when those unplanned admissions occur on the date of the colonoscopy, or during the three days subsequent to the procedure. The measure would only identify hospital visits occurring on days 4, 5, 6 and 7 following the index HOPD visit; index claims for days 0, 1, 2 and 3 would not be created or counted. This missing data skews the measure results by undercounting the number of inpatient admissions attributed to the HOPD. As a result, measure scores cannot be compared across settings.

In the months since this measure was first brought before the MAP and we pointed out this flaw in the measure's design, the developer has looked for ways to work around the three-day payment window policy. Currently, they are proposing to identify colonoscopy claims in the Part B carrier file. ASC facility claims would be identified directly, using ASC facility claims. However, HOPD claims would be identified indirectly, using physician claims. Specifically, the

measure algorithm would look for physician claims for colonoscopy indicating an HOPD place of service (POS) that had an inpatient admission within 3 days *and* lacking a corresponding HOPD claim. It would then count such physician claims as HOPD "claims".

The problem with this approach is that POS coding has a long history of inaccuracy. Over a period of more than a decade, the Department of Health and Human Services Office of Inspector General (HHS OIG) has performed repeated audits of physician POS coding that *consistently demonstrate high error rates*. These errors result in physician claims that indicate the service was performed in the physician office, when in fact the service was actually performed in a hospital outpatient department or ASC. See, as some examples of many such OIG reports over the years: A-02-04-01010 (error rate 88%), A-05-04-00025 (error rate 79%), A-06-04-00046 (error rate 76%), A-01-06-0052 (error rate 81%), A-01-09-00503 (error rate 90%) and, most recently, A-01-10-00516 (error rate 83%) of September 2011. Errors in POS coding are not an isolated, infrequent or insignificant problem. It's not possible to attribute any credibility to a plan that would use POS coding on physician claims as a means of identifying HOPD claims in light of this information.

The practical impact on the measure is this: its plan to rely on POS coding to identify HOPD claims that are missing due to the three-day payment window policy means that a significant number of these missing index HOPD claims *will never be identified*. Yet this is the strategy the measure proposes to use. Any algorithm that relies on using POS coding on physician claims would systematically undercount HOPD events by failing to identify a significant number of the index HOPD visits. As a result, not only would the HOPD rates reported be inaccurate (too low), they would also not be comparable to ASC results.

In this proposed rule, CMS states this concern "relates to the Hospital OQR Program and not the ASCQR Program". However, given that the agency's interest in measures that compare care across settings and their proposal to include the measure in *both programs* and publicly report the results, this concern clearly impacts ASCs in a very direct and palpable way. Unless HOPD claims during the three-day payment window can be accurately identified, the measure routinely disadvantages ASCs by unfairly reporting complete rates for ASCs and incomplete rates for HOPDs. We object in the most strenuous terms to the agency's plan to implement such a fundamentally flawed measure.

C. Measure Rationale and the Three-Day Payment Window Policy

In order to be endorsed, measures must demonstrate meaningful performance gaps. We remain concerned that the three-day payment window policy may also have impacted the data used in the analyses performed to establish the rationale for this measure. These analyses estimated the measure score for both ASCs and HOPDs using 2010 Healthcare Cost and Utilization Project (HCUP) data, and then separately calculated the measure score for HOPDs alone using 2010 data from the Chronic Conditions Data Warehouse (CCW). Both analyses found provider variability. It is unclear how much of this variability may have been a reflection of the three-day payment window policy, which was implemented for dates of service on or after June 25, 2010. Those

Medicare claims before June 25 would have included index HOPD visits that occurred within the three-day window; Medicare claims on or after June 25 would not have included index HOPD visits that occurred within the three-day window. It is possible that conclusions reached regarding variability in performance - based entirely on these analyses - are incorrect, and that the variability observed was actually a function of the change in CMS payment policy in the middle of the period analyzed.

