December 28, 2020

The Honorable Alex Azar II
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: ASA Comments on Regulatory Relief To Support Economic Recovery; Request for Information (RFI); Docket Number: HHS-OS-2020-0016; Action 193, Anesthesia Services

Dear Secretary Azar and Madam Administrator:

I am writing on behalf of the 53,000 members of the American Society of Anesthesiologists (ASA) to request that the Centers for Medicare and Medicaid Services (CMS) rescind the waiver of the Medicare Anesthesia Services physician supervision requirement contained in the Conditions of Participation (42 CFR 482.52(a)(4), 42 CFR 485.639(c)(2), and 42 CFR 416.42 (b)(2)). The waiver is unnecessary and needlessly places the lives of Medicare beneficiaries at risk. Moreover, the underlying rule has no economic impact thus it does not “inhibit economic recovery” – the focus of this request for information.

This waiver suspended the rule providing that anesthesia for Medicare and Medicaid beneficiaries be supervised by a physician. ASA urges CMS to continue to recognize the physician delivered and the physician supervised team-based model of anesthesia as the safe and appropriate standards of care for Medicare and Medicaid patients requiring anesthesia services.

Anesthesiology is the practice of medicine and all anesthesia care must be performed by or supervised by a physician. It is a highly time-dependent critical care-like service that demands the immediate availability of medical decision making. It is fundamentally different from less time-dependent primary care and other physician services that are commonly and safely delivered with lessor requirements for supervision of non-physician providers, such as off-site supervision or retrospective review.

**Summary of our comments**

- **The current supervision rule represents a safe, well-established and functional compromise approach to physician clinical supervision. The unique structure of the rule sets a minimum physician (anesthesiologist or operating practitioner) supervision standard, while giving flexibility to states to utilize higher levels of clinical oversight or to “opt-out” of the rule.**

- **There is no scientific literature to support the safety of eliminating physician clinical oversight of anesthesia. To the contrary, independent literature points to the risk to patients of anesthesia without appropriate physician clinical oversight.**
• CMS has previously recognized that anesthesia procedures are complex, high-risk.

• There was no demonstrated shortage of anesthesia clinicians during the pandemic necessitating the waiver.

• There is no evidence that elimination of the Medicare supervision rule promotes job creation or economic growth. Therefore, the supervision rule does not “inhibit economic recovery.” A change to the rule would only change the model of care under which patients receive their care.

• There is no Medicare budgetary impact associated with the supervision rule. Medicare does not differentiate between anesthesia professionals for payment purposes. The payment is the same regardless of the professional or model of care.

• The education of physician anesthesiologists and nurse anesthetists differs dramatically. Only the physician anesthesiologist has completed the education and training that can provide the necessary critical medical decision-making. By way of example, ASA membership includes nearly 100 physician anesthesiologist-members who previously trained and, in most cases, practiced as nurse anesthetists. These individuals recognized that their nursing education was not complete and did not provide them with the necessary medical knowledge to deliver anesthesia care in the nurse-only model.

• At times, scope of practice rules may impose unnecessary restrictions on professionals. However, the anesthesia supervision rule represents an important exception. The surgical setting and anesthesia care are examples of appropriate scope of practice rules that are necessary to protect a patient’s health and safety from immediate risk.

**Current Compromise Rule is Safe, Well-Established and Functional**

The current supervision rule⁠¹ is the result of a 2001 final rule developed by CMS that maintained a minimum patient safety standard while also granting flexibility to states to set a higher standard or no standard. The final rule was the result of an extended policy discussion and rulemaking period that stretched from 1997 to 2001.

The final rule recognized that Medicare has long had a rule providing for physician supervision or clinical oversight over a nurse anesthetist in Medicare and Medicaid facilities. In most cases, the oversight is provided by an anesthesiologist. However, the rule permits an operating practitioner to also supervise the nurse anesthetist. The practitioner model is frequently employed in relatively straightforward situations such as cataract surgeries and colonoscopies. The 2001 final rule added an additional mechanism – the opt-out.

