DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AP44

Advanced Practice Registered Nurses

AGENCY: Department of Veterans Affairs.

ACTION: Final rule with comment period.

SUMMARY: The Department of Veterans Affairs (VA) is amending its medical regulations to permit full practice authority of three roles of VA advanced practice registered nurses (APRN) when they are acting within the scope of their VA employment. Certified Registered Nurse Anesthetists (CRNA) will not be included in VA’s full practice authority under this final rule, but comment is requested on whether there are access issues or other unconsidered circumstances that might warrant their inclusion in a future rulemaking. The final rulemaking establishes the 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. The services provided by an APRN under full practice authority in VA are consistent with the nursing profession’s standards of practice for such roles. This rulemaking increases veterans’ access to VA health care by expanding the pool of qualified health care professionals who are authorized to provide primary health care and other related health care services to the full extent of their education, training, and certification, without the clinical supervision of physicians, and it permits VA to use its health care
resources more effectively and in a manner that is consistent with the role of APRNs in the non-VA health care sector, while maintaining the patient-centered, safe, high-quality health care that veterans receive from VA.

DATES: This final rule is effective [Insert date 30 days after date of publication in the FEDERAL REGISTER]. Comments on full practice authority for CRNAs must be received by VA on or before [Insert date 30 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted: through http://www.Regulations.gov; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 1068, Washington, DC 20420; by fax to (202) 273-9026. Comments should indicate that they are submitted in response to “RIN 2900-AP44-Advanced Practice Registered Nurses.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at http://www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT: David J. Shulkin, M.D., Under Secretary for Health, (202) 461-7000 or Linda M. McConnell, Office of Nursing Services, (202)
SUPPLEMENTARY INFORMATION:

In a document published in the Federal Register on May 25, 2016 (81 FR 33155), VA proposed to amend its medical regulations in part 17 of Title 38, Code of Federal Regulations (CFR) to permit full practice authority of four roles of VA advanced practice registered nurses (APRN) when they were acting within the scope of their VA employment. We provided a 60-day comment period, which ended on July 25, 2016. We received 223,296 comments on the proposed rule.

The Office of the Federal Register has prepared a document, A Guide to the Rulemaking Process, that states that an agency is not permitted to base its final rule on the number of comments received in support of the rule over those in opposition to it or vice versa. The document further states that an agency must base its reasoning and conclusions on the rulemaking record, which consists of the comments received, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages. This final rule adheres to the guidance established by the Office of the Federal Register.

Section 7301 of title 38 United States Code (U.S.C.) establishes the Veterans Health Administration (VHA) within VA, and establishes that its primary function is to “provide a complete medical and hospital service for the medical care and treatment of veterans, as provided in this title and in regulations prescribed by the Secretary pursuant to this title.” To allow VA to carry out its medical care mission, Congress also
established a comprehensive personnel system for certain medical employees in VHA, independent of the civil service rules. See Chapters 73 and 74 of title 38, U.S.C. As an integrated Federal health care system with the responsibility to provide comprehensive care under 38 U.S.C. 7301, it is essential that VHA wisely manage its resources and fully utilize the skills of its health care providers to the full extent of their education, training, and certification.

By permitting the three APRN roles, Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), or Certified Nurse-Midwife (CNM), throughout the VHA system with a way to achieve full practice authority in order to provide advanced nursing services to the full extent of their professional competence, VHA furthers its statutory mandate to provide quality health care to our nation’s veterans. This regulatory change to nursing policy permits three roles of APRNs to practice to the full extent of their education, training and certification, without the clinical supervision or mandatory collaboration of physicians. Standardization of APRN full practice authority, without regard for individual State practice regulations, helps to ensure a consistent delivery of health care across VHA by decreasing the variability in APRN practice that currently exists as a result of disparate State practice regulations. Certified Registered Nurse Anesthetists (CRNA) will not be included in VA’s full practice authority under this final rule, but comment is requested on whether there are access issues or other unconsidered circumstances that might warrant their inclusion in a future rulemaking.

Standardization of full practice authority to the three APRN roles also aids VA in making the most efficient use of VHA APRN staff capabilities, which increases VA’s capacity to provide timely, efficient, and effective primary care services, as well as other
services. This increases veteran access to needed VA health care, particularly in medically-underserved areas and decreases the amount of time veterans spend waiting for patient appointments. In addition, standardizing APRN practice authority enables veterans, their families, and caregivers to understand more readily the health care services that VA APRNs are authorized to provide. This preemptive rule increases access to care and reduces the wait times for VA appointments utilizing the current workforce already in place. VA’s position to not include the CRNAs in this final rule does not stem from the CRNAs’ inability to practice to the full extent of their professional competence, but rather from VA’s lack of access problems in the area of anesthesiology.

To ensure that VA would have available highly qualified medical personnel, Congress mandated the basic qualifications for certain health care positions, including registered nurses. Sections 7401 through 7464 of title 38, U.S.C., grant VA authority to regulate the professional activities of such personnel. To be eligible for appointment as a VA employee in a health care position (other than Director) covered by section 7402(b), of title 38, U.S.C., a person must, among other requirements, be licensed, registered, or certified to practice their profession in a State. The standards prescribed in section 7402(b) establish only the basic qualifications necessary “[t]o be eligible for appointment” and do not limit the Secretary or Under Secretary for Health from establishing other qualifications for appointment, or additional rules governing such personnel. In particular, 38 U.S.C. 7403(a)(1) provides that appointments under Chapter 74 “may be made only after qualifications have been established in accordance with regulations prescribed by the Secretary, without regard to civil-service
requirements.” As the head of VHA, the Under Secretary for Health has the duty to “prescribe all regulations necessary to the administration of the Veterans Health Administration,” subject to approval by the Secretary. See 38 U.S.C. 7304; see also 38 U.S.C. 501. Pursuant to this authority, the Under Secretary for Health is authorized to establish the qualifications and clinical practice standards of VHA’s nursing personnel and to otherwise regulate their professional conduct.

