American Society of Anesthesiologists®

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December 19, 2016

Acting Administrator Andrew Slavitt
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-5517-FC Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, Final Rule with Comment Period

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

Dear Acting Administrator Slavitt:

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 Period. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repealed the Sustainable Growth Rate (SGR) and established two pathways for clinicians in the Medicare Part B program: the Merit-Based Incentive Payment System (MIPS) and incentives for participation in Advanced Alternative Payment Models (APMs). The Centers for Medicare and Medicaid Services (CMS) established the Quality Payment Program (QPP) which encompasses both MIPS and Advanced APM initiatives. The implementation of this new program will have significant impact on physician anesthesiologists and the patients they serve. ASA welcomes the opportunity to work with you to ensure that our members can successfully participate in this new program and continue to provide Medicare beneficiaries high quality and high value healthcare.

ASA has a long history of investment in initiatives aimed at improving the safety, quality and efficiency of care for the surgical patient. We have developed a clinical registry, operated by the Anesthesia Quality Institute (AQI) that contains detailed files on millions of anesthetic administrations by thousands of physician anesthesiologists across different care settings. These data have led to dozens of published reviews to inform the safe practice of anesthesia.

We have sponsored the Perioperative Surgical Home (PSH) Collaboratives in almost 60 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. These goals are met through shared decision-making and seamless continuity of care for the surgical patient, from the moment the decision for surgery

is made, all the way through recovery, discharge and beyond. In these collaboratives, care redesign exercises have improved outcomes and reduced cost. We are about to launch an expanded series of demonstrations for physician anesthesiologists to further develop the key concepts of care coordination for the surgical patient and maximize the benefits to be derived from these opportunities. Physician anesthesiologists represent the common pathway for nearly all surgical and procedural care patients and can contribute to improved quality and more cost effective care.

ASA appreciates the agency's responsiveness to stakeholders' comments and finalized policies that reflect flexibility in the implementation of the program. We especially appreciate the multiple participation options CMS is offering for the 2017 Performance Year from minimal reporting that will allow Eligible Clinicians to avoid a negative payment adjustment to partial and complete reporting which offers opportunities for positive payment adjustments. ASA also strongly supports the reduction of the reporting period from one year to 90 days for the 2017 Performance Year. We believe these modifications will encourage a smooth transition to the new payment system.

In summary, our comments pertain to the following CMS proposals:

- *MIPS-related Accommodations for Hospital-based Eligible Clinicians:* In light of the enactment of H.R. 34 the "21st Century Cures Act" CMS will exempt Eligible Clinicians who furnish "substantially all" of their Medicare-covered professional services in an ambulatory surgical center (ASC) (POS 24) from the ACI category. In the Final Rule CMS agreed to expand the definition of hospital-based to the on-campus outpatient hospital setting (POS 22) making those Eligible Clinicians meeting the 75 percent threshold in the hospital setting exempt from the ACI category. Therefore, ASA recommends CMS to treat the services provided by Eligible Clinicians practicing in both ASCs and hospital outpatient settings as cumulative for purposes of determining who is exempt from the ACI category. If a physician furnishes a substantial number of services in an ASC and a substantial number in a qualifying hospital setting such that cumulatively the total number of services exceeds the 75 percent threshold, the physician should be treated as hospital- or facility-based for purposes of determining if the eligible clinician is exempt from the ACI category. In addition, ASA recommends CMS further expand the definition of hospital-based Eligible Clinicians to include clinicians furnishing services in off-campus hospital (POS 19).

- *Reweighting to Quality for those Who Do Not Report Advancing Care Information (ACI)*: ASA recommends that for clinicians who do not have ACI scores, CMS substitute a score with a 50 percent base and with the Eligible Clinician's Quality score substituting for the ACI performance score. This approach aligns with the CMS stated goal of allowing the Quality score to carry additional weight when an ACI score is unavailable, while correcting the fundamental disadvantage against these MIPS Eligible Clinicians present in the current finalized policy.