Specifically, the final 2001 rule:

• Included a Medicare supervision rule but established a mechanism whereby a Governor could exempt or “opt-out” the entire state or individual facilities within the state from the physician supervision requirement. The opt-out would be effectuated by an attestation and a letter from the Governor to CMS. No state legislative or regulatory action was required.

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¹ Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services, 66 FR 56762- 01 (November 13, 2001).
• Directed the Agency for Healthcare Research and Quality (AHRQ) to conduct a study of anesthesia outcomes in those states that choose to opt-out of the supervision requirement compared to those states that have not.

Since the implementation of the rule, eighteen Governors have exercised the “opt-out” and a single Governor (Colorado) exercised a partial “opt-out,” exempting some but not all of the states’ facilities from the supervision requirement.

Currently, some states retain the Medicare rule embedded into their state regulations. Maine’s rules provide that “Anesthesia administered by a Certified Registered Nurse Anesthetist (CRNA) must be under the supervision of the operating practitioner or of an anesthesiologist in accordance with 42 C.F.R. § 482.52.”Similarly, Utah rules provide that “Medicaid certified hospitals shall comply with the requirements of 42 CFR 482.52(a), Subpart D, Anesthesia Services.”

To date, AHRQ has not conducted the study of anesthesia outcomes. However, subsequent independent studies have affirmed CMS’s previously stated concerns about the health outcomes of “independent” nurse anesthetist practice.

**There are No Independent Data to Support that Anesthesia Delivery by Nurses Outside of the Supervision Model is Safe for Medicare and Medicaid Beneficiaries**

CMS’s current supervision policy ensures that Medicare and Medicaid beneficiaries have access to safe, high-quality anesthesia services. Because these policies are so important to this patient population, any change in policy being considered should be preceded by the collection of extensive and rigorous independent, scientifically valid evidence that supports the safety of anesthesia care by nurses outside of the supervision model. Such evidence does not exist. In fact, available independent evidence indicates the safety of Medicare and Medicaid patients may be placed at risk with the elimination of the supervision requirement.

**U.S. Department of Veterans Affairs: Evidence Review Raises Questions about “Solo Nurse” Practice**

The most recent federally funded examination of this issue was conducted by the U.S. Department of Veterans Affairs (VA) in 2014. The VA’s Quality Enhancement Research Initiative (QUERI) conducted an evidence review of available literature “to assess the strength and relevance of studies comparing autonomous APRNs with physicians in primary care, urgent care and anesthesia settings for four important outcomes: health status, quality of life, hospitalizations, and mortality.” The VA’s review raised questions regarding the ability of the solo nurse anesthetist model to safely manage complex patient cases.

The September 2014 QUERI document, “Evidence Brief: The Quality of Care Provided by Advanced Practice Nurses”, found that the evidence to support full practice authority related to nurse anesthetists was “insufficient” and at “high risk of bias.” The paper concluded that “[t]he results of these studies do not provide any guidance on how to assign patients for management by a solo CRNA, or whether more complex surgeries can be safely managed by CRNAs, particularly in small or isolated VA

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2 Maine Admin. Code 10-144 CMR Ch. 101, Ch. II, § 90.
3 Utah Admin. Code R.432-100-16.
5 Evidence Brief, pg. 1.
hospitals where preoperative and postoperative health system factors may be less than optimal⁶ [emphasis added].

After consideration of the VA QUERI review, a December 14, 2016 final rule did not eliminate the physician oversight requirement of nurse anesthetists from VA’s policies. VA eliminated the oversight requirements for all other categories of advanced practice registered nurses (APRN) but explicitly excluded nurse anesthetists stating:

“The final rulemaking establishes professional qualifications an individual must possess to be appointed as an APRN within VA, establishes the criteria under which VA may grant full practice authority to an APRN and defines the scope of full practice authority for each of the three roles of APRN. Certified Registered Nurse Anesthetists will not be included in VA’s full practice authority under this final rule”⁷ [emphasis from original].

ASA urges CMS to give full consideration to the QUERI report, particularly the findings that question whether complex cases can be safely managed by nurse anesthetists outside of the team-based model of care.