D. Reliability of the Measure is Too Low for Accountability and Reporting Purposes

The measure developer has acknowledged that the number of outcome events for this measure is already low. To manage this, the measure has been specified in ways that generate large case volumes (for example, the inclusion of physician office claims for colonoscopy in the measure denominator, despite its characterization as a "facility-level measure"). Despite these steps, the results of the reliability testing for this measure were quite low. With two years of data, the intra-class correlation coefficient (ICC) was, on average, 0.335, which according to conventional interpretation is only "fair."

Of note, this subpar result was only obtained *after excluding low volume facilities* from the calculation. As the measure developer explained to NQF, "[b]ecause we expect facilities with relatively few cases to have less reliable estimates, we only included scores for facilities with at least 400 cases in the reliability calculation (i.e., with 200 cases in each of the split samples, about 100 cases/year). This approach is consistent with a reporting strategy that includes smaller facilities in the measure calculation but does not publicly release the measure score for smaller facilities (i.e., labels them in public reporting as having "too few cases" to support a reliable estimate)."

Since originally submitting the measure to NQF for consideration, the developer has recalculated the reliability testing score using the Spearman-Brown prophecy formula, in order to approximate the ICC for a three-year sample. This resulted in a higher ICC of 0.43, which according to conventional interpretation is "moderate" (though on the very low end of moderate, which ranges from 0.41 to 0.60). Though we believe this is a non-standard application of the Spearman-Brown formula, the NQF's All-Cause Admissions and Readmissions Standing Committee has accepted this ICC score, which provides a reliability estimate for three years of data, as sufficient to meet reliability endorsement criteria.

In our opinion, the reliability of a measure intended for public reporting and accountability purposes should be significantly higher. If facilities are to be judged based on the results calculated for this measure, the reliability of those measure scores should be "substantial" (0.61 to 0.80 per convention), at a minimum. We are also concerned that CMS did not acknowledge the lack of reliability in the measure scores for low volume facilities when issuing these proposals. If the agency determines it will include the measure in the ASCQR Program despite its lack of validity, suboptimal reliability and other issues, the measure score should only be

publicly reported for facilities with annual case volumes of qualifying colonoscopies sufficient to generate "substantial" or greater reliability (that is, an ICC of greater than or equal to 0.61) in the measure score.

E. The Measure Score Suffers from a Lack of Actionability in ASCs

The rates of the outcomes the measure seeks to identify are low. As a result the measure has been specified in ways that generate large case volumes, but that diminish its usefulness. Specifically, the need for volume prevents stratification, meaning the measure score would be reported as a single rate for each facility. This presents challenges for actionability because the measure score provides no insight other than how the facility's rate of hospital visits compared to the expected rate. Because the data used to generate the measure score are not accessible to the facility, it would be impossible for the ASC to determine even basic information, such as which patients were affected, the numbers of ED visits, observation stays or inpatient admissions that occurred, or why any subsequent visit occurred. The measure developer has stated, "CMS agrees that the measure score alone provides limited information for quality improvement since the outcome combines ED, observation stays, and admissions, and that more detailed information on patient outcomes would assist facilities with quality improvement. CMS plans to report patient-level data confidentially to facilities that indicates whether the patient had a hospital visit, the type of visit (admission, ED, or observation stays) if any, and the facility to which the patient is admitted."

Although CMS has not proposed to do this, given that CMS provides facility-specific reports to hospitals regarding inpatient re-admissions, we are cautiously optimistic that the measure developer is correct in describing the agency's implementation plans. We are also cautiously optimistic that CMS would include the principal discharge diagnosis for the hospital visit, although the measure developer has not indicated that CMS plans to do so. These steps would be helpful, but ultimately they would not be sufficient to support meaningful quality improvement *in ASCs* because the ASC would have such limited insight into why the patient's hospital visit occurred.

