American Society of Anesthesiologists®

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December 20, 2017

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5522-FC and IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-5522-FC and IFC Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year

[Submitted via http://www.regulations.gov]

Dear Administrator Verma:

The American Society of Anesthesiologists® (ASA), on behalf of our over 52,000 members, appreciates the opportunity to comment on several of the issues in the above-captioned Final Rule with comment and Interim Final Rule with comment. ASA has invested heavily in initiatives aimed at improving the safety, quality and efficiency of care for the surgical patient. We have supported the implementation of the Perioperative Surgical Home (PSH) Collaboratives in over 100 large and small health care institutions. PSH is a patient-centered delivery system that aligns with the National Quality Strategy (NQS) to achieve the triple aim of improving health, improving the delivery of healthcare and reducing costs. A growing body of evidence demonstrates the success of the PSH strategy. These efforts reflect ASA's strong commitment to align with the agency's efforts to reduce costs, enhance the quality of patient care and decrease the regulatory burden on physicians and other providers.

The Quality Payment Program (QPP) is composed of two tracks: the Merit-based Incentive Payment System (MIPS), a program that provides performance based payment adjustments based on the reporting of measures and other data and the Advanced Alternative Payment Model (APM) which provides opportunities for eligible clinicians to earn incentive payments for taking on financial risk through their participation in such models. These regulations finalize changes to the QPP for the calendar year (CY) 2018 reporting period and will affect payments in the CY 2020 payment period.

ASA commends the agency for your responsiveness to stakeholders' comments and finalized policies that reflect flexibility in the implementation of the program and a continued commitment to a gradual transition to MIPS. We appreciate and support many of the finalized policies to accommodate certain categories of eligible clinicians and to promote an overall reduction in the participation burden for everyone. While overall we are supportive of many of the final policies, we continue to have concerns with certain policies. Through our recommendations and comments outlined below, we urge CMS to address these issues through future rulemaking or sub-regulatory guidance. Appendix A of this letter provides a complete listing of all our recommendations.

MIPS

Under MIPS, beginning in the 2019 payment year, eligible clinicians earn a payment adjustment (positive, neutral, or negative) based on their performance in four performance categories: Quality, Advancing Care Information (ACI), Cost, and Improvement Activities (IA). In this section of the letter we are commenting on the following topics:

- MIPS general policies: MIPS performance period, multiple submission mechanisms, facility-based measures, virtual groups, application of the MIPS payment adjustment on Part B drugs, the MIPS performance threshold, and the CMS anesthesiology factsheet
- Quality Performance Category: data completeness threshold, topped-out measures, and definition of data errors in the Quality Clinical Data Registries (QCDRs) environment
- ACI Performance Category: 21st Century Cures exclusion for ambulatory surgical center (ASC)-based eligible clinicians
- Cost Performance Category: cost measures and attribution
- IA Performance Category: IA inventory

MIPS General Policies

MIPS Performance Period

For 2017, the first year of QPP, CMS implemented a slow "on-ramp" transition to MIPS referred to as "Pick Your Pace." Under Pick Your Pace CMS accepts a minimum of continuous 90 days of data. For the 2018 Performance Year, CMS finalized a proposal to maintain a 90-day performance period for IA and ACI and to increase the performance period for the Quality Performance Category to twelve months (January 1 – December 31, 2018).

ASA supports the 12-month performance period for Quality but we remind the agency that the ability of a QCDR to have the correct systems in place and for a physician to be ready to report measures by January 1 is dependent on having access to the measures and measure specifications in a timely manner. By statute CMS must post MIPS measures by November 1 of the prior year. In this final rule, CMS indicated that will post 2018 QCDR measure specifications by January 1, 2018. ASA believes a January 1 posting is not sufficient for a 12-month reporting period. By posting the measure specifications on the day the reporting period begins, and accounting for the ramp-up to full implementation of the measure, you could lose one to two months of time within the reporting period where the measure is not appropriately addressed. This would represent missed opportunities to address priority areas of patient care.

Moving forward, ASA urges CMS to post QCDR measure specifications by December 1. Eventually, ASA would like to see QCDR measures published by November 1 in the QPP Final Rule, similar to the process used for MIPS measures. We believe this is a fair and reasonable approach. Registries and practices need time to update their systems so they are prepared to collect the appropriate measure data. In the case of completely new measures, clinicians need to understand the targets they are trying to meet and will need time to familiarize themselves with the measures and their associated benchmarks. Given that CMS is moving to a 12-month reporting period, the timely posting of measures becomes even more critical.

ASA realizes that if we are requesting CMS to release the QCDR measure specifications at an earlier point in the process, CMS may need to adjust their timeline of when they receive submissions on QCDR measures from the measure stewards. In adapting the process to allow earlier availability of measure specifications, it is critical that sufficient time and staff resources be available for meaningful collaboration between measure stewards and CMS in the refinement of measures, especially creating a shared understanding of the clinical rationale for the measures.

