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VIA Electronic Submission to http://www.regulations.gov

September 15, 2020
Ms. Seema Verma Administrator
Centers for Medicare & Medicaid Services, Department of Health and Human Services
Attn: CMS-1734-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: **[CMS-1734-P]** Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma:

The American Society of Anesthesiologists® (ASA), on behalf of our over 53,000 members, appreciates the opportunity to comment on several of the issues in the above-captioned Proposed Rule. Medicare is an essential program that currently provides healthcare benefits to 58 million Americans. ASA is committed to working with the Centers for Medicare and Medicaid Services (CMS) to promote policies that support high quality care in a fiscally sustainable manner. We are pleased to work with the agency to create a healthcare system that reduces administrative burden on practicing physicians, supports the provision of high quality, cost-effective care and is forward thinking in the development of innovative solutions to overcome the challenges facing clinicians, patients and the Medicare system overall. 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:

- Calculation of the CY 2021 PFS RBRVS and Anesthesia Conversion Factors (CFs)
- Practice Expense (PE) RVUs
- Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID–19 Pandemic
- Proposal to Remove Selected National Coverage Determinations

- Telehealth and Other Services Involving Communications Technology
- Direct Supervision by Interactive Telecommunications Technology
- Quality Payment Program
    - MIPS Value Pathways (MVPs)
    - MVP Guiding Principles
    - MVP Development
    - MVP Submission Questions and Criteria
    - MVPs and Patient Engagement
    - MVPs and Quality Measures
    - MIPS Performance Category Measures and Activities
    - MIPs Final Score Methodology
    - Quality Measure Benchmarks
    - Third Party Intermediaries – Qualified Clinical Data Registries and Qualified Registries

A summary of our recommendations can be found in Appendix A.

Calculation of the CY 2021 PFS RBRVS and Anesthesia Conversion Factors (CFs) (Section VIII.)

Medicare physician payment is based on the application of a dollar-based conversion factor to work, practice expense (PE) and malpractice relative value units (RVUs), which are then geographically adjusted. The proposed 2021 Anesthesia CF is $19.9631, in comparison to the 2020 Anesthesia CF of $22.2016. This reduction of $2.24 represents a negative 10.06 percent adjustment. The 2021 proposed RBRVS CF is $32.2605. This represents a decrease of $3.83 or negative 10.61 percent from the 2020 RBRVS CF of $36.0896.

ASA has grave concerns about the magnitude of the cuts to payments for the services of anesthesiologists. We recognize the limited authority CMS has to modify statutorily mandated budget neutrality adjustment when calculating updates to the conversion factors, however, we are alarmed at the potential cascading impacts on both physician practices and clinical patient outcomes. Resolution of this issue will require action by Congress and others outside of CMS. ASA urges CMS to coordinate with these entities as it relates to updates to the fee schedule and processing claims. The magnitude of the proposed cuts to the anesthesia and RBRVS CFs is significant and has the potential to have a devastating impact on physician practices while the country continues to struggle with the COVID-19 pandemic. For example, the 2021 proposed Anesthesia CF of $19.9631 is practically the same as the 1991 Anesthesia CF of $19.27. The proposed RBRVS CF of $32.2605 is $4 less than the RBRVS CF in 1998 of $36.6873, the first year that CMS established a single RBRVS CF. For all of these reasons, CMS must address the negative impact of this proposed cut.

The COVID-19 pandemic has wreaked havoc on all aspects of life in the United States and across the globe. Healthcare providers have played a critical role in meeting the challenges of providing care to COVID-19 patients and maintaining access to care for all other patients. The pandemic has also created historic financial pressures on large and small practices and health systems across the country. Beyond the financial pressure, providers have had to develop new ways of providing care to reduce exposure to the virus for patients and providers. As practices

across the country are in the midst of a financial crisis an additional almost 11% payment cut on top of the revenue reductions they have already been experiencing will put practices and patient access to care at risk.

Data indicates that physician practices across the country have reported steep declines in revenues. Patient volume has dropped either because patients are avoiding all non-emergency care or social distancing rules results in reduced capacity to see the same volume of patients. A recent survey from the Centers for Disease Control and Prevention found that more than 40% of US adults said they delayed or avoided medical treatment during the pandemic.[1] While telehealth has been helpful for many practices to continue to see patients, it is not an option for all. Even those practices who have increased their utilization of telehealth services, are still experiencing significant revenue declines.[2] There is some indication that physicians who are closer to retirement may be forced into early retirement with an inadequate replacement physician workforce, which will only exacerbate patient access to care issues.

Anesthesiologists in particular have played a unique role in the COVID-19 pandemic. The pandemic has increased the need for anesthesiologists to provide critical care services for the sickest COVID-19 patients. All anesthesiologists have training in critical care medicine during our residency programs. Some anesthesiologists practice critical care medicine full time as intensivists. Those who practice in the operating room use ventilators on most of their patients, including those who are from critical care units. Anesthesiologists also specialize in pain medicine and they, too, have the background to assist in a crisis. Anesthesia care for patients during the pandemic involves a greatly increased risk to the anesthesia professional, especially during virus aerosolizing procedures such as endotracheal intubation. When providing critical care on the frontlines of the pandemic, anesthesiologists are at high risk of exposure to COVID-19 and are putting themselves at a greater risk to ensure appropriate care. Yet, in the proposed rule CMS estimates a negative 8% cut for anesthesiologists and critical care specialists. We fear that many of these practices that are under significant financial stress already will not be able to weather an additional payment cut at this time.

ASA is also concerned that these payment cuts will undermine the government's significant efforts to support healthcare practices during the pandemic. ASA thanks the Administration and Congress for recognizing the financial stress of the COVID-19 pandemic on physicians and practices and for allocating resources to critical relief efforts such as the Provider Relief Fund, the Paycheck Protection Program and Small Business Administration loans. These efforts along with the various waivers and flexibilities implemented during the PHE have provided critical support to physicians and hospitals. While these programs have aided the U.S. healthcare system during this crisis, we fear that this proposed PFS payment cut will derail and undo all of that great work. The COVID-19 pandemic has caused unexpected and significant economic challenges that threaten the viability of medical practices throughout the country. We ask CMS to take measures to protect our nation's medical providers and the patients we serve.

CMS utilization assumptions for new add-on code GPC1X contributes significantly to the increase in spending that is driving the 10.61% budget neutrality adjustment. ASA does

[1] Czeisler MÉ, Marynak K, Clarke KE, et al. Delay or Avoidance of Medical Care Because of COVID-19–Related Concerns — United States, June 2020. MMWR Morb Mortal Wkly Rep 2020;69:1250–1257. DOI: http://dx.doi.org/10.15585/mmwr.mm6936a4external

[2] Rubin R. COVID-19's Crushing Effects on Medical Practices, Some of Which Might Not Survive. *JAMA.* 2020;324(4):321–323. doi:10.1001/jama.2020.11254

not believe these estimates are reasonable and urges CMS to review and reduce its utilization assumptions for GPC1X. The 10.61% reduction in the Medicare RBRVS CF and similar reduction in the Anesthesia CF is the result of an estimated additional $10.2 billion in proposed spending of which $3.3 billion is estimated to come from the reporting of GPC1X. In the CY 2020 PFS Final Rule CMS estimated that the 21 specialties that bill E/M codes would bill code GPC1X with 100% of their office/outpatient visits. ASA has significant concerns with this utilization assumption. We find it highly unlikely that all 21 specialties would furnish that level of complex physician work for every patient coming in for an E/M visit. Additionally, GPC1X will be a new code in 2021 and one that is unlike any other on the physician fee schedule. It always takes a period of time before clinicians start reporting new codes. With the confusion around the appropriate reporting of this code, it may take even longer than usual. ASA reiterates our recommendation made at the beginning of this letter that CMS should reconsider and reduce their utilization assumptions for this code to better reflect the more likely reporting scenarios. Because of the dramatic impact this utilization assumption will have on the entire fee schedule, it is critical that it is grounded in valid and reasonable data. A near 11% reduction in the RBRVS and Anesthesia CFs will be devastating to patients and providers. CMS needs to find ways to mitigate the negative impact of this situation. We believe evidence supports a reduction in the utilization assumptions. Through the years CMS has found ways within their authority to reduce the negative impact of policies on patients and clinicians. We urge you to once again do the same now.

Practice Expense RVUs (Section II.B.)

For CY 2019, CMS worked with market-research company StrategyGen to conduct an in-depth and robust market research study to update the PFS direct practice expense inputs (DPEI) for supply and equipment pricing. Through this initiative, CMS updated the pricing for over 2,000 supply and equipment items used as DPEI. CMS is phasing-in the new pricing over 4 years. CY 2021 is the third year of the transition, which means that PE input pricing for the affected items in 2021 will be based on 75 percent of the new pricing and 25 percent of the old pricing.

