American Society of Anesthesiologists™

1061 American Lane | Schaumburg, IL 60173-4973 | (847) 825-5586
905 16th Street N.W., Suite 400 | Washington, D.C. 20006 | (202) 289-2222

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

September 19, 2019

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1715-P
PO Box 8013
Baltimore, MD 21244-1850

Re: **[CMS-1715-P]** Medicare Program; CY 2020 Revisions to 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

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:

- Valuation of specific codes
  - Somatic Nerve Injection codes (64400-64450)
  - Genicular Injection and RFA codes (CPT Codes 64640, 64XX0, and 64XX1)
  - Radiofrequency Neurotomy Sacroiliac Joint codes (CPT Codes 6XX00, 6XX01)
- Evaluation & Management (E/M) services (99201-99205) (99211-99215) (99XXX)
- Medicare Coverage for Opioid Use Disorder Treatment Services
  - Bundled Payments Under the PFS for Substance Use Disorders

    - Medicare Enrollment of Opioid Treatment Programs
    - Improper Prescribing and Patient Harm
- Scope of Practice for Certified Registered Nurse Anesthetists (CRNAs)
- Solicitation of Comments for Bundled Payments under the PFS
- Quality Payment Program
    - Quality Performance Category
    - Improvement Activities Performance Category
    - Promoting Interoperability Performance Category
    - Cost Performance Category
    - Facility-based Scoring
    - Targeted Review and Data Validation and Auditing
    - Third Party Intermediaries
- MIPS Value Pathways
    - Guiding Principles
    - Stakeholder Engagement
    - Organizing MVPs
    - Promoting Health Information Technology and Interoperability
    - Reducing Barriers to Clinical Movement into APMs
    - Selecting Quality Measures and Activities
    - Selection of MVPs
    - Transition Period
    - Multispecialty Groups
    - Incorporating QCDR Measures into MIPS
    - Scoring MVP Performance
    - Population Health Quality Measure Set
    - Clinician Data Feedback
    - Patient-Reported Outcome Measures
    - Public Reporting MVP Performance Information

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

Valuation of Specific Codes

Somatic Nerve Injection Code Family (CPT Codes 64400, 64408, 64415, 64416, 64417, 64420, 64421, 64425, 64430, 64435, 64445, 64446, 64447, 64448, 64449, and 64450)

The Somatic Nerve Injection Code Family describes the injection(s) of an anesthetic agent(s) and/or steroid into a nerve plexus, nerve, or branch; reported once per nerve plexus, nerve, or branch as described in the descriptor regardless of the number of injections performed. This code family was recently reviewed at the request of the Editorial Board of the *CPT Assistant* to clarify the code definitions and improve the understanding of the appropriate reporting of the code family. The updated code family was approved at the May 2018 CPT Editorial Panel meeting and surveyed for the October 2018 American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) meeting.

Elsewhere in this proposed rule, CMS discusses proposals to address the opioid crisis through the establishment of codes for treatment and counseling for substance use disorders.

Addressing the opioid crisis is a critical priority that falls upon CMS as well as physicians who treat patients with substance use disorders or patients who are at risk for them. The injection services described by the codes in this family can be used as an alternative to opioids for both acute and chronic pain management. While the agency should always strive for fair and appropriate payment for physician services, the role these procedures play in providing an alternative to opioids for pain management, makes an even more compelling case to ensure appropriate payment and access to these services.

A recent interagency task force report on pain management best practices is aligned with this position. The report, released by the Department of Health and Human Services (HHS) in May 2019, recommends non-opioids be used a "first-line therapy" whenever clinically appropriate. The report found that peripheral nerve injections to be advantageous in that they allow for quicker discharge times in ambulatory settings, less postoperative nausea and vomiting because less opioid medication is used, and improved patient satisfaction. To address inconsistencies and delays in insurance coverage, the report encourages CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate.[1] This report, released by HHS, provides further support that CMS should ensure fair and appropriate payment for these important services.

Work RVU Recommendations

ASA was very disappointed that CMS has proposed to reject the RUC work RVU (wRVU) recommendations for 12 of the 18 codes in this family, which recently went through a vigorous survey process. In developing these recommendations, the RUC took a comprehensive approach, which included consideration of robust survey data; input from clinical experts; and maintenance of appropriate relativity within the code family and throughout the Medicare physician fee schedule. In developing specific recommendations, the RUC considered: anatomic location of each nerve, whether the service is typically performed in an office or facility setting, the typical approach used by the dominant specialty to access the nerve and whether the service involves continuous administration via placement of a catheter. All of these critical factors contribute to the valuation of these services. ASA does not believe the agency took them into account when developing their proposals.

While we provide detailed comments on specific codes and proposed values, ASA also wishes to highlight our concerns over the agency's overall approach to developing proposed values for this family of codes.

- Harvard vs RUC Survey Data: The first issue has to do with the consideration of time and other data related to these codes. This family of codes includes many Harvard-based codes. These are codes that have never been surveyed; time is not based on a

[1] U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

direct measurement and the basis for the current valuation is unknown. The family also includes codes that have been surveyed by the RUC and for which there is a documented rationale for the current value of the code. Throughout its review of this family CMS has equated the imputed time from Harvard data with the more reliable RUC survey time. **This is a flawed methodology**. Historically, RUC survey data has been viewed as a more accurate measurement of time versus Harvard time. On a related issue, while it has been a long-standing policy of the agency that a reduction in time does not equate to a one to one reduction of wRVU values, CMS has seemed to apply this approach to the family.

- Selection of Crosswalks and Reference Codes to Establish Values: Historically the selection of crosswalks or reference codes are based not only on similar intra-service time but also clinical similarity. Clinical similarity refers to the complexity, intensity and risk of the procedure. **Throughout this family, CMS has selected reference codes where intra-service time seems to be the only similarity and where there clearly is no clinical similarity to the two procedures**. As an example, in one instance for a surveyed code which is performed predominately in the facility setting as part of post-operative pain management after major surgery, CMS selected a relatively simple procedure performed in the office setting generally performed by a non-physician health practitioner.

ASA has significant concerns with this approach and believes it has resulted in a significant and inappropriate undervaluation of these services. ASA strongly believes the evidence-based RUC recommendations are more appropriate and urges CMS to finalize the RUC recommendations for this entire family. In our comments today we highlight the flaws in the agency's approach as well as those critical factors addressed during the RUC review process that we believe the agency failed to take into account. Our comments focus on 11 codes in this family: 64400, 64415, 64416, 64420, 64421, 64425, 64430, 64445, 64446, 64448, and 64449. Although CMS rejected the RUC recommendation for code 64408 (*Injection(s), anesthetic agent(s), and/or steroid; vagus nerve*), ASA is not commenting on this code since it is not performed by the specialty and we did not survey this code.

Table 1: Summary Table: Somatic Nerve Injection Code Family

Code #	2019 wRVUs	Current Data Source	RUC Rec.	Basis for RUC Rec.	2020 Proposed wRVU	Basis for 2020 Proposed wRVU
64400*	1.11	Harvard	1.00	• Survey data (25th percentile) • Reference code	0.75	• Time ratio methodology • Reference code

Code #	2019 wRVUs	Current Data Source	RUC Rec.	Basis for RUC Rec.	2020 Proposed wRVU	Basis for 2020 Proposed wRVU
64415	1.48	RUC-2009	1.42	• Survey data (25th percentile) • Reference code	1.35	• Time ratio methodology • Reference code
64416	1.81	RUC-2008	1.81	• Survey data (25th percentile) • Reference code	1.48	• Time ratio methodology • Reference code
64420	1.18	Harvard	1.18	• Reference code	1.08	• Time ratio methodology • Reference code
64421**	1.68	Harvard	0.60	• Crosswalk	0.50	• Time ratio methodology • Reference code
64425	1.75	Harvard	1.19	• Survey data (25th percentile) • Reference code	1.00	• Maintain rank order in the family
64430	1.46	Harvard	1.15	• Survey data (25th percentile) • Reference code	1.00	• Maintain rank order in the code family
64445	1.48	RUC-2009	1.18	• Crosswalk	1.00	• Maintain rank order in the code family
64446	1.81	RUC-2008	1.54	• Crosswalk	1.36	• Time ratio methodology • Reference code
64448	1.63	RUC-2008	1.55	• Crosswalk	1.41	• Time ratio methodology • Reference code

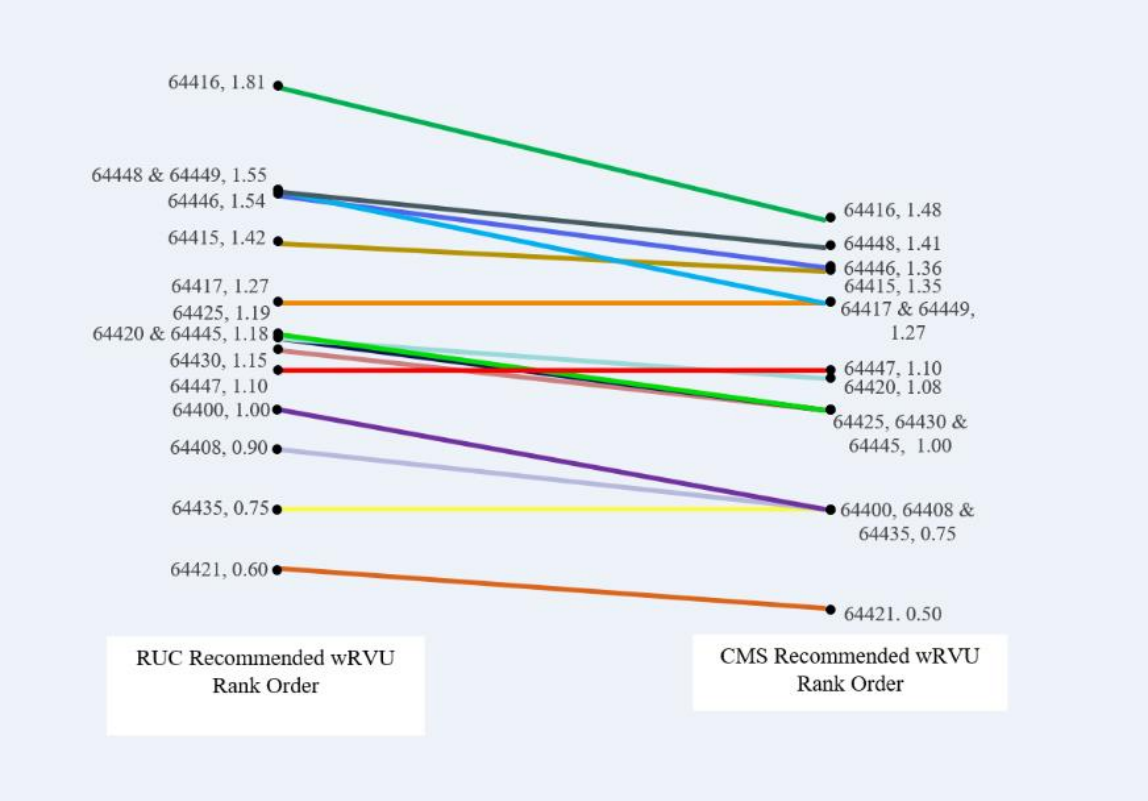
Code #	2019 wRVUs	Current Data Source	RUC Rec.	Basis for RUC Rec.	2020 Proposed wRVU	Basis for 2020 Proposed wRVU
64449	1.81	RUC-2008	1.55	• Crosswalk	1.27	• Time ratio methodology • Reference code

* Survey 25th percentile of dominant specialty performing the service, neurology
**Note, the code definition of 64421 is changing in 2020. It is going from an XXX code to an add-on code that is reported with the base code of 64420.

In proposing values for codes in this family, CMS generally used what is referred to as a "time ratio methodology." By the agency's own admission, the time ratio methodology used by CMS throughout the evaluation of this code family is **not** consistent with their overall approach to valuing codes. Additionally, applying this method to codes that have not been previously surveyed (Harvard) and comparing that time to RUC survey time is a completely flawed methodology.

As part of our analysis, we compared the RUC recommendation to the CY 2020 proposed wRVUs on the basis of rank order, range of wRVU values and wRVU increments between codes. This analysis is summarized in the figure below.

Figure 1: Somatic Nerve Injection Code Family, wRVU Analysis of RUC Recommendation wRVU vs CY 2020 Proposed wRVU



The figure illustrates that:

- the range of the CY 2020 proposed wRVUs do not adequately capture the work being performed;
- the interval or increments between procedures are not adequate; and
- rank order anomalies have resulted with the proposed CY 2020 wRVU values (e.g. 64449 & 64448).

This figure provides further evidence of the appropriateness of the RUC recommendations.

A code-by-code discussion of our proposed recommendations for the Somatic Nerve Injection Code Family follows.

64400 Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64400	1.11	1.00	0.75

Code 64400 describes injection of the trigeminal nerve. The typical patient presents with a normal neurologic exam but reports headaches that include pain in one or more branches of the trigeminal nerve (ophthalmic, maxillary, or mandibular). Code 64400 is currently a Harvard-valued code that has not been previously surveyed. This means that the time was merely extrapolated and not measured directly. The rationale for the basis of the current value is unknown.

The current value for code 64400 is 1.11 wRVUs. The RUC recommendation reduced it to 1.00 wRVUs and CMS is proposing to further reduce it to 0.75 wRVUs. This represents a 25% reduction from the RUC recommended value. The agency's rationale for this reduction is that the intra-service time decreased from 37 to 6 minutes (84 percent reduction) and the RUC-recommended total time decreased from 69 to 20 minutes (71 percent reduction) for CPT code 64400. CMS is basing its recommendation of 0.75 wRVUs on a crosswalk to code 64450 (*Injection(s), anesthetic agent(s); other peripheral nerve or branch)* which CMS indicates has a similar intra-service time.

ASA believes the agency's rationale is flawed and that the proposed crosswalk to 64450 is inappropriate.

In developing its rationale for a proposed value for this code, CMS is comparing intra-service time for a Harvard-based code to times from a RUC survey. As we stated in our introductory comments, this is a flawed methodology. Typically, Harvard time is not based on a direct measure of the service while the RUC surveys are a survey of time specific to the code. ASA believes it is always inappropriate to compare Harvard time to RUC time.

CMS also supports its proposed value with a crosswalk to code 64450. Crosswalks are an effective methodology to assign value in a relative value system. That said, as discussed in our introductory comments to this section crosswalks are only appropriate if the codes are similar in intra-service time and are clinically similar (*e.g.* complexity, intensity and risk). The anatomical location of the injection determines the clinical complexity, intensity and risk of the procedure. Codes 64400 and 64450 are not clinically similar. Code 64450 is not specific to a nerve target and is used when a more specific code is not available. The typical patient for 64450 is described as a patient experiencing a chronic burning pain and a tingling sensation in the plantar aspect of their right foot. A clinically similar service to 64450 is code 20553 (*Injection(s); single or multiple trigger point(s), 3 or more muscles*) which has RUC intra-service time of 10 minutes and is valued as 0.75 wRVUs. In contrast, code 64400 describes an injection of the trigeminal nerve which is inherently more complex than injecting the plantar aspect of the right

foot, the typical patient for the 64450 vignette, which 78 percent of survey respondents to a survey for 64450 found to be accurate.

The RUC's recommendation for code 64400 was based on survey data and a crosswalk to what we believe is a more appropriate crosswalk.

In recommending 1.00 wRVUs, the RUC based this recommendation on the 25th percentile of the dominant specialty reporting the code (neurology). The RUC decided to take this subset approach which is atypical but used in this circumstance because although neurology is the top performing specialty, they represented fewer survey responses than anesthesiology. Neurology is 47 percent of the 2017 Medicare claims whereas anesthesiology is only 10 percent of the claims. ASA believes this is an appropriate approach to take in this circumstance. We would note, that if the RUC would have based its recommendation on the 25th percentile of all survey respondents the recommended value would have been higher than 1.00 wRVUs.

The RUC also strongly supported its recommendation with comparison to CPT code 31575 *Laryngoscopy, flexible; diagnostic* (wRVU = 0.94, intra-service time of 5 minutes, total time of 24 minutes) and MPC code 36620 *Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); percutaneous* **(**wRVU = 1.00, intra-service time of 7 minutes, total time of 17 minutes). ASA believes that these are appropriate reference codes that are both clinically similar (complexity, intensity and risk) as well as have similar in intra-service time.

ASA urges CMS to accept a wRVU of 1.00 for CPT code 64400.

64415 Injection(s), anesthetic agent(s) and/or steroid; brachial plexus

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64415	1.48	1.42	1.35

Code 64415 describes the injection of the brachial plexus. The typical patient presents with persistent, debilitating pain interfering with the ability to complete daily activities. This code was previously surveyed by the RUC in 2009.

The current value for code 64415 is 1.48 wRVUs. The RUC recommendation reduced it to 1.42 wRVUs and CMS is proposing to further reduce it to 1.35 wRVUs. This represents a 5% reduction from the RUC recommended value. CMS indicates that their recommendation is based on their "…time ratio methodology…" although they do not provide details on the methodology. While intra-service time for this code did decrease from the current 15 minutes to 12 minutes with the most recent survey, reducing the value based just on reduced intra-service time would be inconsistent with current CMS policy. CMS' longstanding position is that, "…we do not imply that

the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs." This is reiterated 18 separate times in the CY 2020 Proposed Rule including with this code, however it was disregarded in this instance when proposing an alternate valuation method.

CMS also supported its recommendation by comparing this code to a reference to CPT code 49450 (*Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injections(s), image documentation and report*), which has a wRVU of 1.36 and similar intra-service and total time values to CPT code 64415. ASA believes this rationale is flawed and does not believe the crosswalk is appropriate. Code 49450 was surveyed twelve years ago in 2007.

The RUC's recommendation for code 64415 was based on survey data and with additional support with other reference codes. The RUC recommendation was based on the 25th percentile work RVU and careful review of all of the underlying clinical attributes of the procedure.

The RUC also strongly supported its recommendation with comparison to code 64612 *Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)* (wRVU = 1.41, intra-service time of 10 minutes, total time of 41 minutes) and code 30903 *Control nasal hemorrhage, anterior, complex (extensive cautery and/or packing) any method* (wRVU = 1.54, intra-service time of 15 minutes, total time of 39 minutes). Both of these codes are more recently surveyed than 49450 which is another reason that makes these more accurate and appropriate comparison. Code 64612 was surveyed in 2012 and code 30903 was surveyed in 2016. In particular, we believe code 64612 is a code more clinically similar making it a stronger reference code for 64415. The intensity and risk of an injection of a facial nerve described by 64612 more closely resembles 64416 than the reference code selected by CMS, code 49450.