Multiple Submission Mechanisms
For 2017, eligible clinicians are allowed to use only one submission mechanism per performance category. For 2018, CMS proposed to allow individual MIPS eligible clinicians and groups to submit measures and activities through multiple submission mechanisms within a performance category as available and applicable. CMS delayed the implementation of this proposal until the 2019 Performance Period. Starting with the 2019 Performance Period, groups and virtual groups will be able to utilize multiple submission mechanisms within each performance category.

CMS indicated they were not implementing this policy in 2018 because of operational reasons. ASA agrees that there are substantial, complex operational issues CMS must address. ASA believes it is premature to implement reporting via multiple mechanisms within each category until the implementation process is further developed and there is an opportunity for vetting of a more detailed implementation plan through the public comment process.

ASA recommends that as CMS reviews operational issues, CMS should address administrative structure, information flow and responsibilities for the various entities involved when eligible clinicians submit measures and activities through multiple submission mechanisms.

An example of a critical operations issue CMS needs to address is the engagement of registries with the MIPS program. Many eligible clinicians rely on registries to monitor their individual or group performance. If eligible clinicians are allowed to submit data through multiple submission mechanisms, CMS should provide a means for eligible clinicians to easily access timely and current data on their performance status in MIPS performance categories. Either the registry must be provided this information directly from CMS or there should be a means for eligible clinicians to access such data (*e.g.* online dashboard). Without such an infrastructure, we fear eligible clinicians who use multiple mechanisms may not have a timely and accurate view of their yearly performance.

Currently, eligible clinicians submit quality measures through a single mechanism. ASA has noted benchmarks for a quality measure may vary by submission mechanism. For example, the benchmark for *Diabetes Hemoglobin A1c Poor Control* can be submitted via claims, EHR, and registry/QCDR. Each submission mechanism has a different benchmark. If this measure will now be reported via multiple mechanisms, this could result in yet another benchmark.

ASA recommends that CMS scrutinize how benchmarks are impacted when a measure is submitted through multiple mechanisms. The information should be publicly released and if differences are noted a separate benchmark should be posted when a measure is submitted via multiple mechanisms.

Similar to our previous comments, the timeliness of when information is available is critical. Information on benchmarks and scoring should be available early enough in the performance period for eligible clinicians to make informed decisions on their measure and reporting mechanism choices.

ASA recommends that CMS make all data that impacts the use and scoring of a measure available at the beginning of a reporting period.

Facility-based Measures
The Medicare Access and CHIP Reauthorization Act (MACRA) authorized CMS to use measures from other payment systems (*e.g.,* inpatient hospitals) for the Quality and Cost Performance Categories for "hospital-based" MIPS eligible clinicians but excluded measures from hospital outpatient departments, except in the case of items and services furnished by emergency physicians, radiologists, and anesthesiologists.

For 2018, CMS proposed to implement a voluntary, facility-based scoring mechanism using the Hospital Value Based Purchasing Program (HVBP) as a proxy. This option would be available only to facility-based clinicians who have 75 percent of their covered professional services supplied in the inpatient hospital or emergency department setting. The facility-based measure option converts a hospital's Total Performance Score into MIPS Quality and Cost scores. CMS is delaying the implementation of this proposal for one year. Starting with Performance Period 2019, a MIPS eligible clinician or group may elect to be scored in the Quality or Cost Performance Categories using facility-based measures. CMS indicated that they will use 2018 to ensure that clinicians better understand the opportunity and ensure operational readiness to offer facility-based measurement. ASA thanks CMS for finalizing this policy and looks forward to the implementation of a facility-based scoring mechanism for MIPS.

ASA believes facility-based measures can have several benefits: aligning interests between eligible clinicians working at a specific facility, reducing the reporting burden and providing a pathway towards more meaningful measure reporting. In the current system, CMS is receiving data on the care of the same patient and episodes of care from two sources: the facility and the clinician. Through the implementation of facility-based measures, CMS will only receive this data once through a single source thereby providing data to the agency in a streamlined and efficient manner and reducing the reporting burden on clinicians as well as reducing the administrative burden on the agency to analyze potentially redundant data. While conceptually these are laudable goals, ASA urges CMS to provide more details on how they will be achieved.

ASA recommends CMS use 2018 to further develop the facility-based measures program both from an internal and external perspective. CMS should better detail how hospital quality scores will be translated into MIPS Quality and Cost scores and how will eligible clinicians and their practices be informed that they have met the threshold for choosing the facility-based reporting option. Finally, ASA recommends that CMS automatically select the score that is more favorable (facility-based reporting or regular MIPS reporting for those eligible clinicians reporting through both mechanisms).