ASA continues to support the engagement from the agency to work with CMS contractors and stakeholders to incorporate current pricing data based on invoices into the calculation of direct PE costs. ASA believes that incorporation of new data must be done in a transparent manner where CMS publically documents the criteria used to accept or reject data received from contractors or stakeholders. Incorporating invoice data and other market-based research into the valuation of direct PE inputs for supplies and equipment may be an effective way to price such inputs for appropriate payment for actual costs incurred. CMS also continues to accept invoices and pricing data from other stakeholders. ASA believes that the incorporation of this new data and the process for determining what is accepted and what is rejected should be done in a transparent manner.

Because practice expense accounts for a substantial portion of overall payment made under Medicare, it is critical that the agency uses accurate and current data to calculate PE RVUs. The agency's database for supplies and equipment is made up of thousands of items that range in unit price from a few cents to over a million dollars. Over the years the process of identifying and pricing supplies and equipment has become increasingly complex. The size and scope of the PE supply and equipment database requires the agency to take a methodological approach in updating and maintaining it. Bringing in an outside vendor in addition to accepting invoices from stakeholders is a reasonable approach.

As CMS is presented with data from various sources, the agency goes through an internal process to accept or reject data from contractors and stakeholders. ASA urges CMS to conduct this data vetting process in a transparent manner. When invoices are submitted by stakeholders and are not accepted, we ask the agency to be clear in their response on why the invoice was rejected. Often when invoices are rejected or one invoice is accepted over another, stakeholders are left in the dark about the agency's decision process. ASA urges CMS to be more deliberate and transparent about this decision-making process.

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID–19 Pandemic (Section II.F.)

In the CY 2020 PFS Final Rule, CMS established add-on code GPC1X for office/outpatient E/M visit complexity with an effective date of CY 2021. This code provides payment for visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition. Since the code was established, CMS has received feedback from stakeholders that the definition of the code and rules on when it would be appropriate to report the code is unclear.

Prior to the implementation of this code, CMS should release comprehensive coding and billing guidance for GPC1X. This guidance should include specialty-specific vignettes. The agency should also provide guidance on how claims containing GPC1X will be audited. Code GPC1X is effective January 1, 2021. CPT codes that are established by the American Medical Association (AMA) CPT Editorial Panel are developed through a process where applications for new codes are discussed at a public meeting and there is an opportunity for public input. After a new code is released, the AMA generally releases coding guidance including details on the physician or healthcare professional work captured by the code, a typical patient vignette and what should be included in medical documentation when reporting the code. This type of coding guidance is necessary to support appropriate and consistent reporting of the codes. It is essential guidance for providers to understand how claims will be reviewed by payers. Comprehensive information on new codes benefits the provider so they understand their responsibilities and the payer because it supports appropriate reporting of the code on claims they will be adjudicating.

When G-codes are released, physicians and other healthcare professionals reporting the code rely on the agency for this information. ASA strongly urges CMS to release guidance on appropriate coding for GPC1X. While coding guidance is always needed for new codes, it is especially imperative in this situation. The stakeholder community has already indicated to CMS that there is confusion about what this code describes, the appropriate reporting of the code and what type of medical documentation would be required. CMS has indicated that they anticipate this code will be reported across many different specialties and in some instances in high volume. We would urge the agency to provide specialty-specific guidance through vignettes or other types of coding information. CMS has identified a range of specialties ranging from cognitive providers to proceduralists. From a practical standpoint with such a wide range of specialties expected to report this service, specialty-specific guidance is needed. A vignette or clinical example on the appropriate use of the code that is similar to their practice environment

will be most helpful in directing Medicare clinicians on the appropriate reporting for this code. For example, a vignette that describes the typical patient for an ob/gyn reporting GPC1X may not resonate with a pain management specialist. Appendix C of the CPT Book provides specialty-specific clinical examples for all E/M codes. ASA believes something similar for GPC1X in addition to other coding and documentation guidance would be very helpful.

CMS utilization assumptions for new add-on code GPC1X contributes significantly to the increase in spending that is driving the 10.61% budget neutrality adjustment. ASA does not believe these estimates are reasonable and we reiterate our recommendation for CMS to review and reduce its utilization assumptions for GPC1X. The 10.61% reduction in the Medicare RBRVS CF and similar reduction in the Anesthesia CF is the result of an estimated additional $10.2 billion in proposed spending of which $3.3 billion is estimated to come from the reporting of GPC1X. In the CY 2020 PFS Final Rule CMS estimated that the 21 specialties that bill E/M codes would bill code GPC1X with 100% of their office/outpatient visits. ASA has significant concerns with this utilization assumption. We find it highly unlikely that all 21 specialties would furnish that level of complex physician work for every patient coming in for an E/M visit. Additionally, GPC1X will be a new code in 2021 and one that is unlike any other on the physician fee schedule. It always takes a period of time before clinicians start reporting new codes. With the confusion around the appropriate reporting of this code, it may take even longer than usual. ASA reiterates our recommendation made at the beginning of this letter that CMS should reconsider and reduce their utilization assumptions for this code to better reflect the more likely reporting scenarios. Because of the dramatic impact this utilization assumption will have on the entire fee schedule, it is critical that it is grounded in valid and reasonable data. A near 11% reduction in the RBRVS and Anesthesia CFs will be devastating to patients and providers. CMS needs to find ways to mitigate the negative impact of this situation. We believe evidence supports a reduction in the utilization assumptions. Through the years CMS has found ways within their authority to reduce the negative impact of policies on patients and clinicians. We urge you to once again do the same now.

Proposal to Remove Selected National Coverage Determinations (Section III.J.)

CMS is proposing to use the rulemaking process using criterion established in 2013 to identify and remove NCDs that they believe no longer reflect current medical practice, or that involve items or services that are used infrequently by beneficiaries. Specifically, the agency proposes to remove Extracorporeal Immunoadsorption using Protein A Columns (NCD 20.5), Implantation of Gastroesophageal Reflux Device (NCD 100.9), Apheresis (Therapeutic Pheresis) (NCD 110.14), Abarelix (NCD 110.19), Histocompatability Testing (NCD 190.1), Cytogenetic Studies (NCD 190.3), Electrosleep Therapy (NCD 30.4) (all indications), Magnetic Resonance Imaging (NCD 220.2.1) (all indications), and FDG PET (NCD 220.6.16) (for three specific conditions). Services would be covered at the Medicare Administrative Contractor's (MAC's) discretion. CMS believes this will result in greater contractor flexibility and better serve the needs of Medicare beneficiaries.

ASA appreciates agency efforts to ensure that NCDs are based on current scientific evidence, are relevant to the Medicare population and that the Medicare coverage process is designed to provide greater contractor flexibility. As CMS moves towards greater discretion at the local level for MACs, the agency must ensure a transparent and meaningful process for physician voices to be heard through the Contractor Advisory Committee (CAC) a federally mandated regional committee that provides input on local

coverage determinations (LCDs). In response to the provisions in the 21st Century Cures Act, in January 2019 CMS modified rules governing LCDs, including revisions to the CAC process. Changes impacting CACs include giving MACs the discretion to hold multi-jurisdictional CAC meetings and the inclusion of a summary of a CAC recommendation in the final LCD.

While these changes are still in development and COVID-19 may also had an impact on the transition to new processes, we are concerned that some of these changes may reverse many of the important contributions of the CAC process to local coverage determinations. CAC members provide valuable clinical insight to MACs. They serve as an effective communication bridge between regional contractors and state and national physician groups. The CAC process has always been a transparent process that allowed for the participation of practicing community physicians.

ASA fears that some of the changes implemented such as multi-jurisdictional meetings, will have a negative impact on practicing physicians' input in this important process. We have received feedback that communications about meetings and LCDs open for review and comment have degraded and are not being provided in a timely and organized manner. ASA supports efforts to reduce administrative burden and streamline work processes. We also appreciate that the agency is mandated to implement these changes by statute. Nevertheless, not only does the agency have a responsibility but it is in the program's best interests to ensure that the CACs continue to provide robust feedback to the LCD process. With this proposal the agency moves to give MACs greater discretion, ASA urges CMS to closely monitor the CAC process to ensure that the important contribution of physician input in the LCD process are not lost during a period when CMS is giving MACs more discretion.

