



September 2, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: **CMS-1612-P**, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY2015

Dear Administrator Tavenner:

The American Society of Anesthesiologists® (ASA®), on behalf of over 52,000 members, appreciates the opportunity to comment on several of the issues in the above-captioned proposed rule published in the July 11, 2014, *Federal Register*. As the medical specialty representing the recognized leaders in patient safety and quality, ASA welcomes the opportunity to work with you to ensure high quality and high value care for our Medicare patients.

In this letter, ASA provides comments on the following issues:

1. Epidural Injections and Fluoroscopic Guidance as Potentially Misvalued Services
2. Definition of Colorectal Screening Tests
3. Improving the Valuation and Coding of the Global Package
4. Malpractice Relative Value Units
5. Valuing New, Revised, and Potentially Misvalued Services
6. Sunshine Act Reporting Exclusion for Continuing Medical Education
7. Physician Compare
8. Physician Quality Reporting System
9. Value Based Payment Modifier and Physician Feedback Program
10. Electronic Health Record Incentive Program
11. Medicare Shared Savings Program

ASA commends the Centers for Medicare & Medicaid Services (CMS) for maintaining the current federal physician supervision safety standard for anesthesia services. Substituting nurse anesthetists for highly trained physician anesthesiologists would significantly decrease patient safety and quality of care. Further, such a substitution provides the Medicare program and taxpayers no additional cost savings since Medicare pays the same for anesthesia services whether they are furnished by nurse anesthetists or physician anesthesiologists. Such a rule change also does nothing to enhance access to surgical and anesthetic care for Medicare beneficiaries. Anesthesiology is a “complex, high-risk, dynamic patient care system” (IOM, 1999) and to ensure maximum patient safety should be undertaken under the direct administration or supervision of a physician who has the extensive and necessary educational training and experience.

Potentially Misvalued Services under the Physician Fee Schedule - Epidural Injections and Fluoroscopic Guidance: CPT® codes 62310, 62311, 62318, 62319, 77001, 77002 and 77003

ASA appreciates that CMS heard our concerns and is reconsidering the appropriate valuation of these services that are so important to Medicare beneficiaries. The fact that CMS received thousands of comments on this particular issue demonstrates that the concerns about the CY2014 interim values were widespread and that their valuation merits reconsideration. We are pleased that CMS has restored the valuation using the 2013 work Relative Value Units (RVUs) and the 2013 direct Practice Expense inputs in determining the allowed amounts for these services when provided in CY2015.

We understand that CMS needs more information in regard to valuing the injections and any associated imaging guidance and has placed the codes back onto the “misvalued codes list” to facilitate obtaining that additional information. As such, we have concerns that prohibiting the separate reporting of imaging for CY2015 may be premature. The 2013 data cited in the proposed rule shows considerable variation on the use of fluoroscopic guidance between codes within this family. When done in a facility setting, code 62318 is reported with code 77003 only 3% of the time. This is a marked contrast to use of fluoroscopic imaging for code 62310. Nevertheless, we appreciate the Agency’s willingness to reconsider the matter once the codes have been again reviewed. ASA will work via the CPT (Current Procedural Terminology) and RUC (Relative Value Scale Update Committee) processes to ensure that the codes accurately describe the services performed and that the values accurately capture all the resources and risks associated with providing the care.

Definition of Colorectal Screening Tests

All efforts that encourage patients to undergo colorectal screening are important and we are pleased that CMS acknowledges the important role anesthesia care plays in this regard. We understand that CMS will establish a modifier to be used on claims for anesthesia for screening colonoscopy and we will work to make sure our members understand how it should be used when reporting anesthesia care. ASA also supports the following:

1. As an essential benefit, Medicare should pay the anesthesia provider for the service; payment should not be conditioned on the presence of other specified diseases, conditions, or situations.
2. Payment for this anesthesia service should be determined in the same manner as any other anesthetic, i.e., the “base + time” methodology.