- *Certified Anesthesiologist Assistants (CAAs):* ASA recommends that CMS make it clear in all relevant educational information disseminated by the agency regarding MIPS eligibility that CAAs are included in the definition of MIPS Eligible Clinicians.

- *Anesthesiology Specialty Measure Set:* ASA requests further clarification from CMS to ensure that physician anesthesiologists will be appropriately assessed when reporting fewer than six measures in the Anesthesiology Specialty Measure Set.

Our detailed comments are set forth below.

Merit-based Incentive Payment System (MIPS)

ASA appreciates the accommodations CMS made in the Final Rule but continues to have concerns with certain policies that we urge CMS to address.

MIPS-related Accommodations for Certain Eligible Clinicians

CMS recognizes that certain Eligible Clinicians may not be able to meet MACRA performance requirements based on factors outside of their control. ASA appreciates the accommodations made by CMS for these providers. Both hospital-based and non-patient facing Eligible Clinicians are exempted from the ACI performance category. CMS will redistribute the weight of the ACI category to Quality when the provider does not receive a score for the ACI category. Additionally, CMS reduced the reporting requirement for the Improvement Activities Performance Category for non-patient facing Eligible Clinicians from 4 medium-weight/2 high-weight to 2 medium-weight/1 high-weight category.

ASA agrees that these are important and necessary accommodations for these types of clinicians who either do not control the Electronic Health Record (EHR) systems at their facilities or do not furnish the scope of services that would allow complete reporting in these categories. Because these accommodations reflect an understanding of the limitations certain types of clinicians have with respect to reporting performance in these categories, we believe it is critically important that CMS define appropriate criteria for both hospital-based and non-patient facing Eligible Clinicians that fairly and correctly identify clinicians with such limitations on performance reporting.

For those anesthesiologists who currently have, or in the future will have, access to certified EHR technology (CEHRT), we remain concerned about their capacity to report this use through relevant and meaningful measures. The current set of ACI measures are clearly designed for settings other than the operating room. We appreciate CMS acknowledgement of our concern in the Final Rule and the invitation extended to us. ASA is eager to work with CMS toward a portfolio of ACI measures that accurately reflect use of technology that improves the quality, value and safety of anesthesia care.

Hospital-based Eligible Clinicians

In the Proposed Rule, CMS proposed to define a hospital-based MIPS eligible clinician as one who furnishes 90 percent or more of his or her covered professional services in an inpatient hospital or emergency room setting in the year preceding the performance period. In the Final Rule, CMS expanded the definition of hospital-based to include on-campus outpatient hospital

(POS 22) in addition to the previous proposed settings of inpatient hospital (POS 21) and emergency room (POS 23). CMS also lowered the threshold of professional services furnished in a certain site of service to determine hospital-based MIPS Eligible Clinicians from 90 percent to 75 percent.

ASA was very pleased to see CMS expand the definition of hospital-based to the on-campus outpatient hospital setting. Our members provide care to patients in a variety of facilities and care settings that include inpatient hospital settings, outpatient hospital departments, ASCs and office-based locations. While we appreciate and believe the modification in the Final Rule is in the right direction, we urge CMS to further expand the definition to include off campus outpatient hospital (POS 19) settings. We presume that, in light of the enactment of Sections 16003 and 4002 of H.R.34, the "21st Century Cures Act," CMS will likewise reweight the ACI category to zero for physicians who furnish "substantially all" of their Medicare-covered professional services in an ASC. To that end, we also urge CMS to treat facility-based services as cumulative. If a physician furnishes a substantial number of services in an ASC and a substantial number in a qualifying hospital setting such that cumulatively the total number of services exceeds the 75 percent threshold, the physician should be treated as hospital- or facility-based for purposes of evaluating the physician's relationship with the ACI category. It would be illogical and unfair to subject such a physician to the ACI category simply because he/she does not achieve the 75 percent threshold in a single setting.