Telehealth and Other Services Involving Communications Technology (Section II.D)

Due to the circumstances created by the COVID-19 pandemic, CMS temporarily expanded the Medicare Telehealth list. Telehealth provides a way for Medicare beneficiaries to access routine healthcare services while reducing the risk of exposure to COVID-19 for both beneficiaries and medical staff. As part of its response to the pandemic the agency implemented a number of flexibilities including expanding the services that can be delivered via telehealth; revising their payment policy to allow non-facility-based clinicians to receive the higher non-facility rate versus the facility rate which CMS has historically paid for telehealth services; expanding where Medicare beneficiaries can access services, including their home; exercising enforcement discretion and waiving penalties for HIPAA violations against health care providers that serve patients in good faith through everyday communications technologies, such as FaceTime or Skype; and eventually eliminating these barriers by paying for certain telephone evaluation and management visits and behavioral health services, and paying practitioners at the same rate as similar in-person services. As a result, telehealth utilization has increased dramatically[3] and it is generally believed to be an effective means to access healthcare safely during the pandemic.

[3] ASPE Issue Brief: Medicare Beneficiary Use of Telehealth Visits: Early Data From the Start of the COVID-19 Pandemic (2020, July). *Office of the Assistant Secretary for Planning and Evaluation.* Retrieved from: https://aspe.hhs.gov/pdf-report/medicare-beneficiary-use-telehealth

In the CY 2021 PFS Proposed Rule CMS proposes to add certain services permanently and other service temporarily to the Medicare Telehealth list until the end of the CY during which the COVID-19 PHE ends.

ASA supports CMS' efforts to expand telehealth services while ensuring patients continue to have access to necessary and high quality care. The expanded flexibilities around telehealth have played a critical role in allowing beneficiaries to access telehealth services and we are pleased that CMS is proposing to expand some services permanently and others temporarily. **We were disappointed that the agency failed to propose making permanent other flexibilities which we believe are within their regulatory authority such as the payment policy for non-facility clinicians and flexibilities around audio/visual requirements for telehealth communication technologies. We urge CMS to consider these additional telehealth flexibilities.**

Critical Care Codes 99291-99292

ASA recommends that critical care codes 99291 and 99292 should remain permanently on the Medicare Telehealth list. For the duration of the public health emergency (PHE), CMS added critical care codes 99291 (*Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes*) and 99292 (*Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)*) to the Medicare Telehealth list but has not proposed to keep them on the list either temporarily or permanently beyond the PHE. ASA urges CMS to add these codes to the permanent list of services.

ASA membership includes critical care anesthesiologists who supervise, coordinate, and manage the patient's care with the ICU team and work closely with the surgeons and other specialty consultants as needed. They have played a leadership role in shaping and implementing their facility's response to the pandemic. ASA members have found that the flexibility of being able to provide these critical care services remotely during the pandemic has been very valuable. Critical care services are provided within hospital settings to support care of a diverse set of critically ill patients, particularly during the COVID-19 pandemic. As hospitals have had to extend critical care capacity to deal with surges in COVID-19 infected patients, telehealth has provided support to patients receiving care in non-traditional settings and allowed access to critical care expertise when non-critical care trained physicians, advance practice nurses and bedside nurses are asked to manage these complicated clinical situations. The telehealth critical care services have also provided critically needed support for community hospitals and other health systems to both optimize care within those settings, but also to determine when transfer can be accomplished safely.

There are many benefits to telehealth ICU services that are well aligned with the agency's goals and priorities. Telehealth ICU services promote evidence-based practice, enhance monitoring and early identification of treatment of illness, improved coordination of care; increase night time vigilance, facilitate optimal care across the continuum, and reduce readmission.[4] ASA believes the Medicare program can benefit from the flexibility provided by telehealth ICU services beyond the pandemic and they should be a permanent addition to the Medicare Telehealth list.

[4] Udeh C, Udeh B, Rahman N, Canfield C, Campbell J, Hata JS. Telemedicine/Virtual ICU: Where Are We and Where Are We Going?. *Methodist Debakey Cardiovasc J*. 2018;14(2):126-133. doi:10.14797/mdcj-14-2-126

In the proposed rule CMS states, "CPT guidance makes clear that a variety of other services are bundled into the payment rates for critical care, including gastric intubations and vascular access procedures, among others…we continue to believe that the full range of care for critically ill patients cannot be performed via two-way, audio/video telecommunications technology." ASA agrees that CPT guidance does indicate that gastric intubation and vascular access procedures should not be reported separately if performed when providing critical care services described by codes 99291 and 99292. We also agree that these services cannot be performed remotely but we do not believe that this precludes codes 99291 and 99292 from being permanently added to the Medicare Telehealth list. Gastric intubation and vascular access procedures are not inherent to critical care and often there is not a medical need to perform these services when providing critical care services. In those instances when gastric intubation and vascular access procedures are not being performed, the full range of medically necessary critical care services that are a part of codes 99291 and 99292 can be provided completely and safely to Medicare beneficiaries.

ASA understands that codes G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth*) and G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth*) are permanently on the Medicare Telehealth list but these are distinct services from codes 99291 and 99292 and cannot substitute for them. ASA believes that Medicare beneficiaries, especially those located in rural or other remote areas which may not have access to critical care clinicians 24/7 otherwise, would greatly benefit from access to telehealth ICU services. We urge you to make codes 99291 and 99292 permanent additions to the Medicare Telehealth list.

<u>Remote Critical Care Monitoring Models</u>
CMS solicited comments on whether the current set of CPT and HCPC codes describe the various models for how remote critical care services are currently delivered throughout the country. ASA has found that generally there are two models of remote critical care services; the first which is more of a telehealth consultant has adequate codes to report the service, while the other which allows physicians to provide tele-ICU services which may be enhanced through the use of robotic technology or other methods to complete a clinical assessment of the critically ill patient does not have an appropriate set of codes that describe this service**. ASA urges CMS to develop a set of codes to report the provision of tele-ICU services which may or may not include the use of robots or other similar technology.**

In the telehealth consult model, there is a physician on-site with the patient but the provider is requesting assistance with the diagnosis and management of a complicated clinical situation from a specialist. This model is commonly used to assess and, when appropriate, treat patients suffering from a stroke, where doctors who have advanced training in treating strokes can provide counsel to the clinician on-site who is treating a patient. These services are typically reported using G0508 and G0509.

The other model, where there currently is not the appropriate mix of codes to report the service, is one provided in ICUs with critical care providers who request assistance or may not be present 24/7 or may be provided in hospitals without trained critical care providers. This service may be provided with or without the use of robots or other technologies. These services are always requested based on medical necessity as defined by the requesting physician. The

request for the service can come from a hospitalist, surgeon or others, often initiated by the bedside nurse in response to the request from the physician.

The presence of robots and use of other technologies in the ICU setting is growing as hospital systems across the country are realizing its value in bringing the expertise of an ICU-intensivist to areas that do not have such specialties. ICU patients can strain resources at small facilities and often the clinical volume within these hospitals and communities makes it difficult to provide 24/7 staffing to care for patients requiring diverse critical care management services. Tele-ICU services and the implementation of robotic devices to facilitate evaluation and examination of the patient allow coordination of care among providers on site and those providing the remote assessment. Patients also benefit from being able to be managed closer to home, receive better triage assessment and avoiding the unnecessary transfer from one facility to another reduces risks. Both the presence of robotic and other technologies to facilitate and optimize telehealth services for ICU patients is very valuable and responsive to the currents needs and challenges facing the U.S. healthcare system. ASA urges CMS to develop codes that would allow physicians to report the physician work when these services are provided (cost of robot or other technology captured in the facility payment).

Direct Supervision by Interactive Telecommunications Technology (Section II.D.9)

As part of the flexibilities implemented for the duration of the PHE and in order to limit exposure to COVID-19, CMS revised the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology (85 FR19245). In this rule, CMS proposes to extend this flexibility through the later of the end of the calendar year in which the PHE ends or December 31, 2021. In considering limits to this policy, CMS states "For instance, in complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient's clinical status can quickly change and we believe it is necessary for such services to be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation."

ASA supports the agency's assessment that anesthesia services must be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation. While audio-visual technologies may support virtual direct supervision for other services, ASA agrees with continuing the limitation on physician anesthesia supervision to in-person supervision. The *ASA Standards for Basic Anesthetic Monitoring*[5] state, "Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care." Medical, anesthetic, and surgical complications which may arise unexpectedly will demand immediate medical diagnosis and treatment and thus must be furnished or supervised in-person. ASA appreciates this recognition by CMS to ensure patient safety during anesthesia procedures remains a critical consideration as it sets supervision policy for Medicare physician services.

[5] Standards for Basic Anesthetic Monitoring (2015, October). *Committee on Standards and Practice Parameters, American Society of Anesthesiologists.* Retrieved from: https://www.asahq.org/standards-and-guidelines/standards-for-basic-anesthetic-monitoring

CY 2021 Updates to the Quality Payment Program (Section IV.)