To continue to provide high quality health care to veterans, this final rule will allow three roles of APRNs to practice to the full extent of their education, training, and certification when acting within the scope of their VA employment, regardless of State restrictions that limit such full practice authority, except for applicable State restrictions on the authority to prescribe and administer controlled substances.

The proposed rule stated that VA was proposing to grant full practice authority to four APRN roles. We received 104,256 comments against granting full practice authority to VA CRNAs. The American Society of Anesthesiologists lobbied heavily against VA CRNAs having full practice authority. They established a website that would facilitate comments against the CRNAs, which went as far as providing the language for the comment. These comments were not substantive in nature and were akin to votes in a ballot box. The main argument against the VA CRNAs was that by granting CRNAs full practice authority VA would be eliminating the team based concept of care in anesthesia, which is currently established in VA policy via VHA Handbook 1123, Anesthesia Service. Team based care was not addressed in the proposed rule because we consider it to be an integral part in addressing all of a veteran’s health care needs. Establishing full practice authority to VA APRNs, including CRNAs, would not
eliminate any well-established team based care. The second argument posed against granting full practice authority to VA CRNAs was that there is “no shortage of physician anesthesiologists in VA and the current system allows for sufficient flexibility to address the needs of all VA hospitals.” Again, most of these comments were not substantiated by evidence, though as discussed further below, VA does believe that evidence exists that there is not currently a shortage of anesthesiologists that critically impacts access to care, and therefore VA agrees with the sentiment of this argument.

We similarly received 45,915 comments in support of full practice authority for APRNs as a whole without specific mention of CRNAs. We received 9,613 comments in support of full practice authority for CRNAs. The CRNA-specific commenters stated that “CRNAs currently exercise their full scope of practice in 17 states and in the Army, Navy, Air Force, Combat Support Hospitals, Forward Surgical Teams, and the Indian Health Services, even in some VAs where CRNAs are the only anesthesia providers. Evidence shows that APRN provided care increases access, improves quality, and reduces costs for all Americans. By extending Full Practice authority to CRNAs and other APRNs at the VHA, we can help end delays to high-quality, safe, and cost-effective care for America’s Veterans. Implement this well researched policy change promptly.” The commenters also stated that “APRN’s and CRNAs practicing in a manner which they have been educated and trained to provide expert care has been backed by decades of research.” Several other commenters stated “Over 900 CRNAs provide every type of anesthesia care, as well as chronic pain management services, for our Veterans in the VHA. The safety of CRNA services has long been recognized by the VHA and underscored by peer-reviewed scientific studies, including a major study
published in Health Affairs which found that anesthesia care by CRNAs was equally safe with or without physician supervision.” VA agrees with these comments, but has chosen not to include CRNAs in this final rule due to VA’s lack of access problems in the area of anesthesiology.

Commenters raised anesthesia issues related to the RAND Assessment, which the public can view at http://www.va.gov/opa/choiceact/documents/assessments/Assessment_B_Health_Care_Capabilities.pdf. Specifically, the Department of Veterans Affairs Independent Assessment B, Appendix E-I reported on qualitative interviews with Chiefs of Staff at VA facilities; fourteen comments discussed lack of anesthesia service/support as a barrier to providing care, including for urgent and non-urgent cardiovascular surgeries (three comments), as well as colon cancer / gastrointestinal services such as endoscopy and colonoscopy (eleven comments).\(^1\) As discussed further below, VA understands that there are difficulties hiring and retaining anesthesia providers, but generally believes that this situation is improving. VA reviewed the qualitative interviews with Chiefs of Staff at VA facilities contained in the RAND Assessment but did not determine that data supported granting FPA to CRNAs to solve access issues. Nonetheless, VA is requesting further comments on whether advanced practice authority for CRNAs would bring further improvements.

\(^1\) VA Independent Assessment, Appendices E – I, http://www.va.gov/opa/choiceact/documents/assessments/Assessment_B_Health_Care_Capabilities_Appendices_E-I.pdf
We reviewed the Veterans Health Administration payroll data revealed that, as of August 31, 2016, VHA employs 940 Physician Anesthesiologists (physicians), 5,444 Nurse Practitioners, 937 CRNAs, and 386 Nurse Specialists. Nurse Practitioner is currently #3 in the top 5 difficult to recruit and retain nurse specialties. Additional workforce trend data is available in the Regulatory Impact Analysis.

In a 2015 independent survey of VA general facility Chief of Staffs conducted by the Rand Corporation, approx. 38% (43 of 111) reported problems recruiting or hiring advanced practice providers, such as Nurse Practitioners, and 50% reported problems recruiting or hiring nurses such as clinical specialists. The most commonly reported barriers to recruitment and hiring for these medical experts were: non-competitive wages (72% of 43 responses for advanced practice providers; 64% of 56 responses percent for nurses), Human Resources process (42% for advanced practice providers; 45% for nurses), geographic location of facility (35% for advanced practice providers; 23% for nurses), and lack of qualified applicants (26% for advanced practice providers; 32% for nurses).