The rationale for making the distinction for hospital-based clinicians is to recognize the relationship of clinicians with the facility on both a clinical and administrative level. This relationship does not substantially differ across facility settings from inpatient, outpatient (on and off campus) and the ASC setting. Since CMS is excusing hospital-based physicians who practice above the threshold level in an inpatient or emergency department setting or in an on-campus out-patient setting, and now, per statute, must do the same for physicians who furnish substantially all of their services in the ASC setting, there would be no rational basis for continuing to exclude off-campus outpatient settings as the sole outlier.

Congress directed CMS to exempt from the ACI payment adjustments physicians who furnish substantially all of their Medicare-covered professional services in an ASC in part because there is no EHR certified for the ASC setting. It is patently unfair to penalize providers for factors that are out of their control. In doing so, however, Congress was not thinking about this issue in isolation. The concerns at the root of this change are comparable to the reasons why Congress also created special exceptions for hospital-based physicians. For these reasons, we encourage CMS to also look at these hurdles as a single problem worthy of a comprehensive solution, and to therefore add claims submitted for all qualifying places of service toward a singular 75 percent threshold. Greater pressure must be put on technology vendors to develop technology that meets certification standards, but until this is available in the ASC setting, the same accommodations available for hospital based clinicians must be extended to those in the ASC environment, and services furnished in all of these settings should be treated as a collective whole.

In light of the enactment of H.R. 34 the "21st Century Cures Act" CMS will exempt eligible clinicians who furnish "substantially all" of their Medicare-covered professional services in an ambulatory surgical center (ASC) (POS 24) from the ACI category. In the Final Rule CMS

has agreed to expand the definition of hospital-based to the on-campus outpatient hospital setting (POS 22) making those Eligible Clinicians meeting the threshold in the hospital setting exempt from the ACI category. Therefore, ASA recommends CMS to treat the services provided by eligible clinicians practicing in both ASCs and hospital outpatient settings as cumulative for purposes of determining who is exempt from the ACI category. If a physician furnishes a substantial number of services in an ASC and a substantial number in a qualifying hospital setting such that cumulatively the total number of services exceeds the 75 percent threshold, the physician should be treated as hospital- or facility-based for purposes of determining if the eligible clinician is exempt from the ACI category. In addition, ASA recommends CMS further expand the definition of hospital-based Eligible Clinicians to include clinicians furnishing services in off-campus hospital (POS 19).

Regarding non-patient-facing Eligible Clinicians, CMS introduced the term "non-patient facing" to apply to MIPS eligible clinicians "who typically furnish services that do not involve face-to-face interaction with a patient." In the Final Rule CMS indicates that they believe most anesthesiologists will be non-patient facing. ASA is pleased with this accommodation and believes it appropriately addresses the challenges our members may face meeting MIPS requirements, although we do have concerns with the nomenclature. The application of this category is based on services reported by the provider. ASA will monitor how it is applied to ensure that our members who fall under this category are accurately captured.