ASA believes the reduced value of the RUC recommendation appropriately accounts for the reduction in intra-service time from the previous RUC survey (15 minutes intra-service time) in comparison to the current RUC survey (12 minutes intra-service time).

ASA urges CMS to accept a wRVU of 1.42 for CPT code 64415.

64416 Injection(s), anesthetic agent(s) and/or steroid; brachial plexus, continuous infusion by catheter (including catheter placement)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64416	1.81	1.81	1.48

Code 64416 describes the injection of the brachial plexus with continuous infusion by catheter. The typical patient presents with persistent, debilitating pain interfering with the ability to complete daily activities. This code was previously surveyed by the RUC in 2008.

The current value of the code is 1.81 wRVUs. The RUC recommended maintaining the current value. CMS proposes to reduce the value to 1.48 wRVUs. While the overall time for the code did decrease from 60 minutes to 49 minutes, the current survey resulted in the same intra-service time of 20 minutes as the original survey from 2008. ASA believes this consistency in intra-service time provides support for maintaining the current value of 1.81 wRVUs.

CMS disagrees with the RUC recommendation based on their previously mentioned but not clarified time ratio methodology. The agency bases its proposed value for the code by bracketing it between code 62270 (*Spinal puncture, lumbar, diagnostic*), which has a wRVU of 1.37, identical intra-service, and similar total time to CPT code 64416 and CPT code 91035 (*Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation*), which has a work RVU of 1.59, identical intra-service, and near identical total time values to CPT code 64416.

ASA believes this rationale is flawed and that the crosswalk is not appropriate. CMS proposed value is 18 percent lower than the RUC recommendation, creates rank order in the family and results in an inappropriately low IWPUT of 0.0451. Code 64416 is typically performed in a facility setting. In contrast code 91035 is typically performed by in the office setting. While the intra-service time may be similar, it is very clear that the intensity of these two procedures are not similar. The clinical intensity of a gastroesophageal reflex test (code 91035) is less than injection of the brachial plexus with continuous infusion by catheter (code 64416). Code 91035 is not an appropriate reference code for code 64416. We also find 62270 problematic. While it is typically performed in a facility setting, 62270 is a diagnostic procedure while 64416 is therapeutic and an inherently more intense service.

In contrast to the agency's analysis, the RUC recommendation was based on the 25th percentile wRVU and careful review of all of the underlying clinical attributes of the procedure.

The RUC also strongly supported its recommendation with comparison to code 32554 *Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance* (work RVU = 1.82, intra-service time of 20 minutes, total time of 56 minutes).

ASA urges CMS to accept a wRVU of 1.81 for CPT code 64416.

64420 Injection(s), anesthetic agent(s) and/or steroid; intercostal nerve, single level

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64420	1.18	1.18	1.08

Code 64420 describes the injection of the intercostal nerve. The typical patient presents with persistent, debilitating pain. A trial of intercostal nerve block is scheduled to relieve her pain and improve her function. The code is reported once per nerve regardless of the number of injections performed. Code 64420 is currently a Harvard-valued code that has not been previously surveyed. This means that the time was merely extrapolated and not measured directly. Nor is the rationale for the basis of the current value known.

The current value for code 64420 is 1.18 wRVUs. The RUC recommended maintaining that value, but CMS is proposing to reduce it to 1.08 wRVUs. This represents an 8.5% reduction from the RUC recommended value. Similar to previous codes CMS indicates that their recommendation is based on their "…time ratio methodology…" CMS also establishes the proposed value by referencing code 12011 (*Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.5 cm or less*), which has a wRVU of 1.07, similar intra-service, and total time values to code 64420.

ASA believes the agency's rationale is flawed and that the proposed crosswalk to 12011 is inappropriate.

We reiterate our opposition to comparing RUC survey time to Harvard time. As we previously stated, Harvard time is not based on a direct measure of the service while the RUC surveys are a survey of time specific to the code. ASA believes it is always inappropriate to compare Harvard time to RUC time. The crosswalk or methodology used in the original valuation of this service is unknown and not resource-based, therefore it is invalid to compare the current time and work to the surveyed time and work.

Also, as previously stated, while crosswalks are an effective methodology to assign value in a relative value system, they are only appropriate if the codes are similar in intra-service time and are clinically similar in complexity, intensity and risk. These codes are not clinically similar. The typical patient for code 12011 presents with facial abrasions and cuts and requires simple repair of superficial wounds. The complexity, intensity and risk of code 64420, in which describes the injection of the intercostal nerve to address persistent debilitating pain, is greater than 12011.

The RUC's recommendation for code 64420 was based on survey data and comparison to other codes in the fee schedule. The RUC also strongly supported its recommendation with comparison to code 49082 *Abdominal paracentesis (diagnostic or therapeutic); without imaging guidance* (wRVU = 1.24, intra-service time of 10 minutes) and code 32562 *Instillation(s), via*

chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day (work RVU = 1.24, intra-service time of 10). ASA believes that these codes are more clinically similar to code 64420 than 12011 and provide more appropriate references.

ASA urges CMS to accept a wRVU of 1.18 for CPT code 64420.

+64421 Injection(s), anesthetic agent(s) and/or steroid; intercostal nerves, each additional level (List separately in addition to code for primary procedure)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
+64421	1.68	0.60	0.50

Code 64421 is currently a Harvard-valued code 0-day global code. This means that the time was merely extrapolated and not measured directly. Nor is the rationale for the basis of the current value known. The code has been revised for 2020 and becomes an add-on code to be reported with base code 64420. A ZZZ global period has been assigned to the new code.

The current value of the code is 1.68 wRVUs. The RUC recommended decreasing it to 0.60 wRVUs and CMS is proposing to further reduce it to 0.50 wRVUs. Similar to their rationale for the base code 64420 and other previous codes CMS indicates that their recommendation is based on their "…time ratio methodology…" CMS also establishes the proposed value by referencing code 15276 (*Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)*), which has a wRVU of 0.50 and identical intra-service and total times to code +64421.

This methodology of comparing Harvard, which is not based on survey data, to RUC survey time is inappropriate and inconsistent with agency policy. In contrast, the RUC recommendation is derived from an appropriate direct work value crosswalk from 64421 to CPT code 77063 *Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)* (wRVU = 0.60, intra-service and total time of 8 minutes). The RUC noted that although the survey code involves somewhat more intra-service time, both services require a very similar amount of physician work.

ASA urges CMS to accept a wRVU of 0.60 for CPT code +64421.

64425 Injection(s), anesthetic agent(s) and/or steroid; ilioinguinal, iliohypogastric nerves

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64425	1.75	1.19	1.00

Code 64425 describes the injection of the ilioinguinal, iliohypogastric nerves. The typical patient presents with persistent, debilitating pain and a trial of ilioinguinal /iliohypogastric nerve block is scheduled to relieve pain and improve function. Code 64425 is currently a Harvard-valued code that has not been previously surveyed. This means that the time was merely extrapolated and not measured directly. Nor is the rationale for the basis of the current value known.

Code 64425 is currently valued at 1.75 wRVUs, the RUC recommended a value of 1.19 wRVUs and CMS is proposing to further reduce it to 1.00 wRVUs. CMS only indicates that they disagree with the RUC recommendation and they are proposing to reduce the value in order to maintain rank order. While CMS identified codes to bracket the proposed value, they do not provide a direct crosswalk to support this value.

In contrast, the RUC recommendation is supported by the 25th percentile wRVU from robust survey results, as well as careful review of all underlying clinical attributes of the procedure.

The RUC also strongly supported its recommendation with comparison to CPT code 49082 *Abdominal paracentesis (diagnostic or therapeutic); without imaging guidance* (wRVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes) and code 32562 *Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day* (work RVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes). We would note that the recent survey for code 64425 resulted in 11 minutes intra-service time. ASA believes that the crosswalks identified by the RUC are reasonable and appropriate.

ASA urges CMS to accept a wRVU of 1.19 for CPT code 64425.

64430 Injection(s), anesthetic agent(s) and/or steroid; pudendal nerve

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64430	1.46	1.15	1.00

Code 64430 describes the injection of the pudendal nerve. The typical patient presents with persistent, debilitating pain and a trial of pudendal nerve block is scheduled to relieve her pain and improve her function. The code is reported once per nerve regardless of the number of injections

performed. Code 64430 is currently a Harvard-valued code that has not been previously surveyed. This means that the time was merely extrapolated and not measured directly. Nor is the rationale for the basis of the current value known.

CMS indicates that they disagree with the RUC-recommendation of 1.15 wRVUs and are proposing a wRVU of 1.00, to maintain rank order among comparable codes in the family. They also indicate that another reason for their proposed wRVU is that the survey resulted in a reduction in intra-service time from the current time. We once again note that it is inappropriate and inconsistent with agency policy to compare RUC survey time to Harvard time which was not measured directly.

In contrast, the RUC recommendation was based on the current work RVU which is supported by the 25th percentile work RVU from robust survey results, as well as careful review of all underlying clinical attributes of the procedure.

The RUC strongly supported its recommendation with favorable comparison to code 49082 *Abdominal paracentesis (diagnostic or therapeutic); without imaging guidance* (wRVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes) and code 32562 *Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day* (wRVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes). We further note that the recent survey for code 64430 resulted in 10 minutes intra-service time. ASA believes that the crosswalks identified by the RUC are reasonable and appropriate.

ASA urges CMS to accept a wRVU of 1.15 for CPT code 64430.

64445 Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64445	1.48	1.18	1.00

Code 64445 describes the injection of the sciatic nerve. The procedure is typically used for pain management in the recovery room. The code is reported once per nerve regardless of the number of injections performed. This code was previously surveyed by the RUC in 2009.

The code is currently valued at 1.48 wRVUs, the RUC recommended reducing the value to 1.18 wRVUs and CMS is proposing to further reduce it 1.00 wRVUs to maintain rank order among comparable codes in the family. While CMS identifies reference codes to bookend this proposed value, they do not provide any direct crosswalks. ASA was disappointed with this proposal and finds the agency's rationale to be extremely flawed. The agency did not provide any clear rationale for the proposing the specific value of 1.00 wRVUs.

In contrast, the RUC recommendation is based on a direct crosswalk to code 67810 *Incisional biopsy of eyelid skin including lid margin* (work RVU = 1.18, intra-service time of 13 minutes, total time of 27 minutes). This recommendation is also supported by reference code 32562 *Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day* (work RVU = 1.24, intra-service time of 10 minutes, total time of 40 minutes). We further note that the recent survey for code 64445 resulted in 10 minutes intra-service time. ASA believes that the crosswalk identified by the RUC is reasonable and appropriate.

ASA believes the reduced value of the RUC recommendation from the current value sufficiently accounts for the reduction in intra-service time from the previous RUC survey (15 minutes intra-service time) in comparison to the current RUC survey (10 minutes intra-service time).

ASA urges CMS to accept a wRVU of 1.18 for CPT code 64445.

64446 Injection(s), anesthetic agent(s) and/or steroid; sciatic nerve, continuous infusion by catheter (including catheter placement)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64446	1.81	1.54	1.36

Code 64446 describes injection of the sciatic nerve with continuous infusion by the catheter. It is typically used to manage post-operative pain and facilitate rehabilitation. The service is typically performed in a facility setting. The code was previously surveyed by the RUC in 2008.

The code is currently valued at 1.81 wRVUs. The RUC recommended reducing the value to 1.54 wRVUs and CMS proposes further reducing the value to 1.36 wRVUs. CMS is basing this value on their previously mentioned, although never clarified, time ratio methodology and reference to CPT code 51710 (*Change of cystostomy tube; complicated*), which has a near identical wRVU of 1.35 and similar intra-service and total time values to code 64446.

The RUC recommendation is derived from an appropriate direct work value crosswalk from 64446 to code 30903 *Control nasal hemorrhage, anterior, complex (extensive cautery and/or packing) any method* (work RVU = 1.54, intra-service time of 15 minutes, total time of 39 minutes). Both services have identical intra-service time and total time and involve an identical amount of physician work.

ASA believes the reduced value of the RUC recommendation from the current value reflects sufficient recognition of the reduction in intra-service time from the previous RUC survey (20

minutes intra-service time) in comparison to the current RUC survey (15 minutes intra-service time).

ASA urges CMS to accept a wRVU of 1.54 for CPT code 64446.

64448 Injection(s), anesthetic agent(s) and/or steroid; femoral nerve, continuous infusion by catheter (including catheter placement)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64448	1.63	1.55	1.41

Code 64448 describes injection of the femoral nerve with continuous infusion by catheter. It is typically used to manage post-operative pain and facilitate rehabilitation. The service is typically performed in a facility setting. The code was previously surveyed by the RUC in 2008.

This code is currently valued at 1.63 wRVUs, the RUC recommended reducing it to 1.55 wRVUs and CMS is proposing to further reduce it to 1.41 wRVUs. CMS is basing this value on their previously mentioned, although never clarified time ratio methodology and reference to CPT code 27096 (*Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed*), which has a work RVU of 1.48 and similar intra-service time and total time values to CPT code 64448. While these are both injection procedures, they are not clinically similar in intensity, complexity and risk. We would note that 27096 is performed in the physician office setting nearly 50% of the time while in contrast code 64448 is performed in the facility setting almost 100% of the time. The CMS proposal is further flawed as it compares 64448 to 27096, with 1.48 wRVU, while proposing just 1.41 wRVUs for 64448, a code that is by all comparators much more complex than the proposed reference code.

In contrast, the RUC recommendation is based on a crosswalk to code 62322 *Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance* (wRVU = 1.55, intra-service time of 11 minutes, total time of 39 minutes). The survey code involves somewhat more intra-service time whereas both services only differ on total time by 1 minute and require a very similar total amount of physician work. The RUC also supported its recommendation with MPC code 57452 *Colposcopy of the cervix including upper/adjacent vagina;* (wRVU = 1.50, intra-service time of 15 minutes, total time of 40 minutes). ASA believes this is a much more robust and appropriate rationale than the one proposed by CMS.

ASA urges CMS to accept a wRVU of 1.55 for CPT code 64448.

64449 Injection(s), anesthetic agent(s) and/or steroid; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64449	1.81	1.55	1.27

Code 64449 describes injection of the lumbar plexus, posterior approach with continuous infusion by catheter. The service is typically used to manage post-operative pain and facilitate rehabilitation. It is typically performed in a facility setting. The code was previously surveyed by the RUC in 2008.

Code 64449 is currently valued at 1.81 wRVUs, the RUC recommended reducing it to 1.55 wRVUs and CMS proposes further reducing it to 1.27 wRVUs. CMS is basing this value on their previously mentioned, although never clarified time ratio methodology and reference to CPT code 11755 (*Biopsy of nail unit (eg, plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)*), which has a wRVU of 1.25 and similar intra-service and total times to CPT code 64449. ASA has similar concerns with this reference code that we had with the reference code for code 64448. Code 64449 is used to manage post-operative pain after major surgery and it includes infusion by catheter. The service is typically performed in a facility setting. In contrast code 11755 is a biopsy of a nail unit and is typically performed by in the office setting. While the intra-service time may be similar, it is very clear that the intensity of these two procedures is not at all similar. Code 11755 cannot serve as an appropriate reference code for code 64449.

In contrast, the RUC recommendation is based on a crosswalk to CPT code 62322 *Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance* (wRVU = 1.55, intra-service time of 11 minutes, total time of 39 minutes). The survey code involves somewhat more intra-service time whereas both services only differ on total time by 1 minute and require a very similar total amount of physician work. ASA believes this is a much more accurate and appropriate rationale than the one proposed by CMS.

ASA urges CMS to accept a wRVU of 1.55 for CPT code 64449.

Practice Expense Recommendations

ASA wishes to comment on a Practice Expense (PE) refinement proposed by CMS that impacts a number of the codes in this family. For codes 64400, 64415, 64417, 64420, 64425, 64430, 64445, 64447 and 64450. CMS is proposing a refinement to the clinical activity time for CA011, *provide education/obtain consent.* CMS is reducing the time associated with this activity from

the RUC recommended 3 minutes to 2 minutes. The agency states that the rationale for this refinement is that the standard time for this activity is 2 minutes.

ASA disagrees with this rationale. The RUC PE Subcommittee does not have a standard time allocated for this clinical activity. For clinical activity CA011, the RUC PE Subcommittee guidelines instruct specialty societies to "Include only the additional education/consent activities not included in the pre-service period" for this clinical activity. Since the standard for 000-day global services in the pre-service period for this activity, CA004, *Provide pre-service education/obtain consent,* is zero minutes, ASA and other specialties involved in submitting PE recommendations for these codes explained that 3 minutes of time is needed, which the PE Subcommittee accepted. The societies explained that the time is required because of the potential complications associated with injections and the need to review aftercare instructions.

ASA urges CMS to accept the RUC recommendation of 3 minutes for clinical activity CA011, provide education/obtain consent, for codes 64400, 64415, 64417, 64420, 64425, 64430, 64445, 64447, and 64450.

Genicular Injection and RFA (CPT Codes 64640, 64XX0, and 64XX1)

In May 2018, the CPT Editorial Panel approved the addition of two codes to report injection of anesthetic and destruction of genicular nerves by neurolytic agent: 64XX0 (*Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches including imaging guidance, when performed*), and 64XX1 (*Destruction by neurolytic agent genicular nerve branches including imaging guidance, when performed*). These codes as well as another code in the family, codes 64640 (*Destruction by neurolytic agent; other peripheral nerve or branch*) were reviewed and discussed at the October 2018 and January 2019 RUC meetings.

<u>Work RVU Recommendations</u>

64XX1 (Destruction by neurolytic agent genicular nerve branches including imaging guidance, when performed)
Code 64XX1 (*Destruction by neurolytic agent genicular nerve branches (includes image guidance, when performed*) is a new code that describes destruction of 3 different nerve branches (superomedial, inferomedial, and superolateral genicular nerve branches) at three locations (adjacent to the periosteum on the medial aspect of the tibia, and at both the medial and lateral aspects of the femur) in order to achieve analgesia for the respective knee.

Code#	2019 wRVU	RUC Recommended wRVU	2020 Proposed wRVU
64XX1	N/A	2.62	2.50

Code 64XX1 will be a new code in 2020 so there is no current value for this code. The RUC recommended a wRVU of 2.62. CMS is proposing to reduce it to 2.50 wRVUs.