Similarly, nearly 30% (33 of 111) of Chiefs of Staffs reported problems retaining advanced practice providers, such as NPs, and almost half reported problems retaining nurses, such as clinical specialists. The most commonly reported reasons for problems with retention of these medical experts were: dissatisfaction with supervision/management support (61% of 31 responses for advanced practice

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2 RAND, Independent Assessment B, Appendix G.1.1 Chief of Staff, 2015 Survey of VA Capabilities and Resources, G-5.
3 Id. at G-6. (Totals greater than 100 due to option to select the two most important factors affecting recruiting and hiring. Only respondents who reported problems recruiting specific personnel categories were asked to respond.)
4 Id. at G-7.
providers; 57% of 49 responses percent for nurses) and dissatisfaction with pay (36% of advanced practice providers; 27% of nurses). Chiefs of Staff rarely selected lack of opportunity for professional growth/promotion as a top two reason for retention problems, only 6% selected this option for advanced practice providers and 8% for nurses. Lack of professional autonomy was also not viewed as a significant contributor to retention issues (3% for advanced practice providers, 0% for nurses).

In fiscal years 2011 through 2015, CRNAs were in the top 10 VHA Occupations of Critical Need, but dropped to 12th place in FY 2015. Despite the challenges discussed above, within VHA the occupation has grown approximately 27% between FY 2010 and FY 2014 (166 employees). Total loss rates decreased from 6.6% in FY 2013 to 6.2% in FY 2014, but have ranged from 9.4% to 6.2% between FY 2009 and FY 2014. Voluntary retirements decreased from 3.2% in FY 2013 to 2.7% in FY 2014. Quits increased from 1.9% in FY 2013 to 2.6% in FY 2014. VA has taken steps to improve recruitment of CRNAs, including partnering with the U.S. Army to educate interested and qualified VA registered nurses in the field of nurse anesthesia. Also, as previously stated in this rulemaking, VA CRNAs are a crucial part of the team based anesthesia care. VHA Handbook 1123, Anesthesia Service, states in paragraph 4.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.”

Anesthesiology is not in the top 5 difficult to recruit and retain physician specialties. However, in a 2015 independent survey of VA general facility Chief of Staffs

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5 Id. at G-9.
conducted by the Rand Corporation, 25% (27 of 111) reported problems recruiting or hiring anesthesiologists.\textsuperscript{7} The most commonly reported barriers to recruitment and hiring for these medical experts were: non-competitive wages (78% of 27 respondents), Human Resources process (25%), and geographic location of facility (22.2%).\textsuperscript{8} Nearly 10% of Chiefs of Staff (11/111) reported difficulties retaining anesthesiologists.\textsuperscript{9} The most commonly reported reason for staff retention problems for these medical experts were: dissatisfaction with supervision/management support (27%) and dissatisfaction with pay (55%).\textsuperscript{10} Despite these challenges, over the past 5 years, the number of anesthesiologists VHA hired increased from 87 in FY11 to 149 in FY15. The FY15 turnover rate for anesthesiologists is slightly lower than the turnover rate for physicians overall. VHA has had recent successes in hiring or contracting for Anesthesiology services.

Recruiting, hiring, and retention challenges, as reported by VA facility Chiefs of Staffs struggling with these issues, are similar among advanced practice or specialist nurses and anesthesiologists. These managers did not view lack of advancement opportunity or practice autonomy as significant barriers to retention, which may indicate that increased use of advanced practice authority is unlikely to fully resolve this challenge – both because it may not address the root causes of these problems and because similar challenges constrain hiring of both doctors and nurses. On the other hand, the perceptions of potential applicants and staff may not be fully reflected by a

\textsuperscript{7} RAND, Independent Assessment B, Appendix G.1.1 Chief of Staff, 2015 Survey of VA Capabilities and Resources, G-5.
\textsuperscript{8} Id. at G-6.
\textsuperscript{9} Id. at G-8.
\textsuperscript{10} Id. at G-9.
survey of facility management. Further, it is possible that resources might be available to address some of these underlying issues if efficiencies were realized as a result of advanced practice nursing authority. VA welcomes comment on whether lack of advanced practice authority is a hiring, recruitment, or retention barrier for CRNAs, as well as on the extent to which advanced practice authority could help to resolve these issues either directly or indirectly.

Based on this analysis, VHA believes that VA does not have immediate and broad access problems in the area of anesthesia care across the full VA health care system that require full practice authority for all CRNAs.

However, VA requests comment on the question of whether there are current anesthesia care access issues for particular states or VA facilities and whether permitting CRNAs to practice to the full extent of their advanced authority would resolve these issues. VA also requests comment on potential future anesthesia care access issues, particularly in light of projected increases in demand for VA care, including surgical care, in coming years.

We will, therefore, not finalize the provision including CRNAs in the rule as one of the APRN roles that may be granted full practice authority at this time. However, we request comment on this decision. If we learn of access problems in the area of anesthesia care in specific facilities or more generally that would benefit from advanced practice authority, now or in the future, or if other relevant circumstances change, we will consider a follow-up rulemaking to address granting full practice authority to CRNAs.
VA CRNAs that have already been granted full practice authority by their State license will continue to practice in VA in accordance with their State license and subject to credentialing and privileging by a VA medical facility’s medical executive committee. VA will not restrict or eliminate these CRNAs’ full practice authority.

This final rule uses the term “full practice authority” to refer to the APRN’s authority to provide advanced nursing services without the clinical oversight of a physician when that APRN is working within the scope of their VA employment. Such full practice authority is granted by VA upon demonstrating that the advanced educational, testing, and licensing requirements established in this rulemaking are met and upon the recommendation and approval of the medical executive committee when the provider is credentialed and privileged.