Additionally, we encourage the Agency to apply the essential benefits payment provisions when a screening endoscopy turns diagnostic or therapeutic - if polyps are discovered and removed during the encounter. In order to obtain full advantage of the benefit, both the procedure and the anesthesia should be exempt from deductible and co-payment requirements in this situation as well as when there are no findings of note.

Improving the Valuation and Coding of the Global Package

ASA requests clarification on how CMS plans to phase out 10-day and 90-day global periods by 2017 and 2018, respectively, since that information is a prerequisite to providing solid and constructive feedback. Specifically, we recommend that CMS first work with all stakeholders to identify a fair payment method – one that assures that there would not be any unacceptable unintended consequences – and then establish a timeline. It is vital that a change of this magnitude be implemented only when we can be certain that the methodology ensures that the pre-operative, intra-operative, and immediate post service components of the procedures are accurately valued when care included in the 10-day or 90-day global period is unbundled and separately reported. This would be applicable to work, practice expense, and professional liability. Furthermore, we recommend an analysis on the impact this change could have on beneficiaries to include both the cost-sharing burden and their willingness and ability to receive appropriate follow up care.

In the rule, CMS notes:

“We also seek comment on the best means to ensure that allowing separate payment of E/M visits during the post-operative periods does not incentivize otherwise unnecessary office visits during post-operative periods. If we adopt this proposal, we intend to monitor any changes in the utilization of E/M visits following its implementation but we are also seeking comment on potential payment policies that will mitigate such a change in behavior.”

CMS needs to address both sides of this issue. Unnecessary office visits must be avoided, but necessary office visits should not be discouraged.

We share CMS’s concerns about ensuring that current payment systems should not act as obstacles to new payment models, such as ASA’s Perioperative Surgical Home (PSH). PSH is a patient-centered, innovative model of delivering health care during the entire patient surgical/procedural experience; from the time of the decision for surgery until the patient has recovered and returned to the care of his or her Patient Centered Medical Home or primary care provider. A comprehensive PSH provides coordination of care through all of the clinical microsystems of care and embeds all of the above strategic principles into its framework. **Current Medicare payments undervalue anesthesia care as demonstrated by “the 33% problem” (Medicare payments are approximately 33% of the commercial payer rate), and ASA appreciates CMS’s efforts to ensure the accuracy of existing payment systems for the sake of future models.**

Malpractice Relative Value Units

ASA is pleased that CMS is willing to consider the special circumstances involved with updating the Malpractice Payment (MP) component associated with anesthesia services and intends to delay the anesthesia MP update until CY2016 to allow time to find the most appropriate way to determine the update. Rather than propose any specific method as part of our comment letter, we request the opportunity to work with CMS over the course of the next few months to address the issue and develop an appropriate approach.

Valuing New, Revised, and Potentially Misvalued Services

ASA commends CMS for acknowledging the need for earlier notification of potential changes to values assigned to procedures and services. ASA supports the modified timeline proposed by the American Medical Association (AMA), which is stated in a separate letter to which ASA is a signatory:

“...envisions a process that would deliver RUC recommendations in time for CMS to consider the recommendations, potentially modify them, and then publish CMS-proposed RVUs in a Notice of Proposed Rulemaking that is usually published in late June or early July. New technology/services or others where there is some immediate need for publication would still be published as interim final values in November. At this point, we are far enough into the 2015 and 2016 cycle for making RVU and coding changes, that we believe the earliest that this process could be fully in place is with the publication in July 2016 of the proposed 2017 fee schedule, which would take effect on January 1, 2017.”