Virtual Groups

The MACRA statute allows CMS to establish "virtual groups" for purposes of reporting and measuring performance under MIPS. Virtual groups can be composed of solo practitioners and small group practices that join together to report on MIPS requirements as a collective entity and share the same financial adjustments as the result of that reporting. CMS finalized a proposal to allow for the implementation of virtual groups beginning with the 2018 Performance Period. CMS is limiting the size of eligible participants of virtual groups to solo practitioners and groups of 10 National Provider Identifiers (NPIs) per Tax Identification Number (TIN) or less. ASA thanks CMS for finalizing this proposal. We believe that virtual groups provide a means of reducing the participation burden for solo practitioners and smaller practice groups.

ASA understands that the MACRA statute limits the agency to offering the virtual group option to solo practitioners and groups of 10 NPIs per TIN or less. If the benefits of the virtual group option are borne out, ASA encourages CMS to explore if there are other pathways for the agency to implement a virtual group type of model for groups larger than 10 NPIs per TIN.

In order to appropriately evaluate the impact of the virtual groups and determine if the program needs to be modified, CMS needs to collect data on the program and make available to participants and stakeholders.

ASA recommends CMS collect and publicly report, in a timely manner, data on how many virtual groups were created, general characteristics of virtual groups (e.g. size, geographic locations, specialty(s)) and the performance in MIPS of solo and small practices participating in MIPS via virtual

groups versus those participating in MIPS independently. This data should be used to guide CMS in the future development and potential expansion of virtual groups.

Application of the MIPS Payment Adjustment on Part B Drugs
The MACRA statute authorizes that the MIPS payment adjustment applies only to the amount otherwise paid under Part B for items and services furnished by MIPS eligible clinicians during the year in which the MIPS payment adjustment is applied. In the 2018 Final Rule, CMS clarified that MIPS payment adjustments will be made to payments for both items and services under Medicare Part B, including Part B drugs.

ASA was very disappointed in the agency's final policy. While ASA acknowledges that CMS's position that the MIPS adjustment applies to Part B drugs is consistent with the statutory phrase *items and services*, we do not believe that this was the intent of the MACRA statute. ASA has a number of concerns with applying the payment adjustments to Part B drugs and biologicals -- especially when limited to those charges that can be associated with a MIPS-eligible clinician.

- *Implementation limitations*: Not only is this policy inconsistent with the goals of MACRA, we fear that this policy will only further confuse providers and create unwarranted differentials among clinicians based on practice settings and specialties and specific arrangements that impact how Part B drugs are billed.
- *Drug pricing*: The issue of the true price of drugs is already very confusing and muddied with the various rates, discounts and other adjustments.
- *Disproportionate impact on certain specialties*: This policy may be applied unevenly across specialties and among physicians within the same specialty.
- *Undesirable incentives:* The availability of these payment adjustments may be expected to induce adjustments to business arrangements for the provision of drugs and biological that could increase costs.

Given that CMS has determined that the adjustment will apply to Part B drugs, CMS report on the impact of this policy. This is especially important in the context of higher cost drugs and biologicals where positive adjustments may result in unwarranted windfalls and negative adjustments unreasonable penalties for physicians unrelated to their actual performance.

ASA recommends that CMS monitor and report in a timely manner on the differences in those practices that bill for Part B drugs (where the NPI billing the drug and the NPI billing the administration service can be linked) and those who do not and the differences in MIPS payment adjustment. Understanding and evaluating the impact of the various policies of the MIPS program is important as the program matures. The application of performance-related adjustments on reimbursement for Part B drugs is largely uncharted territory for the agency. This makes it even more critical that the agency closely monitor and report on its impact.

MIPS Performance Threshold
Beginning with the 2019 Performance Period, CMS is required by statute to use either the mean or median MIPS final score from a previous period to set the performance threshold. While CMS did not address this issue in the Final Rule, the agency did indicate they anticipate that, beginning in the 2019 Performance Period, clinicians would likely need to perform well on measures and activities to receive a positive MIPS payment adjustment.

CMS and other observers widely acknowledge that the experience and capacity of eligible clinicians to successfully participate in MIPS varies widely and that a mean or median approach may not be fair for all

MIPS participants. In the first two years of MIPS, CMS gradually increased the performance threshold. It was set at three points in 2017 and CMS finalized a proposal to increase it to 15 points for the 2018 Performance Period. ASA supports the current approach of CMS to slowly increase the threshold. We are very concerned about CMS abruptly switching to a methodology where the threshold is based on the mean or median from a previous period. We believe that this will create uncertainty in the program and is dramatically inconsistent with the largely successful and thoughtful approach CMS implemented in 2017 and 2018.

ASA urges CMS to take an alternative approach in setting the MIPS performance threshold in 2019. Instead of basing the threshold on the mean or median of a previous period, CMS should increase the threshold each year during an extended transition period. By using this approach, the program will become more challenging for eligible clinicians to succeed, but it would allow the agency to continue to have some control and make appropriate adjustments. Over time as the program matures, setting the performance threshold on the mean or median may perceived to be less arbitrary and more reflective of the program's original intent.