In this rulemaking, VA is exercising Federal preemption of State nursing licensure laws to the extent such State laws conflict with the full practice authority granted to VA APRNs while acting within the scope of their VA employment. Preemption is the minimum necessary action for VA to allow APRNs full practice authority. It is impractical for VA to consult with each State that does not allow full practice authority to APRNs to change their laws regarding full practice authority.

The campaign in support of the proposed rule was not as extensive as the campaign against granting full practice authority to CRNAs. The main lobbyists in support of the proposed rule were the American Nurses Association and the American Association of Nurse Practitioners, who supported a letter campaign. We received 45,915 comments in support of the proposed rule. Of these 45,915, we received
specific support of individual APRN roles as follows: 9,613 in support of CRNAs, 1,079 in support of CNM, and 495 in support of CNPs. These commenters agreed that the proposed rule aligns with the Institute of Medicine (IOM) of the National Academy of Sciences 2010 IOM Report in that the rule removes scope of-practice barriers and increases access to VA care. The commenters also agreed that the APRNs are highly skilled in their particular APRN role, as demonstrated by their education and hours of skilled training. Several commenters stated that “APRNs will deliver care to the full scope of their education and training and ensure that the VA has the flexibility to utilize all providers within the healthcare team, maximizing the effective use of resources and providing optimal care for the men and women who have served our country in uniform.” Other commenters supported the proposed rule by stating “this proposal supports the VHA team model of care and promotes efficiency in healthcare delivery by making smarter use of the 6,000 APRNs” that are employed by VA. “Most importantly, this proposal has the ability to make real and significant improvements to the availability of high-quality care for millions of Veterans.” The commenters also stated that “APRN full practice authority within the VA would create nationwide consistency, thereby improving upon the current patchwork of state regulations and making the most effective use of these health care professionals.” We thank the commenters for their support of the proposed rule.

We received a comment in support of the proposed rule from the Federal Trade Commission (FTC). The FTC focuses on the “impact of regulation on competition in the private sector and, ultimately, on consumers.” The FTC’s main interest in the proposed rule was “the extent that the VA’s actions may encourage entry into health care service
provider markets, broaden the availability of health care services outside the VHA system, as well as within it, and yield information about new models of health care delivery.” The FTC believes that its experience “may inform and support the VA’s endeavor.” The FTC staff supports the granting of full practice authority to APRNs, which will benefit “VA’s patients and the institution itself, by improving access to care, containing costs, and expanding innovation in health care delivery.” VA’s actions could also spur competition among “health care providers and generate additional data in support of safe APRN practice,” which could also spill into the private health care sector. We thank the FTC for their support of the proposed rule and make no edits based on this comment.

Several commenters stated that they were concerned with proposed § 17.415(d)(1)(i)(B), where we stated that a Certified Nurse Practitioner (CNP) may order, perform, or supervise laboratory studies. The commenters stated that the proposed language does not “adequately appreciate the levels of complexity involved in laboratory testing” and that there are rigid standards for laboratory tests that require rigorous academic and practical training, which are not part of the training for APRNs. Another commenter stated, “While the VHA uses the word ‘interpret’ in reference to laboratory and imaging studies,” the commenter “…infers that the VA’s intent is to grant the ability for CNPs to interpret laboratory and imaging results, not to interpret or report raw images or data.” The commenter suggested that VA amend the term “‘interpret’ and recommends instead to use ‘integrate results into clinical decision making,’ or some other phrase” in order to avoid confusion between the duties of an APRN and those of a laboratory specialist. We agree with the commenter in that the proposed language
might be construed as allowing CNPs the ability to perform laboratory studies. It is not VA's intent to have APRNs take over the role of laboratory specialists. These specialists perform a crucial role at VA medical facilities and are skillfully trained in performing the various testing techniques that allow health care professionals to properly treat a veteran's medical condition. We are amending proposed § 17.415(d)(1)(i)(B) to now state that a CNP may be granted full practice authority to “Order laboratory and imaging studies and integrate the results into clinical decision making.”

Other commenters were similarly concerned with the language in proposed § 17.415(d)(1)(i)(B), but as it refers to ordering, performing, supervising and interpreting imaging studies. The commenters stated that only trained radiologists, who undergo 10 years of comprehensive training to accurately interpret high-tech imaging exams and safely account for the radiation used in many scans should perform these duties. The commenters further stated that imaging exams should only be performed by registered radiological technologists. It is not VA's intent to replace our highly qualified radiologists or radiological technologists. VA is committed to providing high quality health care for our nation's veterans and is proud of the outstanding work performed by radiologists in our system. We note, however, that during the course of care, other health care providers may review radiology exams and make evaluations based upon the radiologist's findings. These health care providers include providers in emergency departments, primary care clinics, and specialty clinics throughout the VA health care system. All radiology studies are formally performed and read by individuals who are credentialed in radiology. This rulemaking will not change this practice. In order to
avoid confusion, we are amending § 17.415(d)(1)(i)(B) by removing performing, supervising, and interpreting imaging studies and replacing it with “Order laboratory and imaging studies and integrate the results into clinical decision making.”

Some commenters were also concerned that CNPs “may order more imaging studies, which increases the total cost and the radiation dose to the patient.” One commenter cited a study that indicated that CNPs may order imaging more frequently than primary care physicians. However, the study defined advanced practice clinicians to include CNPs and physician assistants, and did not differentiate between these two different types of health care providers in the study. This rulemaking only addresses APRNs, and it is unclear how the study was influenced by including physician assistants. It’s also unclear whether there is actually a significantly higher rate of ordering imaging among these groups. We found no other significant evidence provided by the commenters to support the claim that CNPs order more imaging studies than physicians. For these reasons, we make no changes based on this comment.