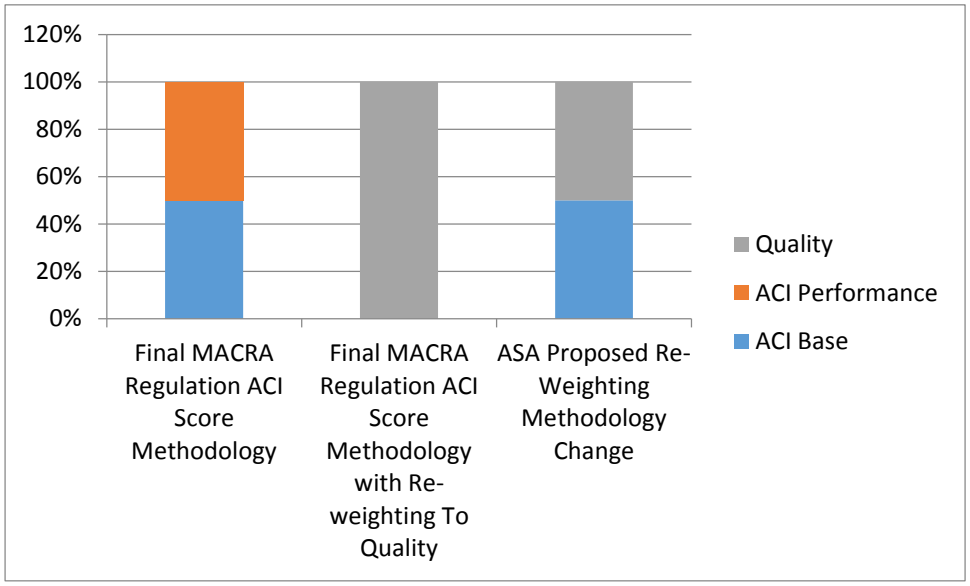
Reweighting to Quality for Those Who Don't Report Advancing Care Information (ACI)
CMS's proposal to assign Cost and ACI Performance Category weights to the Quality Performance Category of MIPS means that quality measures (values and distribution) will have a disproportionate impact on specialties that are unlikely to participate in the other performance categories. In those scenarios where a MIPS eligible clinician would not receive a score for ACI or Cost, CMS intends to redistribute the weight of each category to Quality. For those with no ACI score in 2017, the ACI score will be added to Quality. For 2017, the Cost Performance Category will not be scored, but its earlier proposed weight was nonetheless transferred to the Quality performance category (increasing the Quality weight from 50 percent to 60 percent). As a result of these decisions, the Quality Performance Category will be weighted at 85 percent and CPIA at 15 percent next year. Physician anesthesiologists are particularly likely to fall into this group in 2017 and in future years because of the Cost attribution methodology and the barriers they face in reporting ACI measures.

Because nearly all users of EHR technology will qualify for the ACI "base score" of 50 percent, non-EHR users reweighting this category to the Quality Performance Category will sacrifice this favorable scoring feature and be systematically disadvantaged. We recommended in our Proposed Rule comments that CMS substitute a score for all Eligible Clinicians who will not have an ACI base score (i.e. 50 percent) and reweight the remaining ACI performance score to the Quality component. This approach aligned with the CMS stated goal of allowing the Quality score to carry additional weight when an ACI score is unavailable.

- MACRA Final Rule ACI Score
    - ACI Base (50) + ACI Performance (Possible 80 points, capped at 50)
- MACRA Final Rule ACI Score Replacement when ACI Unavailable
    - Quality (Possible Score 0-100 relative to denominator)

- ASA Recommended ACI Score Replacement when ACI Unavailable
    - ACI Base (50) + Quality Performance (Possible 100 points, re-scaled 0-80 and capped at 50)

Figure 1. ACI Score Components when ACI score is available and when ACI score is re-weighted, CMS Final Rule and ASA Recommended Change



Although we were disappointed that CMS did not address our proposals in our previous comment letter, we are taking this opportunity to reiterate our analysis, providing a more streamlined explanation.

As a first step we considered the range of possible ACI and Quality scores. The Quality score can range from 0 percent to 100 percent of the denominator for Quality. By contrast, assuming the MIPS Eligible Clinician meets the minimum reporting and data protection thresholds for ACI, the ACI score effectively has a more constricted range from 50 percent to 100 percent. Table 1 illustrates the range of possible scores for these components.

