American Society of Anesthesiologists®

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David J. Shulkin, M.D.
Under Secretary for Health
Department of Veterans Affairs
810 Vermont Avenue NW
Washington, DC 20420

Subject: RIN 2900-AP44-Advanced Practice Registered Nurses

Dear Under Secretary Shulkin:

The American Society of Anesthesiologists (ASA) and our 52,000 members are pleased to submit comments in response to the Notice of Proposed Rulemaking entitled Advanced Practice Registered Nurses (RIN 2900-AP-44). This proposed rule seeks to amend the Department of Veterans Affairs (VA) medical regulations to grant full practice authority to all VA advanced practice registered nurses (APRN) when they are acting within the scope of their VA employment, regardless of state law. This proposed rule would specifically include certified nurse practitioners (CNP), clinical nurse specialists (CNS), certified nurse-midwives (CNM), and certified registered nurse anesthetists (CRNA or nurse anesthetists).

ASA focuses its comments on this last category because the proposed rule would fundamentally alter anesthesia care delivery in VA and effectively abandon the most prevalent model and the accepted standard of anesthesia care in VA, the physician-led, team-based model of care. Such a change would impact the quality and safety of care available to Veterans when nothing in the record shows a need for such a change or addresses the accompanying risk to the safety and quality of care.

In addition to serious concerns with the proposed rule's impact on Veterans' safety, the proposed rule exceeds VA's statutory authority to preempt state law and was proposed without proper consultation with state officials. VA also did not perform an analysis to determine how this rule change might affect the small businesses that deliver anesthesia services in the private sector.

To ensure that Veterans continue to receive the highest quality, safest anesthesia care available, **ASA urges VA to revise the proposed rule to exclude nurse anesthetists from the full practice authority model of care advanced in this proposal.** ASA's goals appear to be consistent with recent statements by VA leadership that nurse anesthetists will not be included in the full practice authority model once this proposal is finalized. In a May 29, 2016 VA News Release regarding the proposed rule, VA announced that:

> *At this time, VA is not seeking any change to VHA policy on the role of CRNAs, but would consider a policy change in the future to utilize full practice authority when and if such conditions require such a change….*[1]

Similarly, in an interview with the *Washington Post*, published June 2, 2016, you stated that:

> *I've looked at the data in the VA, and I do not assess that we have an access problem in anesthesia. We are using team based approaches. I do not plan on implementing any change in current policy to our workforce.*[2]

ASA is encouraged by these statements and urges VA to clearly and explicitly formalize this position in the Final Rule.

Executive Summary

ASA is concerned that nurse anesthetists practicing without physician oversight or involvement will disrupt anesthesia care within VHA and compromise the quality and safety of care provided to Veterans. The proposed rule directly conflicts with and seeks to supersede the Veteran-centered, physician-led, team-based model of anesthesia care currently provided for in the consensus VHA Anesthesia Service Handbook. This handbook, which recognizes the role of both physician anesthesiologists and nurse anesthetists, has ensured Veterans' access to safe, high-quality anesthesia care for at least a decade. The model of care advanced in the proposed rule - nurse practice outside of a physician-led team - may be appropriate for other health care settings and care delivery models, but it is not a safe approach for the acute, critical, and perioperative care settings where life-threatening situations occur unpredictably and where physicians' significantly greater education and knowledge increases the likelihood of immediate accurate diagnosis and successful intervention. These high stakes decisions are often required within seconds. ASA believes it needlessly exposes Veterans in VA to risk and poor outcomes.

ASA remains mindful of the challenges that VA faces in delivering care to Veterans. In particular, we recognize and appreciate the responsibility that VA faces in ensuring Veterans have access to necessary types of health care services. We understand that the development and promulgation of the proposed rule is an important mechanism to formally define an expanded role for APRNs in addressing access issues in health care settings where workforce challenges may exist. However, the surgical/anesthesia setting and the circumstances surrounding anesthesia are distinct and deserve unique consideration in this rule.

Discussion

I. There is nothing in the record before VA to support including nurse anesthetists within the proposed rule and VA provides no justification for doing so.

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[1] U.S. Department of Veterans Affairs. *VA Proposes to Grant Full Practice Authority to Advanced Practice Registered Nurses.* News Release, May 29, 2016. Accessed from http://www.va.gov/opa/pressrel/pressrelease.cfm?id=2793.

[2] Rein L. Top VA doc: If there aren't enough doctors, have nurses treat our vets. *The Washington Post*. June 2, 2012. Accessed from https://www.washingtonpost.com/news/powerpost/wp/2016/06/02/top-va-doc-if-there-arent-enough-doctors-have-nurses-treat-our-vets/.