Several commenters were concerned that the value of team-based care would be undermined by granting full practice authority to APRNs. They stated that physicians and other members of a health care team bring unique value to patient care that is based on the individual member’s education, skill, and training. The commenters argued that by eliminating team-based care, patients would be placed at risk. Team-based care is an integral part of VA health care and is used in a wide range of settings, which include polytrauma care, nutrition support, and primary care. VA will continue to provide the already established team-based care to properly treat the veteran’s individual health care needs. The proposed rule only addressed the granting of full
practice authority to APRNs and does not address team-based care. Any change to current VA team-based health care is beyond the scope of this rulemaking. We are not making any edits based on these comments.

Other commenters questioned an APRN’s years of training versus those of a physician, citing an American Medical Association statement that “physicians typically receive a combined total of over 10,000 hours of training and patient experience prior to beginning practice, whereas the typical APRN receives less than 1,000 hours of training and patient experience.” The commenters added that trained physicians should be taking care of the veterans’ medical needs as opposed to a nurse who has not received the same training and education as physicians. APRN education is competency based and APRNs must demonstrate that they have integrated the knowledge and skill to provide safe patient care. Entry into APRN practice is predicated on the requirement to attain national certification. APRNs are held to the same standard as physicians in measuring patient outcomes for safe and effective care. VHA acknowledges the fact there are differences in physician and APRN educational and training models and is not planning on replacing physicians with APRNs in any health care setting within VHA.

APRNs are valuable members of VA’s health care system and provide a degree of much needed experience to alleviate the current access problems that are affecting VA. APRNs, like physicians, are required to maintain their State license and their health care skills are continuously assessed through the privileging process. As we stated in the proposed rule “APRNs would not be authorized to replace or act as physicians or to provide any health care services that are beyond their clinical education, training, and
national certification” and an APRN will require approval of their credentials and privileges by the VA medical facility’s medical executive committee. An APRN will refer patients to a physician for care that goes beyond that of the APRN’s training. We will not make any edits based on these comments.

Several commenters stated that they would like all veterans to receive the best and safest medical care in VA and do not believe that granting APRNs full practice authority will lead to such care. As previously stated in this final rule, VHA’s primary function is to “provide a complete medical and hospital service for the medical care and treatment of veterans” under 38 U.S.C. 7301(b). We also stated in the proposed rule that in carrying out this function, VHA has an obligation to ensure that patient care is appropriate and safe and its health care practitioners meet or exceed generally-accepted professional standards for patient care. The general qualifications for a person to be appointed as a VA nurse are found in 38 U.S.C. 7402(b)(3). In addition to these general qualifications, the proposed rule stated that APRNs would now be required to have “successfully completed a nationally-accredited, graduate-level educational program that prepares the advanced practice registered nurse in one of the four APRN roles; and to possess, and maintain, national certification and State licensure in that APRN role.” VA believes that these additional qualifications for APRNs ensure that VA has highly qualified health care personnel to provide safe health care to veterans. In addition, the VA medical facility’s medical executive committee will be responsible for the quality and oversight of the health care provider. Additionally, the IOM Report states that “the contention that APRNs are less able than physicians to deliver care that is safe, effective, and efficient is not supported by the decades of
research that has examined this question (Brown and Grimes, 1995; Fairman, 2008; Groth et al., 2010; Hatem et al., 2008; Hogan et al., 2010; Horrocks et al., 2002; Hughes et al., 2010; Laurant et al., 2004; Mundinger et al., 2000; Office of Technology Assessment, 1986). No studies suggest that care is better in states that have more restrictive scope-of-practice regulations for APRNs than in those that do not.” We will not make any edits based on these comments.

Several commenters stated that the proposed rule would undermine the State requirement that CNPs need to collaborate with or be supervised by physicians. They were also concerned that the rule would eliminate local control of licensing and regulation of physicians and health care providers, which would result in lower standard of care. We note that there may be discrepancies between State practice acts and this final rule which is why this regulation preempts conflicting state and local law. As we stated in the proposed rule, “In circumstances where there is a conflict between Federal and State Law, Federal law prevails in accordance with Article VI, clause 2, of the U.S. Constitution (Supremacy Clause).” We also stated “where there is conflict between State law and Federal law with regard to full practice authority of APRNs working within the scope of their federal VA employment, this regulation would control.” Again, we emphasize that this rule only preempts State law for VA employees practicing within the scope of their VA employment, and that as a result, any such infringement upon State authority would be limited. Further, this final rule does not eliminate the APRN’s need to possess a license from a State licensing board in one of the recognized APRN roles. This is a requirement in proposed § 17.415(a)(3). Proposed § 17.415(a)(4) also requires an APRN to maintain both the national certification and licensure. In addition
to these requirements, an APRN must demonstrate the knowledge and skills necessary to provide the services described in proposed § 17.415(d) without the clinical oversight of a physician, and is thus qualified to be privileged for such scope of practice by the medical executive committee. These measures will ensure that patients receive care from an APRN that is credentialed and privileged to perform the specified tasks and will promote patient safety. We will not make any edits based on these comments.