Table 1. Range of Possible Scores for ACI and Quality Performance Categories

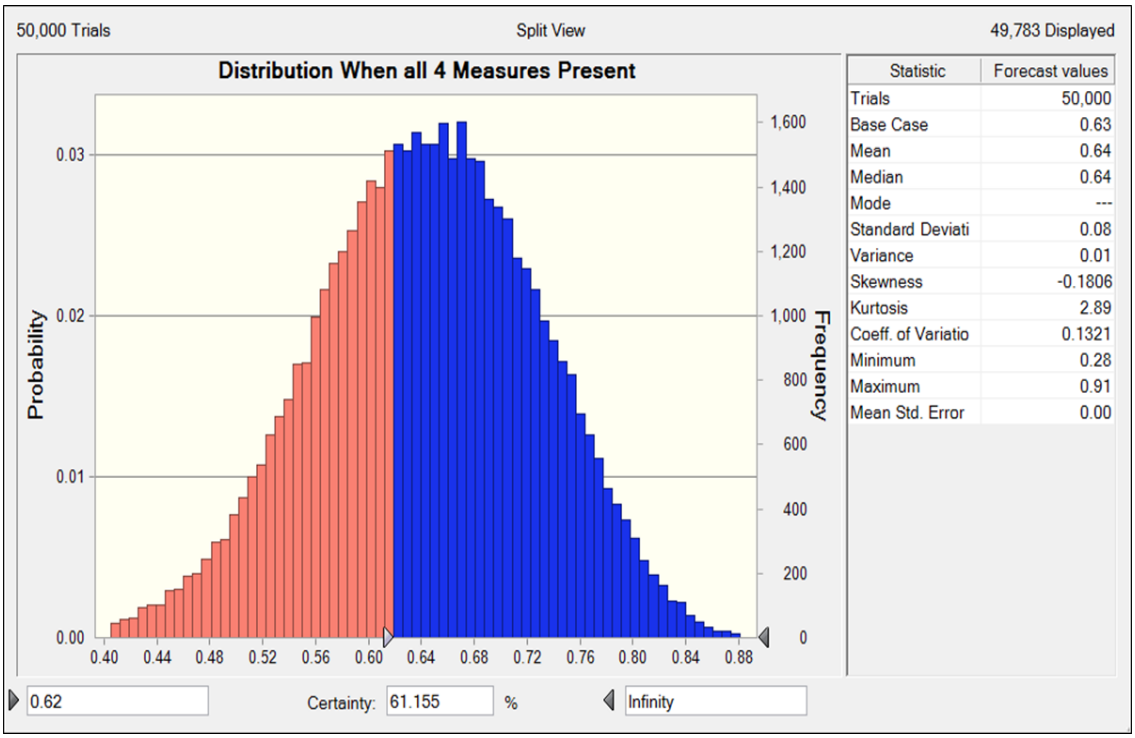
	ACI*	Quality^
Base Score	50	0
Minimum Performance Score	0	0
Maximum Peformance Score	100	100
Cap on Total Category Score	100	100
Range of Possible Scores	50-100	0-100

*Assumes minimum standards met for ACI
^As a percentage of the denominator

ASA then conducted a simulation model to test the expected distribution of MIPS scores for Eligible Clinicians participating in all four MIPS performance categories and compared this group to Eligible Clinicians who are unable to participate in the Cost and ACI Performance Categories (i.e., non-patient-facing Eligible Clinicians). Our analysis in our Proposed Rule

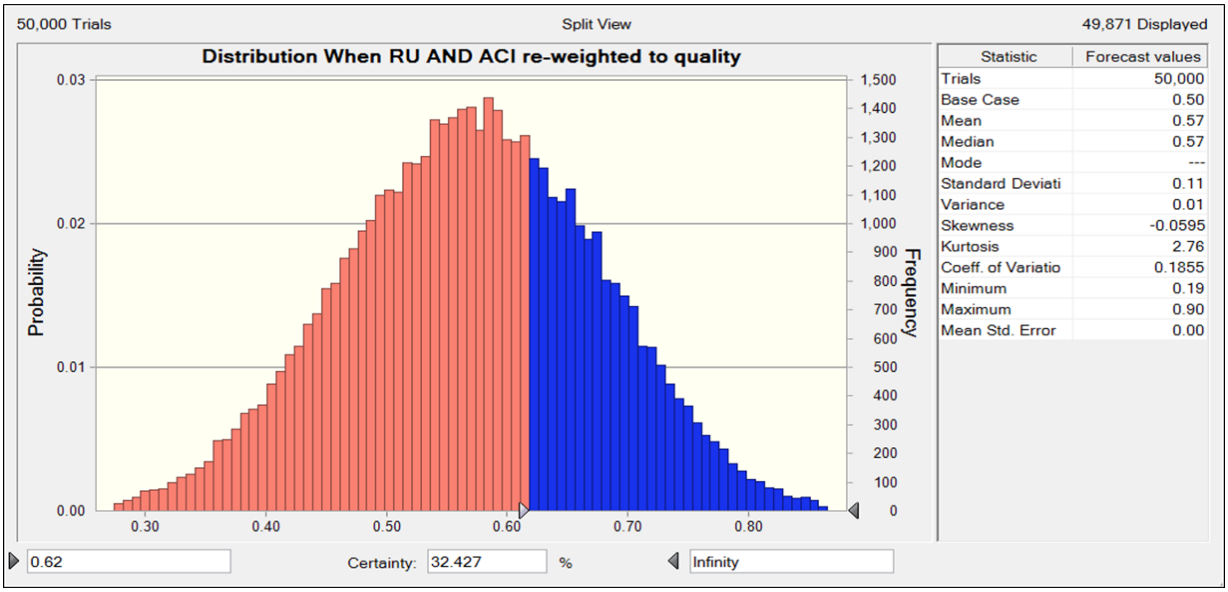
comments showed that Eligible Clinicians without ACI scores were substantially less likely to receive positive adjustments than those who were able to report under all four categories. We reproduce those charts from our Proposed Rule comments below.