CMS and the measure developer have pointed to the improvements in hospital readmission rates as evidence that this measure would produce comparable improvements in colonoscopy outcomes. While it is true that selected hospitals have been successful in reducing readmission rates, these reductions have resulted from analyses that extend well beyond the receipt of a CMS benchmarking report with a few columns of data about their readmissions. Reviews of hospital industry guidance and the case reports of successful hospitals indicate that these improvements have resulted when systems have been put in place that allow the hospital to identify readmissions to their own facility in real time. These systems flag patients that are readmitted, allowing staff to review the patient's record in detail and perform root cause analysis to determine what led to the patient's readmission. Many interview selected patients and their

families at the bedside during the subsequent admission to learn more about why the patient was readmitted and what, if anything, could have been done to prevent it. This allows the hospital to identify and prioritize improvement opportunities. These hospitals are successful precisely because they have access not only to the patient's records from the index admission, but also to the patient's records (and the patient) at the time of readmission.

What CMS and the measure developer have not recognized is that the ASC setting, as a result of legislation and regulation, is markedly different from the hospital setting in ways that would significantly impact the ability to develop a performance improvement initiative around the results of this measure. In accordance with Federal regulation, ASCs are a unique supplier type that serves *solely* as the site for outpatient surgery and is involved with the care of the patient only immediately before, during and immediately after a surgical procedure. Unlike other outpatient surgical settings, such as clinician offices, ambulatory clinics or hospital outpatient departments, ASCs *may not provide post-operative follow-up care* after patient discharge. ASCs, as distinct entities that operate in an entirely separate capacity from physician offices, emergency departments, and hospitals *do not have direct access to the records* of these other providers. As a result of this mandated isolation, ASCs must either interview the patient over the phone or obtain permission from the patient to obtain their medical records from the treating emergency department or admitting hospital in order to obtain the information needed to perform the analyses required for effective improvement activities surrounding this measure. It is certainly possible that selected patients would cooperate with this effort, but in our experience, this willingness diminishes rapidly over time. If an ASC were to contact patients a year or more after their ASC care (which is when the ASC would receive a CMS report on their performance for this measure) we expect the number of patients agreeing to requests for interviews or medical record releases would be very small indeed.

This is why we favor a different approach to the measurement of ED and hospital visits following ASC care and are developing measures that would involve the ASC in the timely collection of patient data in the near-term following patient discharge. Reaching out early in the post-discharge period would maximize the ASC's potential for successfully engaging patients and their families in gathering the information needed to identify opportunities for improvement. There is certainly a data collection burden associated with this approach, but we believe it is better to invest the effort in collecting actionable data that leads to improvement rather than to receive, without effort, information that is dated and not actionable.

F. Limited Ability to Make Distinctions Among Facilities

While administrative claims do not impose additional data collection or submission burdens on providers, they are blunt instruments for assessing quality. This measure suffers from very limited discriminatory power. Using the standard 95 percent interval estimate to report the measure score, the developers indicate 99.5% of facilities would be classified as no different than

expected, 0.4% of facilities as worse than expected and 0.1% of facilities as better than expected. The overwhelming majority of facilities, 99.6%, would receive a measure score indicating their performance was at, or better than, the expected level – with the implicit indication that no improvement effort would be necessary. The number of underperforming facilities would be miniscule; if we extrapolate 0.4% to the entire universe of approximately 5300 Medicare-certified ASCs (not all of which perform colonoscopies, so this is clearly an overestimate), the number of underperforming ASCs would be very generously estimated at twenty-one facilities. All this expenditure of funds and resources to identify, *at the most*, twenty-one ASCs is hard to rationalize. This also means it would be equally unusual for a consumer to be able to discriminate among facilities using the results of the measure.

While the developers state there is variability in performance, as a practical matter the risk standardized results indicate little room for improvement. One could legitimately wonder if this measure would be a candidate for immediate removal from the ASCQR Program based on the proposed criteria for determining when a measure is "topped out" put forth in this rule (and discussed below), if those criteria were to be finalized.