Several commenters were concerned that APRNs would be at a higher risk of malpractice, especially when the APRN's State license does not grant full practice authority. A commenter asserted that the APRN's defense would be diminished when the "state in which the APRN is practicing in deems an act beyond the provider’s scope of practice, but the Federal government has given all APRNs the broadest rights available." Under the Federal Tort Claims Act, 28 U.S.C. 1346(b), 2401(b), 2671-2680, and the Westfall Act, 28 U.S.C. 2679(b)-(d), employees furnishing medical care or services in the exercise of their duties for VHA are immune from personal liability for malpractice in the scope of their employment; the rule clarifies the intent of VA that APRNs will be acting within the scope of employment when performing their duties in the capacities set forth herein. The commenters further stated that the preemption of State law would create a discrepancy with VA policy in that VA states in the proposed rule that an APRN must be licensed by a State. As previously stated in this rulemaking, where there is conflict between State law and Federal law with regard to full practice authority of APRNs working within the scope of their Federal employment, this regulation would control. In doing so, VA is better able to protect the APRNs against any challenge of their State license when practicing within the scope of their VA
employment. VA does not see a disconnect between preemption and the requirement that an APRN must have a State license. Such requirement is established in statute under 38 U.S.C. 7402 for the qualifications of appointment as a health care provider in VA. As we stated in the proposed rule, we are establishing “additional professional qualifications an individual must possess to be appointed as an APRN within VA.” These additional requirements go beyond the requirements of some State licenses and ensure consistency for health care provided within VA. We are not making any edits to the rule based on these comments.

One commenter indicated that the proposed rule stated “Section 4 of Executive Order 13132 requires that when an agency proposes to act through rulemaking to preempt state law, ‘the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such conflict.’” [Emphasis added.] The commenter further stated that “VA did not provide affected state and local officials with such notice.” Specifically, “no state medical boards (whether osteopathic or allopathic) were consulted. By the very nature of the Notice of Proposed Rule Making (NPRM), these state medical boards, who are charged with overseeing independent medical practice and assuring patient safety, are ‘affected State officials.’” Initially, we note that section 1(d) of the Executive Order defines State and local officials as including only elected officials, and we do not believe the officials overseeing State medical boards are elected. Additionally, section 4 of the Executive Order, as cited by the commenter, states that the “agency shall consult, to the extent practicable” with affected State and local officials (emphasis added). Because advanced practice registered nurses, particularly NPs, are typically regulated by state Boards of Nursing rather than by State
medical board we believe they are most affected by this rule.\textsuperscript{11} Although VA did not specifically engage State medical boards, VA reached out to several medical associations, including the American College of Surgeons, American Academy of Family Practice Physicians, American Society of Anesthesiologists, American Medical Association, Association of American Medical Colleges, and, although not a medical association, The Joint Commission-Office of Accreditation and Certification. VA consulted with elected State officials, as required by Executive Order 13132, when it received numerous calls and correspondence from State and local officials in support of this proposed rule. Such State and local officials included State Senators from Georgia and Illinois, State Representatives from Florida, Ohio, Vermont, North Carolina, Georgia, and Illinois, County Commissioners from Nevada, Ohio, and North Carolina, and the State Comptroller and Secretary of State from Illinois, to name a few. We also consulted with the National Council of State Boards of Nursing. We believe that VA’s efforts to consult with State and local officials meet the requirements of section 4(d) of Executive Order 13132. Furthermore, the proposed rule encouraged any comments regarding the granting of full practice authority, which afforded the “affected State and local officials notice and an opportunity for appropriate participation in the proceedings.” As we state in the Federalism paragraph in this rule, at least twelve States responded to VA’s outreach efforts prior to publication of the proposed rule. It would have been impracticable for VA to have consulted with all State medical boards as an outreach effort prior to publication of the proposed rule. We are not making edits based on this comment.

\textsuperscript{11} \textsc{Carolyn Buppert, Nurse Practitioner’s Business Practice and Legal Guide,} Appendix 3-A (5\textsuperscript{th} Ed. 2015). (Delaware and Alabama, with joint oversight authority, are rare exceptions to this general rule.)
Another commenter stated that the proposed rule “will directly affect many individuals and will directly affect small entities.” The commenter further stated that the rule should not be exempt from the initial regulatory flexibility analysis as stated in the Regulatory Flexibility Act (5 U.S.C. 603 and 604), will not maximize net benefits and equity and will raise novel and legal policy issues. Another comment emphasizes only that “some private-sector anesthesiology services” are provided by small physician practices, which “may” include nurse anesthetists. It further notes that in a “limited” number of states, there is a “possibility” that private sector anesthesiologists could be induced to work at VA instead of in the private sector. None of these claims demonstrate that the regulation would have a significant economic effect on a substantial number of small entities; VA found no such effect would result in its proposed rule, and certified this finding as required by 5 U.S.C. 605(b). We further note that private sector providers are not subject to the proposed regulation, which would only regulate the activities of VA employees, and hence would be outside the scope of a required analysis under the Regulatory Flexibility Act. See, e.g., Mid-Tex Electric Cooperative v. FERC, 773 F.2d 327, 342-3 (D.C. Cir. 1985); Cement Kiln Recycling Coalition v. EPA, 255 F.3d 855, 868-9 (D.C. Cir. 2001); and Aeronautical Repair Station Ass’n v. F.A.A., 494 F.3d 161, 174-7. We are not making any edits based on these comments.

Another commenter was in support of the proposed rule, but had concerns regarding prescriptive authority, namely that in some States the prescriptive authority regulations “are linked to scope of practice laws which would create confusion in VA facilities operating within those states.” The commenter further stated that
“collaborative agreements may limit the scope of practice of the advanced practice registered nurse and inhibit full practice authority.” VA understands that the proposed change could create confusion, and as a result, VA will train and educate its APRNs in their authorities based upon this rule to reduce the potential for confusion and to ensure they can practice to the full extent of their authority. We make no edits based on this comment.