Figure 2. Expected distribution of MIPS scores for physicians with 4 component scores



61% of MIPS physicians with 4 component scores are projected to receive a positive adjustment.

Figure 3. Expected distribution of MIPS scores for physicians who cannot participate under Resource Use and ACI



Only 32% of physicians without RU and ACI scores (i.e., non-patient-facing Eligible Clinicians) are expected to have a positive MIPS adjustment.

ASA recommends that for clinicians who do not have ACI scores, CMS substitute a score with a 50 percent base and with the Eligible Clinician's Quality score substituting for the ACI performance score. This approach aligns with the CMS stated goal of allowing the Quality score to carry additional weight when an ACI score is unavailable, while correcting the fundamental disadvantage against these MIPS eligible clinicians present in the current finalized policy.

<u>Certified Anesthesiologist Assistants (CAAs)</u>

In the Proposed Rule, CMS identified MIPS Eligible Clinicians as including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists (CRNAs) and groups that include such clinicians. CMS noted that the term "CRNA" would be defined as found in section 1861(bb)(2) of the Act, which states, "The term "certified registered nurse anesthetist" means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant."

In the Final Rule CMS confirmed that anesthesiologist assistants are considered eligible for MIPS beginning with the CY 2017 Performance Period. ASA is pleased that CMS was responsive to comments from ASA and other stakeholders, and clarified that CAAs are included in the definition of Eligible Clinicians starting with the 2017 Performance Period. While ASA is pleased with this clarification, we continue to believe that there is confusion and misunderstanding surrounding this issue and more transparency is needed. More specifically, the educational material developed by CMS indicates that CRNAs are eligible for MIPS beginning with the CY 2017 Performance Period. Yet, while statutorily CAAs would fall under the CRNA

definition, this is not necessarily clear to those accessing CMS MIPS-related educational material. ASA believes to promote greater transparency and understanding, when CRNAs are identified as eligible for MIPS in educational materials, CMS should also specifically identify CAAs.

ASA recommends that CMS make it clear in all relevant educational information disseminated by the agency regarding MIPS eligibility that CAAs are included in the definition of MIPS Eligible Clinicians.

Anesthesiology Specialty Measure Set

ASA thanks CMS for acknowledging and addressing a number of quality component topics that will have a significant impact on physician anesthesiologists next year. In particular, we appreciate CMS recognizing MIPS #424: Perioperative Temperature Management as an outcome measure. CMS communication and discussions with us over the past year on this measure were constructive and transparent. ASA also applauds the decision of CMS to remove the cross-cutting measure requirement for the quality component as well as in the Qualified Clinical Data Registry (QCDR) reporting mechanism. Although a handful of anesthesiologists may be able to report MIPS #130 or MIPS #317, the cross-cutting measures as previously designated rarely capture physician anesthesiologist workflows or billing patterns.