The proposed rule provides no justification for a change with respect to nurse anesthetists. This proposal represents a drastic change in how anesthesia is delivered in the VA system and in other healthcare systems in the United States, and the proposed rule does not provide justification for such a change.

A. VA's current policies ensure Veterans access to the safest and highest quality anesthesia care.

ASA supports the preservation of the current policies at VA related to nurse anesthetists. Currently, these policies are set through the consensus VHA Handbook 1123, "Anesthesia Service Handbook," which provides that:

> a. In facilities with both anesthesiologists and nurse anesthetists, care needs to be approached in a team fashion taking into account the education, training, and licensure of all practitioners.
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> b. Anesthesia must be practiced at the highest levels of care and quality at all times.
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> c. While ultimate responsibility for the patient's care during the peri-procedure period rests with the practitioner performing the procedure, the choice of anesthetic technique and treatment of intra-operative physiologic changes rests with the anesthesia practitioner of record, whether it is an anesthesiologist or a nurse anesthetist. In facilities where Nurse Anesthetists practice and there is no anesthesiologist, responsibility for intra-operative anesthesia choice is determined by the anesthetist. In those cases, as the anesthesia practitioner of record, only the Certified Registered Nurse Anesthetist (CRNA)'s signature is required on the anesthetic record for purposes of authentication.
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> d. Responsibility for departmental policy rests with the Chief of Anesthesiology, or designee.
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> e. Providers must meet the licensure requirements defined in their respective VHA qualification standards. Facilities are reminded that state license scope of practice establishes the maximum breadth of practice allowable for a provider. VHA facilities, based on local needs, may specify privileges or scopes of practice that are narrower than those established in the state licenses.[3]

This current policy includes physician involvement in Veterans' anesthesia care while also granting necessary flexibility to local VA Chiefs of Anesthesiology and their designees to set appropriate policy subject to state license scope of practice. This policy has assured Veteran patients access to appropriate anesthesia care and excellent anesthesia outcomes.

The proposed rule would drastically change these policies and allow nurse anesthetists to practice without physician clinical oversight or involvement. Such a change requires a reasoned agency decision as well as an appropriate record on which to base such a decision. This is particularly true when dealing with a regulation that would preempt 46 state laws and D.C. law without any demonstrated need to do so.

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[3] U.S. Department of Veterans Affairs. *VHA Handbook 1123: Anesthesia Service*. Issued March 7, 2007; Recertified March 31, 2012. Accessed from http://www.va.gov/vhapublications/.

B. There is no shortage of physician anesthesiologists in VA and no evidence of access issues associated with anesthesia care.

ASA understands the challenges VA faces in addressing primary care and mental health provider shortages. We have no formal comments on those workforce issues. However, nothing in the proposed rule suggests there is a need to change the delivery of anesthesia in order to meet patient demand. In fact, in reviewing material related to VA workforce challenges, ASA can discern no workforce challenges related to physician anesthesiologists or systemic problems associated with delays of care because of anesthesia.

A September 1, 2015 congressionally-mandated study of VA, which was performed by the CMS Alliance to Modernize Healthcare (CAMH) Federally Funded Research and Development Center (FFRDC), made no reference to a shortage of physician anesthesiologists. The researchers conducted interviews and analyzed wait times, and specifically identified shortages in mental health, urology, orthopedic surgery, hospitalist, physical therapy, eye care (ophthalmology and optometry), audiology, ear-nose-and-throat, dermatology, vascular surgery, general surgery, and neurology.[4] The report also includes specific discussions of providers in shortage, referencing psychiatry and/or mental health, gastroenterology, orthopedic surgery, cardiology and primary care.[5] Anesthesiology is not referenced in this report.

Other VA documents reflect similar workforce challenges, but do not identify anesthesiology as an area without sufficient physicians. In December of 2015, VA released its annual Mission Critical Occupations Report, which "identifies the highest ranking ten mission critical (hard-to-fill) occupations ("top 10")" in VHA. The document lists the top 5 nursing and top 5 physician specialties with "hard-to-fill" occupations. Psychiatry, primary care and gastroenterology physicians were ranked 1, 2 and 3 respectively.[6] Neither physician anesthesiologists nor nurse anesthetists were included in this document.