CMS is basing this value on an intra-service time ratio in relation to an existing code in this family of services, CPT code 64640. CMS compared the RUC recommended wRVU, intra-service and total times of CPT codes 64XX1 and 64640 to derive their proposed wRVU of 2.50 by calculating the intra-service time ratio between these two codes, which is a calculated value of 1.25. CMS multiplies this ratio with the RUC recommended work RVU of 1.98 for CPT code 64650, which results in a calculated value of 2.48. This value, CMS states, is nearly identical to the RUC survey 25th percentile value of 2.50 for code 64XX1.

As previously stated, ASA strongly disagrees with CMS' intra-service time ratio methodology in general as well as for the specific circumstance to value code 64XX1. It has been a longstanding position of CMS that treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. ASA is very troubled by this methodology and how the agency has approached valuation of other codes surveyed by ASA for CY 2020 in this proposed rule. CMS seems to have randomly selected various methodologies in proposing values for different codes versus seeking a valid, consistent, transparent and accepted methodology to preserve relativity. Over the years the methodologies used by the RUC (namely, magnitude estimation, survey data and clinical expertise) have been the primary method when developing work values for physician services. We urge CMS not to abandon this approach.

The agency also used code 11622 (*Excision, malignant lesion including margins, trunk, arms, or legs; excised diameter 1.1 to 2.0 cm*) as a reference code to support its proposed value. It has a wRVU of 2.41 and similar time to code 64XX1. ASA disagrees with the reference code. As previously discussed in this letter, reference codes should be similar in both time as well as in clinical similarity. CPT code 64XX1 describes the destruction of three different nerve branches at three locations to provide analgesia for the respective knee and code 11622 which describes excision of a malignant lesion of trunks, arms or legs. The physician work required for 64XX1 is more intense in that it is the destruction of three different nerve branches and if performed incorrectly would have the potential to produce irreversible tissue damage to other motor or sensory nerves in the vicinity of the knee.

During its deliberations the RUC considered these issues and in identified a crosswalk more appropriately aligned code 64XX1. RUC selected code 11642 (*Excision, malignant lesion including margins, face, ears, eyelids, nose, lips; excised diameter 1.1 to 2.0 cm*) which is also a multi-points of comparison code. While the time associated with 11622 and 11642 is similar, code 11642 is an excision on the face, ears, eyelids, nose, lips, which is a more delicate area in which precision is required and it is more intense and complex to complete. The RUC concluded and ASA agrees that 11642 is a more appropriate crosswalk than the one proposed by CMS.

ASA urges CMS to accept a wRVU of 2.62 for code 64XX1.

For the remaining two codes in the family, CMS is proposing the RUC-recommended wRVU recommendations. CMS is proposing 1.98 wRVUs (25th percentile survey value) for CPT code 64640 and the RUC-recommended wRVU of 1.52 (25th percentile survey value) for CPT code of 64XX0. ASA is pleased that CMS is supporting the RUC recommendations for these two codes.

ASA urges CMS to finalize the proposed wRVU values of 1.98 wRVUs for code 64640 and 1.52 for code 64XX0.

Practice Expense Recommendations

CMS is proposing refinements to the RUC recommended direct PE inputs for code 64XX1.

Supply refinements
For code 64XX1, CMS is proposing to refine the quantity of the supply item SD011 *cannula (radiofrequency denervation) (SMK-C10)* from 3 to 1. CMS does not believe that the use of 3 units of this supply would be typical. CMS indicated in the proposed rule that for this procedure they believed for the procedure the nerves would be ablated one at a time using a single cannula, as opposed to ablating the three nerves simultaneously which would require 3 cannulas.

ASA wishes to clarify to the agency that 64XX1 procedure does require 3 units of the cannula (supply item SD011). Three units are required because simultaneous ablation of the three genicular nerves using three distinct cannulas is standard medical practice. Three units are required since the ablation must be performed simultaneously for both patient safety reasons and time efficiency for the clinician performing the procedure. One cannula cannot be used multiple times as rates of infection increase with the reinsertion of the same needle. Since this is standard practice it was therefore the way in which the survey respondents would have completed the survey.

Equipment refinements
CMS is also proposing to refine the equipment time for the equipment item *radiofrequency kit for destruction by neurolytic agent* equipment from 141 minutes to 47 minutes. The radiofrequency kit is a piece of equipment and as part of their PE recommendations the RUC recommends to CMS the number of minutes a piece of equipment is used to perform the associated procedure.

ASA wishes to clarify to the agency that the procedure described by code 64XX1 does require 141 minutes of radiofrequency kit equipment time. In performing the procedure, 3 individual radiofrequency kits (equipment), with three distinct cannula (supply), are placed individually into the respective knee. In the original RUC recommendation, the equipment time recommendation was predicated on the use of 3 of the SD011 supplies for 47 minutes apiece for a total of 141 minutes (47 minutes x 3= 141 minutes). CMS is proposing to refine the equipment time to reflect

their supply refinement to the insertion of 1 cannula (47 minutes). Again, one radiofrequency kit is insufficient in performing this procedure as each cannula will need a radio frequency kit, and as such the total equipment time for the radio frequency kits comes to 141 minutes (47 minutes x 3 = 141 minutes).

ASA urges CMS to accept the RUC practice expense input recommendations for code 64XX1 including 3 units of supply item SD011 and 141 minutes associated with equipment item radiofrequency kit for destruction by neurolytic agent.

Radiofrequency Neurotomy Sacroiliac Joint (CPT Codes 6XX00, 6XX01)

In September 2018, the CPT Editorial Panel created two new codes to describe injection and radiofrequency ablation of the sacroiliac joint with image guidance for somatic nerve procedures.

Work RVU Recommendations

CMS is proposing the RUC-recommended wRVU of 1.52 for code 6XX00 (*Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)*) and the RUC-recommended wRVU of 3.39 for code 6XX01 (*Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)*). ASA is pleased that CMS is proposing to accept the RUC wRVU recommendations for these codes.

ASA urges CMS to finalize the proposed wRVUs of 1.52 for code 6XX00 and 3.39 for code 6XX01.

Practice Expense Recommendations

CMS is proposing refinements to the RUC recommended direct PE inputs for code 6XX00 and 6XX01.

CMS is proposing to refine the quantity of supply item SC028 *needle, 18-26g 1.5-3.5in, spinal,* from three to one for CPT code 6XX00. CMS agrees that the service being performed in CPT code 6XX00 would require a spinal needle but propose that the use of three such needles would be atypical. This code describes four separate injections of three sacral levels. Four separate needles are required to inject the dorsal rami of L5 and the lateral branches of S1, S2 and S3. While the original RUC recommendation indicates only 3 needles are needed, this was an error and should in fact be 4 needles. Standard practice is to place the four needles, then simultaneously inject.

Additionally, CMS is proposing to refine the quantity of supply item SD011 *cannula (radiofrequency denervation) (SMK-C10)* from four to two for CPT code 6XX01. CMS does not believe that the use of four cannula would be typical for the procedure, as the reference code currently used for destruction by neurolytic agent contains only a single cannula. The agency

believes that the nerves would typically be ablated one at a time using this cannula, as opposed to ablating four of them simultaneously. Similar to the injection code (6XX00), the radiofrequency ablation of the nerves innervating the sacroiliac joint requires four cannulas for simultaneous ablation of the four nerves. These cannulas are placed and then guided simultaneously to allow for fewer fluoroscopic images and a safer total radiation dose for the patient and staff. As with the injection codes, this is standard procedure and the physicians surveying this code accounted for their time accordingly.

ASA urges CMS to accept the corrected RUC practice expense input recommendations of 4 units of supply item SC028 for code 6XX00 and 4 units of supply item SD011 for code 6XX01.

Evaluation & Management (E/M) Services (99201-99205) (99211-99215) (99XXX)

In the 2019 PFS Final Rule, CMS finalized changes to the coding and payment structure for E/M services to be effective in CY 2021. In this rule, CMS is proposing to reverse some of the finalized policies and align E/M coding and payment with changes adopted by the CPT Editorial Panel to E/M services (i.e., eliminating code 99201 and revising code definitions). CMS also proposes to accept a number of payment recommendations made by the RUC for the office/outpatient E/M visit codes for CY 2021 and a new add-on CPT code for prolonged service time. The AMA RUC-recommended values would increase payment for office/outpatient E/M visits. In total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services. As such, this is a significant proposal impacting all specialties and the fee schedule across the board. Effective CY 2021 CMS proposes the following changes:

- Adopt the changes to E/M services finalized by the CPT Editorial Panel; CMS notes that the CPT coding changes will also necessitate some changes to CMS' policies for CY 2021, due to forthcoming changes in code descriptors;
- Establish new values for the codes as revised by CPT;
- Assign separate payment rather than a blended rate, to each of the office/outpatient E/M visit codes (except CPT code 99201, which CPT is deleting) and the new prolonged visit add-on CPT code (CPT code 99XXX);
- Delete the HCPCS add-on code CMS finalized last year for CY 2021 for extended visits (GPRO1); and
- Revise, consolidate and revalue the HCPCS add-on codes CMS finalized last year for CY 2021 for primary care (GPC1X) and non-procedural specialized medical care (GCG0X), and to allow the new code to be reported with all office/outpatient E/M visit levels (not just levels 2 through 4).

ASA applauds the focus on incentivizing increased care management by evaluating E/M codes to reflect complex patient care. Yet, we are concerned that while the proposal increases payment for a portion of the specialties billing in high volume for E/M codes, necessary offsets to maintain budget neutrality may require across the reductions borne by all specialties,

including those who do not report E/M services and therefore will not benefit from the proposed increased in payments.

ASA recommends that CMS work with the medical community to urge Congress to implement positive updates to the Medicare conversion factor to offset the deserved increases to office visits.

ASA notes that the CMS proposed changes to E/M codes are not currently proposed to apply to office visits bundled into global codes. As there has always been consistency between services, ASA recommends CMS maintain relativity for payments for office visits across all specialties which would include apply changes to E/M code to office visits bundled into global codes.

ASA urges CMS to reconsider their decision not to apply increases to E/M codes to the global period.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

ASA is pleased CMS is taking steps to implement section 2005 of the SUPPORT Act, establishing rules to govern Medicare coverage of and payment for opioid use disorder (OUD) treatment services and OTPs. ***ASA supports efforts to ensure oral methadone for medicated assisted treatment (MAT) is covered by Medicare, in addition to buprenorphine, naltrexone (or other commercial products that become FDA approved). Some physician anesthesiologists are engaging in addiction medicine; therefore, ASA believes coverage of treatment services furnished by an OTP should include all three medications approved by the FDA.***

ASA also supports the concept of MAT that it must include counseling and behavioral therapy services. Accordingly, we believe the definition of opioid use disorder treatment services, as defined by the SUPPORT Act, which includes "…counseling, individual and group therapy, toxicology testing, and other items and services that the Secretary determines are appropriate," is a comprehensive definition. These services should only be managed and implemented by physicians. ***ASA also supports including intake activities, such as the initial physician examination and initial assessment and preparation of a treatment plan, as well as periodic assessments in the definition of OUD treatment services.***

Bundled Payments Under the PFS for Substance Use Disorders

In ASA's comments to CMS on the CY 2019 Fee Schedule last year, we supported the agency's consideration of a separate bundled payment for substance use disorders (SUDs). ASA is pleased this proposal is progressing. As the opioid crisis continues to impact families across the nation, this proposal could improve access for substance use treatment. Bundling the comprehensive treatment plan such as treatment management, counseling and components of MAT could enable more efficient care for patients, limiting the number of patient visits and decreasing hospital admissions.

CMS recognizes that these services would often be billed by addiction specialty practitioners, but that these codes are not limited to any particular physician, unlike the codes that describe care furnished using the psychiatric collaborative care model (CPT codes 99492, 99493, and 99494), which require consultation with a psychiatric consultant. ASA is pleased the agency is not proposing to require consultation with a specialist as a condition of payment for these codes. In light of the current public health crisis, many physicians not typically involved in these services are seeing patients with SUDs and providing them care. It is important to account for other specialties, beyond addiction that are engaging in these practices. ASA supports this proposal.

ASA supports the proposal to create a code to describe the initial month of treatment, which would include intake activities and development of a treatment plan, as well as assessments to aid in development of the treatment plan in addition to care coordination, individual therapy, group therapy, and counseling. The initial month of treatment can be especially challenging, for both the patient and provider. Accounting for these circumstances and the amount of time and effort that is needed to establish the crucial relationship is appropriate. It is also appropriate to create a code to describe subsequent months of treatment including care coordination, individual therapy, group therapy, and counseling, as OUD treatment must be done over the course of time. ***ASA also supports the concept of an "add-on" code that could be billed in circumstances when effective treatment requires additional resources for a particular patient.*** Sometimes there are complicated circumstances and it is appropriate to have a code to bill to that would account for care provided to these unique patients.

Lastly, ***ASA encourages CMS to create a separately billable code or codes to describe "additional resources" involved in furnishing OUD treatment-related services after the first month.*** As CMS acknowledges, there are circumstances when substantial revisions to the patient's treatment plan are needed. These codes could account for additional follow-up visits as well and the time and tasks required during those patient-visits. For example, additional prescription drug monitoring program checks, urine screening and care-coordination.

<u>Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm</u>

ASA supports the intention to classify OTPs as Medicare providers in order to bill and receive payment. We also commend CMS efforts to ensure that program integrity is maintained including monitoring OTP billing patterns; ensuring the proper payment of OTP claims; performing OTP audits as required by law; making certain that OTP beneficiaries receive quality care; and taking action against non-compliant or abusive OTP providers.

ASA has some concerns regarding the additional requirements that CMS is proposing for physicians employed by OTPs related to prescribing, dispensing and ordering of controlled substances. The Society recognizes that there could be heightened risk in OTP facilities compared to other settings because the services provided involve prescribing and dispensing of controlled substances and a complex subset of patients grappling with addiction. However, ***ASA***

cautions CMS against overly restrictive policies that may hinder patient care or physician practice.

Improper Prescribing & Patient Harm

CMS recognizes that the dispensing of drugs in the treatment of opioid use disorder is an important component of an OTP's function and ASA appreciates that the agency is taking steps to ensure OTP physicians do not prescribe drugs in an improper fashion. Physicians are highly trained and educated. To provide MAT, they must have certain training and follow certain requirements, such as obtaining the data waiver. Physician anesthesiologists, in particular, have a deep understanding of pharmacology and how drugs work and interact. The substance use disorder treatment care that physicians provide in OTPs are part of the practice of medicine. ASA cautions against policies that are overly restrictive or impact clinical practice. It is important to monitor and flag highly egregious prescribers, but ***ASA asks that CMS use strict judgment to ensure physicians prescribing appropriately, at higher doses (beyond some guidelines or recommended thresholds), are not unnecessarily sanctioned or disciplined, as this could have negative impacts on patient care.***

Scope of Practice for CRNAs

ASA opposes the proposed changes to the Conditions for Coverage that would allow nurse anesthetists to perform preoperative assessment of anesthetic risk and pre-surgical evaluation in the (ambulatory surgical center) ASC setting.

In the Medicare Physician Fee Schedule proposed rule, CMS proposes significant changes to the Ambulatory Surgical Centers Conditions for Coverage (CfC).

CMS states in the proposed rule, "the Secretary is responsible for ensuring that the ASC Conditions for Coverage (CfCs) **protect the health and safety** [emphasis added] of all individuals treated by ASCs, whether they are Medicare beneficiaries or other patients" – a goal that physician anesthesiologists share with CMS and focus on each day for our patients. As such we are concerned that the agency has proposed changes to the CfC that will undermine this promise CMS has made to patients and their families. ASA acknowledges and agrees that today's healthcare environment must consider both cost and quality of care and that there are opportunities to utilize non-physician health care professionals. However, a proposal by CMS that cites a controversial study based upon unsupported assumptions and published in *Nursing Economic$* raises significant concerns among our membership of practicing clinicians that CMS is putting cost savings above quality of care and patient safety. This proposal is contrary to the CMS Patients Over Paperwork initiative in that it would remove a regulation that has a demonstrated and defensible use in protecting patient safety.

Based on an "industry association" request, CMS is proposing to allow nurse anesthetists to perform the CfC-requirement that the preoperative assessment of anesthetic risk and pre-surgical evaluation in an ASC be completed by a physician. This CMS proposal would remove current and necessary regulation that has contributed to enhanced patient safety and

procedural efficiency in ASCs. The current regulation is supported by ASA and many other known healthcare industry associations and stakeholders.

ASA opposes this change because physicians, including physician anesthesiologists, have the medical background necessary to assess the patient's underlying condition in an objective, evidence-based and patient-centric way. The clinical training and background of physician anesthesiologists provides the necessary knowledge and skills to assess the patient with respect to anesthetic risk, but also to assess whether each patient's preoperative management has been optimized prior to undergoing a surgical procedure in the ambulatory surgery setting. The extensive training provided to physicians is essential to ensure that the clinical assessment takes into account underlying co-morbidities and to ensure that the ambulatory setting has the resources needed to manage the patient throughout the continuum of perioperative care. A nurse anesthetists' clinical background does not provide the same depth of training in clinical issues beyond those related to delivery of anesthesia care, which is most often provided under physician supervision. Nurse anesthetist training is limited to anesthesia care delivery, not risk assessment, diagnosis or medical decision making outside the scope of an anesthetic. This proposal, based on controversial data and relying on a request from an industry association rather than any scientific evidence or trials, in short, jeopardizes patient safety.

We urge CMS to consider the following points:

- ***Expansion of procedures that can be performed in the ASC setting***
  Many procedures that have previously been performed in the hospital setting are now being performed in ASCs. For example, joint replacement and other complex surgical procedures in patients with significant underlying diseases are increasingly being performed in ambulatory centers. The transitions in site of service are appropriate for some patients, but the patients undergoing some of these procedures must be thoroughly evaluated and their care optimized to minimize the likelihood of complications or need for transfer to an acute care hospital. Unlike patients who receive surgical services in the hospital setting, ASCs do not have the same back up resources needed to manage all clinical needs. As a result, the evaluation by a physician anesthesiologist is essential to not only assess risk, but to determine the appropriate perioperative management to optimize each patient's clinical care and reduce the need for transfer to the hospital setting.