**SILBER 2000: Lower Death and Failure to Rescue with Anesthesiologist Direction**

The VA QUERI assessment references Silber 2000, which remains one of the few large independent anesthesia outcomes studies with thorough risk-adjustment. ASA encourages consideration of this study, titled “Anesthesiologist Direction and Patient Outcomes”, in which the relationship between physician direction and patient outcomes is analyzed.⁸

In any study, it is difficult to determine the effect of anesthesia provider on patient outcome because of the myriad factors that can influence a patient’s outcome. However, the authors of the Silber study used robust risk-adjustment techniques not seen in similar studies that greatly increase the validity of their conclusions. The study found the odds of death to be 8 percent higher and the odds of failure-to-rescue to be 10 percent higher in cases where the administration of anesthesia was not directed by a physician anesthesiologist. This corresponds to 2.5 excess deaths per 1,000 patients and 6.9 excess failure-to-rescue per 1,000 patients with complications. The authors employed a wide array of risk-adjustment methods and multiple statistical analyses to fortify the validity of their conclusions. Such a statistically sound and conclusive study should be considered when making policy decisions about practice models for anesthesia providers.

QUERI notes that Silber’s “comparison group does not directly represent care provided by an independent CRNA.” That statement is true; however, ASA would point out that QUERI’s criticism helps illustrate the strength of the study’s results. As indicated, Silber’s “undirected” group includes nurse anesthetists practicing independently, plus nurse anesthetists working in non-direction team-based models with physician anesthesiologists and other physicians still involved. **Accordingly, it is very likely that the outcomes differences presented by Silber actually understate the true effect of anesthesiologist involvement on patient outcomes.**

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⁶ Evidence Brief, pg. 15.
QUERI also comments about Silber’s risk adjustment methods, noting that “undirected cases were performed in smaller hospitals and hospital size does not adequately explain differences” in outcomes. Much like the comparison group issue, this criticism indicates a likely underestimation of the study’s results. If undirected cases were performed in smaller hospitals and hospital size does not adequately explain the differences in outcomes, then ideal risk adjustment likely would have resulted in differences even larger than Silber reported. ASA urges review of Silber with these comments in mind during consideration of the patient safety implications of eliminating physician supervision of nurse anesthetists.

Memtsoudis: Fewer Unexpected Adverse Outcomes with Anesthesiologist Involved

ASA also urges consideration of the 2012 study titled “Factors influencing unexpected disposition after orthopedic ambulatory surgery”. In this study of ambulatory surgery by Memtsoudis and colleagues, the researchers found, among other results, that the odds of “unexpected disposition” after ambulatory surgery were 80 percent higher when the anesthesia care was provided by only a nurse anesthetist as opposed to a physician anesthesiologist. In the outpatient setting, patients are expected to undergo a relatively low-risk surgery and be discharged to their place of residence on the same day. Any other outcome was considered an “unexpected disposition.” Unexpected dispositions may occur due to the patient experiencing an unanticipated adverse outcome from their procedure or anesthesia care, which may also result in additional costs to payers. The Memtsoudis study illustrates that even for low-risk procedures such as ambulatory knee and shoulder surgery, physician anesthesiologists achieve better outcomes than nurse anesthetists practicing outside of the team-based model of care.

Cochrane Collaboration Literature Review: Authors Could Not Demonstrate “Increase In Confidence” in Nurse Anesthetists and the “QZ Problem”

Nurse anesthetists seeking to practice outside of the team-based model often cite a literature review prepared by the Cochrane Collaboration. They assert that the review, titled “Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients”, supports nurse anesthetist practice outside of the team-based model.

But the review does no such thing. To the contrary, the report notes that while the authors had “hoped that [the review] may lead to an increase in confidence in the skills of NPAs [nurse anesthetists] within the anaesthetic community…” the review could provide no such support [emphasis added].