These findings have been affirmed explicitly by VA in recent months. In a March 2, 2016, Congressional hearing exchange, it was affirmed that VA has recognized no access problems related to anesthesia:

> Congressman Jolly: So you support the existing anesthesiologist requirement?
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> Under Secretary Shulkin: Right now. We spent some time with the Chairman and Ranking Member on this yesterday. Right now, in the VA, we believe the current system is serving Veterans adequately and safely. We do think that, in the future, we may have to take a look at this – if access does become a problem, that's a different issue and so, in the future, we may have to look at this differently but, right now, we believe it is serving Veterans adequately.[7]

[4] RAND Corporation. Independent Assessment of the Health Care Delivery Systems and Management Processes of the Department of Veterans Affairs: Assessment B (Health Care Capabilities). 2015: pg. 87.
[5] Assessment B, page 87-89.
[6] Thomas L, Hetrick J. "VHA 2015 Mission Critical Occupations Report." Department of Veterans Affairs Memorandum 2015: pg. 1.
[7] Testimony of David J. Shulkin, M.D. before the Military Construction, Veterans Affairs and Related Agencies Subcommittee, Appropriations Committee, U.S. House of Representatives, March 2, 2016.

Similarly, in a *Washington Post* interview published June 2, 2016, you stated: "I've looked at the data in the VA, and I do not assess that we have an access problem in anesthesia."[8]

More recently, at a June 29, 2016 Congressional hearing, Maureen McCarthy, M.D., VA's Assistant Deputy Under Secretary for Health for Patient Care Services, stated: "If you look across our system, we do have access challenges in primary care, metal health, specialties care and so forth, but we have not identified significant shortages of anesthesiologists, for instance…"[9]

Moreover, ASA closely tracks the opening for physician anesthesiologists on USAJobs.gov, the official employment website for the federal government. On June 7, 2016, the number of openings for physician anesthesiologists numbered 7 vacancies throughout the entire country, or a job openings rate of 0.59% among 1,188 physician anesthesiologists in the VA.[10] The average job openings rate in the health care industry is 4.9%.[11]

In sum, there is simply no evidence that VA needs to permit nurse anesthetists to practice outside of the physician-led, team-based approach in order to provide adequate anesthesia care to Veterans. As such, there is no basis for applying the proposed rule to nurse anesthetists.

C. The record provides no evidence that permitting nurse anesthetists to practice outside of the team-based approach would be safe for Veterans.

Nurse anesthetists work in an environment that is higher risk than other health care settings. The proposed rule provides no discussion of these differences and no data to show that the rule would not harm patients or otherwise reduce the quality of their care.

1. Anesthesia is a complex, high-risk medical practice that requires physician involvement, especially for the less healthy Veteran patient population.

Anesthesiology, itself, is specifically a "complex, high-risk, dynamic patient care system…"[12] Patients in these settings are exposed to a higher risk of complications, and the complications to which they are exposed have a greater potential to threaten health and life. Further exacerbating this risk is the well-documented health status of the Veteran population. Multiple peer-reviewed studies have documented that VA patients have poorer health status (e.g. diabetes, congestive heart failure, cardiovascular disease, peripheral vascular disease and chronic obstructive pulmonary disease).[13] [14] [15] The risk for this population is elevated compared to a similarly aged non-Veteran patient

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[8] Rein L. Top VA doc: If there aren't enough doctors, have nurses treat our vets. *The Washington Post*. June 2, 2012. Accessed from https://www.washingtonpost.com/news/powerpost/wp/2016/06/02/top-va-doc-if-there-arent-enough-doctors-have-nurses-treat-our-vets/.

[9] Testimony of Maureen McCarthy, M.D. before the Veterans Affairs Committee, U.S. Senate, June 29, 2016.

[10] www.USAJob.gov website, accessed June 7, 2016.

[11] Bureau of Labor Statistics. *Job Openings and Labor Turnover – May 2016*. Press Release USDL-16-1454. July 12, 2016.

[12] Institute of Medicine (IOM). To Err is Human: Building a Safer Health System. 2000. Washington, DC: The National Academies Press, pg. 164.

[13] Agha Z, Lofgren RP, VanRuiswyk JV, et al.: Are Patients at Veterans Affairs Medical Centers Sicker? A Comparative Analysis of Health Status and Medical Resource Use. *Archives of Internal Medicine* 2000 Nov; 160(21):3252-7.

[14] Selim AJ, Berlowitz DR, Fincke G, et al.: The Health Status of Elderly Veteran Enrollees in the Veterans Health Administration. *Journal of the American Geriatric Society* 2004 Aug; 52(8):1271-6.

[15] Jha AK. Learning from the Past to Improve VA Health Care. *JAMA* 2016; 315(6):560.

population. Accordingly, Veterans should be ensured physician involvement in their anesthesia care in order to reasonably expect outcomes consistent with the non-VA standard of care.