ASA appreciates CMS' continued focus on improving the Quality Payment Program (QPP) and, in particular, the Merit-based Incentive Payment System (MIPS) pathway for individuals and groups. Especially in light of COVID-19, we believe that CMS has proposed several common sense QPP policy changes that will benefit Eligible Clinicians (ECs) and their groups.

MIPS Value Pathways (MVPs)

In 2019, ASA proposed several recommendations to CMS regarding how MVPs could be constructed to take into account the contributions of multiple clinicians who may treat the same patient during an episode of care. We are heartened to see that CMS agreed with our recommendation that MVPs should be interdisciplinary, claimed by multiple specialties, and focused on patient care.

The MVP framework has the potential to move MIPS along the "path to value," transforming the program by better informing and empowering patients to make decisions about their healthcare and helping clinicians to achieve better outcomes. We appreciate that CMS acknowledges MIPS as a complex program for physicians and their groups to fully understand. ASA believes there has been a desire among anesthesiologists to have more meaningful data collected that is focused on greater alignment between the quality measures an individual or group reports and its relationship to improvement activities and cost.

ASA agrees with CMS to delay the implementation of MVPs to the 2022 performance year. The delay in implementation will allow eligible clinicians the opportunity to recover from the Public Health Emergency (PHE) and further understand the requirements and scoring of MVPs. This delay also allows the health care community to have more time to develop MVPs, resulting in a meaningful program for clinicians and patients. When making policy for the 2022 performance year, we encourage CMS to allow ECs and groups to voluntarily report MVPs and determine scoring based upon a fair, transparent process.

CMS should provide feedback to MVP developers and stakeholders regardless of whether the MVP will be proposed for implementation. We thank CMS for meeting with us in February 2020 to discuss an anesthesiology-specific MVP. As discussed during that call, ASA focused on a specialty-specific MVP that would be able to accommodate a broad spectrum of anesthesiology professionals. Yet we also offered continued support for an episode-specific MVP, such as one for a joint replacement. Although we recognize that COVID-19 disrupted many plans and discussions, feedback from CMS experts would have been welcome, especially as our physician committees debated future MVPs. We urge CMS to create a feedback loop on submitted MVPs that will enhance how an MVP developer may improve their MVP in the future.

CMS should provide concrete deadlines for MVP candidate submissions to receive feedback. In the 2021 proposed rule, CMS seeks comment on how they could make the process more transparent in future years. ASA encourages CMS to provide additional detail on the expectations for a feedback loop. ASA supports a policy decision to have open lines of communication throughout the review process, rather than a single informational meeting or presentation. Due to the effort it will take for an MVP developer to build an MVP; it would be our hope that CMS could create these transparencies to incentivize the work done by MVP developers. A transparent process would allow us and other developers to strategically allocate

resources such as staff, physician volunteer time, and testing of the MVP. We would also need time to coordinate with and receive contributions from other stakeholders. Without early feedback or appropriate encouragement from CMS, it would be increasingly difficult to engage external stakeholders, vendors and other entities to contribute and test an MVP that has an uncertain future. Likewise, without feedback on an MVP, we would not know whether to improve our candidate MVP or to discard it altogether.

To expand engagement with known and unknown stakeholders, we believe that CMS should publish a rolling list of MVPs that are under consideration. We request that CMS create a website to identify the MVPs under development, the steward or owner of the MVP, and their contact information. The website should also include CMS initial assessment of the MVP so that future developers can see whether the episode is worth pursuing further, if it ran into problems, or if it is considered a strong candidate for future implementation. CMS should also make available the status of MVPs, including those that are proposed and finalized, in a central location with the steward, developer and other contributors to the MVP listed.

To appropriately vet MVP proposals, CMS should convene an advisory committee or identify physician and other clinical experts who are knowledgeable about the MVP episode of care. CMS should have a sufficient number of experts available to review the MVPs as applicable to the specialty and/or to the episode of care. Because MVPs are built from established and tested quality and cost measures as well as vetted improvement activities, the work of a technical expert panel should be rather straight-forward. We do not believe that the National Quality Forum or other external entity is necessary for this process. Instead, we believe a CMS-convened interdisciplinary technical expert panel can identify measure gaps or opportunities, enhance the value, and increase reporting of the MVPs by ECs and their groups. The face validity that this expert panel would provide to an MVP would grant the MVP process more authority and legitimacy.

ASA agrees that ECs and groups should have opportunities to align their local initiatives, priorities and responsibilities with MVP reporting. Anesthesiologists represent one of the few specialties that contribute to nearly all surgical and procedural patient care. We provide care coordination and are instrumental in improving quality and delivering more cost-effective care. Anesthesiologists deliver patient care in many settings, including but not limited to, inpatient, outpatient, office-based and non-operating room anesthetizing locations. Importantly, many anesthesiologists have subspecialty expertise in, among others, ambulatory care, critical care medicine, obstetrics, and pain medicine. We believe that CMS should support the development of multiple surgical and procedural MVPs to represent the breadth of anesthesia practice settings in order to provide sufficient MVP choices for ECs and groups to report.

We request CMS allow ECs and groups the ability to choose an MVP to report or to participate in the traditional MIPS program. Allowing such flexibility to participate would allow CMS to promote and encourage a gradual and meaningful adoption of the MVPs as well as allowing the clinicians to make informed decision on their choice to participate. At the same time, CMS should provide guidance on the mechanics of scoring an MVP to help physicians or their groups choose the most advantageous path to report.

ASA is concerned about the reliance of MVPs on features of MIPS that are not applicable to anesthesiologists. In the 2021 proposed rule, CMS states, “The MVP framework incorporates a foundational layer consisting of Promoting Interoperability measures and administrative claims-

based quality measures focused on population health, provides data and feedback to clinicians, and enhances information provided to patients." Anesthesiologists rarely, if ever, report population health measures and our members are mostly exempt from the Promoting Interoperability performance category. CMS should pursue MVPs that are composed and reported on by multiple specialties and allow those specialties without population health measures and with a promoting interoperability exemption to use the scores of their peer reporters. Without this allowance, physician anesthesiologists and other non-patient facing physicians and groups would not be able to report MVPs and be at a scoring and MIPS participation disadvantage.

MVP Guiding Principles

The additional detail CMS added to the five MVP Guiding Principles this year will help ECs and groups better understand the intent of the program.

> *(1) MVPs should consist of limited, connected complementary sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, align scoring, and lead to sufficient comparative data.*

While we agree with the first Guiding Principle, the term "limited" could be used to define MVPs too narrowly and exclude specialties from being assessed on relevant episodes of care. **CMS should balance the interests of multiple specialties under each proposed MVP.**

> *(2) MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care; MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.*

ASA supports subgroup reporting as anesthesia groups often treat different patient populations on a daily basis. The ability to allow for subgroup reporting is essential so that each individual clinician reporting in the MVP has relevant feedback to their performance within the MVP. If subgroup reporting is allowed, CMS should ensure that groups are not overwhelmed by having to report on multiple MVPs. A modest sized group may wish to focus on one, perhaps two, MVPs but should not have to report on multiple MVPs just to ensure 50% or 60% of its ECs are participating in the MVP. CMS should refrain from setting a burdensome threshold for reporting MVPs (or multiple MVPs) that would discourage physicians and groups from participating in an MVP.

We recognize the importance of the Medicare population to use a public reporting website to make effective choices about the care they expect to receive. ASA suggests that CMS develop and manage a website, similar to Physician or Care Compare, which provides MVP information to patients. Before publication of MVP data, CMS should allow ECs and groups to review their performance and allow for appeals to take place. We encourage CMS to solicit and accept explanatory notes from individual stakeholders and specialties for the MVP public posting beforehand. Those notes should detail, for the patient, the role that each specialist provides.

> *(3) MVPs should include measures selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included, to encourage performance*

improvements in high priority areas. MVPs should support proactive communication and partnered decision-making between healthcare providers and patients, families, and caregivers and reinforce a care relationship that is based on trust and inclusion of individual values and beliefs.

CMS efforts to engage with the patient community and ensure clinicians are providing meaningful information to improve the patient experience is necessary. ASA requests clarity on whether each contributor to an MVP will be required to incorporate the patient's voice. While ASA understands the importance of patient feedback, we fear this may lead to increased burden on the MVP developer to ensure each specialist represented in the MVP has a patient satisfaction, experience, or patient-reported outcome to report. Instead, we believe that the patient and their experience should be engaged per episode of care and not per specialist reporting the episode of care. Therefore, one or two measures or assessments of patient satisfaction and experience should serve as a proxy for each specialty reporting the MVP. We also request clarity on how CMS will evaluate and verify the inclusion of the patient voice. ASA urges CMS to ***not*** require each MVP stakeholder to include patient testing, especially for measures that have already been validated by such testing.