  In addition, as more complex surgical procedures are transitioned to the ASC setting, patients previously thought to be too sick to undergo procedures in an ASC are now receiving surgical care in the ambulatory setting. With improved surgical capabilities, patients with significant comorbidities, including but not limited to diabetes, cardiovascular issues, hypertension and obesity, are undergoing surgery in ASCs. In order to safely provide care to these patients in the ambulatory setting, each patient requires a comprehensive assessment and perioperative plan to ensure safety throughout the surgical procedure and safe and timely discharge to home. Without such an assessment, patients may require transfer to a hospital setting or require hospital admission after discharge from the ASC to manage perioperative complications.

- ***Nurse anesthetists do not have the education or training to provide this evaluation***
  Nurse anesthetists are valued members of the anesthesia care team. However, their training does not include the knowledge and skills necessary to expand their role in the manner CMS is proposing. The Standards for Accreditation of Nurse Anesthesia Educational Programs, as revised January 2018, describes the required perianesthetic competencies to be included in an accredited nurse anesthesia educational program as follows:

  1. Provide care throughout the perianesthetic continuum.
  2. Use a variety of current anesthesia techniques, agents, adjunctive drugs, and equipment while providing anesthesia.
  3. Administer general anesthesia to patients of all ages and physical conditions for a variety of surgical and medically related procedures.
  4. Provide anesthesia services to all patients, including trauma and emergency cases.
  5. Administer and manage a variety of regional anesthetics.
  6. Function as a resource person for airway and ventilatory management of patients.
  7. Possess current advanced cardiac life support (ACLS) recognition.
  8. Possess current pediatric advanced life support (PALS) recognition.
  9. Delivery culturally competent perianesthetic care throughout the anesthesia experience.
  10. Perform a comprehensive history and physical assessment.
      Note: Per the standards, “Specific assessment related to anesthesia should be stressed in the practical experience of nurse anesthesia students.”

  These educational requirements address the anesthesia-specific needs of the patient, but do not address the assessment, management or anesthetic and perioperative implications of underlying medical conditions. The standards for nurse anesthetist preoperative evaluation is defined as follows: *Review of all available patient data prior to initiating anesthesia*. Their training and curriculum do not extend beyond provision of anesthesia care and do not include the specific skills and background essential for the aspect of perioperative care.

- ***Alignment between the CfC requirements for the pre-surgery examination/evaluation and the pre-discharge evaluation will not reduce regulatory burden or contribute to improved care and outcomes***
  The CfCs allow either a physician or an anesthetist to evaluate patients for proper anesthesia *recovery*. This evaluation is within the scope and training of a nurse anesthetist. However, assertions that this proposal to align the pre-procedure examination/evaluation of anesthesia and the procedure with the pre-discharge evaluation in the pursuit of reducing regulatory burden is unfounded. Further, claims that doing so would “provide for continuity of care for the patient and allows the patient’s anesthesia professional to have familiarity with the patient’s health characteristics and

> medical history" are troubling. Familiarity with the medical history is not sufficient to ensure appropriate preoperative assessment and management. Based on this argument, is one to infer that under the established, effective and efficient current CfC requirements, nurse anesthetists are providing care without being sufficiently familiar with a patient's health and medical history?

ASA is concerned that the CMS proposal also relies upon language alignment instead of a critical understanding of why such preoperative assessments are part of a physician's responsibilities. Patient safety should not be jeopardized based upon regulatory language simplification that "the anesthetic risk and pre-surgery evaluation standard [should align] with the pre-discharge standard" – an unfortunate conflation of two separate processes of patient assessment, care and expectations. An anesthetic risk and pre-surgery evaluation is a comprehensive process that physician anesthesiologists or other physicians perform in ASCs and other settings using skills and training honed from years in medical school, residency, personal experience with patients and understanding the uniqueness of each patient.

Finally, ASA believes that changes to the CfCs are ***beyond the scope of a physician payment rule***. If CMS wishes to further consider this proposed change, we believe it should be considered in a more appropriate manner.

ASA opposes proposed provisions in the MPFS that would allow nurse anesthetists to perform the functions of a physician in completing an anesthetic risk and pre-surgery evaluation.

ASA urges CMS to not finalize and withdraw this proposal.

Solicitation of Comments for Bundled Payments Under the PFS

While historically CMS has made separate payment for each service provided under the PFS, in recent years CMS has developed bundled payment approaches for the PFS and other Medicare payment systems. Many of these models have been implemented under the authority of the CMS Center for Medicare and Medicaid Innovation (Innovation Center). CMS is soliciting comments on opportunities to expand the concept of bundling to improve payment for services under the PFS. While by statute CMS is required to pay for services based on the resources required, they indicate in the proposed rule that they believe there is flexibility within the PFS to become more efficient.

While ASA supports efforts around improving the efficiency of the program that benefits both providers and patients, we are concerned about the intent of this solicitation for comments. As stated in the proposed rule, bundling payments for services can achieve better care for patients, better health for communities, and lower costs in the health care system. However, CMS does not have the authority to create bundled payments under the Medicare PFS. The PFS requires payment for each individual service furnished to a beneficiary (Section 1848 of the SSA), based on the relative resources involved in providing the service.

The Innovation Center was established by Section 1115A of the Social Security Act. Congress explicitly enumerated authority for the Secretary of HHS to test "innovative payment and service

delivery models to reduce program expenditures…while preserving or enhancing the quality of care." CMS does not have this same level of flexibility outside of the Innovation Center.

We would note that in recent years we have seen multiple services bundled into a single CPT code but believe this is a very different scenario that CMS is proposing. CPT codes that describe bundled services (e.g. imaging bundled with an existing procedure/service) go through a rigorous process for both development of code nomenclature as well for the valuation process.

Since Congress hasn't explicitly granted the authority under PFS, the contrary dictates "per service" payment. ***ASA would request that CMS provide greater detail on their thinking in this area. We would also ask CMS to clarify how they will ensure that they are meeting their legal obligations of providing payment based on the relative resources involved in providing the resources.***

Quality Payment Program

Quality Payment Program – Quality Performance Category

ASA supports the increased threshold for data completeness to 70% for several reasons, including our ability to improve the data that individual eligible clinicians (ECs) and groups submit to our registry. MIPS is currently structured so that practices who choose their measures oftentimes choose those measures that are easy to collect and report as part of their existing clinical workflows. To better enable ECs and groups to meet this higher threshold, CMS should ensure there is a sufficient number of applicable measures to choose from in the program.

As CMS increases the data completeness threshold, the agency should also amend the timeline for MIPS CQMs and QCDR measures to be publicly posted. ASA recommends that the finalized list of available measures and measure specifications should be available at a similar time when ICD-10 and CPT Codes are released or by November 1 at the latest.

ASA also notes the ability for anesthesia groups to meet a 70% data completeness threshold rests upon the availability of the same measures to report from year to year. ***ASA requests that all measures, including QCDR measures, be approved for multiple years.*** The greatest burden on ECs and groups often occurs at the beginning of the year when they must choose which measures to report, train their staff on how to collect the measure and update their data collection protocols. Approving measures for multiple years and posting updated specifications by November would allow individuals and groups a better opportunity to meet the data completeness threshold.

ASA recommends CMS finalize the proposal to increase the data completeness threshold for quality measures to 70%.

CMS has proposed that topped out measures may be retained if the measure would include a higher data completeness threshold – such as 80% or 90% of applicable cases. ASA believes that allowing ECs and groups to select from a wide range of quality measures means that chosen measures are more likely to exceed minimum thresholds. We agree with CMS arguments that performance gaps on topped out measures could benefit from increasing the minimum reporting threshold. The elimination of two "topped out" anesthesiology measures in 2019 was more burdensome to anesthesiologists than if CMS had required a higher data threshold requirement. We support CMS beginning with an 80% data completeness threshold for topped out measures and then increase the threshold over time. We encourage CMS to work with measure stewards to monitor and see if a change in "topped out" status has occurred as a result of implementing this policy.

ASA supports the 80% data completeness threshold for topped out measures and urges CMS to finalize this proposal.

CMS has proposed to increase enforcement and auditing of data that the agency believes is part of a "cherry-picking activity." ***ASA agrees that CMS should audit data that they believe has been "cherry-picked" or if CMS believes that submitted data is otherwise not accurate.*** However, CMS should be mindful that third party vendors, especially specialty society clinical data registries, do not have the capacity to tell whether a group has specifically submitted false or incomplete data. The registry receives data directly from a practice and, once the data has been cleaned and appropriately formatted, the registry submits that data directly to CMS. Should the practice submit erroneous data to AQI NACOR, it is the responsibility of the EC or group to demonstrate to CMS that their data is accurate and complete using documentation as described by CMS in this rule.

CMS has established safeguards and beneficial policies for ECs and groups to be accurately scored. Such policies include the ability for an EC or group to submit as many measures as possible and having CMS determine the best score possible. AQI NACOR does not have any method or technology to choose specific or individual data that is sent to CMS nor to determine what an EC or group's MIPS quality component score may be. We encourage ECs and groups to submit complete and accurate data on as many measures as they wish CMS to score them on.

AQI NACOR is not an extension of the individual EC or the group – the registry functions as a mechanism for our members to submit MIPS data to CMS. Therefore, should CMS find either through statistical validation or otherwise that a group or individual is suspected of "cherry-picking" its data, a request for auditing should be sent to those ECs and groups. AQI NACOR's responsibility should be limited to working with audited participants by providing data reports and dashboard access to help ensure that they can perform the appropriate analysis between the data they submitted to AQI NACOR and their primary source data records.

ASA encourages CMS to release additional instructions for individual ECs and groups to understand their responsibilities in submitting accurate and complete data. CMS should

publish aggregate (not individual EC or specific group) findings from their 2018 auditing of ECs and groups with regard to suspected instances of cherry-picked data.

CMS has proposed that stewards of new MIPS quality measures will need to provide a rationale as to how the measure relates to other MIPS performance categories.
ASA cautiously supports this proposed requirement that stewards of new MIPS quality measures will need to provide a rationale as to how the measure relates to other MIPS performance categories. We believe that it might be beneficial for CMS to require the same assessment by an Improvement Activities (IA) submitter as the agency would for a new MIPS measure. In many cases, quality measure concepts can be more readily identified from specific improvement activities. We welcome the opportunity to work with CMS on such measure and IA sets.

We caution that this policy change should not be used to deny a well-constructed and meaningful measure from inclusion in MIPS. An informal survey of anesthesia ECs and groups revealed that many anesthesiologists choose their measures independent of their choice of IAs. Although the Anesthesiology Smoking Abstinence MIPS measure and Anesthesia Patient Satisfaction QCDR measure could be tied to specific IAs, ECs and groups may find other anesthesiology measures difficult to link one-to-one with an IA.

CMS has proposed to remove QCDR measures if CMS determines that the MIPS quality measure has not been made widely available for most eligible clinicians. ***CMS should use objective criteria to determine why a measure is not in widespread circulation. ASA would support CMS policy if the agency uses defensible and objective criteria to determine whether such unavailability occurs as a result of a QCDR refusing to license the measure or if the steward is charging significant or exorbitant fees for a vendor to use. We also encourage CMS to work directly with the measure steward to better understand the root cause of why the measure has been identified as not widely available.*** For instance, ASA and AQI NACOR have multiple measures available for reporting by our QCDR participants that are not found in other QCDRs – the measures are available for licensing but other QCDRs have not requested a license to report that measure. In this way, CMS should ensure that those quality measures that few, if any, other registries wish to license, be maintained in the program.

CMS has proposed to include the Multimodal Pain Management measure into the Anesthesiology Measure Set.
Physician anesthesiologists are national and local leaders in reducing unnecessary opioid prescriptions and exploring effective alternative pain medicine treatment for surgical patients. ASA has developed, tested and collected performance data on the proposed Multimodal Pain Management measure over the past several years. We support its inclusion in the Anesthesiology Measure Set and expect that many anesthesiologists working in in-patient and ambulatory settings will use the measure.

The Multimodal Pain Management measure aligns with the CMS Meaningful Measures Initiative as it seeks to manage postoperative pain through multimodal pain strategies instead of using

just opioids. The measure promotes the initiative's goal of "effective prevention and treatment of chronic disease" and specifically the "prevention and treatment of opioid and substance use disorders." Use of multimodal pain management strategies is widely supported and favorable for addressing postoperative pain. However, we know there is considerable room for improvement based on preliminary measure performance data. If accepted into MIPS, this measure would serve as a meaningful indicator of quality and at the same time, limit a critical access point for opioid use, abuse or dependence while still effectively managing pain. This measure has incredible implications for effective pain management and reducing prescriptions for opioids to treat postoperative pain.

ASA recommends CMS finalize the proposal to include the multimodal pain management measure into the Anesthesiology Measure Set.

Quality Payment Program – Improvement Activities Performance Category

ASA opposes the CMS proposal to increase the threshold from one EC to 50% of a group's ECs to attest to an IA. The proposed increase is significant for all groups, regardless of size, in that it increases the burden of documentation and will lead to reduced revenues and additional costs for the EC or group. In addition, such a proposal would undermine the CMS Patients Over Paperwork initiative as it would reduce clinical time physicians have with patients and increase administrative overhead and regulatory burden.

The proposed policy change does not contemplate common management structures of specialty groups and departments. Anesthesia groups often facilitate quality initiatives, data and training through a select few clinical quality leaders or, for larger groups, quality committees. Management structures of group practices, whether in a small group of 10 or 15 ECs or a large group with upwards of 1,000 ECs, are often structured with one or a handful of quality champions who must then communicate with and train members of the group on initiatives, goals and best practices in quality improvement. We believe that CMS should take these management structures into account when increasing the IA participation threshold.

We recognize that CMS may perceive that one physician or EC in a large group of 1,000 ECs may not have the ability to directly impact or represent the performance or quality improvement activities of hundreds of his or her colleagues. Yet on the other hand, a group may find it challenging and burdensome to document IA participation, including staff meetings, attendance sheets, non-aggregated patient experience scores and other documentation requirements for hundreds of ECs. For example, many anesthesia groups collect patient satisfaction and experience surveys and report IA_BE_6: "Collection and follow-up on patient experience and satisfaction data on beneficiary engagement." In the past, this would be a group activity to ensure that a physician quality leader would implement protocols for beneficiary engagement and overall initiatives for improving patient satisfaction. As proposed by CMS, the question would now be whether each individual EC would have to provide documentation that beneficiary engagement occurred – an activity once reserved for the practice but now proposed to be implemented at the individual level.

The proposal to increase the threshold and require the IA to be performed during the same time period may also prevent anesthesiologists from full participation in facility initiatives. It is not uncommon for anesthesia groups to provide services in multiple hospitals and across a health system. Each hospital or service area within a health system may have significantly different goals from the anesthesia group and use different timetables for the implementation of such initiatives or cross-department trainings (e.g. infection prevention, antibiotic stewardship, opioid stewardship). Such initiatives are often outside of the control of an anesthesia group. The IA proposed changes would present a burden for practices not just to meet the 50% EC threshold but the requirement that it take place during in the same 90-day period. We expect that the result of this rule would further isolate individual groups from working across medical departments within healthcare settings.

When reviewing this proposal and future IA proposals, CMS should also consider the interests and burdens of multispecialty groups. For example, a multispecialty group consisting of equal numbers of anesthesiologists, emergency physicians, hospitalists, pathologists and radiologists may have multiple quality improvement priorities that are based upon the priories of a specific specialty. Requiring an IA to span two of these specialties to reach the 50% threshold may not fulfill the objectives of the IA or meet the group's quality improvement goals.

We recommend that CMS pilot a more reasonable number of ECs within groups who would be required to participate in an IA. ASA recognizes that some IAs lend themselves to widespread participation – such as being a part of a group that provides 24/7 access to care or participation in a Patient Safety Organization. We recommend that CMS differentiate those IAs best suited for individual improvement from those that may be applicable to a group quality champion, champions or committee. We believe there are ways that CMS can describe documentation requirements for each sort of IA, including whether the quality champion or champions facilitated the transfer of knowledge and/or best practices from the group's leadership to individual members of that group.

ASA opposes the CMS proposal to increase IA attestation to 50% of the TIN AND the proposal that the TIN's clinicians must perform the same activity for the same continuous 90-day period.

Consolidation and Availability of Improvement Activities
ASA agrees with CMS proposals to streamline certain improvement activities and supports the inclusion of the two newly proposed improvement activities. We do not believe these changes will impose a significant burden on anesthesia groups. ASA encourages CMS to conduct direct outreach to ECs and groups about receiving credit on the proposed "tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes." ASA believes that increasing the number of ECs and groups who report these codes will help to facilitate the creation of meaningful cost measures and alternative payment models.

ASA agrees with CMS proposals to remove and consolidate designated Improvement Activities.

CMS auditing requirements for Improvement Activities
ASA and AQI NACOR are increasingly concerned that CMS intends to shift the responsibilities of validating improvement activity data from the agency to qualified registries (QRs) and qualified clinical data registries (QCDRs). Since the implementation of MIPS in 2017, QRs and QCDRs have only been required to submit EC and group attestations for IAs to CMS and were not required to maintain supporting documentation that validates the attestation. The portal CMS uses for IA attestation likewise collects attestation information, not specific information that would validate if such an activity occurred (e.g. meeting minutes, attendance sheets, quality improvement plans).

CMS should maintain the authority to audit individual practices on their IA attestations.

Recent discussions on QR and QCDR vendor calls have indicated that CMS may shift that auditing and validation responsibility to vendors. Such an action would represent a significant burden on vendors as the collection of data from a group to validate an IA (let alone the added expense should CMS require that 50% of a group participate in an IA), would explode registry and vendor costs while imposing a crushing amount of data that the registry would have to collect from an individual practice. We likewise are concerned that CMS has provided only modest assistance and descriptions of what data would be necessary to validate that an individual EC or group could appropriately attest to a specific activity.

ASA and AQI NACOR support the current responsibilities of the QR and QCDR to submit attestations directly to CMS and that CMS directly audit the individual practice for required documentation in support of that attestation.

<u>Quality Payment Program – Promoting Interoperability (PI) Performance Category</u>

Physician anesthesiologist workflows, limited control of hospital and facility EHRs and documentation procedures have made our specialty unique with regard to federal interoperability policy and EHR and health IT implementation prerogatives. Anesthesiologists provide care to patients in a variety of facilities and care settings that include hospitals, ambulatory surgery centers (ASCs) and office-based locations. We interact with a variety of technologies, facility administrations and patient populations that carry their own facility-specific workflow challenges. In addition, PI measures, both established and proposed, may be readily applicable to an anesthesiologist in one setting (perhaps a pre-op clinic) but not necessarily in another setting the next day (operating room). CMS has provided appropriate exemptions to physician anesthesiologists and their groups in the PI component and we support the continued use of all MIPS special status categories.