2. Anesthesia care provided without the clinical oversight or involvement of a physician is a rare model of care.

The most common models of anesthesia practice in the United States are anesthesia delivered personally by a physician anesthesiologist or in a physician-led team-based model of anesthesia care. Nurse anesthetist practice outside of the team-based model is rare because most state laws provide for physician oversight of anesthesia care. While ASA cannot speak to the nature of practice of all APRNs, full nursing practice authority in anesthesia or practice without physician oversight of anesthesia is limited per state law. ASA's analysis of state laws and Medicare regulations reflects that patients in all but three states are assured some level of physician oversight or involvement in their anesthesia care, whether through supervision, collaboration, delegation or other model of physician oversight or involvement.[16]

The proposed rule states that "[a]s of March 7, 2016 CRNAs have full practice authority in 17 states." This is incorrect. This sentence seems to reference the 17 states which have opted-out of Medicare's patient safety requirement. Under existing Medicare regulations, a nurse anesthetist must be "under the supervision of the operating practitioner or of an anesthesiologist" to provide anesthesia care in the facility.[17] Beginning in 2001, Medicare regulations include a provision commonly referred to as "opt-out" whereby a governor may exempt the state from the Medicare supervision requirement provided certain processes and attestations are met. However, the governor's actions to exempt a state from the Medicare requirement do not nullify or otherwise modify the state's existing laws or regulations. It is important to clarify that Medicare "opt-out" in and of itself does not authorize statewide independent practice in every setting in those states. Fourteen of the "opt-out" states have existing laws or regulations requiring nurse anesthetists to be overseen by or involved with a physician. Accordingly, while 17 states may no longer be subject to the Medicare safety supervision language, all but three of those opt-out states maintain a state-level requirement providing for some level of physician oversight or involvement in anesthesia care. Acknowledging the difference between the Medicare supervision requirement and state laws on the practice of anesthesia, advocates in opt-out states have continued to pursue changes to state law that would permit nurse anesthetists to practice without the oversight or involvement of a physician. It is illogical that they would do so if the gubernatorial opt-out of the Medicare requirement were sufficient.

It is worth highlighting that as a mechanism to ensure flexibility, both Medicare and the states speak to the involvement of a physician (not necessarily a physician anesthesiologist) when anesthesia is administered by a nurse anesthetist. Patients receive optimal anesthesia care when a physician anesthesiologist is providing anesthesia or overseeing their anesthesia care. Oversight or involvement by an operating practitioner or physician assures flexibility for those facilities where a physician anesthesiologist may be unavailable.

The proposed rule's rationale - that 17 states allow for nurse anesthetists to practice without physician clinical oversight - is simply incorrect. Thus, the proposed rule would depart from the current model in a significant way if it includes nurse anesthetists.

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[16] Utah's state law does not require physician involvement in anesthesia. However, Utah complies with the Medicare Conditions of Participation supervision requirement.

[17] 42 C.F.R. § 482.52: Conditions of Participation: Anesthesia Services.

3. **There are no independent data to support that anesthesia delivery outside of a physician-led, team-based model of care is safe for Veterans.**

VA's current policies promoting team-based models of anesthesia care ensure Veteran patients access to safe, high-quality anesthesia services. Because these policies are so important to Veteran patient care, any change in policy being considered should be proceeded by the collection of extensive and rigorous independent, scientifically valid evidence that supports the safety of anesthesia care outside of the team-based model. As VA's own assessment concluded, such evidence does not exist. Indeed, available independent evidence indicates patients are best served by some level of clinical oversight of anesthesia by a physician.

ASA commends VA for utilizing its own research resources to investigate the quality of care implication of anesthesia delivered by a nurse anesthetist outside of a team-based model. 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 4 important outcomes: health status, quality of life, hospitalizations, and mortality."[18] With regard to anesthesia, 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."[19] The paper stated 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 hospitals where preoperative and postoperative health system factors may be less than optimal."[20] ASA urges VA to give full consideration to the document's findings, particularly the findings that question whether complex cases can be safely managed by nurse anesthetists outside of the team-based model of care.

The QUERI assessment references Silber 2000, which remains one of the few independent anesthesia outcomes studies. ASA encourages consideration of this study, titled, "Anesthesiologist Direction and Patient Outcomes," in which the relationship between physician direction and patient outcomes is analyzed.[21] 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 this study use robust risk-adjustment techniques not seen in similar studies that greatly increase the validity of their conclusions. This study should inform responsible policy decision-making in the future when comparing anesthesia providers. 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 failures-to-rescue per 1,000 patients with complications. The authors employ a wide array of risk-adjustment methods and multiple statistical

[18] McCleery E, Christensen V, Peterson K, Humphre L, Helfand M. Evidence Brief: The Quality of Care Provided by Advanced Practice Nurses. Department of Veterans Affairs Health Services Research and Development Service.2014: pg. 7.
[19] Evidence Brief, pg. 1.
[20] Evidence Brief, pg. 15.
[21] Silber JH, Kennedy SK, Evan-Shoshan O at al. Anesthesiologists direction and patient outcomes. Anesthesiology. Jul 2000; 93(1): 152-163.

analyses to fortify the validity of their conclusions. Such a statistically sound and conclusive study should be considered when making policy decisions about scope of practice 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. Accordingly, it is very likely that the outcomes differences presented by Silber actually understate the true effect of anesthesiologist involvement on patient outcomes.