Quality Performance Category

Data Completeness Threshold

For the 2018 MIPS Performance Period, CMS previously finalized (in the 2017 QPP Final Rule) that the data completeness threshold would increase to 60 percent for data submitted on quality measures. CMS proposed to maintain a 50 percent data completeness threshold for the 2018 MIPS Performance Period in the proposed rule, but the agency decided not to finalize this proposal. The data completeness threshold will increase to 60 percent for the 2018 Performance Period. CMS also indicated in the 2018 Final Rule that as MIPS eligible clinicians gain experience with reporting quality data, further increases to these minimum reporting thresholds will occur.

ASA was disappointed that CMS did not finalize their proposal to maintain the data completeness threshold at 50 percent. A 60 percent threshold is an increase from the historical threshold of 50 percent that was maintained in the legacy Physician Quality Reporting System (PQRS) program. We believe eligible clinicians need more time to adjust to a higher threshold especially as they are transitioning to the new and different participation requirements of the MIPS program.

ASA appreciates that the agency needs to collect a sufficient amount of measure data from clinicians for benchmarking purposes as well as to test a measure's reliability and validity. ASA supports this position but the need for quality data to differentiate the care provided by one eligible clinician from another must be balanced by the feasibility and resources expended towards meeting the increased data threshold.

ASA urges CMS to carefully monitor the performance of the wide-range of MIPS clinicians and their experience in meeting these thresholds prior to further increasing the data completeness threshold. In future rulemaking, CMS should display data supporting that an increased completeness threshold can be met by a significant majority of MIPS participants to substantiate any increased data completeness threshold. The marginal benefit of increasing the data completeness threshold must also be balanced by the consideration of the marginal cost to the clinician's practice.

Topped Out Measures

ASA recognizes the need for CMS to choose quality measures based upon their ability to differentiate the quality of care one eligible clinician provides to a patient in relation to the performance of another clinician. However, eligible clinicians and their practices require sufficient time to assess their performance and scoring on quality measures prior to a performance year. Although CMS is transparent in detailing a four-year process for removal of any such MIPS measures, we request the same structure be applied to QCDR measures. The agency appears to agree in their QPP 2018 Final Rule, stating "QCDR

measures that consistently are identified as topped out according to the same [MIPS measures] timeline would not be approved for use in year 4 during the QCDR self-nomination review process." We agree with this outlined policy and believe its immediate and retroactive implementation of this policy on QCDR measures would allow physician anesthesiologists and their practices an opportunity to transition away from topped out measures to measures where a significant gap exists. We request the 2017 Performance Year to serve as Year One in the four-year timeline for topped out QCDR measures.

A gradual removal of topped out measures would be more in line with the current direction of CMS to decrease the burden on eligible clinicians while emphasizing the creation and implementation of new and more meaningful process and outcome measures. We believe it is better to retain topped out MIPS and QCDR measures for several more years. We believe that allowing eligible clinicians to continue to receive some points for a topped out measure is better than the alternative of 0 points when an eligible clinician does not find six applicable measures to report. This "soft landing" approach would reduce the burden among eligible clinicians and their practices who, in some settings, may struggle to find a minimum number of measures to replace those that CMS did not approve for use in 2018.

Recent CMS activities regarding the Measures Under Consideration (MUC) as well as the Meaningful Measures initiative may have the unintended consequences of decreasing the choices that eligible clinicians may have with quality measures. This year, CMS proposed just 32 measures for the MUC list out of 184 measures that were submitted. Of these 32, only a handful were specialty-specific and none of these measures have a clear pathway for physician anesthesiologists to report. Between the MUC list, the Meaningful Measures initiative and CMS's intention to retire topped out MIPS and QCDR measures, eligible clinicians across a range of specialties may struggle in future years to find a minimum number of measures to report.

ASA recommends that CMS should apply the same standards of removing topped out measures over a four-year period for QCDR measures as CMS has applied to MIPS quality measures. This process should be retrospectively applied to QCDR measures approved for the 2017 Performance Year.

Data Errors in the QCDR Environment
ASA thanks CMS for clarifying the requirements for retaining data submitted by MIPS eligible clinicians through the registry. We appreciate CMS applying consistent policy across programs and regulations in this regard. ASA intends to further educate and provide our members with tools to use regarding their individual and practice responsibilities in documenting and maintaining any records they gather and submit to CMS, regardless of submission mechanism or attestation.