CMS has shown flexibility when finding appropriate PI measures for ECs to report and in exploring new measure concepts that fit within the scope of this component. CMS has likewise amended PI scoring to make the program more rigorous and more understandable to participants. Although a handful of anesthesiologists have opted to participate in PI, the physicians who have reported PI nonetheless have benefitted from greater clarity by CMS.

ASA supports CMS proposals to:

- ***Make the Query of the Prescription Drug Monitoring Program (PDMP) optional and eligible for five bonus points. CMS should encourage the development of Certified EHR Technology (CEHRT) to be improved in such a way to accept PDMP data. We recognize that there are states that do not require that the PDMP be checked and that regulation has lagged behind patient safety and quality care initiatives. Regardless, CEHRT should make PDMP easily accessible to physicians and other relevant healthcare users.***
- ***Remove the "Verify Opioid Treatment Agreement" measure from the PI performance category in performance period CY 2020.***
- ***Lower the threshold for hospital-based special status from 100% of the individual EC or group's covered professional services in certain places of services to 75%. This proposal is consistent with other special status criteria and will reduce unnecessary burdens on individual hospital-based ECs and their groups.***

ASA is pleased the SUPPORT Act includes provisions with new requirements and funding for PDMP enhancement, integration and interoperability to help reduce opioid misuse and overprescribing. Under the Act, federal Medicaid matching rates for certain state expenditures relating to qualified PDMPs are available if certain requirements are met. ASA supports the requirements that a PDMP must facilitate information regarding the prescription drug history of a covered individual with respect to controlled substances; the number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period; and the name, location, and contact information of each covered provider who prescribed a controlled substance to the covered individual during at the least the most recent 12-month period. This also stipulates that the PDMP must facilitate integration of the information into the workflow of a covered provider. ASA believes that the matching funds provided by the SUPPORT Act will encourage a more uniform PDMP system in the nation and further widespread interoperability. ASA also supports the Act's requirement that CMS work in consultation with the Centers for Disease Control and Prevention (CDC) to issue guidance on best practices on the uses of PDMPs. Again, this will encourage data-sharing and promote PDMP integration into EHRs.

Another program to further enhance PDMPs and interoperability is the work that CDC and Office of the National Coordinator for Health Information Technology (ONC) are doing to collaborate on PDMP integration with health IT systems. ASA is pleased to learn the Consolidated Appropriations Act of 2018 supports these efforts.

Because there are these existing initiatives to support PDMPs and interoperability, ASA agrees with CMS that more time is needed to evaluate the Query of the PDMP measure.

ASA acknowledges that the original intent of the Meaningful Use program was to move from electronic capture and transmission of data to focusing on CEHRT to improve health outcomes. Although we recognize CMS's desire to expand the program to include additional PI measures, we caution the agency about drifting too far into repurposing quality measures to score a

meaningful EHR user, demonstrate interoperability or assess data sharing between physicians and other ECs.

Before CMS assigns NQF-endorsed quality measures for PI scoring, we recommend that CMS develop a pathway for quality measures to be converted into PI measures. For quality measure development, CMS publishes a Measure Development Blueprint – a similar blueprint does not yet exist for PI measures. Quality measures such as the claims based NQF #2940, #2950 and #2951 process measures are likewise not specified for individual ECs or groups, but rather for health plans and population health. A quick description within the proposed rule does not tell the EC or group how they may be scored, what actions they may take to understand and alter their prescribing habits and whether there is an expectation that an individual EC would need to better coordinate or communicate with other prescribers.

Although ASA recognizes the importance of the CDC Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline) during this time when the nation is facing an opioid crisis, ASA has concerns about relying on the CDC Guideline for standardizing clinical decision support. Challenges exist with trying to standardize prescribing decisions, as it is difficult to predict every scenario for individualized care. Because the CDC guideline is not appropriate for all patients, ASA cannot support its direct translation into standardized, shareable, computable decision support artifacts using CDS Hooks at this time. Furthermore, ASA has been concerned about the misapplication of the CDC Guideline by state medical and disciplinary boards, public and private payers, pharmacies and others.

We applaud the work of the CDC in developing 16 clinical quality improvement (QI) opioid measures based upon the 12 guideline recommendation statements. ASA recognizes that the QI measures were developed with the use of CEHRT in mind. However, we note that CDC states the measures "are for QI purposes to support safe and effective opioid prescribing and pain management, rather than official performance measurement."

Should CMS finalize the CDC measures for use, the agency should score users based on their collection of data rather than using actual performance scores as a basis for that score.

Request for Information (RFI) on a Metric to Improve Efficiency of Providers within EHRs
ASA supports CMS efforts to improve CEHRT efficiencies and improvements to the exchange of relevant clinical data between physicians and other healthcare providers. As described within our response to the PI component, anesthesiologists work in a variety of settings, including outpatient and ambulatory settings, preoperative clinics, inpatient settings and operating rooms – each with their own workflow and information sharing challenges.

We encourage CMS to develop a pathway describing how the agency believes each specialty can work with regulators and industry to achieve workflow efficiencies in each of these settings.

RFI on the Provider to Patient Exchange Objective

ASA recognizes that CMS works closely with ONC and that policies and proposed rules are often developed concurrently between the two agencies. ASA submitted our comments on June 3, 2019 for both the CMS proposed rule regarding interoperability and patient access as well as the ONC 21st Century Cures Act implementation proposed rule. Until those rules are finalized, we cannot provide meaningful feedback on how hypothetical situations might be incorporated into the PI component.

Although physician anesthesiologist workflows and lack of control of CEHRT have impeded their participation in the MIPS PI component, we fully support CMS developing IAs that acknowledge the use of CEHRT and health IT by individuals and their groups. As discussed in the RFI, we believe CMS can develop IAs that would recognize how anesthesiologists "promote engagement in the health information exchange across the care continuum" and acknowledge their effective and innovative use of health IT as well. ASA believes that the anesthesia community can contribute to the goal of achieving interoperability of medical devices, including contributing to the completeness of electronic medical record data. We likewise see an opportunity to collect health IT data that could be used to minimize environmental waste associated with anesthesia clinical care. For example, a measure characterizing anesthetic gas usage including waste anesthetic gases could inform local policies and procedures, improving safe practices for health care workers. We welcome continued conversations with you on approving such IAs in the future.

Our position on patient matching remains unchanged from previous comments. We recognize that there are several emerging private sector-led approaches in patient matching that may prove to be effective. Several matching services that leverage referential matching technology have emerged in the market recently, yet evaluations of this type of approach has either not been conducted or has not been made public. ASA asks that ONC and CMS evaluate these services and publicly report findings. ASA acknowledges that other innovative technical approaches such as biometrics, machine learning and artificial intelligence, or locally developed unique identifier efforts, when used in combination with non-technical approaches such as patient engagement, supportive policies, data governance, and ongoing data quality improvement efforts may enhance capacity for matching.

<u>Quality Payment Program – Cost Performance Category</u>

Under the Merit-based Incentive Payment System (MIPS), the performance of eligible clinicians is based on their performance in four categories (Quality, Cost, Improvement Activities and Promoting Interoperability), each with a separate weight that contributes to the total MIPS score. Since MIPS was first implemented in 2017, the weight of the Quality Performance Category has comprised the greatest proportion of the score and Cost the smallest portion of the score (cost was not scored in the first year). By statute the weight of the Cost Performance Category must increase to 30 percent by CY 2022 and the agency has laid out its plan in this rule, with the Cost Performance Category increasing to 20% in 2020, 25% in 2021 and 30% in 2022.

For the Cost Performance Category CMS utilizes two cost measures: the Total Per Capita Cost (TPCC) measure and the Medicare Spending Per Beneficiary (MSPB) Clinician measure as well as a series of episode-based cost measures.

The intent of the TPCC and MSPB Clinician measures provide meaningful information about the costs associated with delivering care to beneficiaries. The Cost Performance Category of MIPS measures resources eligible clinicians use to care for patients. As such, the cost measures are only relevant if they are attributed to clinicians who have control over the costs of patient care. Generally, the TPCC and MSPB Clinician measures are not attributed to anesthesia practices participating in MIPS under the group reporting option. Based on the services typically provided by an anesthesia practice, ASA believes that this is appropriate. Through feedback from our membership, it has come to our attention that there are instances where the TPCC and MSPB Clinician measure are only attributed to 1% of the practice, yet it contributes to the score for the Cost Performance Category for the entire group. ASA believes that this is a flawed methodology that undermines the intent of the measures as well as the overall intent of the Cost Performance Category.

While ASA generally appreciates and supports the flexibility CMS has built into the design of the group reporting option, we believe in this instance that it needs to be modified. ASA believes that a greater proportion of clinicians from a practice should be contributing to a cost measure for it to be contributing to the score of the Cost Performance Category. ASA proposes that CMS establish a threshold of clinicians attributed to the TPCC and/or MSPB Clinician cost measures before the measures can contribute to a group's Cost score. ASA believes that a threshold of 5-10 percent is reasonable.

ASA recommends that CMS establish a minimum threshold of 5-10% of clinicians in a group must have the TPCC and/or MSPB Clinician cost measure attributed to them for it to contribute to the overall score of the Cost Performance Category.

In this rule CMS is proposing revisions to the attribution methodology for the TPCC measure. CMS is proposing to exclude candidate events if they are performed by clinicians who frequently perform non-primary care services (*e.g.,* global surgery, chemotherapy, anesthesia, radiation therapy) or are in specialties unlikely to be responsible for providing primary care to a beneficiary. ASA is supportive of this proposal. We believe it will help to deter the type of scenarios described above where a practice that typically does not provide services which would result in the attribution of a cost measure finds themselves scored on a cost measure as the result of a small proportion of the practice having the TPCC and/or MSPB Clinician cost measures attributed to them.

ASA urges CMS to finalize the proposal to exclude candidate events if they are performed by clinicians who frequently perform non-primary care services or are in specialties unlikely to be responsible for providing primary care to a beneficiary.

<u>Quality Payment Program – Facility-based Scoring</u>

Physician anesthesiologists have no doubt benefited from having the option of being scored under their facility-based measures in 2019. We supported CMS's decision to assign an EC or group score based upon the higher score of either their MIPS quality and cost components or their facility-based scores. We look forward to the results of the 2019 reporting year and the number of individuals and groups who received a facility-based score. ***CMS should release data on the number of ECs and groups receiving a facility-based score. CMS should display the data on a specialty-by-specialty basis. CMS should also provide an analysis of average scores for those who received a facility-based score vs those who were scored using traditional MIPS methodology.*** Such data would be beneficial to understanding the needs of our members and the services we can provide in the future to encourage their continued participation in registry reporting.

Quality Payment Program – Targeted Review and Data Validation and Auditing

Physician anesthesiologists and their groups have requested targeted reviews and, in some cases, used the review as a way to better understand how their MIPS score was determined. Surprisingly in 2019, many anesthesia groups were scored on the Total Per Capita Cost (TPCC) measure, but the practices were unable to drill down into specific cases that CMS used to determine the score. Improving feedback reports either electronically or in print may lessen the number of practices submitting a data review.

ASA and AQI NACOR support the continued policy that a third-party intermediary may request a targeted review on behalf of MIPS participants. We believe this policy takes into account the limited resources that a small or mid-sized group has when preparing for a targeted review of their data and MIPS score. We agree that the 60-day targeted review time period is an appropriate length of time and support the CMS expectation that participants will receive final notice of their review in October of the year prior to the payment year.

AQI NACOR participants have received audit letters from CMS during Summer 2019, however, these letters appear to be sent on a rolling basis instead of within a specific time frame. AQI NACOR supports those practices by providing data reports to these ECs and groups. We recommend that CMS be more transparent in future years related to the timeline, process and expectations of the individual or group audits but also for the third-party vendors. Such notification can help streamline the audit process for our AQI NACOR participants.

ASA recommends that CMS provide a one-time extension of the 30-day requirement for an individual or group to submit additional. For many anesthesiologists and their groups, their quality data may be held within a facility EHR or app vendor and only accessible by a lengthy request period. Although claims and billing data may be readily available in house and their aggregated data found within the registry, the primary source documentation sometimes takes more than 30 days to access.

As mentioned in the MIPS Quality component, we support CMS's ability to audit an EC or group if the agency believes that "cherry-picking of data may be occurring." Each EC or group should be aware that "using data selection criteria to misrepresent a clinician or group's performance

results in data submissions that are not true, accurate or complete" and that CMS can reopen and revise the individual or group's MIPS payment adjustment.

ASA recommends that CMS provide a one-time extension of the 30-day requirement for an individual or group to submit additional information during the targeted review. ASA supports CMS actions to discourage "cherry-picking" of data.

Quality Payment Program – Third Party Intermediaries

The 2020 Quality Payment Program proposed rule includes several provisions that would significantly increase the burden on qualified registries and qualified clinical data registries. ASA is concerned that CMS is increasingly proposing rules that would alter business plans, missions and customer service priorities of clinical data registries. ASA and AQI NACOR are concerned that CMS is attempting to shift costs and burdens of administering the MIPS program onto our QR and QCDR. We encourage a strict dichotomy between the independence and responsibilities of QRs and QCDRs to its customers from QR and QCDR responsibilities in complying with CMS regulations and administration of the program.

ASA and AQI NACOR provide MIPS quality and improvement activity attestation reporting services for over 17,000 ECs and their anesthesia groups. Although AQI NACOR has explored expanding its options for collecting data on the PI component, the cost of providing this service to just a handful of anesthesiologists would represent a significant financial burden that would be passed on to participants, the vast majority of whom are exempt from the PI performance category. In addition, the requirement to expand this option to meet the theoretical needs of more than 17,000 ECs and their groups would cost significant amounts of money in building out the platform and dashboards, purchasing data storage space and educating participants – a problem that will not be solved within one year. ***CMS should not finalize this proposal.***

CMS has provided appropriate exemptions to physician anesthesiologists and their groups in the PI component and we support the continued use of all MIPS special status categories. Since AQI NACOR earned its status as both a QR and QCDR, we have fielded few participant questions on whether we accept and report PI performance category data. When these rare questions are asked, we direct those practices to submit data directly to CMS as the agency has established a portal to receive such data. We feel this publicly available portal fulfills the needs of the modest number of anesthesia groups who wish to submit PI data.

We likewise are concerned that the proposed process for exempting a QR or QCDR from having to report the three components is unclear. CMS has proposed to exempt those QRs and QCDRs whose participants receive an exemption under the special status categories. Likewise, AQI NACOR allows participants to choose those components for which they wish to submit data. We do not request data or verify whether any EC or group has a PI exemption. Within this policy proposal, CMS does not provide an indication as to the percentage of participants that would have be exempt for the QR or QCDR to not have to accept and submit PI data. ASA and AQI NACOR believe that market conditions and business plans of a QR or QCDR should drive its decision to accept or not accept quality, PI or IA data from MIPS participants – not CMS.

ASA opposes the CMS proposal to require all QRs and QCDRs to collect each of the three MIPS components – Quality, Promoting Interoperability and Improvement Activities.

As a clinical data registry, AQI NACOR provides our participants and those who use our QR and QCDR services with opportunities to submit anesthesia-related data and to analyze that data outside of Quality Payment Program (QPP) regulations. As a specialty-society registry, we provide our members with a wide variety of products and services that foster quality improvement, education and best practices in anesthesia care. We understand that CMS wishes to further delineate those QCDRs who provide such services from those who function as a conduit for submission of MIPS data. We feel this proposal to require QCDRs to describe in detail their products and services for fostering quality improvement among their participants is unnecessary.

We are concerned that the proposed policy is unclear, vague and could be used in an arbitrary fashion. CMS has not proposed any criteria for what might constitute improvement activity or the number of services that must be made available to an individual or group to "foster quality improvement." We are unclear regarding the end goal of this proposed regulation – would details of quality improvement services be made public? Would CMS use the data to compare or rank QCDRs against one another? Would ECs or groups, let alone a patient, need this information to make a medical, clinical or business decision?

ASA and AQI NACOR believe CMS should use established methods and regulations to ensure that approved QCDRs are clearly focused on clinical quality improvement in addition to MIPS reporting. ASA and AQI NACOR are pleased with the progress CMS has made in weeding out vendors who held QCDR status but did not provide quality improvement or other services that are routinely provided by a physician-led, clinical data registry. We believe the narrowing of available QCDRs will continue so long as CMS continues to enforce existing regulations.

ASA and AQI NACOR oppose proposed requirements for QCDRs to describe how they foster services to clinicians and groups to improve the quality of care provided by their ECs.

AQI NACOR encourages its participants to routinely submit data throughout the year and to frequently review their dashboard reports. However, it is not uncommon for AQI NACOR participants to submit their quality measure data and attest to IAs in the fourth quarter of the performance year or the first quarter of the following year. Individuals and groups have understandable reasons for completing this task 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.

ASA agrees with CMS's intent for individuals and groups to routinely submit data but believes such a proposal is not practical and will be burdensome on individuals, groups and clinical data registries.

For registry operations, ASA and AQI NACOR encourage registry participants to submit data throughout the year and to review their individual and group-specific dashboards at least once a month. We do not believe that QR or QCDR data submission to the registry and displaying of participant data by April 1 would be a burden.

Instead, we are concerned about how to best manage staff resources devoted to compliance with previous year data submission with those devoted to participant and customer service for the reporting year. The burden on AQI NACOR to submit data for the previous year by March 31 for more than 17,000 ECs consumes a great amount of staff resources. Because of this compliance-related deadline, AQI NACOR would not have adequate staff resources to track and enforce an arbitrary April 1 submission deadline on our participants. We are also unclear on the criteria for validating how much data or what quality of data must be submitted by April 1 to comply with this CMS proposal. The proposal would increase the burden on a registry because it would require AQI NACOR to report to CMS an individual or group that was tardy in submitting data.

ASA and AQI NACOR recommend that CMS explore other options to assist and encourage data submission earlier in the reporting year. We recommend CMS consider awarding bonus points to practices who have submitted a valid data file to a registry and have accessed their EC or group-specific reports by April 1. We also encourage CMS to explore whether credit can be awarded in the IA component for practices who successfully submit data to a registry each month (three times) during a 90-day period.

ASA does not believe CMS should finalize its proposed requirement that individuals and groups must submit any data to a QR or QCDR by April 1 of the reporting year.