Reports of Payments or Other Transfers of Value to Covered Recipients: Continuing Education Exclusion (§403.904(g)(1))

CMS has proposed revoking the existing Sunshine Act reporting exclusion for continuing medical education (CME) activities, due in large part to requests from accrediting bodies that they be added to the list of exempt organizations covered by the exclusion. Instead, the proposal would exempt third party transfers to CME only where an industry donor is unaware of the recipients/beneficiaries before and after the funds are transferred. Industry can easily learn the identities of speakers/faculty and, potentially, participants after the funds have been transferred through brochures, programs, and other publications, or through their physician-employees’ participation in CME activities (either as speakers/faculty or attendees). ASA is concerned that imposing the requirement that the donor must remain unaware of the recipients/beneficiaries after the funds have already been transferred is unrealistic and would have a significant, chilling impact on CME/CE, by decreasing industry funding for CME/CE and thereby decreasing access to CME/CE, which runs contrary to the public interest. ASA requests that CMS not rescind §403.904(g)(1) of the Open Payment program if commercially supported accredited programs are following the ACCME standards of commercial support, maintaining independence.

As noted in a separate August 5, 2014 AMA letter to which ASA is a signatory, we strongly recommend that CMS modify the proposal to add the language that the exemption applies under 42 CFR 403.904(i)(1) when an applicable manufacturer provides funding to a CME provider, but does not select or pay the covered recipient speaker/faculty directly, or provide the CME provider with a distinct, identifiable set of covered recipients to be considered as speakers/faculty for the CME program. The Agency can include guidance in the regulation that the foregoing is achieved where the industry donor is unaware of the speakers/faculty and other participants before committing to fund the activity under §403.904(i)(1). This would accomplish CMS's goal while eliminating the potential for negatively impacting CME. To allow CME providers time to ensure that their processes comply with the modified exemption, ASA urges CMS to make this change effective six months after the final rule is issued.

Physician Compare

ASA recognizes CMS's efforts to ensure that physician data is accurate on the website and that physicians have opportunities to review and correct inaccurate data. ASA supports CMS's proposals to ensure that measures displayed on Physician Compare are valid, reliable, and accurate. This support includes the minimum sample size of 20 patients, routine testing of data, and the method a physician used to report quality measures. However, we request that CMS continue to seek an expeditious and more efficient process for physicians to correct inaccurate information about their demographic data and their practice sites. We also urge CMS consider a 60-day preview period for physicians to review their quality data prior to posting.

We support transparency, but also believe that required public reporting on first year data for new non-PQRS QCDR measures is premature. Although the Anesthesia Quality Institute's (AQI) National Anesthesia Clinical Outcomes Registry (NACOR) is collecting data, we believe additional time for analysis of practice data will allow ASA and other specialty groups to develop meaningful benchmarks. A scaled or tiered approach will ensure that public reporting is meaningful for physicians, patients, and the public. We urge CMS to consider a longer timetable for posting non-PQRS QCDR measures.

Patients should receive information on a physician's participation in quality programs but they should also be provided with information on why a physician may not, because of his or her specialty, participate in such programs. Physician anesthesiologists currently have an Electronic Health Record (EHR) Incentive Program hardship exemption because of the nature of the patient-anesthesiologist relationship as well as recognition of the interoperability challenges between Anesthesia Information Management Systems and a facility's EHR system.

Physician Quality Reporting System

Earlier this year, CMS approved AQI's NACOR as a Qualified Clinical Data Registry (QCDR) – an action that expands the number of measures physician anesthesiologists may report. However, while the QCDR option may benefit those practices that have the ability to submit data electronically, physician anesthesiologists overwhelmingly use the claims-based reporting option. **We urge CMS to continue this reporting option past 2015. ASA advocates for the continued use of the Claims-Based Measure-Applicability Validation (MAV) process for those EPs who have zero measures to report.**

Cross-Cutting Measures

ASA requests that CMS decrease the proposed number of cross-cutting measures an EP must report to just one cross-cutting measure. As proposed, the eighteen measures mainly focus on primary care and leave few options for physician anesthesiologists to report. Although the requirements encompass three reporting options, many of the measures may be submitted by just one or two reporting methods. We recognize that CMS has extended the MAV process to these cross-cutting measures. However, ASA often fields questions from members who are confused as to which measures may apply to their practice. By including these cross-cutting measures, we fear the unintended consequences of an increased reporting burden on our members and duplicative efforts taking place between multiple physicians, possibly without an added benefit, on the same patient. Similar to our previous argument, we ask that CMS extend the MAV cross-cutting process to physicians who report zero cross-cutting measures.