The Cochrane authors noted concerns regarding the validity of data presented in certain parts of the literature. For example, two of the studies (Dulisse and Pine) used the Medicare billing modifier “QZ” to identify nurse anesthetist-only cases. Under Medicare billing rules, the “QZ” modifier is used for a full range of purposes. It is used by nurse anesthetists to bill for services when they are supervised by the operating practitioner. It is also used by nurse anesthetists legitimately practicing without physician involvement in states that have both opt-out of the Medicare supervision rule and that also have a state law and regulation that permits nurses to practice without physician supervision or other involvement. But the “QZ” modifier is also used to report cases in which the physician anesthesiologists providing clinical oversight did not complete all of the requirements of medical direction – the highest, most focused level of clinical oversight.

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11 Ibid, pg. 4.
Accordingly, the “QZ” cases used in these studies actually includes cases with high although technically incomplete levels of physician oversight. As the authors referenced, in some studies “it was difficult to be confident about whether a physician anesthetist was actually administering anesthetic.” Further, the Dulisse study was funded by the American Association of Nurse Anesthetists as an advocacy study and was accordingly identified by the Cochrane authors for “high risk” of bias due to funding source.

In light of these data validity concerns, the Cochrane Collaboration “aimed to include RCTs [randomized controlled trials]" in their review. However, of the six studies reviewed by the Collaboration, none was an RCT.

Why was no RCT available? One reason cited by the authors should inform any decision related to appropriate anesthesia care models: “randomization may be unacceptable to health service providers, research ethics committees and patients, particularly for high-risk patients and procedures” – a strong suggestion that randomly assigning a solo nurse anesthetist to a patient regardless of the procedure or patient acuity would be resisted by patients and may be too risky to even test in a scientific trial.

Nursing Community Advocacy Documents: Self-Funded Studies at High Risk of Bias

Other studies frequently cited as relevant to the question of safe anesthesia care are Hogan 2010, Negrusa and Hogan (Medical Care) 2016, and Dulisse (Health Affairs) 2010. These studies have been cited as evidence that nurse anesthetists can provide the same level of care as physician anesthesiologists and the physician-nurse team-based model of care. However, among other flaws, these studies are advocacy studies directly funded by the American Association of Nurse Anesthetists. Funding sources are often recognized as potential causes of biases in studies of this type.

The Institute of Medicine report, “The Future of Nursing: Leading change, advancing health”, is also frequently cited as supporting nurse anesthetist practice outside of the team-based model of care. While this study may be relevant to discussions about certain categories of APRNs, it is not relevant to nurse anesthetists. The subject matter of the “Future of Nursing” report focuses almost exclusively on the non-surgical setting, and there is no meaningful discussion of the surgical anesthesia setting. The report states that “[n]urses thus are poised to help bridge the gap between coverage and access, to coordinate increasingly complex care for a wide range of patients, to fulfill their potential as primary care providers to the full extent of their education and training, and to enable the full economic value of their contributions across practice settings to be realized” [emphasis added].

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12 Ibid, pg. 11.
13 Ibid, pg. 5.
14 Ibid, pg. 15-16.
CMS has Previously Recognized Anesthesia Procedures as Complex and High Risk that Should be Supervised In-Person

In the 2021 Proposed Physician Fee Schedule rule, Direct Supervision by Interactive Telecommunications Technology (Section II.D.9), CMS recognized as part of the flexibilities implemented for the duration of the PHE and in order to limit exposure to COVID-19, the importance of in person physician supervision. In this rule, CMS revised the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology (85 FR19245) and proposed to extend this flexibility through the later of the end of the calendar year in which the PHE ends or December 31, 2021. Yet, in considering limits to this policy, CMS stated

“For instance, in complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient’s clinical status can quickly change and we believe it is necessary for such services to be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation.” [emphasis added]

In ASA’s official comment letter on the 2021 Physician Fee Schedule rule, ASA supported the agency’s assessment that anesthesia services must be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation, stating that “While audio-visual technologies may support virtual direct supervision for other services, ASA agrees with continuing the limitation on physician anesthesia supervision to in-person supervision. The ASA Standards for Basic Anesthetic Monitoring state, “Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care.” Medical, anesthetic, and surgical complications that may arise unexpectedly will demand immediate medical diagnosis and treatment and thus must be furnished or supervised in-person. ASA appreciates this recognition by CMS to ensure patient safety during anesthesia procedures remains a critical consideration as it sets supervision policy for Medicare physician services.