(4) MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

CMS should identify the methodology that specialties can use to achieve APP or APM status. We agree that MVPs can be used as a bridge to move ECs and groups from the MIPS program into an APM. However, the current set of APM measures is limited in scope as there are many more measures and options available for primary care physicians than specialists. These primary care measures make it unclear what long-term outcomes our members should target when working across specialties. CMS has indicated their belief that a combination of factors including quality of care and patient experience, cost, continuous improvement and innovation, as well as efficient management of resources and transfers of information, will help remove barriers to APM participation. To the average anesthesiologist or group, this list detailing qualities of a MIPS APM can be daunting. CMS should publish guidance or case studies on how individuals or groups have leveraged their MIPS participation into APM agreements. Such a blueprint will help specialties better engage their members.

Because cost is a significant feature of APMs, CMS should strive to work with specialties and MVP owners on identifying applicable cost measures for the MVP. Anesthesiologists rarely receive attribution in the cost performance category. Therefore, the linkage to cost measures within an MVP is concerning to us. We request CMS be transparent in their cost attribution methodology and provide information to groups regarding how their cost scores are calculated. With this transparency, the inclusion of relevant cost measures in MVPs would be more meaningful and understandable to clinicians.

(5) MVPs should support the transition to digital quality measures. Our future vision for reducing MVP reporting burden; the use of digital performance measure data submission technologies to indicate our commitment to leveraging digital innovations that reduce MIPS related clinician burden. Digital Quality Measures (dQMs) originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems examples of digital sources include electronic health records (EHR), health information exchanges (HIEs), clinical registries,

case management systems, electronic administrative claims systems, electronically submitted assessment data, and wearable devices.

We request additional information and clarity on the development and use of "digital quality measures." In the 2021 proposed rule, CMS describes "digital measures" but did not provide a specific definition of what would be considered a digital measure. ASA believes that CMS can define these measures as those not specified as eCQMs and not claims-based measures. In short, an eCQM has digital features but may not be considered a "digital quality measure." We note, however, that even digital quality measures may be extracted from an Electronic Health Record, they are not necessarily eCQMs. While "digital measures" would reduce burden for some groups, this would in turn create additional burden for a most eligible clinicians and groups that are not working with digital means of data capture.

MVP Development

CMS should define a governance structure for MVPs. As previously stated, the ASA is excited about the opportunity to develop MVPs based upon an episode of care. However, we believe that CMS should define a governance structure for MVPs that allow for a central point of contact and responsibility for maintenance without significantly limiting the role of stakeholders in contributing their quality measures and other MVP components. In this way, we want to ensure the owner of an MVP cannot arbitrarily remove features of an MVP that may adversely affect other stakeholders and specialties who report that MVP.

CMS should incentivize collaboration between specialty societies to craft and test MVPs. CMS states that MVPs must be created by using a consistent set of parameters and criteria to ensure that MVPs are constructed and implemented in a uniform manner. ASA suggests routine discussions with CMS and MVP stakeholders during the creation of MVPs. By CMS designating a standardized process for developers to submit an MVP candidate, CMS has the ability to ensure that all relevant specialties are included in the process.

CMS should allow multiple stakeholders to share the burden of fulfilling the base criteria of an MVP. ASA requests CMS provide detail on how the proposed MVP criteria will be assessed when approving an MVP. CMS encourages stakeholders to work collaboratively in the development of an MVP and should not penalize one specialty if another specialty represented in the MVP can complete the reporting criteria. As previously stated, anesthesiologists are often exempt from reporting the Promoting Interoperability performance category and are rarely assessed by population health measures.

MVP Submission Questions and Criteria

In reviewing the criteria for submission, ASA offers the following comments:

- *Does the MVP act as a vehicle to incrementally phase clinicians into APMs? How so?*

CMS can better define this criteria and/or make common language available for MVP developers to use. Although we believe that MVPs can be a vehicle to drive participants toward APMs, our understanding of the process, in moving MIPS participants first to MVPs and then to APMs, is still somewhat elusive. CMS could improve this question or our understanding

by clearly defining a pathway to APMs or providing an example of how a group or individual matriculated into an APM.

- *Is the MVP comprehensive and understandable by patients?*

We believe this question is premature. ASA is considering working with our colleagues in several patient advocacy organizations to test whether our MVP proposal(s) are supported by patient populations. We are cautious on this approach since we also have been told by CMS contractors that anesthesia quality measures are not published in Physician Compare because patients would not understand the clinical importance of the measures. The criteria of "comprehensive and understandable to patients," at the same time does not necessarily fulfill a gap since patients most likely are not familiar with MIPS requirements or the four categories that physicians are currently scored.

- *Does the MVP take into consideration the patient voice? How?*

ASA expects to provide opportunities for public comment on our MVPs and we also have partners to contact regarding the patient voice and MVPs. CMS has provided flexibilities for what constitutes the patient voice and ASA agrees with this criteria. However, we request CMS delay this requirement until the 2023 performance year to allow stakeholders time to convene technical expert panels with patient representatives.

- *How are patients involved in the MVP development process?*

ASA agrees with this criteria, however, would request CMS delay this requirement until the 2023 performance year to allow stakeholders time to convene technical expert panels.

- *Must include the full set of PI measures.*

As non-patient-facing clinicians, most anesthesiologists are exempt from having to report Promoting Interoperability. We believe that the proposed MVP requirement to use the full set of Promoting Interoperability measures places our specialty at a disadvantage. CMS can address this issue by allowing anesthesiologists to participate in and contribute to an MVP that includes other specialists who do report Promoting Interoperability measures. In lieu of this, **we would encourage CMS to maintain the current Promoting Interoperability exemptions and allow those exemptions to be used as a proxy for the Promoting Interoperability measure requirement. Without these flexibilities, the MVP process will not function equitably.**

MVPs and Patient Engagement

ASA supports elevating the patient's voice, but we request patient evaluation or contributions to MVPs be delayed until the 2023 performance year. CMS states that as a part of the MVP development process, they believe that it is important to develop MVPs in a manner that takes into consideration the patient's experience, satisfaction, and outcomes. ASA agrees with this intention and would support the use of patient reported outcome measures, where appropriate, in MVPs. ASA understands that one of the most direct ways to accomplish patient engagement is through the development of a technical expert panel. However, due to the tight turn-around time for the submission of an MVP for performance year 2022, we request

that CMS re-evaluate the requirement for patient engagement for candidate MVPs in performance year 2022.

MVPs and Quality Measures

CMS should use Qualified Clinical Data Registry (QCDR) measures as part of an MVP. Since the introduction of the QCDR, ASA has spent a significant amount of resources developing quality measures via our QCDR. Our processes follow the CMS Blueprint and our measures are used by thousands of anesthesiologists and other anesthesia professionals during the reporting year. To encourage members to use MVPs, CMS should allow MVP developers latitude to include QCDR measures into the MVP.

We agree with CMS that QCDR measures in the Quality Payment Program and within an MVP should be adequately tested for feasibility, reliability and validity. We appreciated and supported the CMS delay of onerous testing requirements until the 2022 performance year. However, data for reliability and performance rates are often more robust after the QCDR measure has been available for MIPS reporting for at least one year. Therefore, for MIPS use, we recommend that CMS continue to approve QCDR measures using 2020 performance year standards. We support the use of face validity, reliability testing and feasibility testing for QCDR measures to be used in MVPs.

Because data to fully test an anesthesia quality measure for validity is difficult to capture, we cannot support requirements that each measure be tested for validity beyond face validity. Our physician leaders in quality, our research and analytics team and other subject matter experts in anesthesia quality measures have determined that few, if any, anesthesia measures would meet CMS expectations for validity testing as described in this rule. We recognize that CMS has attempted to gradually implement these requirements over the next two to three years. Even with this time lag, we believe that fully testing more than a dozen measures on data that is not readily accessible will not be feasible. The implications of this for anesthesia quality measures could be profoundly devastating.

CMS should maintain the approval of QCDR measures for two years and not remove CMS endorsement unless approved by the measure steward. ASA members and AQI NACOR participants have noted that one of the greatest burdens placed on their groups is when measures are retired at the end of a reporting year. CMS policies to approve QCDR measures for two years ensures stability in the program and allows QCDRs and measure developers adequate time to prepare for measures to be retired or replaced. We support CMS removing the measure if it reflects an outdated clinical deadline or if the QCDR that nominated the measure is no longer in good standing. We do not support CMS removing a measure before its second year for it being topped out or duplicative of a more robust measure. We have confidence that CMS will have appropriately vetted the measure in the previous year.