ASA requests additional clarity from CMS on the scoring of the Quality component for physicians who may not be able to report the minimum number of six measures. We appreciate that CMS has moved away from an all-or-nothing approach to scoring Eligible Clinicians, however, the challenge for some anesthesiologists, particularly those working in an ambulatory or emergency room setting, remains. We ask CMS for further clarification on the algorithms they will use to ensure physician anesthesiologists are reporting all measures that are applicable to their practice. For example, in some scenarios, physician anesthesiologists working in an ambulatory setting may only be able to report MIPS #404 and #426. We welcome the opportunity to work with CMS to ensure the algorithms used to determine which measures apply to physician anesthesiologists in certain settings is accurate.

Anesthesiology Specialty Measure Set: ASA requests further clarification from CMS to ensure that physician anesthesiologists will be appropriately assessed when reporting fewer than six measures in the Anesthesiology Specialty Measure Set.

Alternative Payment Models (APMs)

While the ASA notes that for the vast majority, participation in the QPP will be through the MIPS pathway, we, nevertheless, see the potential value of Advanced APM participation for our members and other specialists. The ASA is committed to the agency's stated goals of moving from volume to value and have spearheaded efforts to design a patient care model to meet those goals.

Perioperative Surgical Home (PSH)

As part of our shared vision with CMS of shifting healthcare delivery from volume to value, the ASA has been organizing and partnering with other medical specialties to implement the Perioperative Surgical Home (PSH) care delivery model in healthcare organizations across

America. The PSH is a patient-centered, physician-led, interdisciplinary and team-based system of coordinated patient care, which spans the entire experience from decision of the need for any invasive procedure—surgical, diagnostic, or therapeutic—to discharge from the acute-care facility and beyond. The PSH strives to achieve the triple aim of better patient experience, better healthcare, and reduced expenditures for all patients undergoing surgery and invasive procedures.

Since the publication of the MACRA Proposed Rule, the ASA has been assessing the PSH's core strengths within this new Advanced APM landscape. Since the PSH is a multi-disciplinary approach to patient care, it has several unique qualities that position it well to have a varied and robust impact on physicians who will be reporting under both the MIPs and the Advanced APM pathway. Several of these strengths are listed below:

- Team-based and physician-focused: Physicians across the care spectrum can participate.
- Proven track record of cost and care: Data collected from organizations participating in the PSH Collaborative have shown consistent improvement in patient care and cost reduction.
- Flexibility with current payment initiatives: The PSH payor-agnostic framework aligns well with several of the existing and emerging value-based payment models under CMS and private payor payment initiatives.
- Flexibility for practitioners: As an integrated care delivery model, the breadth and depth of clinical settings and patient subgroups can be considered through a tailored approach to care.

The ASA is excited about the improvement to patient care and physician team integration that the PSH model can bring to this area of payment reform. Considering our continued focus on patient care improvement and care integration, we hope that CMS considers feedback from outside stakeholders (especially practicing physicians) on each new proposed APM. Models that are developed that focus simply on cost reduction or meeting minimum reporting requirements, without creating effective mechanisms to help organizations and physicians alike systemically improve care and meet quality targets, create incentives in which patient care improvement is a potential byproduct, not a goal. We encourage CMS to evaluate efficient means to consider the real-world feasibility and clinical efficacy of models from relevant physicians and other healthcare professionals involved in the model under review. We look forward to have an open dialogue with CMS and other stakeholders about the future of Advanced APMs and how the PSH can be integral.

Expanding Participation in Advanced APMs

The ASA is pleased that CMS acknowledges the limited opportunities that will exist in 2017 for specialists to participate in an Advanced APM. It is encouraging that the agency has already begun work on expanding the current suite of CMMI Innovation models to fit into the Advanced APM pathway. CMS in July proposed new models, one of which expands the CJR model to be considered an Advanced APM. Providers who are required to be in these programs should have reasonable opportunities to realize the scoring advantages within the Advanced APM track. The ASA is encouraged with these initial signs that opportunities will increase and is committed to working with the agency on this important expansion process.

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,

Jeffrey Plagenhoef, M.D.
President
American Society of Anesthesiologists