However, ASA was troubled that CMS did not respond to our request of defining a registry data inaccuracy or error that could result in a registry being placed on probation or worse – suspension. In our 2018 QPP Proposed Rule comments, we stated, "In defining data errors, CMS would give power to registries to mitigate data problems early in the year." Although CMS has provided some indication through the sub-regulatory process of what may constitute an inaccuracy or error, greater clarity and transparency is critical so that registries can implement appropriate checks. This is particularly important if CMS expects registries to identify additional data inaccuracies or errors beyond those that are detected through each registry's CMS approved data validation plan.

Each year, CMS provides each registry with a "Data Issue Report." Some of the elements in the Data Issue Report are capable of being detected in advance by a registry through its validation checks. These issues could presumably be identified by CMS and counted against a registry as a "data inaccuracy." For example, counts of TIN/NPIs where the numerator is greater than the denominator for specific measures should be considered a data inaccuracy.

Yet other issues identified in the Data Issue Report either cannot be detected in advance by a registry or are outside of the registry's control and thus would be unfair to count against such registry as an inaccuracy or error that warrants its placement on probation or suspension. For example, registries should not be held responsible for individuals and practices who withhold Medicare billing data or their QPP status from the registry. For instance, in previous years, CMS has identified a data issue scenario when an individual clinician or practice submitted data to a registry on a procedure but failed to submit the corresponding physician fee schedule claim to CMS. In other cases, a data issue report was generated because a practice belonged to an Accountable Care Organization but did not notify the registry of this prior to its data submission to CMS.

Registries can proactively work with such clinicians or practices in the following reporting year to ensure such issues are not repeated. ***ASA requests CMS provide retrospective data to the registries to help mitigate such circumstances. Moreover, when individuals or practices withhold Medicare billing data, this unavailable data should not be counted against the registry as an inaccuracy or error since the registry has no way to identify this issue in advance without access to CMS' claims data.*** CMS noted in the 2018 QPP final rule that MIPS eligible clinicians are responsible for the data submitted to registries and to ensure their third-party intermediaries meet their needs. Subsequently, registries should not be held responsible for individuals and practices who withhold Medicare billing data or their QPP status from the registry.

Another example of a previously identified data issue included when a clinician or practice submitted data that did not meet the minimum 50% data reporting threshold. Under PQRS, submission of data by a registry for a clinician that was less than the minimum threshold was reported on the registry's Data Issue Report even though the clinician requested that the registry submit the practice's data to CMS. Likewise, we ask for clarification if a "null" or "0" value is submitted for a measure would result in an inaccuracy or error that is counted against the registry. We understand that it is CMS's intent for registries to assist clinicians to reach the minimum reporting requirements via feedback reports and education, however this action requires that clinicians are receptive to such input from the registry. In some instances, the eligible clinician or their practice may be privy to these issues and desire that the registry submit data nonetheless to CMS. Because the QPP criteria differs from PQRS, we expect that CMS will accept data that fails to meet the minimum threshold and that the registry would not be cited for a data inaccuracy or error. This problem could be further compounded if CMS finalizes the use of multiple reporting mechanisms in 2019.

While we understand that the Data Issue Report will likely change under the new QPP program criteria, given the overlap in reporting elements between PQRS and QPP, clarifying whether the issues identified in such Report will count against a registry's performance is of critical importance. Similarly, CMS should declare any other issues outside of those detectable through the registry's CMS approved data validation plan that will be counted against a registry.

ASA requests that CMS publish the types of circumstances that will constitute an "error" with respect to identification of data inaccuracies as it relates to probation and disqualification of registries.

Anesthesiology Fact Sheet

ASA appreciates the work and consideration CMS staff and its contractors made in developing the MIPS "Measures for Anesthesiologists and Certified Registered Nurse Anesthetists" (CRNA). ASA staff have distributed this useful resource to educate our members and for their use when considering how they wish to participate in MIPS. Although we recognize the regulatory language that includes Certified Anesthesiologist Assistants (CAAs) under the CRNA description, the growing employment of CAAs in anesthesia practices, we believe, necessitates that clear messaging from CMS and the QPP Help Desk emphasize this relationship.

ASA requests that future materials developed for anesthesiologists and certified registered nurse anesthetists also include reference to "Anesthesiologist Assistants." We also ask that CMS develop an FAQ or other materials to help practices understand that Certified Anesthesiologist Assistants who meet program thresholds are considered MIPS eligible clinicians.

Advancing Care Information (ACI) Performance Category

21st Century Cures Exclusion for Ambulatory Surgical Center (ASC)-based Eligible Clinicians

CMS is finalizing a proposal to implement a provision in the 21st Century Cures Act that ASC-based physicians (which CMS defined as furnishing 75 percent of their services in an ASC setting) will have their ACI Performance Category automatically reweighted to zero. Prior to the implementation of the QPP, ASA supported the continued use of the general hardship exemption for anesthesiologists. Under the current QPP rules and in relation to the 21st Century Cures Act, we recognize that some anesthesiologists who have the appropriate technology and work in certain settings may wish to participate in ACI to diversify their scores.