The ability for ECs and anesthesia groups to meet a 70% data completeness threshold rests upon the availability of the same measures to report from year to year. We request that all QCDR measures be automatically approved for at least two years. The greatest burden on individuals and groups often occurs at the beginning of the year when they must choose which measures to report, train their staff on how to collect the measure and to update any data collection protocols. This burden is a particular challenge for newly implemented QCDR measures. Approving measures for multiple years and posting updated specifications by November would allow individuals and groups to meet the data completeness threshold more easily. We believe that the November posting would not affect the current deadline for the QCDR self-nomination period.

In a whiteboarding session hosted by CMS to discuss the QCDR self-nomination process on February 6th, 2019, several medical specialties, including ASA, advocated for two-year approval for QCDR measures that demonstrate a consistent performance gap and are based on a stable

body of clinical evidence. Implementation of two-year approval for such QCDR measures would add much-needed stability to MIPS, which would reduce burden for ECs, vendors and QCDRs.

In addition to allowing two-year approval for historically stable measures, CMS should also grant two-year initial approval for new QCDR measures in the MIPS program. The introduction of new QCDR measures requires significant effort on the part of ECs, practices, and third-party vendors to update their data collection systems and policies in order to correctly implement and report the measures. The cost for practices to annually review, select and implement new quality measures is oftentimes more expensive than the positive payment adjustment a practice receives.

For QCDRs, the learning curve associated with implementing new measures, in combination with the earlier deadline to submit a self-nomination application starting in 2019, presents a significant barrier to collecting meaningful, representative performance data on the measure in time to be included in the next self-nomination application. A two-year initial approval window at least for new QCDR measures would ensure a stable period of data collection for new measures that will give a more accurate representation of their true performance.

ASA requests that QCDR measures be approved for two years and specifications be made available by November 1, 2019.

During the QCDR self-nomination process, CMS reviewers assess QCDR measures using several criteria, including consistency with clinical guidelines, ability to attribute performance to an individual clinician and whether the clinical actions or outcomes reflect a standard of care. QCDRs appreciate the insight and recommendations that CMS reviewers contribute to this challenging measure development process. As CMS has reduced the number of broadly applicable quality metrics, QCDRs that represent anesthesiology are increasingly pressed to develop specialized clinical measures that may have more narrowly focused target populations. While the current process does not include a formal role for subject matter experts, CMS has an opportunity to incorporate anesthesiology clinical subject matter experts to supplement and enhance the CMS measure review and comment process. Along with existing CMS expertise, such clinicians with subject matter expertise can assist CMS quality measure reviewers in balancing programmatic priorities with clinical importance when making QCDR measure approval decisions, while emphasizing the importance of feasibility across the scope of anesthesiology practice. Based on the ample time allotted for measure review with the new QCDR self-nomination application deadline, we encourage CMS to consider this opportunity to leverage its existing expertise with the additional contribution of such subject matter experts for our specialty.

CMS should establish a formal role for subject matter experts in the QCDR measure review process.

ASA supports CMS policies to encourage transparent harmonization processes. We request more clarity on CMS' expectations for harmonizing and licensing QCDR measures. In the past, when two QCDRs have self-nominated with similar measures, CMS has indicated that the

QCDRs should harmonize the measures without providing guidance on the expected outcome of that harmonization (e.g., aligned denominator populations, definitions). In other instances, CMS would recommend that one QCDR request to license a measure without also notifying the steward of that QCDR measure who would be granting the license. This incomplete communication of expectations regarding harmonization and licensing of measures between QCDRs has led to confusion and delays as the QCDRs work to clarify what is required for the measures.

We support CMS's proposals regarding harmonization in this rule and offer additional recommendations for CMS consideration:

- ***Provide a single communication including both parties that clearly describes CMS' rationale for the request and the expected outcome of licensing and/or harmonization activities.***
- ***Acknowledge the provenance of each measure—a QCDR that has stewarded a measure in the program for three years should be afforded some benefit over a newly-developed measure on a similar process or outcome of care.***
- ***Recognize when one QCDR measure steward fails to acknowledge or work in good faith with a second QCDR in the harmonization process.***
- ***Notify QCDR measure stewards of all parties who have indicated they have permission to license their measures and give measure stewards the opportunity to confirm that permission has been granted.***

ASA and AQI NACOR support CMS auditing of data that the agency believes is part of "cherry-picking activity." ASA agrees that CMS should audit data that they believe has been "cherry-picked" or if CMS believes that the submitted data is otherwise not accurate. However, CMS should be mindful that third party vendors, especially specialty society clinical data registries, do not have the capacity to tell whether a group has specifically submitted false or incomplete data. The registry receives data directly from a practice and, once the data has been cleaned and appropriately formatted, the registry submits that data directly to CMS. Should the practice submit erroneous data to AQI NACOR, it is the responsibility of the group or individual EC to demonstrate to CMS that their data is accurate and complete using documentation as described by CMS in this rule.

AQI NACOR is not an extension of the individual EC or the group – the registry functions as a mechanism for our members to submit MIPS data to CMS. Therefore, should CMS find either through statistical validation or otherwise that a group or individual is suspected of "cherry-picking" its data, a request for auditing should be sent to those ECs and groups. AQI NACOR's responsibility should be limited to working with audited participants by providing data reports and dashboard access to help ensure that they can perform the appropriate analysis between the data they submitted to AQI NACOR and their primary source data records.

ASA encourages CMS to release additional instructions for individual ECs and groups to understand their responsibilities in submitting accurate and complete data. CMS should publish aggregate (not individual EC or specific group) findings from their 2018 auditing of ECs and groups with regard to suspected instances of cherry-picked data.

In each of the past three years, AQI NACOR has submitted data to CMS for more than 17,000 anesthesia providers – most of them were represented by group practices, but over 1,300 reported data as individuals. Current CMS guidance and regulations allow for group administrators to collectively attest that the group wishes to have NACOR submit QPP data on their behalf to CMS. NACOR staff, however, must contact and collect more than a thousand attestations from eligible clinicians who are submitting data as individuals even though they may be part of a group practice. This process of tracking down individual attestations has become a significant burden for QCDRs. CMS can reduce administrative burden for individual eligible clinicians, groups and QCDRs by allowing the group administrator or representative to provide a blanket consent for all persons within the group who submit QPP data as individuals.

In the QPP Participation Status tool, CMS should explore methods for enhancing how physicians with multiple TIN-NPI understand their responsibilities for reporting MIPS data.

CMS previously finalized and has reemphasized in this rule that disqualification of a third party intermediary will be based on submitted data that includes "TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies that affect more than 3 percent of the total number of MIPS ECs or groups for which data was submitted by the third party." ASA and AQI NACOR believe that CMS has enhanced the ability for registries to meet these requirements as the agency has improved the transparency of the QPP webpage and produced tools to be used by registries to validate TIN/NPI combinations.

Although CMS has provided some indication through the sub-regulatory process of what may constitute an inaccuracy, greater clarity and transparency is critical so that registries can implement appropriate checks. This is particularly important if CMS expects registries to identify additional data inaccuracies or errors beyond those that are detected through each registry's CMS approved data validation plan. A transparent process of assessing data inaccuracies will assuage fears among registries on what may constitute an event that could place a QR or QCDR on probation or worse, disqualify a third parties from submitting data from ECs participating in the QPP. We urge CMS to consider developing a report that describes and differentiates errors as well as other "issues" that should be brought to the registry's attention and clearly define what is considered when calculating an error rate.

ASA encourages greater detail regarding CMS's description of criteria that may disqualify a third-party intermediary.

ASA supports CMS policy to allow anesthesiologists and their groups to voluntarily report MIPS and be eligible for payment adjustments. We believe that practices spend too much time understanding which physicians must participate in the QPP and whether the individual TIN is responsible for reporting. The QPP Participation Status tool allows individual NPIs to see all TIN-NPIs that they are associated; however, the tool is not an infallible solution for all NACOR participants. For anesthesia, business names are often very similar and it is difficult for NACOR to verify NPI or TIN-NPI eligibility with absolute accuracy based on business name alone. For

the hundreds of NACOR participants who have multiple TIN-NPIs combinations, we believe the process could be improved by allowing a TIN-NPI combination and return results for the TIN-NPI combination only. Otherwise, CMS could provide the last four digits of the TIN with each TIN-NPI combination with the query results in the current version of the tool.

CMS should not implement a policy that requires QRs or QCDRs, when submitting data for a QPP reporting year, to identify eligible clinicians or their groups as reporting as required by QPP, opting-in to MIPS or voluntarily reporting MIPS data.

When individuals or practices withhold Medicare billing data, this unavailable data should not be counted against the registry as an inaccuracy since the registry has no readily available solution to address this issue without access to current CMS' claims data. For these cases, we agree with CMS as the agency noted in the 2018 QPP final rule that MIPS eligible clinicians are responsible for the data submitted to registries and to ensure their third-party intermediaries meet their needs. We also agree with CMS's previous concern in the 2017 QPP Final Rule that "If the third-party intermediaries data is incomplete or inaccurate, this can adversely affect the program as a whole and all MIPS eligible clinicians may suffer from inaccurate or missing data." Regardless, registries should not be held responsible for individuals and practices who withhold Medicare billing data from the registry.

CMS should clearly define a registry's responsibility to address data inaccuracies that can be attributed to data that the registry has access to, controls and manages.

Our customers, both individual ECs and practices, depend on registries to submit their data to CMS believing that they will avoid a penalty and have the best opportunity to earn a payment incentive under the QPP. For many practices who have struggled to submit data to a registry, the thought of not submitting data to CMS because a registry indicates they may miss certain thresholds is contrary to the reasons why they join and participate in a registry. In short, a registry must balance the regulatory requirements to submit accurate and complete data to CMS with the desires of a practice to submit data that they believe is gives them an opportunity to show their quality data to Medicare.

For data submitted by a registry, CMS should not consider an eligible clinician's status as a non-MIPS eligible clinician, a Qualified APM Participant or other APM participant as a data inaccuracy.

In prior CMS programs such as the Physician Quality Reporting System (PQRS), registries were cited for submitting less than the required number of quality measures. As CMS explores MIPS Value Pathways and as the agency increases the data completeness threshold for quality measures, we expect that registries will not incur an "error" because the data submitted does not meet appropriate thresholds.

CMS should not count instances where an EC or their practices submits fewer than the required measures or less than the data completeness threshold as data inaccuracies.

MIPS Value Pathways (MVPs)

MIPS Value Pathways – Guiding Principles
CMS has proposed four guiding principles for defining and developing MVPs. The guiding principles are:

1. MVPs should consist of limited sets of measures and activities that are meaningful to clinicians, which will reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data.
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.
3. MVPs should include measures that encourage performance improvements in high priority areas.
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 has asked whether the agency should consider other guiding principles.

ASA recognizes CMS's goal of simplifying the MIPS program and ensuring that MIPS meets the regulatory and statutory requirements. We believe that the guiding principles should also include a statement supporting physicians and other clinicians to be assessed on MVPs that reflect their specialty training, sub-specialization and their individual or group priorities.

Physician anesthesiologists represent one of the few specialties that contribute to nearly all surgical and procedural patient care. Anesthesiologists provide care coordination and are instrumental in improving quality and delivering more cost-effective care. Anesthesiologists provide patient care in many settings, including but not limited to, inpatient, outpatient, office-based and non-operating room anesthetizing locations. Many anesthesiologists have subspecialty expertise in, among others, ambulatory care, critical care medicine, obstetrics and pain medicine. CMS should also pay attention to how group size and resources may influence group participation and success in MIPS or under the MIPS Value Pathways. For anesthesiology groups in AQI NACOR, small and mid-sized groups often struggle to collect and report data. In short, we are concerned that a one- or two-size fits all strategy for MVPs will not work for anesthesiologists or their individual groups.

CMS should include a guiding principle supporting physicians and other clinicians to be assessed on MVPs that reflect their specialty training, sub-specialization and their individual or group priorities.

MIPS Value Pathways – Stakeholder Engagement
ASA and AQI NACOR welcome the opportunity to assist CMS in better defining and constructing MVPs. Because we expect anesthesiologists to have the ability to participate in episode-based MVPs, we recommend that CMS convene technical expert panels or conduct targeted outreach on proposed MVPs. Regardless of how MVPs are organized, CMS should

issue calls for specialty society expertise when forming, revising and finalizing MVPs. CMS should also engage third-party intermediaries on MVP development. Because CMS is proposing to alter how ECs and groups participate and are scored in the Quality Payment Program (QPP), Qualified Registries (QRs) and Qualified Clinical Data Registries (QCDRs) should be engaged to identify any feasibility or reporting burden issues that ECs, groups and vendors may encounter.

ASA supports a "Call for MVPs" process that would be structured in a similar way as the "Call for Measures" process. The current "Call for Measures" allows for ample specialty society influence and engagement in measure approval processes and discussions with CMS. We do not support a process similar to the "Call for Measure Sets." In previous years, CMS arbitrarily included measures into the anesthesiology specialty measure set without our consultation. That process led to many questions from anesthesiologists and their groups about how to report non-anesthesiology measures. CMS should develop a balanced approach to who will develop and maintain the MVP with multiple touchpoints with specialties who use those MVPs.

MIPS Value Pathways – Organizing MVPs

CMS has requested information on how MVPs should be organized, including whether MVPs should be based around specialties, diseases or areas of practice. CMS also asked how the agency can ensure that MVPs will result in comparable and comprehensive information that is meaningful for the clinicians, patients, and the Medicare program.

ASA believes that CMS should explore and make available multiple MVPs that are structured around episodes of care (preferred), specialty and care settings. We also recommend that CMS develop cross-specialty MVPs. ASA recommends that CMS also test and implement a minimum threshold of cases that have a complete set of MVP measure data submitted by the provider.

ASA agrees with CMS's overall goal that MVPs should foster opportunities for ECs and groups to join APMs; however we believe the ability for an EC or group to join an APM is based upon whether that particular specialty group is accountable to the patient and payer, if it has a "seat at the table" and has responsibilities not just for patient safety and care but cost management and quality improvement.

- ***MVPs Structured around an Episode of Care***
  If the intent is for MIPS ECs and groups to eventually participate in an APM, then CMS could focus on the development of MVPs structured around an episode of care. Most APMs are specific to episodes of care – a structure that can easily take into account quality measures, cost measures and improvement activities (IAs).

  ASA believes MVPs based on Episodes of Care could work for anesthesiologists because:
  - Anesthesiology measures can be applied to many different surgeries and episode of care.
  - Anesthesiology measures span the perioperative period.

- Anesthesiologists are central to care coordination activities of a surgical patient, leading to cost and patient outcome optimization across multiple providers.

ASA believes MVPs based on Episodes of Care may fall short of CMS's MVP development objectives because:

- ECs and groups may not participate in a sufficient number of episodes to render the MVP statistically valid.
- ECs and groups may find reporting on just one or two episodes of care is not reflective of the totality of care they provide to patients.
- Efforts to improve care on the episode may stall if an anesthesia group does not report the same episode as their surgical colleagues.

CMS should not allow one specialty to monopolize or control an MVP based upon an episode of care.

- ***MVPs Structured around a Specialty***

ASA believes that structuring MVPs based upon specialty designation may be too broad for anesthesiologists to fully engage in MIPS and appreciate the MVP. As previously mentioned, anesthesiologists work in different settings and many anesthesiologists have subspecialized expertise. Providing for a generic anesthesiology MVP based upon the quality measures currently available does little to break down silos between anesthesiologists and our surgical colleagues.

ASA believes MVPs based on a Specialty designation could work for anesthesiologists because:

- ECs and groups may appreciate that it provides for the least amount of change from current reporting requirements.
- Quality measures, IAs and other specialty specific options recommended for anesthesiologists and other qualified anesthesia providers are currently available on the QPP website.
- Group practices often choose measures and IAs based upon the aggregate need of all ECs in the TIN. This scenario, with its ease of reporting, has led many practices to focus less on subspecialties and more on standardization of reporting the same measures across multiple ECs and care settings.

ASA believes MVPs based on a Specialty designation may fall short of CMS's MVP development objectives because:

- A specialty-specific MVP would continue to place specialties in competition with one another in a similar way as current MIPS reporting.
- There is little incentive for ECs or groups to engage with their clinical colleagues on cross-specialty, local quality improvement initiatives.
- Important clinical outcomes that physician anesthesiologists want to measure (e.g., acute kidney injury, surgical site infection) are oftentimes influenced by factors other than anesthesia care. Such outcomes are rarely attributed only to the care delivered by an anesthesiologist.

- A general anesthesiology MVP diminishes the role subspecialists have in the MIPS program. For example, an anesthesiologist working in an ambulatory surgical center most likely reports on different quality measures and IAs than a cardiovascular anesthesiologist or a pain medicine physician.

- ***MVPs Structured around a Care Setting***
  As CMS allows additional procedures once performed in inpatient settings to be performed in ambulatory settings, ASA believes CMS should determine whether the MVPs for these procedures are comparable. For example, a total joint replacement in an inpatient setting will most likely cost significantly more than a similar procedure in an outpatient setting. Perioperative workflows, patient selection and patient recovery would also likely challenge comparisons between the two settings.

  ASA believes MVPs based on a Care Setting designation could work for anesthesiologists because:
  - Subspecialties among anesthesiologists could be better represented among MVPs.
  - Quality measures and IAs could more readily be tailored by ECs and groups to align with the strategic objectives of the facility.

  ASA believes MVPs based on a Care Setting designation would fall short of CMS's MVP development objectives because:
  - Patients may find information comparing different care settings for the same procedure confusing.
  - Some ECs and groups may not meet the minimum thresholds needed to make the MVP statistically valid.
  - ECs and groups may find data collection more difficult in some settings, such as ambulatory surgery centers, than others.

We welcome the opportunity to discuss these three different MVP structures with CMS.

ASA also encourages CMS to explore the merits of developing MVPs that would span multiple specialties within one facility or within a healthcare system. As stated in the previous paragraphs, ASA is very concerned that the MVPs may end up further isolating anesthesiologists and anesthesia groups from their perioperative colleagues. At the same time, we also have ECs and groups participating in the Medicare Shared Savings Program where the role of anesthesiologists is not captured based upon the quality measures that are available. As these MVPs are currently proposed by CMS, there is little incentive for any specialty to work across departments to improve care or share in patient outcomes.