A commenter stated a belief that there is a distinction “between the ability of APRNs to perform tasks autonomously and their ability to practice independently. The former is a well-established practice, while the latter is controversial.” The commenter distinguished “‘autonomy’ from ‘independence,’ the latter referring to practitioners acting alone and not in a team-based model.” The commenter stated that they support “highly trained APPs who are part of a care team practicing autonomously within the scope and ability of their licensure. This is generally accomplished with collaborative practice between a collaborating physician and APPs on the care team.” We previously stated in this final rule that team-based care was not addressed in the proposed rule. Team-based care is an integral part of VA health care, and we will continue to adhere to the already established team-based models of care within VA. We are not making any edits based on this comment.

Several commenters stated that VA should include physician assistants (PA) in the final rule and grant them full practice authority as well. Other commenters were opposed to the granting of full practice authority to PAs. We similarly received comments requesting that we include pharmacist practitioners in the rule. The granting of full practice authority to PAs and pharmacist practitioners was not addressed in the
proposed rule and granting such authority in this final rule is beyond the scope of the proposed rule. VA would only be able to address the granting of full practice authority to PAs and pharmacist assistants in a future rulemaking.

One commenter opposed the proposed rule and urged VA “to instead focus on ways to improve access to care provided to veterans in community settings through the Choice Program. This would reduce wait times for appointments for all veterans, and free up VA clinicians to care for sicker and more complex patients in VA facilities prepared to address their unique needs.” The Veterans Choice Program is authorized by section 101 of the Veterans Access, Choice, and Accountability Act of 2014. The program is implemented in 38 CFR 17.1500 through 17.1540. The proposed rule did not address the Veterans Choice Program, and in no way affects the Veterans Choice Program. This comment is beyond the scope of this rulemaking. We are not making any edits based on this comment.

One commenter suggested that VA amend its application process for hiring physicians citing that there are delays in the usajobs.gov job portal that often leads physicians to remove themselves from job contention. The application process for physician positions was not addressed in the proposed rule, and this issue is beyond the scope of this rulemaking. We are not making any edits based on this comment.

VA received many comments that expressed general support or opposition to this rulemaking and raised various issues related to administration of the VA health care system or VA benefits that are beyond the scope of this rulemaking. We make no changes based on these comments.
We are making a minor typographical edit by adding a comma in proposed § 17.415(e) to correct an error in the proposed rule. We are also amending the last sentence of the paragraph to now read “Any State or local law, or regulation pursuant to such law, is without any force or effect on, and State or local governments have no legal authority to enforce them in relation to, activities performed under this section or decisions made by VA under this section.” The proposed rule inadvertently did not include the phrase “activities performed under”. We are now adding this clarifying language.

Based on the rationale set forth in the Supplementary Information to the proposed rule and in this final rule, VA is amending the proposed rule with the edits stated in this final rule.

**Executive Order 13132, Federalism**

Section 4 of Executive Order 13132 (titled “Federalism”) requires an agency that is publishing a regulation that preempts State law to follow certain procedures. Section 4(b) of the Executive Order requires agencies to “construe any authorization in the statute for the issuance of regulations as authorizing preemption of State law by rulemaking only when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute or there is clear evidence to conclude that the Congress intended the agency to have the authority to preempt State law.” Section 4(d) of the Executive Order requires that when an agency proposes to act through rulemaking to preempt State law, “the agency shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.” Section
4(e) of the Executive Order requires that when an agency proposes to act through rulemaking to preempt State law, “the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.”

Section 6(c) of Executive Order 13132 states that “no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation, (1) consulted with State and local officials early in the process of developing the proposed regulation; (2) in a separately identified portion of the preamble to the regulation as it is to be issued in the Federal Register, provides to the Director of the Office of Management and Budget a federalism summary impact statement, which consists of a description of the extent of the agency’s prior consultation with State and local officials, a summary of the nature of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met; and (3) makes available to the Director of the Office of Management and Budget any written communications submitted to the agency by State and local officials.”

Because this regulation addresses preemption of certain State laws, VA conducted prior consultation with State officials in compliance with Executive Order 13132. Such State officials include State Senators from Georgia and Illinois, State Representatives from Florida, Ohio, Vermont, North Carolina, Georgia, and Illinois, County Commissioners from Nevada, Ohio, and North Carolina, and the State Comptroller and Secretary of State from Illinois, to name a few. Although not necessarily required by the Executive Order, VA sent a letter to the National Council of
State Boards of Nursing to state VA’s intent to allow full practice authority to VA APRNs and for the National Council of State Boards of Nursing (NCSBN) to notify every State Board of Nursing of VA’s intent and to seek feedback from such Boards of Nursing. In response to its request for comments, VA received correspondence from the Executive Director and other relevant staff members within NCSBN, which agreed with VA’s position that this rulemaking properly identifies the areas in VA regulations that preempt State laws and regulations.

VA additionally engaged other relevant external groups on the proposed changes in this rulemaking, including the American Association of Nurse Anesthetists, American Association of Nurse Practitioners, American College of Surgeons, American Academy of Family Practice Physicians, American Society of Anesthesiologists, American Medical Association, Association of American Medical Colleges, The Joint Commission-Office of Accreditation and Certification, American Association of Retired Persons, American Legion, Blinded Veterans Association, Vietnam Veterans of America, American Women Veterans, Disabled American Veterans, Paralyzed Veterans of America, and Veterans of Foreign Wars. VA also engaged the Senate and House Veterans’ Affairs Committees and the Senate and House Armed Services Committees.