Our vision for an MVP episode of care would incorporate quality measures from multiple specialties, but those quality measures should be reported via each specialty's designated QCDR. We believe that a QCDR should not be required to collect and report data on all quality measures included in an MVP, especially those outside of the designated specialty's expertise. For instance, anesthesiologists may participate in a variety of episodes of care that may have separate MVPs. Anesthesiologists may use one set of anesthesiology measures for joint replacement procedures, another group of measures for cardiac surgery and

still other measures for obstetric cases. Our QCDR would be able to collect data on anesthesiology measures but could not handle the reporting of data from multiple specialties. We feel that this would be common among most, if not all, medical or specialty society registries. We likewise know it is not in our interest to have a separate specialty, such as radiologists, report to an anesthesiology QCDR or anesthesiologists reporting to a radiology QCDR.

ASA is supportive of a CMS policy decision to allow one specialty to report QCDR CQMs and another specialty represented within the MVP to report MIPS CQMs. We understand that CMS's emphasis on common measure testing for both MIPS and QCDR CQMs is intended to level the playing field between measures. We believe that the 2022 performance year launch date for MVPs will allow for appropriate testing and vetting of measures to occur.

We also recognize that CMS expressed concern with whether the inclusion of QCDR measures would be unfair to those not wishing to report via a QCDR. ASA currently licenses our QCDR measures to seven other QCDRs, allowing individual EC and groups' options for reporting QCDR measures. **We do not believe there will be a barrier for individuals or groups to participate in an MVP solely because of the inclusion of QCDR measures.**

MIPS Performance Category Measures and Activities

CMS appropriately reviewed and has proposed meaningful changes to how MIPS is scored during the 2021 performance year. ASA agrees with the CMS proposal to reduce the Quality performance category by five (5) points and increase the Cost performance category by five (5) points, resulting in Quality comprising 40% and Cost comprising 20% of the MIPS final score for ECs and groups in 2021. We also agree with CMS revising the performance threshold to 50 points for the upcoming performance year.

<u>Quality Performance Category</u>
In the Quality performance category, CMS should ensure that specialties have an adequate number of measures to report. We appreciate that CMS has maintained the anesthesiology measure set for 2021. This action allows anesthesiologists stability between the 2020 and 2021 reporting years. We likewise recognize that CMS has proposed topped out scoring changes to encourage anesthesiologists and their groups to report quality measures that are not topped out. We believe scoring mechanisms are the most effective way for CMS to encourage ECs and groups to report non-topped out measures.

<u>Cost Performance Category</u>
ASA appreciates CMS considering the pros and cons of keeping or increasing the cost performance category score. Although anesthesiologists and their groups may receive a cost score based upon the Medicare Spending Per Beneficiary (MSPB) measure, most anesthesiologists have the Cost performance category reweighted. We believe the introduction of facility-based scoring has benefited many of our members. This option has addressed some of the concerns we had with the Cost performance category.

CMS feedback reports should clearly identify the cases that an individual EC or group was assessed under the Cost performance category. Anesthesiologists and their groups have expressed an interest in improving their Cost scores but are unable to do so because they are unaware of which cases they should assess. In a recent case, staff at an anesthesia group

spend more than two weeks assessing their data, understanding the cases that may have been attributed to their group and working with QPP customer service to file a complete appeal. A significant amount of time was spent on understanding and applying the Medicare Spending Per Beneficiary measure, including its exclusions and exceptions, to the data they had available. Although the appeal application and instructions were clearly identified, the response to their appeal was not specific or instructive on how a denial or approval of an appeal was adjudicated. We also believe that CMS should be more transparent about the costs attributed to each specialist in the episode so that specialists may work with one another to better understand drivers of cost.

CMS should also reconsider how the MSPB and other Cost performance category measures affect small, medium and large group practices differently. For small practices, reaching the minimum 35 case threshold for MSPB is difficult and CMS has made an effective policy decision to limit their exposure to these measures. However, for a large group, the Cost performance category score may reflect less than 5%, even 1%, of their total cases. Although we recognize that the measure has been tested and reliably scored, we nonetheless believe that CMS should explore a minimum percentage of cases for the measure to be applied to groups. We would welcome the opportunity to further discuss this option with CMS.

As CMS is well aware, the Cost performance category is increasingly important in a MIPS score but can also be used by ECs and groups to demonstrate their performance to non-Medicare payers and, most importantly, patients. An appeals process that rewards earnest efforts by groups to understand their data and to make effective improvements to the care they provide is needed. Webinars and other events to aid individuals and groups in understanding the cost distribution and patient attribution logic prior to the appeal period would reduce EC and group burden in deciding whether an appeal should be made. At the same time, it would help MIPS participants to leverage their scores when holding discussions with non-Medicare stakeholders.

Improvement Activities Performance Category

We agree with many CMS proposals to alter the Improvement Activities performance category. In particular, we recognize that COVID-19 caused CMS to rethink how anesthesiologists and other physicians can receive credit for their day-to-day work. We agree that CMS should be able to develop and implement Improvement Activities during a public health emergency and support CMS providing clarifying letters and language to better explain how individuals and groups can receive credit. The flexibility that CMS has shown in this category leads us to believe that quality and cost measures can be broadly applicable to multiple Improvement Activities.

Earlier this year, we were grateful to meet with CMS staff and discuss how anesthesiologists can claim improvement activities credit based upon their treatment of COVID-19 patients and coordination among their clinical colleagues. CMS recognized how anesthesiologists were being called to the frontlines of this pandemic and how anesthesiologists were finding unique ways to care for patients and protect themselves and their colleagues from being infected. Locally, anesthesiologists participated in personal protective equipment (PPE)-related in-service training to ensure healthcare worker safety, converted anesthesia machines to ICU ventilators to mitigate shortages and established protocols for COVID-19 screening and testing. Among all the actions that anesthesiologist departments have taken, the three proposals we presented to CMS that day were interdisciplinary in nature, unfortunately lasted for more than a 90-day continuous period and oftentimes could be met by more than 50% of a group's NPIs. We thank

CMS for their letter directing our members to pre-existing Improvement Activities where they could claim appropriate credit for their COVID-19 work.

Promoting Interoperability Performance Category

The majority of physician anesthesiologists benefit from receiving non-patient-facing status and not having to report the Promoting Interoperability performance category. This long-standing policy from CMS recognizes anesthesiologist workflows, their limited control of hospital and facility EHRs and documentation procedures that have made our specialty unique with regard to federal interoperability policy and EHR and health IT implementation prerogatives. Regardless, physician anesthesiologists and pain medicine physicians may opt-in to reporting this performance category to diversify their performance scores.

We believe that the updates to the Promoting Interoperability measures are prudent and reflect current technologies and limitations of technology. CMS should maintain the Query of the Prescription Drug Monitoring Program (PDMP) as optional and increasing the bonus from 5 to 10 points. As noted in the proposed rule, CMS understands the difficulties that some physicians have faced when accessing and using PDMP data. Although additional work is needed to improve Health Information Exchanges (HIE), ASA supports CMS continuous efforts to incentivize clinicians to exchange information and engage with HIEs.

CMS should better define the responsibilities of non-patient-facing ECs and groups with regard to Promoting Interoperability and MVPs. ASA supports the general direction of promoting interoperability performance category and the alignment with the 21st Century Cures Act, but would like CMS to reconsider their proposed pace of change as health practices are recovering from the economic downturn caused by the COVID-19 pandemic. Throughout the pandemic, anesthesiologists have saved lives, coordinated and allocated local resources, converted anesthesia machines for use as ventilators in intensive care units and worked across specialties to ensure care coordination and patient care was a team endeavor. Yet at the same time, a survey of our members indicated that more than 80% of our groups experienced a decline of 50% or more revenue in the first half of 2020. ASA anticipates that many anesthesia groups will need additional time to recover from this financial strain before they will be able to invest in Certified Electronic Health Record Technology (CEHRT) and health IT. ASA strongly urges CMS and the ONC to consider that small practices, rural practices, and others will need additional resources and time to implement future regulations.

ASA believes that the thoughtful development of standards, interoperability protocols and procedures, as described in this rule, should strike a proper balance between all stakeholders to maximize patient safety, efficiency, and patient outcomes. Many anesthesiologists work in facilities which continue to use paper charting for the anesthesia record. Anesthesia records are complicated, include multiple clinical data points and free text that are not always easily translatable to EHRs. Moreover, anesthesiologists provide care to patients in a variety of facilities and care settings that include hospitals, ambulatory surgery centers and office-based locations where an anesthesiologist does not control or own the EHR. Anesthesiologists interact with a variety of technology, facility administrations and patient populations that carry their own facility-specific workflow challenges. To an individual or group, the burden of understanding differences between systems in multiple locations, including how data is gathered, pulled and submitted for reporting purposes can be overwhelming.