Qualified Clinical Data Registry

We propose that CMS maintain the current one outcome measure requirement for an EP to report via the QCDR option. Although the CMS-approved QCDR may be able to establish reportable outcome and patient experience measures, physician anesthesiologists practice in a number of environments and encounter a variety of patients. An outcome measure applicable to one anesthesiologist may not be applicable to a different anesthesiologist – a scenario our members routinely encounter with anesthesia care PQRS measures and the MAV process. **We request CMS delay the implementation requirement of reporting three outcome measures until sufficient data is collected and analyzed to ensure that physician anesthesiologists and other EPs would be able to report on more than one outcome measure.**

Second, ASA supports the proposed rule to increase the number of QCDR non-PQRS measures from 20 to 30 measures. This proposal will have a significant impact on physician anesthesiologists who practice in a variety of settings, encounter a diversity of patients, and are pursuing new practice models. This proposal will also allow greater latitude for NACOR to develop a sufficient number of outcome measures for most physician anesthesiologists to report.

In addition, ASA recommends that QCDRs be allowed to submit non-PQRS measures for consideration throughout the year. As instituted, the QCDR is required to submit a list of measures in March of the reporting year. This timeframe, though manageable for 2014, can be improved by establishing a year-round cycle of measure submission and review. We know that EPs and their practices will benefit from having advanced notice on future reportable QCDR measures.

For non-PQRS QCDR measures, ASA requests that CMS establish a dual six-month and twelve-month reporting cycle. We ask that non-PQRS measures, once approved by CMS in the spring of the reporting year, be reported by EPs for a six-month period from July to December. Once the measure has been established, EPs would then be required to report the measure for the twelve-month reporting cycle the following year. ASA believes this process would establish manageable timelines while incentivizing QCDRs to methodically develop and test innovative measures. At the same time, the timeline would protect physicians who may not have been recording a particular measure in the first six months of the year against the risk of not meeting the 50% reporting threshold.

ASA agrees with the proposal for extending the data submission and calculation deadline to March 31. We support provisions for more routine submissions of quality data and recommend that QCDRs be allowed to submit quality data quarterly. We believe quarterly submission will permit the QCDR to hone its reporting capabilities, improve efficiency, and ensure physicians receive timely feedback from the QCDR and CMS.

Regarding CMS's proposal to require QCDRs to publish quality measures data online, ASA requests a 60-day period. CMS currently proposes a 30-day post-data submission timeline to post such data (April 30). We believe a 60-day period is reasonable considering the burden to report data to CMS the previous month, codify the data into an understandable and patient-friendly format, and securely and accurately post the data on the QCDR website.

ASA supports the direction of CMS and other health care advocates who seek to improve patient satisfaction and experience. We appreciate CMS encouraging QCDRs to allow physicians to report the Surgical Consumer Assessment of Healthcare Providers and Systems (S-CAHPS) survey and to develop modules that are reflective of specialty priorities. NACOR has included the anesthesiology component of the S-CAHPS as a non-PQRS QCDR measure. However, we are concerned that CMS will not be providing financial support for practices implementing that survey tool or those of other CAHPS. We urge CMS to explore options for decreasing the financial burden incurred by practices implementing these important patient-centered tools in the future, especially if CMS requires the surveys, or measures derived from such surveys, to be reported.

Physician Quality Reporting System Measures Under Consideration

We are encouraged by CMS's decision to permit stakeholders to submit measures for PQRS consideration throughout the year. We ask that the process of reviewing such measures include specialists for whom these measures would

affect. The process would benefit from enhanced communication between measure reviewers, experts, and the entities submitting measures.