Many external stakeholders expressed general support for VA’s positions taken in the proposed rule, particularly with respect to full practice authority of APRNs in primary health care. However, we also received comments opposing full practice authority for CRNAs when providing anesthetics. To aid in VA’s full consideration to this issue, VA encouraged any comments regarding the proposed full practice authority. In
this way, VA provided all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.

VA’s promulgation of this regulation complies with the requirements of Executive Order 13132 by (1) in the absence of explicit preemption in the authorizing statute, identifying where the exercise of State authority conflicts with the exercise of Federal authority under Federal statute; (2) limiting the preemption to only those areas where we find a conflict exists; (3) restricting the regulatory preemption to the minimum level necessary to achieve the objectives of the statute; (4) receiving and considering input from State and local officials as indicated above; and (5) providing opportunity for comment through this rulemaking.

**Effect of Rulemaking**

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA’s implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

**Paperwork Reduction Act**

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).
Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This final rule directly affects only individuals and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order."

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866 because it is likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order. VA’s impact analysis can be found as a supporting document at http://www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA’s Web site at http://www.va.gov/orpm/, by following the link for “VA Regulations Published From FY 2004 Through Fiscal Year to Date.”

**Unfunded Mandates**

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule has no such effect on State, local, and tribal governments, or on the private sector.
Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are: 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert D. Snyder, Chief of Staff, Department of Veterans Affairs, approved this document on September 2, 2016, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices,
Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Date: December 8, 2016

____________________________________
Jeffrey Martin
Office Program Manager
Regulation Policy & Management
Office of the Secretary
Department of Veterans Affairs
For the reasons set forth in the preamble, we amend 38 CFR part 17 as follows:

PART 17 -- MEDICAL

1. The authority citation for part 17 is revised to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

Section 17.415 is also issued under 38 U.S.C. 7301, 7304, 7402, and 7403.

2. Add an undesignated center heading immediately after § 17.410 and add new § 17.415 to read as follows:

Nursing Services

§ 17.415 Full practice authority for advanced practice registered nurses.

(a) Advanced practice registered nurse (APRN). For purposes of this section, an advanced practice registered nurse (APRN) is an individual who:

(1) Has completed a nationally-accredited, graduate-level educational program that prepares them for one of the three APRN roles of Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), or Certified Nurse-Midwife (CNM);

(2) Has passed a national certification examination that measures knowledge in one of the APRN roles described in paragraph (a)(1) of this section;

(3) Has obtained a license from a State licensing board in one of three recognized APRN roles described in paragraph (a)(1) of this section; and
(4) Maintains certification and licensure as required by paragraphs (a)(2) and (3) of this section.

(b) **Full practice authority.** For purposes of this section, full practice authority means the authority of an APRN to provide services described in paragraph (d) of this section without the clinical oversight of a physician, regardless of State or local law restrictions, when that APRN is working within the scope of their VA employment.

(c) **Granting of full practice authority.** VA may grant full practice authority to an APRN subject to the following:

(1) Verification that the APRN meets the requirements established in paragraph (a) of this section; and

(2) Determination that the APRN has demonstrated the knowledge and skills necessary to provide the services described in paragraph (d) of this section without the clinical oversight of a physician, and is thus qualified to be privileged for such scope of practice.

(d) **Services provided by an APRN with full practice authority.** (1) Subject to the limitations established in paragraph (d)(2) of this section, the full practice authority for each of the three APRN roles includes, but is not limited to, providing the following services:

(i) A CNP has full practice authority to:

(A) Take comprehensive histories, provide physical examinations and other health assessment and screening activities, diagnose, treat, and manage patients with acute and chronic illnesses and diseases;
(B) Order laboratory and imaging studies and integrate the results into clinical decision making;

(C) Prescribe medication and durable medical equipment;

(D) Make appropriate referrals for patients and families, and request consultations;

(E) Aid in health promotion, disease prevention, health education, and counseling as well as the diagnosis and management of acute and chronic diseases.

(ii) A CNS has full practice authority to provide diagnosis and treatment of health or illness states, disease management, health promotion, and prevention of illness and risk behaviors among individuals, families, groups, and communities within their scope of practice.

(iii) A CNM has full practice authority to provide a range of primary health care services to women, including gynecologic care, family planning services, preconception care (care that women veterans receive before becoming pregnant, including reducing the risk of birth defects and other problems such as the treatment of diabetes and high blood pressure), prenatal and postpartum care, childbirth, and care of a newborn, and treating the partner of their female patients for sexually transmitted disease and reproductive health, if the partner is also enrolled in the VA healthcare system or is not required to enroll.

(2) The full practice authority of an APRN is subject to the limitations imposed by the Controlled Substances Act, 21 U.S.C. 801 et seq., and that APRN’s State licensure on the authority to prescribe, or administer controlled substances, as well as any other limitations on the provision of VA care set forth in applicable Federal law and policy.
(e) **Preemption of State and local law.** To achieve important Federal interests, including but not limited to the ability to provide the same comprehensive care to veterans in all States under 38 U.S.C. 7301, this section preempts conflicting State and local laws relating to the practice of APRNs when such APRNs are working within the scope of their VA employment. Any State or local law, or regulation pursuant to such law, is without any force or effect on, and State or local governments have no legal authority to enforce them in relation to, activities performed under this section or decisions made by VA under this section.

[FR Doc. 2016-29950 Filed: 12/13/2016 8:45 am; Publication Date: 12/14/2016]