ASA welcomes the opportunity to discuss with CMS our unique and complex situation with

regard to MVPs and their use within different sites of service. We see benefits for patients, physicians, and other stakeholders by increasing access to electronic health information and making that information more user friendly. However, interoperability challenges will need multiple solutions to ensure all types of anesthesia practices can follow the shift to advanced health IT, if it is possible, both from a financial and workflow standpoint. ASA needs to further explore how to support our members transitioning from paper records to EHRs in a timely fashion that minimizes administrative and financial burdens for anesthesiologists.

MIPS Final Score Methodology

Anesthesiologists and their groups have benefited from the evolution of MIPS scoring and reweighting of categories that CMS has developed over the years. The emphasis by the Agency to focus on providing options for MIPS participants to report data and for the Agency to take the higher of certain scores builds confidence in the program and demonstrates transparency. We appreciate that CMS has delayed significant scoring changes until 2022. **We encourage CMS to provide additional guidance well before the 2022 proposed rule is released about possible scoring methods for MIPS and MVPs.**

Quality Measure Benchmarks

CMS should continue to focus on providing ECs and groups with the best opportunity to score well in MIPS. We have worked with CMS over the years to improve anesthesiology measure benchmarks and have appreciated the CMS policy to use same-year benchmarks for measures that have met the minimum criteria for benchmarking to occur. We support, regardless of COVID, that CMS reviews each measure using the same-year benchmark. CMS should still publish historical benchmarks to help MIPS ECs and groups determine if a measure may be topped out or at least to indicate what better care looks like, but current year data would provide more reasonable data for an individual or group to be assessed under MIPS.

Third Party Intermediaries – Qualified Clinical Data Registries and Qualified Registries

The Anesthesia Quality Institute, an affiliate of the ASA, and its registry, the National Anesthesia Clinical Outcomes Registry (AQI NACOR) have submitted MIPS data for more than 17,000 anesthesia providers in each of the last five years. Our participants rely on AQI NACOR for their reporting and we strive to ensure that their participation is not burdensome, their data correctly captures their performance and can be used not just for quality reporting but for local quality improvement purposes as well.

Several of the new proposals for Qualified Registry and QCDR auditing will increase the burden on our participants. The uniqueness of anesthesiology data capture at the point of care or facility is oftentimes quite different than other specialties. In addition, many of our quality measures are derived from multiple sources, making the burden of collecting data, and in submitting data in support of an audit, cumbersome for individuals and groups. This is especially true for practices who are collecting quality data on paper or practicing in numerous locations – a very common occurrence for anesthesia practices.

ASA and AQI NACOR support regulations that allow data validation plans to span multiple submitter types. We do not support data validation plans specific to submitter type. AQI NACOR supports both the QCDR and Qualified Registry reporting mechanisms and

reasonable data validation plan requirements that support QCDRs and Qualified Registries in verifying that the data submitted is true, accurate and complete. We believe CMS intends for data validation to serve a meaningful purpose and not create unreasonable burdens for the clinicians or for QCDRs and Qualified Registries.

The proposal to conduct data validation for each submitter type would result in some individuals or groups being audited more often and less randomly. The vast majority of anesthesiologists and their groups report as groups via the QCDR reporting option. For example, AQI NACOR had nearly 400 groups reporting via QCDR in 2019 and less than two dozen report via the Qualified Registry. The number of ECs reporting as individuals is also quite low as many practices prefer to report as a group. Because of the low number of participants reporting via the Qualified Registry as individuals, the randomized auditing on a small sample would result in this unintended consequence of increasing their burden without necessarily improving the quality of data submitted. Such a blanket policy change would result in some practices being audited multiple times, sometimes within the same year, based on their submission category. **Therefore, 2020 CMS policies for data validation are sufficient and CMS should not finalize their burdensome proposal to require data validation for each submitter type.**

CMS has also proposed to increase the reporting and documentation burden on practices that will be audited either by AQI NACOR or the agency. We are concerned that the language included in the proposed rule, particularly "meaningful validation" of a clinician activity or clinical outcome is not effective in meeting the intended goals of the program. As part of its data validation efforts, AQI NACOR requires groups and individuals to submit relevant evidence that demonstrates that the data submitted matches primary source documents and records at the practice. This new CMS proposal includes language that could invalidate certain records that are not "clinical documentation" in nature. For instance, MIPS 404 requires that an anesthesiologist or their proxy counsel a patient to not smoke on the day of surgery. Documentation of that action may be in clinical or medical notes, spreadsheets, apps, or other locations that are not necessarily tied directly to the patient record. By requiring "clinical documentation," CMS is increasing the burden on practices to a higher yet unnecessary level of substantiating their actions.

We recommend that CMS provide flexible auditing guidance that is not overly prescriptive in nature to Qualified Registries and QCDRs. Appropriate guidance is particularly necessary for the Promoting Interoperability and Improvement Activities performance categories. For the promoting interoperability category, anesthesiology groups do not have adequate access to the CEHRT, especially when practicing in multiple locations where the ownership of their EHR is not in their control. For improvement activities, AQI NACOR supports more than 50 improvement activities and we believe that meaningful validation of what constitutes compliance may vary from one group to another. In some cases, documentation may not be clinical in nature but meaningful for practice improvement. In other cases, clinical documentation of improving workflows, adhering to standard protocols and tracking compliance might be more readily available. Although it is important and necessary for CMS to clearly communicate its expectations with respect to audits conducted by the Qualified Registry and QCDR, such guidance must allow flexibility in order to account for varying practice conditions and constraints that may present when completing an audit. We believe that CMS has final authority to determine whether the documentation provided to support those improvement activities meets the spirit of the individual Improvement Activity.

CMS should not require collection of more protected health information (PHI) than is necessary to achieve its purpose. Like many other medical registries, our registry is designed to collect only that PHI which is needed to achieve the objectives of improving the quality of anesthesia care through our data analysis. We are concerned that the codification of multiple auditing requirements related to clinical documentation and patient information could jeopardize our business model and trust that we have built with anesthesiologists over the past ten years. We believe CMS should narrowly define what should be collected via an audit, with such criteria preserving the confidentiality of patient information and not subjecting QCDRs and Qualified Registries to additional risks that they would not otherwise assume.

The role of targeted and routine audits of participant data should balance the timing of when data is submitted by the individual or groups with CMS priorities. ASA agrees with CMS's intent for individuals and groups to routinely submit data but believes enhanced auditing proposals are not practical and will be burdensome on individuals, groups and clinical data registries. Despite requirements by QCDRs and Qualified Registries to routinely submit and review data throughout the year, some ECs and groups submit their quality measure data and attest to IAs late in the performance year. There are understandable reasons that these tasks may be completed late in the year that include, but are not limited to, the time it takes to choose measures at the beginning of the year, to training individuals on collecting measures and the costs associated with merging billing and quality data. For some practices, the ability to collect measure data is delayed by actions outside of their control, including when EHR and quality app vendors are able to load new measure specifications into their platforms for data collection. The timing of data submission by some ECs and groups to the third-party intermediary is, in short, incompatible with the vision and proposed requirements of CMS.

AQI supports CMS efforts to ensure all QCDRs submit true, clean, and accurate data to the MIPS program. But the process, as proposed by CMS, will have a detrimental effect on the ability for a third-party intermediary to implement a significant yet targeted audit of data submitted. The proposed requirements of CMS to increase the number of NPI/TINs and patient data that is audited is burdensome to the individual practices and to the workflows and limited resources that medical society registries often have at their disposal.

As a medical society registry, we prioritize the importance of quality improvement and implementing best practices to improve our systems, the data we collect and our participants' desire to improve the care of their patients. We likewise know that identifying the root cause of data errors by groups prior to our CMS submission is one way that we have and will continue to ensure accurate and complete files. However, as a third-party intermediary, while the QCDR and Qualified Registry is responsible for communicating identified errors, it is the responsibility of the individual or group reporting to the third-party intermediary to correct their files before our registry sends their data to CMS. **CMS should amend their guidance to note that it is the responsibility of the individual or group to amend their data files prior to the Qualified Registry, QCDR or third-party intermediary submitting data on their behalf.**

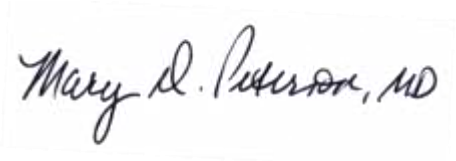
Similar to CMS's desire, we too want to avoid repeating any errors that we find in our audit and validation reports. However, we request more information on how AQI NACOR's registry errors collected on anesthesiology practices would have relevance to QCDRs and others that may not use the same methods to collect, validate, and submit participant data to CMS. AQI NACOR agrees that those using the same vendor or who collect data from participants in a similar manner may benefit from sharing best practices. However, the approach to solving data errors

will not be readily available through a one-size-fits all approach. We request that CMS discuss this further with QCDRs and Qualified Registries and develop a more clear and transparent policy. A listening session on this issue would benefit the policy and, we believe, lead to improved Qualified Registry and QCDR operations in the Quality Payment Program.