Clinicians who practice in an ASC setting do not have access to certified EHR technology. While the final policy as defined by CMS will be helpful to many clinicians who practice solely in an ASC setting, many anesthesiologists and other clinicians who practice in multiple facility settings will not be able to meet the threshold. In the 2017 QPP Final Rule, CMS finalized an ACI exemption for hospital-based clinicians. Under this exemption policy, eligible clinicians who practice in the inpatient, on-campus outpatient or emergency department settings are exempted from ACI reporting. These settings present the same limitations to physicians in terms of their ability to meet ACI reporting standard as those underlying the ASC policy. Many clinicians split their time between an ASC and the inpatient or outpatient hospital setting. These clinicians may find themselves in a position where they cannot meet the 75 percent threshold under *either* the ASC or hospital-based clinician exemption but do meet a threshold of 75-percent of their services in the ASC and hospital settings *combined*.

We believe CMS should extend the hospital-based clinician exception policy to the ASC setting and allow for services provided in all the identified outpatient facility settings to be summed cumulatively to determine which eligible clinicians meet the threshold. This approach fully captures the intent of the provision. It has been generally accepted that physicians practicing in a facility environment have less control of their administrative environment and thus may not have access to the appropriate EHRs or the ability to use them in a meaningful way; this consideration is applicable to all facility-based places of service identified above. It would be illogical and unfair to subject a physician who provides services predominantly in facility settings to a penalty simply because he/she does not achieve the threshold in a single setting. Physician anesthesiologists may disproportionately find themselves in this position because, unlike their surgical colleagues who also practice in ASCs, they do not perform and report E/M visits in the office setting where a certified EHR may be available.

ASA urges that when determining of the hospital-based clinician threshold has been met for the purposes of the ACI exemption, CMS should expand the definition of hospital-based clinicians to include physician anesthesiologists and other MIPS eligible clinicians who work principally in facility settings by pooling the utilization of services provided in the inpatient (POS 21), on-campus outpatient (POS 22), off-campus outpatient (POS 19), emergency room (POS 23), and ASC (POS 24) settings.

Cost Performance Category

Cost Measures and Attribution

For the 2018 Performance Period CMS is implementing the Cost Performance Category with a weight of 10% in 2018. CMS will be implementing the Medicare Spending Per Beneficiary (MSPB) and Total Per Capita Cost measures for the Cost Performance Category. These measures have established

methodologies for attribution. Each MSPB episode is attributed to the one TIN responsible for the plurality of carrier per beneficiary services, as measured by Medicare allowed amounts, performed by EPs during the episode's index hospitalization.

For the Per Capita Costs for All Attributed Beneficiaries measure, beneficiaries are attributed to a single TIN in a two-step process that takes into account the level of primary care services received (as measured by Medicare-allowed charges during the performance period) and the provider specialties that performed these services. ASA appreciates these are well-established measures with significant history in the Medicare program. The attribution process has been in place for a period time and tested and considered by the agency in various programs.

As CMS moves forward with the creation of a new set of episode-based cost measures currently in development, ASA urges CMS to reconsider its approach to attribution. In the typical practice environment for physician anesthesiologists, purchasing and acquisition decisions related to a procedure in which anesthesia is required are most often not within the control or discretion of the anesthesiologist.

An individual physician anesthesiologist is often one member of a larger team of healthcare professionals providing services to a Medicare beneficiary. Depending on the needs of the patient and the other providers involved, the physician anesthesiologist may play a different role with different patients. These varying roles will impact the resources or costs that can be attributed to the MIPS eligible clinician. Any measure or method developed to estimate costs attributed to a provider should be sensitive to differentiate among the varying roles that a physician anesthesiologist may play as a member of a larger team. The use of Patient Relationship Categories of codes could help address these differences. As CMS further develops cost measures, ASA looks forward to better understanding how Patient Relationship Categories of codes will be used to better capture a more complex and complete picture of how resources should be attributed to different providers and facilities.

ASA recommends that, as CMS develops new cost measures, that the agency develop a methodology that equitably attributes resources to all providers and facilities involved in rendering the service. We believe such a methodology is aligned with the concept of shared accountability.

Improvement Activities (IA) Performance Category

IA Inventory

In the Final Rule, CMS clarified that for PSPA_2, participation in the ASA Simulation Education Network fulfills the requirement for this Improvement Activity. The ASA thanks the agency for finalizing its proposal to implement the PSH Care Coordination Improvement Activity for the QPP Year 2 and Future Years. We also thank the agency for clarifying via email on August 25, 2017, that the proposed PSH Population Management Strategies within a Perioperative Surgical Home Improvement Activity will be encompassed under the now finalized IA_PSPA_8 "Use of Patient Safety Tools" for the QPP Year 2 and Future Years. Our members and physicians from other specialties are very excited about these new improvement activities that will be available to them in the QPP 2018 Program.