There is No Demonstrated Shortage of Anesthesiologists Necessitating the Waiver

ASA is aware of no shortage of anesthesiologists or nurse anesthetists impacting access to services during the public health emergency (PHE).

With the current “surge,” many facilities, including large health care systems, are reducing the volume of surgical and procedural cases. For example, the Kaiser Permanente system in California has halted elective services at 21 hospitals in Northern California and 15 hospitals in Southern California19.

Earlier in the year, with the CMS announcement “that all elective surgeries, non-essential medical, surgical, and dental procedures be delayed during the 2019 Novel Coronavirus (COVID-19) outbreak”20 and with states taking similar action, the volume of surgeries and procedures requiring anesthesia

dropped 70 to 80% from pre-PHE levels. An oversupply of anesthesiologists and nurse anesthetists resulted.

Because hospitals and practices recognized the essential need for having physician anesthesiologists attend to the cases that did take place, many nurse anesthetists were furloughed while anesthesiologists were kept active. Nurse anesthetists experienced particularly noteworthy furloughs and work schedule reductions in virtually every region of the country, according to press reports. A practice in Connecticut furloughed 90% of its nurse anesthetists. In Idaho, a practice furloughed over 50 nurse anesthetists. Similar reductions were reported in North Carolina, Pennsylvania, and Texas.

The Medicare waiver was unnecessary because there was no workforce shortage associated with the public health emergency.

**The Elimination of the Medicare Supervision Rule Does Not Promote Job Creation or Economic Growth**

There is no evidence that the Medicare supervision rule waiver promotes job creation and economic growth. Accordingly, it is not consistent with the Executive Order directing agencies to make permanent those “regulatory standards that may inhibit economic recovery.” Moreover, the literature regarding the supervision rule indicates that the waiver is not in alignment with the Order’s qualification that regulatory actions be consistent with the “protection of the public health and safety.” The elimination of the supervision requirement would place the health and safety of patients at risk.

Anesthesia professionals, whether physician anesthesiologists or nurse anesthetists, do not generate surgical or procedural volume or hospital activity. The anesthesia providers are essential, facilitating the successful care of the surgeons’ and proceduralists’ work and supporting the facility’s capacity to provide

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27 Executive Order 13924, 85 FR 31353 (2020).

28 Ibid.

29 Ibid.
services. Changes to the supervision rule will have no impact on economic growth. The changes will simply change the model of anesthesia care available to patients in the facility.

**There is No Medicare Budgetary Impact Associated with the Supervision Rule**

The Medicare Conditions of Participation: Anesthesia Services rule is a Part A requirement. There is no payment policy attached to the rule; thereby, there is no budgetary impact tied directly to the supervision rule.

Similarly, there is no budgetary impact in Part B where the anesthesia payment policies are found. Anesthesia services are paid on a system composed of base units plus time units multiplied by a dollar conversion factor. Payment modifiers are used to indicate whether a service is provided by an anesthesiologist only, a nurse anesthetist only, or a team-based model such as “medical direction” – a model specifically prescribed in Medicare anesthesia payment rules. Importantly, there is no payment differential based upon the clinician or clinicians providing an anesthesia service. The Medicare payment for a nurse anesthetist-only service is the same as for an anesthesiologist-only service. And in the medical direction model, the same payment is divided evenly between the anesthesiologist and nurse anesthetist – 50% to 50%. As an illustration, an anesthesia service that pays a physician anesthesiologist $300 also pays a nurse anesthetist $300. If the same service is provided in a team-based model, the anesthesiologist receives $150 and the nurse anesthetist receives $150. The elimination of supervision requirements will not result in any federal budgetary savings from Medicare.