CMS should delay the implementation of enhanced auditing requirements by at least one year. AQI NACOR has benefited from a positive relationship with CMS with regard to honing our auditing plan during the nomination period and in the agency's willingness to understand the burdens placed on clinicians and groups during the audit process. We have worked alongside our practices to help them understand the audit process and what must be submitted to achieve compliance with our plan and CMS's requirements. However, the new requirements proposed by CMS increases both the burden and cost to individuals, groups and third-party intermediaries during a time when resources are strained. We have noted our sincere concerns above and request that CMS not finalize these proposals. Instead, CMS should delay their implementation and work with registries to understand what can and should be done.

Thank you for your consideration of our comments. We would be very glad to follow up with you as necessary on any issues for 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,



Mary Dale Peterson, MD, MHA, FACHE, FASA
President

APPENDIX A: SUMMARY OF RECOMMENDATIONS

Calculation of the CY 2021 PFS RBRVS and Anesthesia Conversion Factors (CFs)

- ASA has grave concerns about the magnitude of the cuts to payments for the services of anesthesiologists. We recognize the limited authority CMS has to modify statutorily mandated budget neutrality adjustment when calculating updates to the conversion factors, however, we are alarmed at the potential cascading impacts on both physician practices and clinical patient outcomes. Resolution of this issue will require action by Congress and others outside of CMS. ASA urges CMS to coordinate with these entities as it relates to updates to the fee schedule and processing claims.
- CMS utilization assumptions for new add-on code GPC1X contributes significantly to the increase in spending that is driving the 10.61% budget neutrality adjustment. ASA does not believe these estimates are reasonable and urges CMS to review and reduce its utilization assumptions for GPC1X.

Practice Expense (PE) RVUs

- ASA continues to support the engagement from the agency to work with CMS contractors and stakeholders to incorporate current pricing data based on invoices into the calculation of direct PE costs. ASA believes that incorporation of new data must be done in a transparent manner where CMS publicly documents the criteria used to accept or reject data received from contractors or stakeholders.

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID–19 Pandemic

- Prior to the implementation of this code, CMS should release comprehensive coding and billing guidance for GPC1X. This guidance should include specialty-specific vignettes. The agency should also provide guidance on how claims containing GPC1X will be audited.
- CMS utilization assumptions for new add-on code GPC1X contributes significantly to the increase in spending that is driving the 10.61% budget neutrality adjustment. ASA does not believe these estimates are reasonable and we reiterate our recommendation for CMS to review and reduce its utilization assumptions for GPC1X.

Proposal to Remove Selected National Coverage Determinations

- ASA appreciates agency efforts to ensure that NCDs are based on current scientific evidence, are relevant to the Medicare population and that the Medicare coverage process is designed to provide greater contractor flexibility. As CMS moves towards greater discretion at the local level for MACs, the agency must ensure a transparent and meaningful process for physician voices to be heard through the Contractor Advisory Committee (CAC) a federally mandated regional committee that provides input on local coverage determinations (LCDs).

Telehealth and Other Services Involving Communications Technology

General Comments

- ASA supports CMS' efforts to expand telehealth services while ensuring patients continue to have access to necessary and high quality care.

- We were disappointed that the agency failed to propose making permanent other flexibilities which we believe are within their regulatory authority such as the payment policy for non-facility clinicians and flexibilities around audio/visual requirements for telehealth communication technologies. We urge CMS to consider these additional telehealth flexibilities.

Critical Care Codes 99291-99292

- ASA recommends that critical care codes 99291 and 99292 should remain permanently on the Medicare Telehealth list.

Remote Critical Care Monitoring Models

- ASA urges CMS to develop a set of codes to report the provision of tele-ICU services which may or may not include the use of robots or other similar technology.

Direct Supervision by Interactive Telecommunications Technology

- ASA supports the agency's assessment that anesthesia services must be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation.

Quality Payment Program

MIPS Value Pathways (MVPs)

- ASA agrees with CMS to delay the implementation of MVPs to the 2022 performance year.
- CMS should provide feedback to MVP developers and stakeholders regardless of whether the MVP will be proposed for implementation.
- CMS should provide concrete deadlines for MVP candidate submissions to receive feedback.
- To expand engagement with known and unknown stakeholders, we believe that CMS should publish a rolling list of MVPs that are under consideration.
- ASA agrees that ECs and groups should have opportunities to align their local initiatives, priorities and responsibilities with MVP reporting.
- We request CMS allow ECs and groups the ability to choose an MVP to report or to participate in the traditional MIPS program.

MVP Guiding Principles

- CMS should balance the interests of multiple specialties under each proposed MVP.
- ASA supports subgroup reporting as anesthesia groups often treat different patient populations on a daily basis.
- CMS efforts to engage with the patient community and ensure clinicians are providing meaningful information to improve the patient experience is necessary.
- CMS should identify the methodology that specialties can use to achieve APP or APM status.
- We request additional information and clarity on the development and use of "digital quality measures."

MVP Development

- CMS should define a governance structure for MVPs.
- CMS should incentivize collaboration between specialty societies to craft and test MVPs.

- CMS should allow multiple stakeholders to share the burden of fulfilling the base criteria of an MVP.

MVP Submission Questions and Criteria

- CMS can better define MVP submission criteria and/or make common language available for MVP developers to use.
- We believe the question "*Is the MVP comprehensive and understandable by patients?"* is premature. ASA is considering working with our colleagues in several patient advocacy organizations to test whether our MVP proposal(s) are supported by patient populations.
- ASA expects to provide opportunities for public comment on our MVPs and we also have partners to contact regarding the patient voice and MVPs.
- ASA agrees with this criteria, however, would request CMS delay this requirement until the 2023 performance year to allow stakeholders time to convene technical expert panels.
- We encourage CMS to maintain the current Promoting Interoperability exemptions and allow those exemptions to be used as a proxy for the Promoting Interoperability measure requirement. Without these flexibilities, the MVP process will not function equitably.

MVPs and Patient Engagement

- ASA supports elevating the patient's voice, but we request patient evaluation or contributions to MVPs be delayed until the 2023 performance year.

MVPs and Quality Measures

- CMS should use Qualified Clinical Data Registry (QCDR) measures as part of an MVP.
- CMS should maintain the approval of QCDR measures for two years and not remove CMS endorsement unless approved by the measure steward.
- Our vision for an MVP episode of care would incorporate quality measures from multiple specialties, but those quality measures should be reported via each specialty's designated QCDR.
- ASA is supportive of a CMS policy decision to allow one specialty to report QCDR CQMs and another specialty represented within the MVP to report MIPS CQMs.
- We do not believe there will be a barrier for individuals or groups to participate in an MVP solely because of the inclusion of QCDR measures.

MIPS Performance Category Measures and Activities

- Cost Performance Category: CMS feedback reports should clearly identify the cases that an individual EC or group was assessed under the Cost performance category.
- Promoting Interoperability Performance Category: CMS should better define the responsibilities of non-patient-facing ECs and groups with regard to Promoting Interoperability and MVPs.

MIPs Final Score Methodology

- We encourage CMS to provide additional guidance well before the 2022 proposed rule is released about possible scoring methods for MIPS and MVPs.

Third Party Intermediaries – Qualified Clinical Data Registries and Qualified Registries

- ASA and AQI NACOR support regulations that allow data validation plans to span multiple submitter types. We do not support data validation plans specific to submitter type.
- Therefore, 2020 CMS policies for data validation are sufficient and CMS should not finalize their burdensome proposal to require data validation for each submitter type.
- We recommend that CMS provide flexible auditing guidance that is not overly prescriptive in nature to Qualified Registries and QCDRs.
- CMS should not require collection of more protected health information (PHI) than is necessary to achieve its purpose.
- The role of targeted and routine audits of participant data should balance the timing of when data is submitted by the individual or groups with CMS priorities.
- CMS should amend their guidance to note that it is the responsibility of the individual or group to amend their data files prior to the Qualified Registry, QCDR or third-party intermediary submitting data on their behalf.
- CMS should delay the implementation of enhanced auditing requirements by at least one year.