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 understatement 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 as it considers the patient safety implications of the proposed rule's application to nurse anesthetists.

ASA also urges consideration of the 2012 study titled "Factors influencing unexpected disposition after orthopedic ambulatory surgery."[22] In this study of ambulatory surgery by Memtsoudis et al., 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

Nurse anesthetists seeking to practice outside of the team-based model often cite a literature review prepared by the Cochrane Collaboration.[23] They assert that the review, titled "Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients," supports nurse anesthetist practice in the full practice authority model. But the review does no such thing. To the contrary, 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…"[24] the review could provide no such support. In fact, the review presented no new data and included no studies that focused on outcomes for high-risk patients (such as our Veterans).

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[22] Memtsoudis SG, Ma Y, Swmidoss CP, Edwards AM, Mazumdar M, Liguori GA. Factors influencing unexpected disposition after orthopedic ambulatory surgery. *J Clin Anesth* 2012; 24(2):89-95.
[23] Lewis SR, Nicholson A, Smith AF, Alderson P. Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients. *Cochrane Database of Systematic Reviews* 2014, Issue 7.
[24] Cochrane, pg. 4.

In addition, the Cochrane authors noted concerns regarding the validity of data presented in certain of the studies. For example, two of the studies (Dulisse and Pine) used the Medicare billing modifier "QZ" to identify nurse anesthetist-only cases. But these cases often include physician anesthesiologist involvement that does not show up on billing data. As the authors stated in the review, "it can be difficult to be confident about whether a physician anesthetist was actually administering anesthetic."[25] Additionally, Dulisse 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)"[26] in their review. However, of the six studies reviewed by the Collaboration, none was an RCT.

Why was no RCTs available? One reason cited by the authors is telling: "randomization may be unacceptable to health service providers, research ethics committees and patients, particularly for high-risk patients and procedures"[27] – an acknowledgement that full practice authority by nurse anesthetists (without the clinical oversight of a physician) may be too risky to even test in a scientific trial.

Nursing community advocacy documents

Other studies frequently cited as relevant to the question of safety anesthesia care are Dulisse (Health Affairs) 2010, Hogan 2010 and Negrusa and Hogan (Medical Care) 2016.[28] [29] [30] 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. 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. As mentioned previously, the Dulisse study was identified by the Cochrane Collaboration authors as a "high risk" for bias because of its funding source.

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 "Nurses 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"

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[25] Cochrane, pg. 11.
[26] Cochrane, pg. 5.
[27] Cochrane, pg. 15-16.
[28] Dulisse Brian, Cromwell, Jerry. No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians. *Health Affairs* 2010; 29(8):1469-75.
[29] Hogan PF, Seifert RF, Moore CS, Simonson BE. "Cost effectiveness analysis of anesthesia providers". Nursing Economic$, 2010; 28(3):159-69.
[30] Negrusa B, Hogan PF et al. Scope of Practice Laws and Anesthesia Complications: No Measurable Impact of Certified Registered Nurse Anesthetist Expanded Scope of Practice on Anesthesia-related Complications. *Medical Care* 2016: Epub ahead of print.

[Emphasis added].[31] The two studies cited in the report related to anesthesia are advocacy studies funded directly by the AANA. They are at high risk of bias due to funding source.

4. **Other justifications in the proposed rule do not support extending full practice authority to nurse anesthetists.**

The U.S. Department of Defense (DoD) and its anesthesia delivery policies are cited as a potential model for VA. While DoD utilizes a variety of anesthesia delivery models to provide care to service members, the military still relies heavily on physician anesthesiologists, who have a significant presence in the armed services, for delivery of care. Physician anesthesiologists are aggressively recruited for service, serve in all branches of the U.S. military and are regularly deployed. Indeed, because of their extensive education, skills, and training and ability to provide high-quality anesthesia care, the U.S. Army facilities have specific patient safety regulations in place providing for the physician anesthesiologist-led, team-based model of anesthesia for patients.[32] The regulations utilize nurse anesthetists in limited settings outside of the team-based model of care and provide that:

> For patients in ASA physical status classification 3, 4, 5, or 6, CRNAs will collaborate with a physician (anesthesiologist, if available) or oral surgeon before induction of anesthesia. This collaboration may be face-to-face or by telephone. In an MTF without an assigned or available anesthesiologist, this collaboration will be with the operating surgeon. The CRNA will document the results of this interaction in the medical record prior to the start of the case. There is no requirement for the collaborating physician or oral surgeon to be privileged in the administration or management of anesthetics.