G. Extremely Long Timeframe Means the Measure Score Could Mislead

As a result of the already low rate of the outcomes for this measure, a very long data collection period (3 years) is required in order to generate measure scores that are even moderately reliable. Even if we set aside the issue of the significant lag time from the generation of claims to the reporting of measure results, the measure's extended data collection timeframe means that past performance would continue to impact the measure score for each facility for a long time. The publicly reported measure score would not be a reflection of current, or even recent, performance. In fact, the score would obscure either significant improvement or significant deterioration in recent performance. As a result, consumers could be misled by the lack of timely data. They could mistakenly believe a facility is no different from others, when in fact it has made significant recent improvements and would be a superior choice. Or they could be led to believe a facility is no different from others when in fact the facility has had a recent (and even steep) decline in performance and would be an inferior choice.

H. Incomplete Adaptation to the Outpatient Setting

As noted above, the measure developer has relied heavily on previous work performed to develop a measure of inpatient readmissions in constructing key elements of this outpatient measure, such as the planned admission algorithm and risk adjustment model. Unfortunately, the measure that has been put forth to the NQF retains elements of the inpatient measure that are not appropriate, an indication that the measure has not been thoroughly reviewed and fully adapted for outpatient use. As just one example, certain condition categories (CCs) are not included in risk adjustment if they are only recorded at the time of the colonoscopy, as they are considered to be possible adverse outcomes. Although end stage renal disease (ESRD) would not be a

complication of colonoscopy diagnosed and recorded at the time of the procedure, it was included on the list of CCs.

The measure developer has indicated it will review the list of CCs with their technical experts, though this group is said to have already reviewed the measure details last year. Revised specifications are needed and should be reviewed independently to ensure that outpatient adaptation is complete. If CMS determines it will implement this measure despite it many problems, these revised specifications should be in place and independently reviewed prior to implementation.

II. Proposed Implementation Timeline for the Proposed New Measure for the CY 2017 Payment Determination and Subsequent Years

CMS has proposed to use paid Medicare FFS claims from a 12-month period from July 1 of the year that is three years prior to the payment determination year to June 30 of the following year as the data collection period for this measure. Thus, for the CY 2017 payment determination for this measure, claims from July 1, 2014 to June 30, 2015 would be used. The agency indicates this time period provides for the timeliest data possible while aligning the proposed data submission requirements with its Hospital OQR Program proposals.

The principal difficulty with this proposal is that, as noted above, this measure requires three years of data to achieve even modestly reliable measure scores for high volume facilities. The two-year reliability of the measure was reported to be just "fair" and therefore the one-year measure reliability score would be even lower due to the small number of observations. One year of data collection would not be sufficient and is not something we can support. If the agency adopts the proposed measure, it should extend the data collection period to three years in order to remain consistent with timeframe of reliability data submitted to NQF for consideration of endorsement, and in order to ensure at least some semblance of reliability in the measure scores it would plan to report to the public.

In summary, the proposed time period of July 1, 2014 through June 31, 2015 is of significant concern to us. Further, we are not supportive of retroactive implementation dates. If this measure is implemented, data should be collected over a three-year period beginning July 1, 2015 and continuing through June 30, 2018, making the data available for the CY 2020 payment determination.

III. Delayed Data Collection and Proposed Exclusion for ASC-11 for the CY 2016 Payment Determination and Proposed Voluntary Data Collection for ASC-11 for CY 2017 and Subsequent Payment Determination Years

CMS finalized ASC-11: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) for inclusion in the ASCQR Program despite

overwhelming public opposition to the measure, which was based primarily on its lack of feasibility in the ASC setting. Since then, the agency has "come to believe that it may be operationally difficult at this time for ASCs to collect and report this measure." As a result, implementation of the measure has been delayed twice, most recently until January 1, 2015 for the CY 2016 payment determination. CMS is now proposing to exclude ASC-11 from the CY 2016 payment determination measure set, saying it would not subject ASCs to a payment reduction with respect to this measure for the CY 2016 payment determination. We agree with this proposal.