**Only a Physician Anesthesiologist Has Complete Education and Training Needed For Safe Anesthesia Care**

Physician anesthesiologists bring a unique capacity to safely provide anesthesia care to Medicare and Medicaid beneficiaries. These critical capacities were gained through four years of comprehensive medical school training following undergraduate education, and four years of rigorous residency training, acquiring authoritative understanding of the human body and its systems in health and disease states, as well as the complex physiologic interactions between the body’s processes and the effects of anesthesia and surgery. These critical capacities are derived not only from didactic sessions but equally importantly from hundreds of increasing complex clinical interactions.

A physician’s education and training include at least 12 to 14 years after high school and anywhere from 12,000 to 16,000 hours of patient care training. The breadth of medical courses plus the hours of course work allow for detailed, comprehensive medical knowledge. In contrast, a nurse anesthetist’s education and training ranges from 4 to 6 years after high school and an average of approximately 2,000 hours of patient care training.

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### Education and Training

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<th>Anesthesiologists</th>
<th>Nurse Anesthetists</th>
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<tr>
<td><strong>Length of graduate-level training</strong></td>
<td>4 years</td>
<td>2-3 years (45-75 credit hours)</td>
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<tr>
<td><strong>Length of residency/fellowship training</strong></td>
<td>4-6 years</td>
<td>None</td>
</tr>
<tr>
<td><strong>Total Patient Hours</strong></td>
<td>12,000-16,000 hours</td>
<td>2000 hours minimum*</td>
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*Source: American Medical Association*

The physician anesthesiologist is educated and trained to assume full responsibility for the medical needs of the patient and to lead the patient care team. Throughout a physician’s decade or more of education and training, they were closely supervised and tested as they gradually acquired and demonstrated the ability to meet the clinical needs of the patient.

Specifically, the classwork and clinical experience ensure the development and maintenance of the medical expertise and split-second critical decision-making skills required to address immediate and long-term patient care needs.

Nurse anesthetists, on the other hand, are trained to work within the physician-led care team, under physician supervision. All nurse anesthetists’ education programs, except for one in Oregon, are located in states that require a level of physician clinical oversight of nurse anesthetists. Thus, the vast majority of nurse anesthetists are not educated or trained to practice in the nurse-only model. Overall, their nursing-based training, with its limited classroom duration and fewer hours of clinical training, does not allow for detailed, comprehensive medical knowledge.

This limited clinical training extends to nurse anesthetist practice doctorates or Doctors of Nurse Practice. The minimum clinical cases and clinical hours are the same whether obtaining a masters or doctorate in nurse anesthesia, with both pathways identifying a minimum of 600 clinical cases and 2,000 clinical hours. Significant portions of nursing doctorates are on-line learning, practice-level clinical research hours, and added classes such as leadership and management, business of anesthesia/practice management, health policy, and healthcare finance – these again underscore the difference between a doctor of medicine (MD) or doctor of osteopathy (DO) and practice oriented nursing doctoral degrees offered in nurse anesthetist programs. While useful for attaining additional background in an academic setting, the practice doctorate is not a physician doctorate and does not meet the rigor, depth, or expertise attained through the successful completion of an MD, DO or a PhD program.

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31 American Medical Association (2019), Education Matters.
The medical practice of anesthesia is integral to the safety of patient care. Before surgery, physician anesthesiologists, individually or working with their care team members of nurse anesthetists and anesthesiologist assistants, ensure patients are optimally prepared for surgery by addressing underlying medical problems. During surgery, the physician anesthesiologist is the medical expert monitoring the anesthetized patient’s brain, heart, lungs, kidneys, and more.

In experiences that are unique to physicians, medical students complete rotations in a range of physician specialties including internal medicine and surgery, prior to their anesthesiology residencies. These two rotations in particular average two months each and provide an extensive education and a unique level of exposure to human physiology and the surgical experience. This education is foundational to the physician anesthesiologist. As part of their residency, they additionally complete broad education in fundamental clinical skills of medicine relevant to the practice of anesthesia including internal medicine, surgery, pediatrics, critical medicine, and emergency medicine. Should any medical complications arise during the surgery, the physician anesthesiologist is prepared to address the problem. After surgery, the physician anesthesiologist similarly ensures the patient’s medical needs are addressed in the post-anesthesia care unit.