ASA recommends CMS build and test several cross-specialty MVPs. A cross-specialty MVP would include the four MIPS components and may initially be based upon an episode of care. Different specialties, including ECs and groups not affiliated with the same TIN, could negotiate the quality measures and IAs for the MVP group to be scored on while the cost category would be based upon one or more established cost measures (e.g. MSPB). Data

collected from this cross-specialty MVP would be available to all participants in the MVP, leading to greater communication and planning in the year ahead. In this way, CMS could facilitate greater communication between specialties locally and each specialty would have an incentive to assess and contribute to cross-specialty objectives and goals.

Table 2: Cross-Specialty MVP Structure

Quality	Cost	Improvement Activities	Promoting Interoperability
Each MVP specialty reports 2-3 quality measures: • Anesthesiology • Surgery • Pathology • Hospitalist CMS develops scoring mechanism across specialties while providing measure-specific scores to all MVP participants	Each specialty receives same cost measure score for the specific episode. All cost data shared with each participating EC/group.	MVP participants must independently choose which improvement activities to perform for the 90-day period based upon their TIN. Each MVP specialty receives same score aggregated across the different specialties participating in this MVP.	Participation would be based upon MIPS special status designations.

Physician anesthesiologists have a number of measures that are applicable to nearly every surgical procedure in inpatient, ambulatory settings and other procedural care settings. MVPs based upon a surgical episode should take into account the care of multiple physicians and specialties who contribute to the care of the patient.

ASA recognizes, however, that this proposal would need further discussion with CMS and other stakeholders. As discussed below, this might be most applicable to large, multispecialty group practices or those physicians who are employed by a facility. Such data capture might be easier for those groups. Should CMS pursue this proposal, we believe that a closer look at how small and mid-sized group expect to perform or use this as a stepping stone to APMs is warranted.

ASA welcomes the opportunity to discuss this proposal further with CMS.

<u>MIPS Value Pathways – Promoting Health Information Technology and Interoperability</u>
Although physician anesthesiologist workflows and lack of control of CEHRT have impeded their participation in the MIPS PI component, we fully support CMS developing MVPs that acknowledge the use of CEHRT as well as health IT by individuals and their groups. We believe CMS can build MVPs that would recognize how anesthesiologists "promote engagement in the

health information exchange across the care continuum" and acknowledge their effective and innovative use of health IT as well. ASA believes that the anesthesia community can contribute to the goal of achieving interoperability of medical devices, including contributing to the completeness of electronic medical record data. We likewise see an opportunity to collect health IT data that could be used to minimize environmental waste associated with anesthesia clinical care. For example, a measure characterizing anesthetic gas usage including waste anesthetic gases could inform local policies and procedures, improving safe practices for health care workers. Similarly, opportunities for cost containment can be assessed using data and analytics in comparing types of anesthetic delivery on episode of care, such as physician anesthesiologists providing intravenous anesthesia whenever applicable would lead to a safe yet more rapid discharge of the patient from the recovery room.

CMS should continue the MIPS Special Status designations for MVPs but explore other opportunities to receive credit for use of non-CEHRT health IT via the Improvement Activities performance category.

MIPS Value Pathways – Reducing Barriers to Clinical Movement into APMs
In this proposal, CMS believes that a significant barrier to clinician movement into APMs is a group's "inexperience with cost measurement and lack of readiness to take on financial risk." ASA believes that if CMS and facilities provided sufficient cost data to all participants in an episode of care, anesthesiologists would be in a better position to work with their surgical colleagues on identifying cost savings, forming APMs and taking on additional financial risk. Anesthesiologists are rarely the drivers of cost but can potentially reduce costs if more granular data was made available.

The current cost measures used by CMS in the MIPS program do not provide a significant amount of actionable data for ECs or groups. ECs and groups may know how they scored under the Total Per Capita Cost (TPCC) and Medicare Spending Per Beneficiary (MSPB) measures, but the costs incurred by other physicians and clinicians on those specific patients are hidden. This lack of transparency in costs across specialties ensures that ECs and groups have little incentive to engage others based upon a limited amount of available data. The reorganization of the four MIPS components into MVPs, as currently proposed, will not incentivize an EC or group to pursue or join and APM.

MIPS Value Pathways – Selecting Quality Measures and Activities
CMS should ensure that ECs and groups have more measures to choose from than are required for reporting. Although we are concerned that the ability for ECs and groups to choose from a wide variety of measures has contributed to some measures being "topped out", we believe that MVPs can be carefully constructed to ensure the appropriate measures are made available. ASA is supportive of current CMS criteria related to the inclusion and scoring of MIPS and QCDR measures. Such criteria reflect CMS priorities for ECs and groups to report outcome measures, intermediate outcome measures, patient experience measures and other high priority measures.

ASA believes that CMS should work with specialty societies and specialty-specific subject matter experts to assign quality measures to specific MVPs.

We caution that an MVP policy that requires quality measures to be directly tied to IAs should not be used to deny a well-constructed and meaningful measure from inclusion in an MVP. An informal survey of anesthesia ECs and groups revealed that many anesthesiologists choose their measures independently from their choice of IAs. Although the Anesthesiology Smoking Abstinence MIPS measure and Anesthesia Patient Satisfaction QCDR measure could be tied to specific IAs, ECs and groups may find other anesthesiology measures difficult to link one-to-one with an IA. Similar to our arguments for quality measure selection, CMS should make more IAs available to report in an MVP than the minimum required. We see potential opportunities linking quality measures with cost measures; however, such opportunities should be fully vetted before implementation. For example, there may be opportunities for cost saving measures that anesthesiologists can engage in such as improved transfusion practices or, at the level of preoperative assessment units, by decreasing unnecessary testing or surgical optimization, for example treating preoperative anemia.

ASA and AQI NACOR strongly believe that third party vendors should not be required to collect data on quality measures outside of their current customer base (e.g. CMS requiring AQI NACOR to collect quality measures for radiologists) and vendors should be able to determine which types of measures it will collect. We recognize that there are several types of measures available for ECs and groups to report (e.g. eCQMs, MIPS Clinical Quality Measures [MIPS CQMs], CMS Web Interface, or QCDR measures). We believe CMS should demonstrate consistency between MIPS and MVPs by allowing QCDRs and other vendors to choose which types of measures they will accept. We likewise do not believe that CMS should award bonus points or other incentives for eCQMs. Anesthesiologists are experienced in collecting and reporting registry-based measures, but a significant majority of our members do not have access to and cannot report eCQMs. ASA supports the stratification of measure scores based upon submission method.

ASA supports CMS's desire to link quality measures with cost measures and IAs but we caution CMS that such links may not reflect the business objectives of ECs and groups.

We note that specialty accreditation programs like those administered by the American College of Surgeons include the expertise and contributions of anesthesiologists and other specialties. ECs and groups who work in facilities accredited by such programs should receive equal credit based upon an attestation that the department has contributed to the awarding and maintenance of such accreditation.

ASA supports CMS awarding full IA credit to an EC or group who participates in a specialty accreditation program.

Most physician anesthesiologists and their groups have typically not been assessed under the TPCC or MSPB. We believe that the MVPs should be developed with the goal of encouraging widespread participation and should be equitable across different specialties. ASA supports

CMS providing ample opportunities for ECs to participate in MVPs, regardless of whether they participate in the Promoting Interoperability performance category or are scored on a cost measure.

CMS should not disqualify ECs who do not have an applicable cost measure from participating in MVPs.

MIPS Value Pathways – Selection of MVPs

CMS has requested information on whether clinicians and groups should be able to report more than one applicable MVP and allow clinicians to select their MVP(s). CMS has asked which tools might be helpful for clinicians to understand what MVP(s) might be applicable.

ASA recommends that CMS identify EC and group reporting responsibilities based upon whether the MVP would increase or decrease burdens associated with the current MIPS reporting process. CMS may allow, but should not require, an EC or group to report more than one MVP but the aggregate burden should be limited to no more than six quality measures and four medium-or two high-weighted IAs. Similarly, CMS should recognize the special statuses that an EC or group may have in the MIPS program and not require those ECs or groups with a promoting interoperability exemption to be scored on the PI category under an MVP.

ASA supports the right for ECs and groups not just to opt-in to MVPs but to have several MVPs to choose from. As described in our previous responses, anesthesiologists work in a variety of care settings and include several subspecialties. At the EC level, providing multiple options would fulfill the desire of CMS to make MIPS more relevant to that individual physician. At a group level, the ability for the group to choose from multiple MVPs will allow a group to choose an MVP that reflects its practice priorities and quality improvement initiatives.

ASA opposes CMS arbitrarily assigning ECs or groups specific MVPs to report.

MIPS Value Pathways – Transition Period

ASA supports a pilot period for testing and implementing MVPs until all specialties have an appropriate number of MVPs to select from. Such a modest “on ramping” method for MVP rollout would allow ECs and groups an opportunity to better understand MVPs and to compare their potential MVP scores against current MIPS performance. Since CMS proposes to move most ECs into MVPs within three to five years, we believe a period of trial and testing is necessary. We believe that CMS has been prudent in previous program rollouts, displayed most recently when CMS finalized several cost component measures and its facility-based scoring policy.

MVP goals as described by CMS will immediately disrupt EC and group participation in the QPP. After several years of learning about MIPS and becoming familiar with the four different components, CMS is asking ECs and groups to forego their self-determined measures and IAs for a more defined set of metrics. ECs and groups have spent a significant amount of time and money in understanding MIPS, collecting data and modifying their business objectives to meet

program requirements. Disrupting their established administration workflows will lead to additional costs in the short-term. The proposals are also unclear on the role of third-party intermediaries and the responsibilities of those vendors to collect and report data on behalf of MVP ECs and groups to CMS. Depending on the complexity of the program, some vendors may not be able to meet the 2021 deadline for reporting specific measures and IAs as required by yet-to-be-determined MVPs.

ASA supports a pilot period for testing and implementing MVPs until all specialties have an appropriate number of MVPs to select from.

MIPS Value Pathways – Multispecialty Groups

CMS has requested information regarding considerations for multispecialty practice participation in MVPs and the minimum and maximum number of MVPs such a group could report. CMS has asked for recommendations on how a multispecialty group would be identified and if a multispecialty group could have its TIN split when reporting MVPs. CMS has solicited comment on how multispecialty groups may be scored under MVPs.

As CMS develops MVPs for specialties and episodes of care, we believe that the agency should be creative in how they approach MVPs for multispecialty practices. To avoid isolating individual specialties within a multispecialty group, ASA recommends CMS explore the development of MVPs for these groups based upon an improvement activity that might unify a common goal among the different specialties within that group. Based upon an improvement activity, the multispecialty MVP could choose from a wide variety of MIPS and QCDR measures (applicable across multiple specialties in their practice) that support the activity. For instance, in a group composed of anesthesiologists, pathologists, radiologists and hospitalists, each subspecialty may be responsible for contributing two quality measures to the MVP. Like our proposed cross-specialty MVP, the specialties within the group would be assessed equally in the other three categories.

ASA supports the option for multispecialty groups to report multiple MVPs but believes that CMS should find the correct balance between making MVPs more meaningful to groups with protecting multispecialty groups from an overwhelming reporting burden.

ASA and AQI NACOR support a policy to allow multispecialty groups to split their TIN. Although we proposed a new way of thinking about MVPs above, we also realize that CMS may pursue specialty-specific MVPs. We believe that allowing groups to split their TIN and participate in specialty-specific MVPs will be relatively easy for QRs and QCDRs to collect and report data. We support CMS using the National Plan and Provider Enumeration System (NPPES) taxonomy to identify such opportunities. We are hesitant to support TIN MVP identification based upon the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Although the majority of anesthesiologists are identified by PECOS “05,” there is a significant number of anesthesiology subspecialists who might wish to participate in anesthesiology-specific MVPs regardless of their PECOS designations.

Because the structure of MVPs has not been established, the ASA does not have specific recommendations on scoring.

CMS should test different MVP models and scoring proposals prior to implementing any specific scoring methods for multispecialty groups.

MIPS Value Pathways - Incorporating QCDR Measures into MIPS

ASA and AQI NACOR support the inclusion of QCDR measures into MVPs. Many anesthesia groups and subspecialties rely on the development and use of QCDR measures to demonstrate their quality of care. The current anesthesiology measure set, though important, lacks both the flexibility and granularity of anesthesia QCDR measures. For example, anesthesia ECs and groups who work in ambulatory surgery centers have just one MIPS quality anesthesiology measure set measure to report but may have more than six QCDR measures to report. The QCDR measure approval process has become more robust and meaningful, leading to a greater number of long-term measures to be incorporated. ***ASA and AQI NACOR encourage CMS to provide a two-year approval process for QCDR measures so that practices have continuity in the measures they can report from year to year.***

MIPS Value Pathways – Scoring MVP Performance
CMS has requested information on how MVPs should be scored, including how to create equity across MVPs and clinician types as well as how to score multiple MVPs that multispecialty groups may be required to report. ***Because the structure of MVPs has not been established, the ASA does not have specific recommendations on scoring. We agree that CMS should test different MVP models and scoring proposals prior to implementing any specific scoring methods.***

MIPS Value Pathways - Population Health Quality Measure Set
CMS has requested information on applying administrative claims-based quality measures to MVPs that have already been specified and/or tested at the clinician and group practice level. The agency believes the inclusion of these measures would reduce the reporting burden among ECs and groups.

If the reason to create MVPs is to engage physicians, more energy should be spent on measures that the physician controls. Administrative claims and quality measures based on those claims fall short in describing the actions of an anesthesiologist to APM administrators and other specialties who potentially would like to partner with anesthesiologists in an APM. Current administrative claims data oftentimes do not apply to anesthesiologists and rarely capture the personalized care an anesthesiologist provides to patients. We believe that expanding the number of population health quality measures applicable to ECs and groups is unfair to specialties and undermines the original intent of the QPP. Data from these measures would not provide actionable information for specialty-specific MVPs and would likewise be too general to affect how an EC or group would approach an episode-based MVP.

ASA opposes the inclusion of population health quality measures in MVPs.

MIPS Value Pathways – Clinician Data Feedback
CMS requests information on the types of data from quality and cost measures that would be helpful for ECs and groups to move towards joining APMs. The agency requests whether administrative claims data and quality measures would be helpful. CMS also requests information on the granularity of data to be included in feedback reports.

For anesthesiologists to matriculate into APMs in greater numbers, APMs need to understand the central role anesthesiologists play in care coordination, cost reduction and overall management of a patient in the perioperative period. Administrative claims and quality measures based on those claims fall short in describing the actions of an anesthesiologist to APM administrators and other specialties who potentially would like to partner with anesthesiologists in an APM. CMS should likewise not repackage the current Medicare Shared Savings Program emphasis on primary care and administrative claims measures to fit an MVP model. Anesthesiologists who participate in the MSSP typically rely on other physicians in the MSSP to report those primary-care and population health-centric measures.

Quality and cost measure feedback mechanisms must be framed around the question of whether the EC or group has control over the measure. As MIPS is currently structured, anesthesiologists are often not scored in the all-cause readmission measure and will likely not be scored in other administrative claims-based measures for the program. Regardless, if anesthesiologists were scored in those measures, it would be hard for the anesthesiologist, siloed from other hospital departments and specialties who also received that data, to act on improving the quality of care for those patients most in need. In short, the data is not actionable. Coordination of data sharing and analysis among clinicians in a health-system or facility has a greater potential to foster the migration of ECs to APMs than administrative claims data.

ASA sees greater potential for ECs and groups to move toward APMs based upon the use of more granular data and national benchmarks on cost measures, including the current TPCC and MSPB measures. Through feedback from our membership, it has come to our attention that there are instances where the TPCC and MSPB clinician measures were only attributed to 1% of the practice yet it contributed to the score for the Cost Performance Category for the entire group. The feedback reports aggregated the episodes that were attributed instead of identifying each episode and the total amount of costs across specialties identified by CMS. Allowing ECs and groups to see each cost attributed to the measure, including those specific to their particular contribution, would enhance an EC or group effort to better understand the contributions of other clinicians. Such data would enhance care coordination and lead to the development of APMs based upon common interests of all clinicians involved in the episode of care for the patient.

MIPS Value Pathways – Patient-Reported Outcome Measures
CMS has requested information on whether patient satisfaction measures and patient-reported outcome measures should be included in MVPs. In addition, CMS seeks further information on the reliability of such measures and their applicability to individual specialties. Last, CMS seeks

information on how ECs and groups can be incentivized to collect and report patient satisfaction and patient-reported measures in individual MVPs.

ASA has long supported the use of patient satisfaction surveys to improve the care that a patient receives. Although surgical patients are asked few questions about anesthesia care in Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, including CAHPS Surgical Care Survey (S-CAHPS), our members nonetheless understand that the care provided to patients affects the overall experience of care a patient receives throughout the facility. ASA has developed an anesthesia-specific patient experience survey that is currently a QCDR measure. There are several vendors who assist anesthesia groups in collecting this data – albeit these surveys cost groups money to administer. We also share concerns with other healthcare and patient stakeholders that patients are suffering from survey fatigue.

With this in mind, ASA believes that patient satisfaction measures should be reflective of the way an MVP is developed. Should CMS pursue MVPs based upon a general specialty designation, we would expect that ECs and groups should have the ***option*** of reporting the anesthesia specific QCDR patient satisfaction measure. We support flexibility because of the cost to practices for administering the survey. The anesthesia-specific QCDR patient satisfaction measure is applicable in inpatient, outpatient and office-based settings. We also believe the survey applicable to multiple anesthesia subspecialties.

Should CMS develop MVPs based upon episodes of care, the agency should develop a pathway to develop flexible patient satisfaction surveys focused on that specific episode. As discussed in previous sections, anesthesiologists contribute their expertise throughout the perioperative period and should be scored on patient experience in a comprehensive fashion with their surgical, nursing and other clinical colleagues. In this way, CMS could start with assigning specific CAHPS surveys, including S-CAHPS, to these episodes of care and then apply that score equally across all specialties participating in that MVP for those specific patients. Anesthesiologists who have access to these CAHPS or other episode-specific patient satisfaction scores would then be able to work across specialties and with their clinical colleagues to comprehensively improve patient experience at that specific location for those episodes of care.

ASA supports the concept and development of patient-reported outcome measures, but we caution CMS about using the measures prematurely. Anesthesiologists are central to enhanced recovery initiatives and participants in the ASA Perioperative Surgical Home have developed innovative models that have improved patient recovery times, reduced length of stay and contributed to a patient's return to function. We are encouraged that some commercial vendors and anesthesia groups are piloting patient-reported outcomes. However, the current time and resource costs required to develop survey instruments used to collect and report patient-reported outcome measures, in addition to patient satisfaction measures, represents an increased burden on ECs and groups with limited resources.