CMS further proposes to continue to include this measure in the ASCQR Program measure set for the CY 2017 payment determination and subsequent years on a strictly voluntary basis. ASCs would not be subject to a payment reduction for failing to report this measure. Any data submitted voluntarily would be publicly reported by CMS.

It is our belief that the number of ASCs that would voluntarily report this measure would be very small indeed. This belief is based on very low levels of participation for the corresponding PQRS measure - 215 of the more than 7,300 cataract physicians in the US - in 2013. Given that the measure is very challenging and expensive for ASCs to implement, we anticipate the number of ASCs that would voluntarily participate would be much lower than the number of physicians that have participated. However, if any ASCs do report measure data, CMS contractors will still have to perform all the tasks necessary to develop and maintain the means to collect and publicly report the information. We question the value of this effort and do not believe it would have any appreciable impact on ASC performance or provide enough consumer information to warrant the effort. We believe taxpayer dollars would be more wisely expended in the support of other agency objectives. Therefore, we recommend the removal of the measure from the Program.

IV. Data Submission Requirements for ASC-8 (Influenza Vaccination Coverage Among Healthcare Personnel) Reported via the National Healthcare Safety Network (NHSN) for the CY 2016 Payment Determination and Subsequent Years

Last year, CMS proposed that ASCs would have until August 15, 2015 to submit their 2014-2015 influenza season data to NHSN, this being the latest date possible that would allow sufficient time for the agency to make the CY 2016 payment determinations. August 15 is also the data entry deadline for the ASCQR Program structural measures entered via QualityNet. Some commenters supported this proposal, while others expressed disagreement, and ultimately the agency did not finalize the August 15, 2015 deadline.

This year CMS is proposing that the deadline for data submission be on May 15 of the year in which the influenza season ends, similar to the Hospital IQR and OQR Programs. For example, for the CY 2016 payment determination, ASCs would be required to submit their 2014-2015 influenza season data by May 15, 2015. This proposal would align the ASC submission deadline

with the May 15 deadline used in the Hospital IQR and OQR Programs for this measure.

As we stated last year, though we recognize August 15 is not consistent with the deadline for other quality reporting programs that enter data for the influenza vaccination measure via NHSN, and is well beyond the close of the 2014-2015 influenza season, we support the August date. Although it is in its infancy, the ASCQR Program is already complex, featuring different data collection time frames, data submission deadlines and data submission methodologies. The Program is already more complicated than is strictly necessary. Any steps that can be taken to simplify and streamline program requirements would be helpful toward reducing the burden of keeping track of, and complying with, the already numerous requisites. If the agency desires a consistent data submission deadline across settings, it should consider the August 15 date for the Hospital IQR and OQR Programs, as well.

V. Proposals for the Removal of Quality Measures from the ASCQR Program

In this proposed rule, CMS has offered several proposals around the removal of previously adopted ASCQR Program measures.

A. Proposed Criteria for Immediate Removal of Measures

In circumstances where evidence arises that the continued use of a measure as specified raises patient safety concerns, CMS proposes to immediately remove said measure, notifying ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServ and the QualityNet website. The agency would subsequently confirm the removal of said measure in the next OPPS/ASC rulemaking cycle. This is the same process the agency has implemented and/or proposed to adopt for other of its quality reporting programs. We support this proposal, but recommend that the agency notify providers by mail and also post notification on the CMS website on the ASC Quality Reporting webpage under the "Announcements" heading.