This measure review process is further complicated by the legislative requirements that CMS must adhere to when engaging the Measure Application Partnership (MAP). ASA is concerned that the MAP process suffers from a lack of physician participation which has resulted in measures, essential to specialists, being overlooked or de-emphasized by persons either not impacted by such measures or willfully neglectful of specialty priorities. We were alarmed that none of the anesthesia care measures were recommended by the MAP last year and by the number of other specialty-specific submitted measures that were not recommended by that body. We suggest CMS reevaluate the MAP process and encourage an ethos among MAP participants of measure inclusion rather than measure exclusion.

Measures Proposed for Removal

ASA objects to the proposed removal of PQRS #30: Timing of Prophylactic Antibiotic – Administering Physician and similar measures related to perioperative care. CMS argues that the measure is approaching 100% performance and has noted in public forums that these measures typically have a 99% performance rate at the 75th percentile. However, ASA has tested the measure using both the Medicare 5% Limited Data Set Standard Analytical Files (Medicare SAF) along with physician data submitted to NACOR. The data show performance rates between 92 and 97% among those providers who report the measure. The performance rates demonstrate to ASA and AQR that 3-8% of patients, *among whose providers report this measure*, may not be receiving a prophylactic antibiotic when indicated. For 3-8% of patients, the notion of a measure approaching 100% performance may not balance with a patient's basic understanding of what constitutes their own safety. **Nearly half of all providers are not reporting PQRS #30. It is critical at this time that CMS ensure patient safety for all patients and not just the patients whose providers report data. We caution CMS against extrapolating performance rates from EPs who report a measure and applying them to those who do not.** As reporting requirements and payment adjustments begin to take full effect and additional providers are brought into the PQRS and VM programs, it is important to ensure that new participants share similar performance rates as those already reporting before removing an important patient safety metric.

If CMS should remove PQRS #30 from the program, we urge CMS to provide clear direction on how the removal of this measure would impact MAV clusters. It will be important for CMS to monitor trends in Surgical Site Infections (SSIs) and Healthcare Acquired Infections to ensure that removal of PQRS #30 from the program does not negatively impact SSIs.

We are also concerned with the removal of other measures that physician anesthesiologists and pain medicine physicians report, notably PQRS #109: Osteoarthritis (OA): Function and Pain Assessment and the Back Pain Measures Group (PQRS #148, #149, #150, #151). For PQRS #109, we ask that CMS establish a comprehensive process to identify whether other specialty societies may wish to maintain this or any measure prior to removing the measure from PQRS. CMS has argued that the Back Pain Measures Group represents clinical assessments commonly utilized to provide effective treatment for patients diagnosed with back pain. While we object to the proposed removal of these measures, more importantly, we caution against this argument believing that it could encourage a slippery slope scenario leading to the removal of additional clinical PQRS process measures that are integral to ensuring that patients receive safe, quality care.

We propose CMS provide a three-year advance notice to measure stewards, EPs and stakeholders potentially affected by the removal of a measure. This would address our concerns stated above and ensure adequate time for measure stewards to develop and test new meaningful measures to prevent gaps in measure portfolios.

Value-Based Payment Modifier and Physician Feedback Program

It appears that CMS is not introducing any significant structural changes to the Value-Based Payment Modifier (VM) for CY2017 and is continuing its previously stated plans to apply the modifier to all physicians and non-physician EPs (eligible provider) who provide care and submit claims for Part B services to Medicare beneficiaries. However, we are concerned about the proposal to increase the amount at risk from 2% of allowed charges in the CY2016 payment adjustment period to 4% for the CY2017 payment adjustment period. CMS is proposing to double the amount at risk

while at the same time deactivating measures that will allow specialties with a limited number of applicable quality measures to satisfactorily report 2015 Physician Quality Reporting System (PQRS) and thereby qualify as a Category I (Cat I) provider for 2017 VM. **We recommend no increase to the amount at risk for 2017.** CMS states that it has seen that a 1% or 2% PQRS incentive did not result in widespread participation with PQRS. Since the VM must be budget neutral, it appears that CMS is proposing an increase in the amount at risk to support an increase to the maximum positive adjustment.