Advanced Alternative Payment Models (APMs)

ASA notes that the majority of participating physicians within the QPP will be through the MIPS pathway. Nevertheless, we see the potential value of Advanced APM participation for our members and other specialists. ASA urges the agency to continue its efforts moving from volume to value, including providing pathways for all specialists an opportunity to participate in APMs.

Definition of Physician-Focused Payment Model (PFPM)

In the CY 2017 QPP Final Rule (81 FR 77496) CMS finalized the requirement that PFPMs be tested as APMs with Medicare as a payer. In the proposed rule, CMS sought comments on whether to broaden the

definition of PFPM to include payment arrangements that involve Medicaid or the Children's Health Insurance Program (CHIP). CMS did not finalize this proposal and, for now, the Physician-focused Technical Advisory Committee (PTAC) will be limited to considering Medicare payment proposals. ASA was disappointed that CMS did not finalize this proposal. Through our experience with the PSH models that have been implemented across the country, evidence has shown that children and adults have different needs and developing different strategies to meet these needs is critical. Maternity care-related proposals would also not be captured if the focus is limited to the Medicare program, missing an opportunity to use the APM model to pursue the Triple Aim in this very high volume category of services.

This more narrow approach will not encourage the development of models that cross program silos and apply across different age ranges and populations nor do we believe it is an effective approach to exclude Medicaid, which is a massive government payor. ASA appreciates that the PTAC process is just one of multiple avenues in the development of payment models but we believe it can play an important role in this area and encourage CMS to allow PTAC to take a broad-based approach in the type of models it reviews.

If CMS is excluding PTAC from reviewing non-Medicare programs, ASA strongly recommends that the agency ensures that there are sufficient other pathways for the development of pediatric and maternity models both independently as well as models that can interact with the Medicare program.

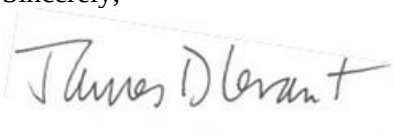
Extreme and Uncontrollable Circumstances

Over the past several months, numerous clinicians have been affected in many areas of the country due to Hurricanes Harvey, Irma, and Maria, which occurred during the 2017 MIPS performance period. For the transition year, if a MIPS eligible clinician's CEHRT is unavailable as a result of extreme and uncontrollable circumstances (e.g., a hurricane, natural disaster, or public health emergency), the clinician may submit a hardship exception application to be considered for reweighting of the Advancing Care Information performance category. This application is due by December 31, 2017. This final rule with comment period extends this reweighting policy for the three other performance categories (Quality, Cost, and Improvement Activities) starting with the 2018 MIPS performance period. This hardship exception application deadline is December 31, 2018.

ASA appreciates the agency considering the unique and challenging circumstances many Medicare providers have found themselves in recently due to severe weather conditions. We fully support the extreme and uncontrollable circumstances hardship exception and urge CMS to implement as described in the Final Rule.

Thank you for your consideration of our comments. We would be very glad to follow up with you as necessary on any issues on which you need additional information or would like further discussion. Please contact Sharon Merrick, M.S., CCS-P, ASA Director of Payment and Practice Management or Matthew Popovich, Ph.D., ASA Director of Quality and Regulatory Affairs at (202) 289-2222.

Sincerely,



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APPENDIX A – SUMMARY OF RECOMMENDATIONS

MIPS

MIPS General Policies

MIPS Performance Period

- Moving forward, ASA urges CMS to post QCDR measure specifications by December 1. Eventually, ASA would like to see QCDR measures published by November 1 in the QPP Final Rule, similar to the process used for MIPS measures. We believe this is a fair and reasonable approach. Registries and practices need time to update their systems so they are prepared to collect the appropriate measure data. In the case of completely new measures, clinicians need to understand the targets they are trying to meet and will need time to familiarize themselves with the measures and their associated benchmarks. Given that CMS is moving to a 12-month reporting period, the timely posting of measures becomes even more critical.

Multiple Submission Mechanisms

- ASA recommends that as CMS reviews operational issues, CMS should address administrative structure, information flow and responsibilities for the various entities involved when eligible clinicians submit measures and activities through multiple submission mechanisms.

- ASA recommends that CMS scrutinize how benchmarks are impacted when a measure is submitted through multiple mechanisms. The information should be publicly released and if differences are noted a separate benchmark should be posted when a measure is submitted via multiple mechanisms.

- ASA recommends that CMS make all data that impacts the use and scoring of a measure available at the beginning of a reporting period.

Facility-based Measures

- ASA recommends CMS use 2018 to further develop the facility-based measures program both from an internal and external perspective. CMS should better detail how hospital quality scores will be translated into MIPS Quality and Cost scores and how will eligible clinicians and their practices be informed that they have met the threshold for choosing the facility-based reporting option. Finally, ASA recommends that CMS automatically select the score that is more favorable (facility-based reporting or regular MIPS reporting for those eligible clinicians reporting through both mechanisms).