B. Proposed Criteria for Removal of Measures Through Regular Rulemaking

For situations in which continued use of a measure does not raise specific safety concerns, the agency is proposing to use the regular rulemaking process to remove a measure. CMS is proposing to use the same list of the criteria it uses to determine whether to remove measures from the Hospital IQR Program as the basis for determining whether to remove measures from the ASCQR Program. These criteria are: (1) measure performance among facilities is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped out" measures); (2) availability of alternative measures with a stronger relationship to patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic; (5) the availability of a measure that is more proximal in time

to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

There appears to be an error in the list of criteria in the ASC section of this proposed rule, wherein criteria (2) and (6) are essentially duplicative. We referenced both the Hospital IQR criteria and Hospital OQR proposals, and have determined CMS likely intended item (2) to read as follows: "(2) performance or improvement on a measure does not result in better patient outcomes."

We support the following criteria for application to all measure types: (3) a measure does not align with current clinical guidelines or practice; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. The remaining criteria should be applied more selectively on a measure-by-measure basis, and with consideration of the value of the information the measure provides to the consumer and the provider community affected by the measure.

C. Proposed Criteria for Identification of "Topped-Out" Measures

A measure is considered "topped-out" when performance among entities is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. CMS believes these measures should be considered for removal from the ASCQR Program because their reporting burden may outweigh the value of the quality information they provide. The agency is proposing that a measure under the ASCQR Program would be considered "topped-out" when it meets both of the following criteria:

- Statistically indistinguishable performance at the 75^{th} and 90^{th} percentiles; and
- A truncated coefficient of variation less than or equal to 0.10

To identify if a measure has statistically indistinguishable performance at the 75^{th} and 90^{th} percentiles, CMS would determine whether the difference between the 75^{th} and 90^{th} percentiles for a measure is within two times the standard error of the full dataset. The coefficient of variation (CV) measures the standard deviation as a percentage of the sample mean; this provides a statistic that is independent of the units of observation. A large CV would indicate a broad distribution of individual ASC scores, with large and potentially meaningful differences in performance. A small CV would indicate the distribution of individual scores is tightly clustered around the mean, suggesting the measure is not useful for drawing distinctions regarding performance. The truncated CV excludes observations whose rates are below the 5^{th} percentile and above the 95^{th} percentile. Use of this value would remove the highest and lowest outliers, which could widen the distribution of scores. These same criteria have been proposed for adoption in the Hospital VBP and IQR Programs.

We believe this approach is too simplistic, and could prompt the removal of valuable program measures. Examples would include patient safety measures, whose goal is to drive toward and sustain zero harm, critical outcome measures such as surgical site infection rates and patient experience measures. These types of measures could, over time, develop performance scores with the statistical characteristics enumerated above, but we believe they would have enduring value to consumers and providers despite this. Consequently, we cannot support the criteria CMS has proposed.

VI. Alternative Data Collection Mechanisms

In the past, CMS sought public comment on alternative data collection strategies, particularly regarding the collection of patient-level data through registries or other third-party data aggregators, and via certified EHR technology.

The ASC QC remains convinced CMS should allow ASCs to meet the requirements of the ASCQR Program using registry-based reporting and would like to take this opportunity to draw the agency's attention to this option once more. Registry-based reporting of quality metrics is already an option under the Physician Quality Reporting System (PQRS). This option should be extended to ASCs as well. In the case of the ASCQR Program, which already incorporates requirements that must be fulfilled through three separate reporting mechanisms, CMS should offer a registry-based reporting option that would allow ASCs to fulfill *all program requirements* through the single mechanism of a registry in order to simplify and streamline the process of data submission. The ASC QC has a strong interest in developing an ASC-specific registry. It is our intent that the registry will collect data from participating ASCs on a broad variety of quality measures, including all the measures CMS has adopted under the ASCQR Program. We further anticipate this registry would collect patient-level quality measure data, regardless of payment source.

While the ASC QC's registry project remains in the planning stages, other registries are already in existence. Examples include the GIQuIC and Ophthalmic Patient Outcomes Database registries, which may currently be used to satisfy PQRS reporting requirements. These registries are potential avenues for registry-based reporting for selected single-specialty ASCs. As they are already operational, we encourage CMS to issue proposals for ASC registry-based reporting in next year's rulemaking.

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.