We do not agree that an increase to the amount at risk is warranted at this time since CMS's analysis of 2012 claims shows that about 6% of all EPs are in a Cat I Taxpayer Identification Number (TIN) that would get a positive adjustment, about 11% are in a TIN that would get a negative adjustment, and the remaining 83% would be neutral. With all the programs at play (PQRS, Meaningful Use, VM) the amount at risk is already substantial and those who are subject to maximum penalties will find it increasingly difficult to move toward the high quality/low cost care that is the ultimate goal of these programs.

Electronic Health Record Incentive Program

ASA appreciates the hardship exemption CMS has provided for physician anesthesiologists to avoid the EHR payment adjustment. This exemption recognizes the state of commercially available EHR technology for physician anesthesiologists, workflow challenges, and the nature of the patient-anesthesiologist relationship. ASA strongly supports the continuation of the hardship exemption for physician anesthesiologists and other hospital-based professionals through Stage 3 and beyond.

We are concerned with the proposal to use previous electronic Clinical Quality Measures (eCQMs) measure specifications if current specifications are incorrect or produce inaccurate results. Although this has affected few measures, we worry about the time and efficiency costs that would accrue to providers needing to resubmit data if the error is discovered in the midst of a reporting period. In addition, the current eCQM measures often fail to address the underlying challenge for physician anesthesiologists to report specialty-specific measures that are meaningful to individual practices. ASA asks that CMS explore additional avenues to develop and implement specialty-specific eCQMs applicable for EP reporting to both PQRS and EHR programs.

ASA is encouraged by CMS proposals to seek greater alignment between the EHR Incentive Program and PQRS and would support the group reporting of eCQMs to include the QCDR reporting option. A very small percentage of physician anesthesiologists report via the Group Practice Reporting Option (GPRO) – primarily because of the measure set and available reporting methods. However, allowing groups to qualify for GPRO as well as the EHR Incentive Program through an EHR-QCDR option would be consistent with CMS efforts to simplify and harmonize the two programs.

Medicare Shared Savings Program

CMS has placed significant emphasis on facilitating coordination and cooperation among providers in an effort to improve the quality of care Medicare beneficiaries receive and to reduce unnecessary costs. Although a minority of ASA members participates in Accountable Care Organizations (ACOs), we nonetheless ask that CMS explore additional measures that are applicable to and inclusive of all EPs working for an ACO. As proposed, the ACO quality measures mostly impact primary care physicians who provide a number of services for patients, including chronic care management.

Physician anesthesiologists and other specialists who participate in ACOs face a perioperative paradigm. The care our members deliver to patients and the cost efficiencies accrued to CMS are often tied to primary care providers. Measure assessments are often not dependent on the perioperative care that patients may receive from physician anesthesiologists, surgeons, or other specialists. The ACO measure set includes 33 measures; yet few measures truly capture the care physician anesthesiologists provide. We ask CMS to explore opportunities to include measures that are meaningful to physician anesthesiologists working within an ACO.

We appreciate your consideration of our comments. If you have any questions please contact ASA's Director of Payment and Practice Management, Sharon Merrick, M.S., CCS-P (s.merrick@asahq.org) or ASA's Director of Quality and Regulatory Affairs, Maureen Amos, M.S. (m.amos@asahq.org) at (202) 289-2222.

Respectfully yours,

A handwritten signature in black ink that reads "Jane C.K. Fitch MD". The signature is written in a cursive, flowing style.

Jane C.K. Fitch, MD
President
American Society of Anesthesiologists