Virtual Groups

- ASA understands that the MACRA statute limits the agency to offering the virtual group option to solo practitioners and groups of 10 NPIs per TIN or less. If the benefits of the virtual group option are borne out, ASA encourages CMS to explore if there are other pathways for the agency to implement a virtual group type of model for groups larger than 10 NPIs per TIN.

- ASA recommends CMS collect and publicly report, in a timely manner, data on how many virtual groups were created, general characteristics of virtual groups (e.g. size, geographic locations, specialty(s)) and the performance in MIPS of solo and small practices participating in MIPS via virtual groups versus those participating in MIPS independently. This data should be used to guide CMS in the future development and potential expansion of virtual groups.

Application of the MIPS Payment Adjustment on Part B Drugs

- ASA recommends that CMS monitor and report in a timely manner on the differences in those practices that bill for Part B drugs (where the NPI billing the drug and the NPI billing the administration service can be linked) and those who do not and the differences in MIPS payment adjustment. Understanding and evaluating the impact of the various policies of the MIPS program is important as the program matures. The application of performance-related adjustments on reimbursement for Part B drugs is largely uncharted territory for the agency. This makes it even more critical that the agency closely monitor and report on its impact.

MIPS Performance Threshold

- ASA urges CMS to take an alternative approach in setting the MIPS performance threshold in 2019. Instead of basing the threshold on the mean or median of a previous period, CMS should increase the threshold each year during an extended transition period. By using this approach, the program will become more challenging for eligible clinicians to succeed, but it would allow the agency to continue to have some control and make appropriate adjustments. Over time as the program matures, setting the performance threshold on the mean or median may perceived to be less arbitrary and more reflective of the program's original intent.

<u>Quality Performance Category</u>

Data Completeness Threshold

- ASA urges CMS to carefully monitor the performance of the wide-range of MIPS clinicians and their experience in meeting these thresholds prior to further increasing the data completeness threshold. In future rulemaking, CMS should display data supporting that an increased completeness threshold can be met by a significant majority of MIPS participants to substantiate any increased data completeness threshold. The marginal benefit of increasing the data completeness threshold must also be balanced by the consideration of the marginal cost to the clinician's practice.

Topped Out Measures

- ASA recommends that CMS should apply the same standards of removing topped out measures over a four-year period for QCDR measures as CMS has applied to MIPS quality measures. This process should be retrospectively applied to QCDR measures approved for the 2017 Performance Year.

Data Errors in the QCDR Environment

- ASA requests CMS provide retrospective data to the registries to help mitigate such circumstances. Moreover, when individuals or practices withhold Medicare billing data, this unavailable data should not be counted against the registry as an inaccuracy or error since the registry has no way to identify this issue in advance without access to CMS' claims data.

- ASA requests that CMS publish the types of circumstances that will constitute an "error" with respect to identification of data inaccuracies as it relates to probation and disqualification of registries.

Anesthesiology Fact Sheet

- ASA requests that future materials developed for anesthesiologists and certified registered nurse anesthetists also include reference to "Anesthesiologist Assistants." We also ask that CMS develop an FAQ or other materials to help practices understand that Certified Anesthesiologist Assistants who meet program thresholds are considered MIPS eligible clinicians.

Advancing Care Information (ACI) Performance Category

21st Century Cures Exclusion for Ambulatory Surgical Center (ASC)-based Eligible Clinicians

- ASA urges that when determining of the hospital-based clinician threshold has been met for the purposes of the ACI exemption, CMS should expand the definition of hospital-based clinicians to include physician anesthesiologists and other MIPS eligible clinicians who work principally in facility settings by pooling the utilization of services provided in the inpatient (POS 21), on-campus outpatient (POS 22), off-campus outpatient (POS 19), emergency room (POS 23), and ASC (POS 24) settings.

Cost Performance Category

Cost Measures and Attribution

- ASA recommends that, as CMS develops new cost measures, that the agency develop a methodology that equitably attributes resources to all providers and facilities involved in rendering the service. We believe such a methodology is aligned with the concept of shared accountability.

Advanced Alternative Payment Models (APMs)

Definition of Physician-Focused Payment Model (PFPM)

- If CMS is excluding PTAC from reviewing non-Medicare programs, ASA strongly recommends that the agency ensures that there are sufficient other pathways for the development of pediatric and maternity models both independently as well as models that can interact with the Medicare program.

Extreme and Uncontrollable Circumstances

- ASA appreciates the agency considering the unique and challenging circumstances many Medicare providers have found themselves in recently due to severe weather conditions. We fully support the extreme and uncontrollable circumstances hardship exception and urge CMS to implement as described in the Final Rule.