Ultimately, the well-being of patients should be paramount to the decision regarding the anesthesia delivery model utilized. VA and the deployed service member patient populations are very different. While VA patients are a unique population due to their generally poor health status, deployed service members are an equally unique population because of their excellent health status. As referenced previously, studies have consistently demonstrated that VA patients are in disproportionately poor health. In contrast, military readiness requirements ensure that deployed service members are extremely healthy and fit. With few exceptions, these service members lack the diabetes, heart disease, lung disease and other systemic diseases often present in the VA population that can complicate surgical anesthesia delivery. Indeed, it is because VA patients remain among the most challenging of patients to care for that VA's current policies provide for physician involvement in anesthesia care.

II. **As applied to nurse anesthetists, the proposed rule would be in direct conflict with long standing and stable state regulation with limited Congressional authorization and without proper consultation with state regulators.**

As discussed above, the proposed rule suggests that 17 states allow nurse anesthetists to practice without physician oversight or involvement, when in reality the number is four. Thus, the proposed rule has a major impact on state licensing regimes. It does so in an area where VA's statutory authority to preempt state law is not established, and where VA has not engaged in any meaningful dialog with the appropriate state regulators.

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[31] Institute of Medicine (IOM). The Future of Nursing: Leading Change, Advancing Health. 2011. Washington, DC: The National Academies Press, pg. 3.

[32] Department of the Army. Army Regulation 40-68: Medical Services - Clinical Quality Management. Washington, DC: 26 February 2004.

A. The statutory framework for VA does not suggest broad, preemptive powers.

The proposed rule relies on several sections of the VA's statute as the basis for allowing APRNs to practice without physician clinical oversight. These authorities do not authorize VA providers to engage in activities that their licenses do not cover. Moreover, these authorities suggest Congress intended VA to work with the state licensing structures and not outside of them, and not to preempt them.

The proposed rule cites to three sections of the statute to justify issuing rules that not only set the standards for the scope of what APRNs may do, but also that it may preempt conflicting state law. 38 U.S.C. § 7421(a) says that "[n]otwithstanding any law, Executive order, or regulation, the Secretary shall prescribe by regulation the hours and conditions of employment and leaves of absence of" registered nurses. This provision has been interpreted by the courts as exempting VHA employees from other federal civil service laws.[33] The courts have treated this provision as relating to "hiring, firing and compensating employees."[34] 38 U.S.C. § 7304(a) provides in full:

> (a) Unless specifically otherwise provided, the Under Secretary for Health shall prescribe all regulations necessary to the administration of the Veterans Health Administration, including regulations relating to—
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> > (1) travel, transportation of household goods and effects, and deductions from pay for quarters and subsistence; and
> >
> > (2) the custody, use, and preservation of the records, papers, and property of the Administration.

The proposed rule quotes from paragraph (a) for the proposition that the Under Secretary has broad authority to make rules, but leaves out the limiting examples.

38 U.S.C. § 7403(a)(1) says that appointments as a nurse "may be made only after qualifications have been satisfactorily established in accordance with regulations prescribed by the Secretary, without regard to civil-service requirements." This talks about the qualifications to serve as a nurse, not what a nurse may or may not do. In fact, the rest of Section 7403 deals with hiring, promotions, and firing, not about what nurses and doctors may do.

Within the context of these relatively sparse, and not entirely on point statutory authorities, the other relevant statutory provision is 38 U.S.C. § 7402(b), which says that physicians at VA must "be licensed to practice medicine, surgery, or osteopathy in a State." In other words, the statutory framework specifically looks to state law as the basis for whether a person is allowed to practice as a physician at VA. Indeed, Section 7402 continues to recognize state law as an important basis for determining qualifications, because it says that a person may not be a physician or nurse at a VA facility if:

> A person may not be employed in a position under subsection (b) (other than under paragraph (4) of that subsection) if—
>
> > (1) the person is or has been licensed, registered, or certified (as applicable to such position) in more than one State; and

[33] U.S. Dep't of Veterans Affairs v. Fed. Labor Relations Auth., 9 F.3d 123, 128 (D.C. Cir. 1993).
[34] Curry v. United States, 66 Fed. Cl. 593, 595 (2005).