Until the patient-reported outcome measures are fully tested and validated, as well as their costs fully assessed, CMS should not include patient-reported outcomes in any MVPs.

MIPS Value Pathways – Public Reporting MVP Performance Information

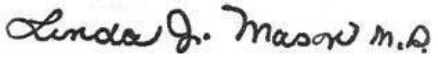
CMS has requested comment on the considerations for public reporting MVP data, including data elements to include, if all measures and activities should be displayed and whether such data would be useful for patients. CMS also seeks to understand other factors that could be considered to ensure that publicly report MVP information is comparable across relevant clinicians and groups. Because the MVP is still in development, ASA cannot make specific recommendations on the types of information that should be publicly displayed or if a star-rating system is preferable to the current information available on Physician Compare.

ASA believes that the questions CMS seeks to answer should fall into two categories – public reporting for patients and their caregivers and public reporting for the purposes of comparing ECs and groups. Despite the best efforts of CMS, its contractors and measure stewards to develop Physician Compare into something that patients can review and use to understand quality measures and physician performance, such data continues to be of a dubious nature to patients. For anesthesiology measures, patients most likely will not make the connection that keeping a patient at an appropriate temperature during the procedure contributes to reduced complications after the procedure. CMS should display data relevant to a patient's personal experience that may include but not be limited to whether the patient is safe, did the patient experience unnecessary discomfort and did the patient understand the costs of the procedure.

On the other hand, Physician Compare has in the past and the MVP value indicator could in the future make significant contributions to research and be used in the support of groups joining APMs. The Physician Compare database has been valuable in ascertaining participation rates among specialties in various components as well as specific measures that the EC or group has reported. Such information, if detailed enough, could help ECs and groups understand the situation of potential APM partners found in other specialties. The data is also instructive to quality improvement initiatives, should ECs and groups wish to compare their performance against national benchmarks.

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

Sincerely,



Linda Mason, M.D., FASA
President

APPENDIX A – SUMMARY OF RECOMMENDATIONS

Valuation of specific codes

Somatic Nerve Injection codes (64400-64450)

- ASA urges CMS to accept the RUC recommended wRVUs for the somatic nerve injection code family as the RUC recommendations are based on robust survey data, have clinically appropriate crosswalks and reference codes, and are not based on the flawed CMS time ratio methodology or generic rank order comparison.
    - ASA urges CMS to accept a wRVU of 1.00 for CPT code 64400.
    - ASA urges CMS to accept a wRVU of 1.42 for CPT code 64415.
    - ASA urges CMS to accept a wRVU of 1.81 for CPT code 64416.
    - ASA urges CMS to accept a wRVU of 1.18 for CPT code 64420.
    - ASA urges CMS to accept a wRVU of 0.60 for CPT code +64421.
    - ASA urges CMS to accept a wRVU of 1.19 for CPT code 64425.
    - ASA urges CMS to accept a wRVU of 1.15 for CPT code 64430.
    - ASA urges CMS to accept a wRVU of 1.18 for CPT code 64445.
    - ASA urges CMS to accept a wRVU of 1.54 for CPT code 64446.
    - ASA urges CMS to accept a wRVU of 1.55 for CPT code 64448.
    - ASA urges CMS to accept a wRVU of 1.55 for CPT code 64449.
- ASA urges CMS to accept the RUC recommendation of 3 minutes for clinical activity CA011, provide education/obtain consent, for codes 64400, 64415, 64417, 64420, 64425, 64430, 64445, 64447, and 64450. This time is required because of the potential complications associated with injections and the need to review aftercare instructions.

Genicular Injection and RFA codes (CPT Codes 64640, 64XX0, and 64XX1)

- ASA urges CMS to accept the RUC recommended wRVU of 2.62 for code 64XX1.
- ASA urges CMS to finalize the proposed wRVU values of 1.98 wRVUs for CPT code 64640 and 1.52 for code 64XX0.
- ASA urges CMS to accept the RUC practice expense input recommendations for code 64XX1 including 3 units of supply item SD011 and 141 minutes associated with equipment item radiofrequency kit for destruction by neurolytic agent. This procedure requires the simultaneous ablation of the three genicular nerves.

Radiofrequency Neurotomy Sacroiliac Joint codes (CPT Codes 6XX00, 6XX01)

- ASA urges CMS to finalize the proposed wRVUs of 1.52 for code 6XX00 and 3.39 for CPT code 6XX01.
- ASA urges CMS to accept the corrected RUC practice expense input recommendations of 4 units of supply item SC028 for code 6XX00 and 4 units of supply item SD011for code 6XX01.

Evaluation & Management (E/M) services (99201-99205) (99211-99215) (99XXX)

- ASA recommends that CMS work with the medical community to urge Congress to implement positive updates to the Medicare conversion factor to offset the deserved increases to office visits.

- ASA urges CMS to reconsider their decision not to apply increases to E/M codes to the global period.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Overarching Recommendations

- ASA supports efforts to ensure oral methadone for medicated assisted treatment (MAT) is covered by Medicare, in addition to buprenorphine, naltrexone (or other commercial products that become FDA approved). Some physician anesthesiologists are engaging in addiction medicine; therefore, ASA believes coverage of treatment services furnished by an OTP should include all three medications approved by the FDA.
- ASA also supports including intake activities, such as the initial physician examination and initial assessment and preparation of a treatment plan, as well as periodic assessments in the definition of OUD treatment services.

Bundled Payments Under the PFS for Substance Use Disorders

- ASA supports the proposal to create a code to describe the initial month of treatment, which would include intake activities and development of a treatment plan, as well as assessments to aid in development of the treatment plan in addition to care coordination, individual therapy, group therapy, and counseling.
    - ASA also supports the concept of an "add-on" code that could be billed in circumstances when effective treatment requires additional resources for a particular patient.
    - ASA encourages CMS to create a separately billable code or codes to describe "additional resources" involved in furnishing OUD treatment-related services after the first month.

Medicare Enrollment of Opioid Treatment Programs and Enhancements to General Enrollment Policies Concerning Improper Prescribing and Patient Harm

- ASA supports the intention to classify OTPs as Medicare providers in order to bill and receive payment.
- ASA has some concerns regarding the additional requirements that CMS is proposing for physicians employed by OTPs related to prescribing, dispensing and ordering of controlled substances. ASA cautions CMS against overly restrictive policies that may hinder patient care or physician practice.

Improper Prescribing and Patient Harm

- Physicians are highly trained and educated, and prior to providing MAT, they must undergo additional training. ASA asks that CMS use strict judgement to ensure physicians prescribing appropriately, at higher doses (beyond some guidelines or recommended thresholds), are not unnecessarily punished, as this could have negative impacts on patient care.

Scope of Practice for Certified Registered Anesthetists (CRNAs)

- ASA opposes the proposed changes to the Conditions for Coverage that would allow nurse anesthetists to independently perform preoperative assessment of anesthetic risk and pre-surgical evaluation in the ASC setting.
- The ASA urges CMS to consider the following points:
    - Expansion of procedures that can be performed in the ASC setting. As more complex surgical procedures are transitioned to the ASC setting, patients previously thought to be too sick to undergo procedures in an ASC are now receiving surgical care in the ambulatory setting.
    - Nurse anesthetists do not have the education or training to provide this pre-surgical evaluation. Their training and curriculum do not extend beyond provision of anesthesia care and do not include the specific skills and background essential for the aspect of perioperative care.
    - Alignment between the CfC requirements for the pre-surgery examination/evaluation and the pre-discharge evaluation will not reduce regulatory burden or contribute to improved care and outcomes.
- ASA opposes proposed provisions in the MPFS that would allow nurse anesthetists to perform the functions of a physician in completing an anesthetic risk and pre-surgery evaluation. ASA urges CMS to not finalize and withdraw this proposal.

Solicitation of Comments for Bundled Payments under the PFS

- ASA would request that CMS provide greater detail on their thinking in this area. We would also ask CMS to clarify how they will ensure that they are meeting their legal obligations of providing payment based on the relative resources involved in providing the resources.

Quality Payment Program

Quality Performance Category

- ASA requests that all measures, including QCDR measures, be approved for multiple years.
- ASA supports the 80% data completeness threshold for topped out measures and urges CMS to finalize this proposal.
- ASA agrees that CMS should audit data that they believe has been “cherry-picked” or if CMS believes that submitted data is otherwise not accurate.
- ASA encourages CMS to release additional instructions for individual ECs and groups to understand their responsibilities in submitting accurate and complete data. CMS should publish aggregate (not individual group) findings from their 2018 auditing of ECs and groups with regard to suspected instances of cherry-picked data.
- ASA cautiously supports this proposed requirement that stewards of new MIPS quality measures will need to provide a rationale as to how the measure relates to other MIPS performance categories as it may contribute to the development of MVPs.
- CMS should use objective criteria to determine why a measure is not in widespread circulation. ASA would support CMS policy if the agency uses defensible and objective criteria to determine whether such unavailability occurs as a result of a QCDR refusing to license the measure or if the steward is charging significant or exorbitant fees for a

vendor to use. We also encourage CMS to work directly with the measure steward to better understand the root cause of why the measure has been identified as not widely available.
- ASA recommends CMS finalize the proposal to include the multimodal pain management measure into the Anesthesiology Measure Set.

Improvement Activities Performance Category
- ASA opposes the CMS proposal to increase the threshold from one EC to 50% of a group's ECs to attest to an IA.
- ASA opposes the CMS proposal to increase IA attestation to 50% of the TIN and that the TIN's clinicians must perform the same activity for the same continuous 90-day period.
- ASA agrees with CMS proposals to remove and consolidate designated IAs.
- CMS should maintain the authority to audit individual practices on their IA attestations.
- ASA and AQI NACOR support the current responsibilities of the QR and QCDR to submit attestations directly to CMS and that CMS directly audit the individual practice for required documentation in support of that attestation.

Promoting Interoperability Performance Category
- ASA supports CMS proposals to:
    - Make the Query of the Prescription Drug Monitoring Program (PDMP) optional and eligible for five bonus points. CMS should encourage the development of Certified EHR Technology (CEHRT) to be improved in such a way to accept PDMP data. We recognize that there are states that do not require that the PDMP be checked and that regulation has lagged behind patient safety and quality care initiatives. Regardless, CEHRT should make PDMP easily accessible to physicians and other relevant healthcare users.
    - Remove the "Verify Opioid Treatment Agreement" measure from the PI performance category in performance period CY 2020.
    - Lower the threshold for hospital-based special status from 100% of the individual EC or group's covered professional services in certain places of services to 75%. This proposal is consistent with other special status criteria and will reduce unnecessary burdens on individual hospital-based ECs and their groups.
- CMS should score users based upon their collection of data rather than using actual performance scores as a basis for that score.
- ASA encourages CMS to develop a pathway describing how the agency believes each specialty can work with regulators and industry to achieve workflow efficiencies in each of these settings.

Cost Performance Category
- ASA recommends that CMS establish a minimum threshold of 5-10% of clinicians in a group must have the TPCC and/or MSPB Clinician cost measure attributed to them for it to contribute to the overall score of the Cost Performance Category.

- ASA urges CMS to finalize the proposal to exclude candidate events if they are performed by clinicians who frequently perform non-primary care services or are in specialties unlikely to be responsible for providing primary care to a beneficiary.

Facility-based Scoring

- CMS should release data on the number of ECs and groups receiving a facility-based score. CMS should display the data on a specialty-by-specialty basis. CMS should also provide an analysis of average scores for those who received a facility-based score vs those who were scored using traditional MIPS methodology.

Targeted Review and Data Validation and Auditing

- ASA recommends that CMS provide a one-time extension of the 30-day requirement for an individual or group to submit additional information during the targeted review. ASA supports CMS actions to discourage "cherry-picking" of data.

Third Party Intermediaries

- ASA opposes the CMS proposal to require all QRs and QCDRs to collect each of the three MIPS components – Quality, Promoting Interoperability and Improvement Activities.
- ASA and AQI NACOR oppose proposed requirements for QCDRs to describe how they foster services to clinicians and groups to improve the quality of care provided by their ECs.
- ASA agrees with CMS's intent for individuals and groups to routinely submit data but believes such a proposal is not practical and will be burdensome on individuals, groups and clinical data registries.
- ASA does not believe CMS should finalize its proposed requirement that individuals and groups must submit any data to a QR or QCDR by April 1 of the reporting year.
- ASA requests that QCDR measures be approved for two years and specifications be made available by November 1, 2019.
- CMS should establish a formal role for subject matter experts in the QCDR measure review process.
- ASA supports CMS policies to encourage transparent harmonization processes. We request more clarity on CMS' expectations for harmonizing and licensing QCDR measures.
- ASA supports CMS's proposals regarding harmonization in this rule and offer additional recommendations for CMS consideration:
    - Provide a single communication including both parties that clearly describes CMS' rationale for the request and the expected outcome of licensing and/or harmonization activities.
    - Acknowledge the provenance of each measure—a QCDR that has stewarded a measure in the program for three years should be afforded some benefit over a newly-developed measure on a similar process or outcome of care.
    - Recognize when one QCDR measure steward fails to acknowledge or work in good faith with a second QCDR in the harmonization process.

    - Notify QCDR measure stewards of all parties who have indicated they have permission to license their measures and give measure stewards the opportunity to confirm that permission has been granted.
- ASA and AQI NACOR support CMS auditing of data that the agency believes is part of "cherry-picking activity."
- In the QPP Participation Status tool, CMS should explore methods for enhancing how physicians with multiple TIN-NPI understand their responsibilities for reporting MIPS data.
- ASA encourages greater detail regarding CMS's description of criteria that may disqualify a third-party intermediary.
- CMS should not implement a policy that requires QRs or QCDRs, when submitting data for a QPP reporting year, to identify eligible clinicians or their groups as reporting as required by QPP, opting-in to MIPS or voluntarily reporting MIPS data.
- CMS should clearly define a registry's responsibility to address data inaccuracies that can be attributed to data that the registry has access to, controls and manages.
- For data submitted by a registry, CMS should not consider an eligible clinician's status as a non-MIPS eligible clinician, a Qualified APM Participant or other APM participant as a data inaccuracy.
- CMS should not count instances where an EC or their practices submits fewer than the required measures or less than the data completeness threshold as data inaccuracies.

MIPS Value Pathways

Guiding Principles

- CMS should include a guiding principle supporting physicians and other clinicians to be assessed on MVPs that reflect their specialty training, sub-specialization and their individual or group priorities. ASA is concerned that a one- or two-size fits all strategy for MVPs will not work for anesthesiologists or their individual groups.

Stakeholder Engagement

- ASA supports a "Call for MVPs" process that would be structured in a similar way as the "Call for Measures" process. The current "Call for Measures" allows for ample specialty society influence and engagement in measure approval processes and discussions with CMS. ASA believes that CMS should develop a balanced approach to who will develop and maintain the MVP with multiple touchpoints with specialties who use those MVPs.

Organizing MVPs

- ASA recommends that CMS also test and implement a minimum threshold of cases that have a complete set of MVP measure data submitted by the provider.
- CMS should not allow one specialty to monopolize or control an MVP based upon an episode of care.
- ASA believes that CMS should explore and make available multiple MVPs that are structured around episodes of care (preferred), specialty and care settings. We also recommend that CMS develop cross-specialty MVPs. We recommend that CMS also

test and implement a minimum threshold of cases that have a complete set of MVP measure data submitted by the provider.
- ASA agrees with CMS's overall goal that MVPs should foster opportunities for ECs and groups to join APMs; however we believe the ability for an EC or group to join an APM is based upon whether that particular specialty group is accountable to the patient and payer, if it has a "seat at the table" and has responsibilities not just for patient safety and care but cost management and quality improvement.

Promoting Health Information Technology and Interoperability
- CMS should continue the MIPS Special Status designations for MVPs but explore other opportunities to receive credit for use of non-CEHRT healthIT via the Improvement Activities performance category.

Selecting Quality Measures and Activities
- ASA believes that CMS should work with specialty societies and specialty-specific subject matter experts to assign quality measures to specific MVPs.
- ASA supports CMS's desire to link quality measures with cost measures and IAs but we caution CMS that such links may not reflect the business objectives of ECs and groups.
- ASA supports CMS awarding full IA credit to an EC or group who participates in a specialty accreditation program.
- CMS should not disqualify ECs who do not have an applicable cost measure from participating in MVPs.

Selection of MVPs
- ASA recommends that CMS identify EC and group reporting responsibilities based upon whether the MVP would increase or decrease burdens associated with the current MIPS reporting process.
- ASA opposes CMS arbitrarily assigning ECs or groups specific MVPs to report.

Transition Period
- ASA supports a pilot period for testing and implementing MVPs until all specialties have an appropriate number of MVPs to select from.

Multispecialty Groups
- ASA supports the option for multispecialty groups to report multiple MVPs but believes that CMS should find the correct balance between making MVPs more meaningful to groups with protecting multispecialty groups from an overwhelming reporting burden.
- Because the structure of MVPs has not been established, the ASA does not have specific recommendations on scoring. We agree that CMS should test different MVP models and scoring proposals prior to implementing any specific scoring methods for multispecialty groups.

Incorporating QCDR Measures into MIPS

- ASA and AQI NACOR encourage CMS to provide a two-year approval process for QCDR measures so that practices have continuity in the measures they can report from year to year.

Scoring MVP Performance

- Because the structure of MVPs has not been established, the ASA does not have specific recommendations on scoring. We agree that CMS should test different MVP models and scoring proposals prior to implementing any specific scoring methods.

Population Health Quality Measure Set

- ASA opposes the inclusion of population health quality measures in MVPs. If the reason to create MVPs is to engage physicians, more energy should be spent on measures that the physician controls.

Clinician Data Feedback

- ASA sees greater potential for ECs and groups to move toward APMs based upon the use of more granular data and national benchmarks on cost measures, including the current TPCC and MSPB measures. Allowing ECs and groups to see each cost attributed to the measure, including those specific to their particular contribution, would enhance an EC or group effort to better understand the contributions of other clinicians. Such data would enhance care coordination and lead to the development of APMs based upon common interests of all clinicians involved in the episode of care for the patient.

Patient-Reported Outcome Measures

- Until the patient-reported outcome measures are fully tested and validated, as well as their costs fully assessed, CMS should not include patient-reported outcomes in any MVPs.