Finally, many ASCs, either through common ownership or on a contractual basis, rely on others to implement, maintain, and support their IT infrastructure. For those measures that are reported

but once a year into QualityNet, developing a mechanism that would allow required data to be submitted in a batch file for multiple ASCs would significantly reduce the data submission burden for these facilities. We encourage the agency to make this option a near-term priority.

VII. Minimum Threshold for Claims-Based Measures Using Quality Data Codes (QDCs)

The current minimum threshold for successful reporting for measures submitted using QDCs is that at least 50 percent of claims meeting measure specifications contain QDCs. In the past, CMS has stated it intends to propose increasing this percentage for future payment determinations. In light of isolated instances where ASCs, administrative contractors and billing clearing houses have experienced implementation challenges, we appreciate the consideration the agency has shown by continuing the 50 percent threshold in the initial years of the ASCQR Program. We believe these issues have been resolved, and therefore recommend CMS increase the minimum threshold in future rulemaking.

VIII. Measure Applications Partnership (MAP) Process Improvements Are Needed

CMS relies on the recommendations of the MAP in issuing proposals for measures for future inclusion in the ASCQR Program. We appreciate the work of the individuals serving on the MAP Coordinating Committee and its various workgroups, and the improvements in the MAP that have been made over time, but continue to be concerned about two issues: the public comment process and the practice of submitting measure concepts for consideration.

MAP procedures for the consideration of public comment at critical junctures - including workgroup meetings, meetings of the Coordinating Committee, and the issuance of the draft Pre-Rulemaking Report – remain completely unsatisfactory, treating public input as an afterthought that is not worthy of consideration. Although MAP agendas currently include opportunities for public comment, these opportunities are scheduled after voting on agenda items has been completed. As a result, there is no opportunity for the public to present important information, or correct misinformation, prior to decision-making. Similarly, there is no opportunity for the public to address the Coordinating Committee regarding topics under discussion until after it has completed deliberations. While the public is given the opportunity to comment on the draft Pre-Rulemaking Report issued by the MAP, these comments are not considered by the Coordinating Committee and therefore do not result in any revisions to the recommendations in the final report. Public comments are merely summarized in a very general fashion by NQF staff and then appended to the report. This lack of consideration should not be allowed to continue. MAP administrative procedures should be revised so that public comment is solicited prior to, rather than after, voting on agenda items. In addition, the MAP Coordinating Committee should be required to formally consider and respond to public comments received in response to its draft report and then make any appropriate revisions to its recommendations prior to issuing a final report.

As a measure developer, we find the agency's practice of asking the MAP to consider and make recommendations regarding measure "concepts" that have not been fully developed troublesome. There are many challenges in taking a measure from the conceptual stage to completed form; not all concepts and drafts are successfully developed. The agency appears to be developing a habit of advancing incomplete ideas in an apparent rush to get a stamp of approval from the MAP, and then pointing to conditional recommendations regarding measure topics and incomplete measure sketches as evidence of consensus. The MAP's decisions carry significant weight. With so much at stake, it is not reasonable to issue recommendations based on measure concepts or measure drafts. When "concepts" are presented, MAP should determine whether the measure concept/draft would fill a measure gap but reserve further judgment for the completed measure.

Further, the inclusion of measure "concepts" results in an unreasonably large number of items for the MAP to consider. As a result, thoughtful consideration of each is very difficult, if not impossible, in the compressed timeline allotted. We urge CMS to take steps to promote a pre-rulemaking process in which due consideration of fully developed measures becomes the norm.

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Thank you for considering these comments. We look forward to continuing our dialogue with the agency regarding the ASCQR Program and 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

Covenant Surgical Partners

Florida Society of Ambulatory Surgical Centers

Hospital Corporation of America, Ambulatory Surgery Division

Outpatient Ophthalmic Surgery Society

Regent Surgical Health

Surgery Partners

Surgical Care Affiliates

Symbion

The Joint Commission

United Surgical Partners International