(2) either—

(A) any of those States has terminated such license, registration, or certification for cause; or

(B) the person has voluntarily relinquished such license, registration, or certification in any of those States after being notified in writing by that State of potential termination for cause.[35]

Thus, unlike other areas of federal employment where there is a presumption that states may not impose licensing requirements on federal employees, the VA system is based on state licensure. If Congress intended to provide preemptive authority in this area, then it is unlikely that it would have imposed these statutory requirements that physicians be licensed by a state.

The proposed rule would require APRNs to be licensed in a state in one of the areas recognized. Yet, the very states that issue those licenses for nurse anesthetists - with limited exceptions - are not licensing those nurses to practice without a physician's clinical oversight or involvement. Thus, the proposed rule is looking to state licensure as a qualification when the license is not granted for the purpose of independent practice.

Finally, the one court to address the preemptive effect of VA's regulation of physicians found that "preemption does not apply…In fact…Congress explicitly left the licensing of federally employed physicians to the states."[36] That court went on to say:

> The federal statutes cited by the Petitioner do not express a clear intent to preempt state law, nor does the federal legislation contain an implicit barrier to the actions taken by the Board against Dr. Vickers. Further, the federal regulatory scheme is not so expansive that it can be said to occupy the entire field, leaving no room for state oversight of its licensees that are also federal employees. In fact, as alluded to above, Congress explicitly left the licensing of federally employed physicians to the states. This indicates that licensing standards and disciplinary procedures implemented by state legislatures are actually in harmony with the federal regulatory scheme. Moreover, merely because a VA physician charged with unprofessional conduct might be subject to disciplinary proceedings at the federal level does not foreclose the State from sanctioning the same conduct. Indeed, it defies logic to suggest that Congress left licensing decisions to the states, but did not intend that states also have the power to reprimand their licensees or take more serious action affecting their ability to practice.[37]

Thus, the one case to consider whether VA statutes would preempt state disciplinary activity analyzed the issue in almost the opposite fashion that VA has laid out in the proposed rule.

In sum, VA's statutory authority to preempt state law is questionable at best. There is clearly no express preemption provision in VA statutes. Nor is there a suggestion that Congress intended to "occupy the field," given the extensive reliance on state licensing in the statutes. Finally, given the

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[35] 38 U.S.C. § 7402(f).
[36] *Vickers v. Maine State Bd. of Licensure in Med.,* No. Civ.A. AP-04-67, 2005 WL 2722922, at *4 (Me. Super. Apr. 6, 2005).
[37] Id.

lack of any evidence that VA needs to allow nurse anesthetists to practice without physician oversight, it is not clear what federal purpose would be frustrated if the proposed rule is not adopted.

B. The consultation described in the proposed rule does not satisfy Executive Order 13132 or the 2009 Presidential Memorandum Regarding Preemption.

Given the broad scope of preemption VA has proposed to exercise, and the impact this would have on state licensing, the consultation VA has described in the proposed rule is woefully inadequate.

The proposed rule recognizes that "[m]any external stakeholders expressed general support for VA's position taken in this proposed rule, particularly with respect to full practice authority of APRNs in primary health care." It goes on to note that it "received comments opposing full practice authority for CRNAs when providing anesthetics." Thus, the only feedback the proposed rule describes with respect to its federalism inquiries for nurse anesthetists opposes the change.

The proposed rule describes its consultation with the National Council of State Boards of Nursing (NCSBN) and its request for comments from the state boards of nursing (which request VA apparently only made through the NCSBN). It describes having received "calls and correspondence" from state officials "in support of the" proposed rule, but does not discuss whether those comments addressed or even considered nurse anesthetists as opposed to general practice APRNs. No outreach appears to have been made to state physician boards, governors, or others involved in the process of determining the scope of practice of physicians as opposed to nurses. Nothing in the record suggests the outreach that was done specifically discussed preemption issues and how state licensing might be affected.

This lack of consultation suggests VA has not satisfied the requirements of Executive Order 13132, which President Obama specifically reiterated is controlling in his May 2009 Memorandum on preemption. As such, at a minimum, VA should undertake a much more comprehensive and rigorous federalism analysis before promulgating a final rule.

III. The proposed rule makes no effort to address potential risks to patients and does not consider disruption to the nurse anesthetist labor market that could affect small businesses.

The proposed rule also fails a number of other rulemaking processes and should not be moved forward without appropriate analysis.