The education and training of a physician anesthesiologist is rigorous, thorough, and complete. It prepares the anesthesiologist with a base of knowledge necessary for medically evaluating the patient perioperatively, formulating differential diagnoses, and applying medical judgement intraoperatively and postoperatively. The education and training of a nurse anesthetist is appropriate for the role of the clinician but is by no measure as complete.

Source: Accreditation Council for Graduate Medical Education

The Average Number of Required Weeks by Discipline: 2017-2018

Source: Accreditation Council for Graduate Medical Education

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The completeness of this preparation of physician anesthesiologist education and training is best reflected in the fact that among its members, ASA has nearly 100 clinicians who previously were educated, trained, and, in most cases, practiced as nurse anesthetists yet subsequently attended medical school and anesthesiology residencies and fellowships and now practice as physician anesthesiologists. These former nurse anesthetists have formally stated that:

“The signatories to this letter – all physicians engaged in the medical practice of anesthesiology but who previously formally trained and, in most cases, practiced as nurse anesthetists – wish to express our strong opposition to changes to the team-based model of anesthesia care.”

“In a high risk medical activity where a patient's physiologic functions are deliberately slowed or stopped, and where the margin between the routine and the disastrous is literally measured in seconds and in cubic centimeters of potent drugs, the capacity to rapidly and correctly invoke medical judgement is indispensable.”

“Those in the nursing community who argue for nurse anesthetist practice outside of the team-based model of care, cannot understand the differences. We do because we have been trained both as nurse anesthetists and then as anesthesiologists. We fully understand the difference.”

_Some Scope of Practice Restrictions Are Appropriate and Necessary_

ASA acknowledges the Administration’s concerns that there are times when scope of practice laws and rules may impose unnecessary restrictions on professionals. However, as the Administration’s report on health care competition “Reforming America’s Healthcare System Through Choice and Competition” recognizes, there may be times when scope of practice restrictions are necessary for protecting patient safety. The report notes that:

“SOP laws and regulations, like other health and safety regulations, may be justified when there are substantial risks of consumer harm. These regulations may be especially important with respect to certain healthcare professions, where consumers might be at risk of serious harm if they were treated by unqualified individuals, and where patients might find it difficult (if not impossible) to assess quality of care at the time of delivery.”

The risk of serious harm does exist in anesthesia delivery. And because most patients do not choose their own anesthesia provider, patients have no opportunity to assess the anesthesia care they will receive, thus making patients’ assessment of quality indeed virtually impossible.

The surgical setting is a unique care setting and anesthesia is a high-risk medical practice. Unsupervised care may be appropriate for some health care settings and services, but it is not a safe approach for Medicare beneficiaries in the surgical setting. In such setting, life-threatening situations occur unpredictably and a physicians’ oversight increases the likelihood of immediate accurate identification, diagnosis, and successful treatment.

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36 Blaylock, MD, Suzanne, et al. Letter to President Donald Trump, 9/21/2020
38 Ibid. Pg 31.
ASA believes that the reversal of the CMS waiver and the retention of the Medicare supervision requirement is wholly consistent with the Administration’s report on health care choice and competition.

**Conclusion**

The current supervision rule assures safe anesthesia care for millions of Medicare and Medicaid beneficiaries each year. It is a pro-beneficiary, pro-patient safety mechanism that adds no additional cost to Medicare. The rule’s value is supported by currently available independent literature and by the complete education of the supervising physician. As CMS seeks to implement a measured approach to the use of scope of practice laws and rules in health care, ASA believes this rule provides for physician supervision of procedures in the surgical setting and is appropriate and necessary for retention.

ASA thanks you for your time and consideration.

We appreciate your leadership and are ready to work with you to address this unprecedented health crisis. If you have any questions, please do not hesitate to contact me at B.Philip@asahq.org or Manuel Bonilla, Chief Advocacy and Practice Officer of the ASA, at M.Bonilla@asahq.org.

Sincerely,

Beverly Philip, MD, FACA, FASA
President, American Society of Anesthesiologists