First, the proposed rule says that it will have no effect on small entities because APRNs are individuals. With respect to anesthesiology, some private-sector anesthesiology services are provided by small physician practices, which may include nurse anesthetists. Given that in a limited number of states these private sector nurse anesthetists may practice without physician oversight or involvement, there is a distinct possibility that such nurse anesthetists may desire to practice at VA where they would be given more authority to practice without physician involvement. As such, this rule could have a large impact on the nurse anesthetist workforce in the private sector. We have no idea, however, since VA did not conduct any analysis to consider this issue. Moreover, because VA proposes to remove APRNs from any state oversight when they are acting without physician oversight or involvement, it might be much more difficult for anesthesiology practices to evaluate the quality of nurses they are hiring if the nurse has VA experience. Again, this is speculative, but since VA gave no consideration to that issue, we simply cannot know the impact and it should be evaluated before making such a major change. In contrast, for general practice nurses, where many more states

already grant full practice authority, there may not be nearly the impact as on small-business anesthesiologists.

Finally, the proposed rule's Impact Analysis is completely lacking with respect to nurse anesthetists. The entire discussion focuses on primary care; the words "anesthesiology" and "anesthetist" do not appear in the document. There is a discussion about full practice authority existing in 21 states.[38] That discussion relates only to general practice nurses, not nurse anesthetists. The analysis says that there are "no significant quantifiable impacts associated with this rulemaking." Yet there is no discussion about the increased risks to patients, particularly with respect to anesthesiology patients. As discussed above, there are serious questions about the quality of patient care under the proposed rule. The analysis does nothing to address or attempt to quantify those risks. Similarly, there is no discussion about the potential for increased malpractice claims against VA, which could present a significant risk. Finally, the analysis does not discuss the potential flow of nurse anesthetists from the private sector to VA. As noted above, nurse anesthetists who want to expand their work might leave private practice and go to VA, thus draining resources from the private sector. But a related impact could be that nurse anesthetists want to leave the predominate model because they do not perform well and think that they can avoid negative performance reviews if they are no longer subject to physician oversight or involvement. The result would be a transfer of underperforming APRNs to VA, which could significantly increase the impact of the rule. Again, we do not know, because the analysis was not done.

Conclusion

ASA appreciates the opportunity to submit these comments on the proposed rule. With respect to nurse anesthetists, there are serious issues that VA has not addressed. At the most basic level, VA has not shown that there is a need for the change or that the change is safe for Veterans. Beyond that, VA has not performed an analysis on the proposed change with respect to anesthesia. What little information specific to nurse anesthetists that appears in the proposed rule is misleading and flawed. Accordingly, given the lack of objective need and the risk of harm to the VA patient population, ASA urges VA to exempt nurse anesthetists from its final rule. Adopting the rule as proposed and then clarifying whether nurse anesthetists would be granted full practice authority in policy guidance is not sufficient, nor is it permissible under the law.

Respectfully submitted,

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Appendix: Laws & Regulations Require Nurse Anesthetists Work Within These Types of Relationships With Physicians In Various Settings

[38] The analysis repeatedly refers to this as "almost 50 percent" of the 50 states plus the District of Columbia (which is one of the full practice jurisdictions counted in the 21). This is 41.2 percent, which is not really "almost 50 percent," given that it would require five more states (i.e., ten percent of the states) to reach one-half.

LAWS & REGULATIONS REQUIRE NURSE ANESTHETISTS WORK WITHIN THESE TYPES OF RELATIONSHIPS WITH PHYSICIANS IN VARIOUS SETTINGS

PHYSICIAN DIRECTION
Alabama
Arizona
Connecticut
Florida
Georgia
Indiana
Kentucky
Louisiana
Nevada
Tennessee

SUPERVISION
Arkansas
Hawaii
Michigan
Missouri
New Jersey
New York
Ohio
Oklahoma
Pennsylvania
Virginia
West Virginia
Wyoming

DELEGATORY AUTHORITY
Texas

WHEN ORDERED/ REQUESTED BY PHYSICIAN
Kansas
Washington

DISCRETION OF PHYSICIAN/PHYSICIAN RESPONSIBILITY
California
Maine

CONSULTATION AND/OR COLLABORATION WITH PHYSICIAN; OR WRITTEN PROTOCOL
Alaska
Colorado
District of Columbia
Idaho
Illinois
Iowa
Maryland
Massachusetts
Minnesota
Mississippi
Nebraska
New Mexico
North Carolina
North Dakota
Rhode Island
South Carolina
South Dakota
Wisconsin

TIME-LIMITED COLLABORATION
Delaware
Vermont

RELATIONSHIP DETERMINED BY HOSPITAL RULES
Oregon

NO SPECIFIED RELATIONSHIP
Montana
New Hampshire
Utah