James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
james.madara@ama-assn.org

October 5, 2023

The Honorable Denis McDonough
Secretary
U.S. Department of Veterans Affairs
Office of Regulations, Appeals and Policy (10BRAP)
810 Vermont Avenue, NW
Washington, DC 20420

RE: Announcement of Public Listening Sessions to Inform VA's Standards of Practice

Dear Secretary McDonough:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments to the Department of Veterans Affairs (VA) in connection with the National Standards of Practice (NSP) Listening Sessions concerning known state variances for select health care occupations and recommendations on what should be included in the VA's NSPs.[1]

The AMA's main concern with the VA's effort to develop NSPs is that it may allow non-physician providers to independently deliver services and perform procedures outside the scope of their education, training, and licensure. This will undermine the physician-led team approach and ultimately lead to a lower standard of care for veterans. While we greatly value the contribution of our non-physician colleagues to the physician-led care team, their training is not equivalent to that of a physician. Physicians complete four years of medical school plus a three- to seven-year residency program, including 12,000-16,000 hours of clinical training. As resident physicians gain experience and demonstrate growth in their ability to care for patients, they are given greater responsibility and independence. No other health care profession comes close to this level of training, which is necessary to develop the acumen and clinical judgment required for the independent practice of medicine. In short, the educational programs non-physicians undergo do not prepare them to develop clinical judgment or skills similar to a physician. For this reason, physicians and non-physicians are not interchangeable on a care team.

The AMA urges the VA to provide our veterans with the highest possible quality of care and to rescind the implementation of the Federal Supremacy Project or, at a minimum, ensure that physician-led team-based care is maintained and that physician representation be mandatory on all the Work Groups, not just the Physician Work Group.

According to a survey conducted by the American Legion, 74 percent of veterans believe that it is important that their care is provided by a physician-led care team. If the Supremacy Project moves forward, models of care that are rarely used in the private sector will be formalized across the VA. This

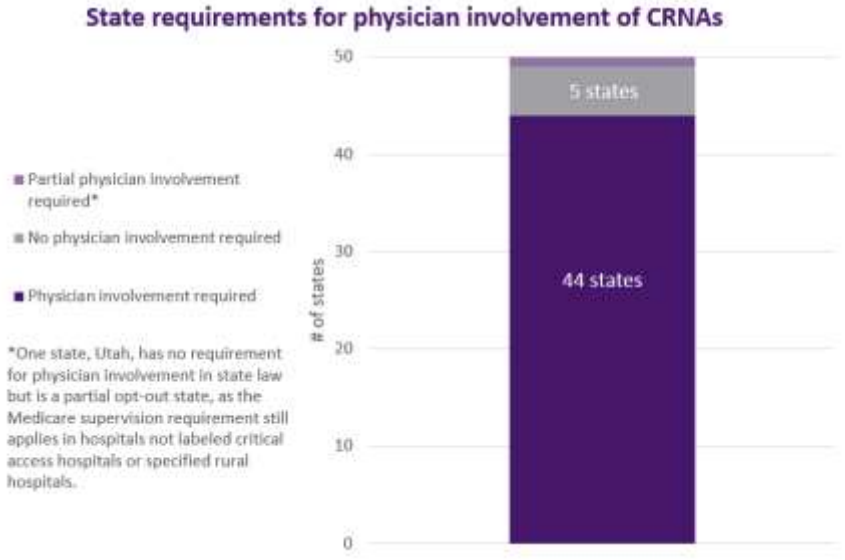
[1] https://www.federalregister.gov/documents/2023/08/14/2023-17309/announcement-of-public-listening-sessions-to-inform-vas-standards-of-practice.

will make the VA an outlier in the medical community, erode public trust in the system, and lead to worse health outcomes for our veterans. We strongly encourage the VA to closely review the current status of state laws and also understand and appreciate the genesis of these laws. State legislatures have been considering scope of practice issues for decades. The variability of scope of practice laws among the states is a testament to each state legislature's thoughtful consideration and debate of these issues. In fact, legislation often develops over several years after thorough research, extensive debate, and negotiations among all parties. While we have not discussed the nuances among state laws in this letter, we are happy to provide any additional details to the VA.

The comments below will focus on five occupations—certified registered nurse anesthetists (CRNAs), optometrists, pharmacists, physician assistants, and psychologists—where the physician community is particularly concerned that efforts to expand scope of practice will threaten the health and safety of patients. Inappropriate scope of practice expansions are of particular concern for our veteran population, who are often medically complex and deserve physician-led care.

Certified registered nurse anesthetists

Anesthesia care is the practice of medicine. It is a highly time-dependent critical care service that demands the immediate availability of a physician's medical decision-making skills, especially for the veteran patient population. CRNAs complete a fraction of the formalized, accredited, and standardized education and training of physicians, with CRNAs completing only two to three years of graduate level education and no residency requirement. As such, it is rare for states to allow independent CRNA practice. Only five states have no requirement for physician involvement of CRNAs in state law and have opted out of the Medicare supervision requirement. In addition, one state has no requirement for physician involvement in state law but is a partial opt-out state, as the Medicare supervision requirement still applies in hospitals not labeled critical access hospitals or specified rural hospitals.



To underscore, the vast majority of the country does not allow for the independent practice of CRNAs. State legislatures have not been quick to change the scope of practice of CRNAs. For example, this year at least 15 states considered legislation that would have impacted CRNA scope of practice, including

reducing physician supervision requirements for CRNAs, weakening collaboration requirements, or allowing for the independent practice of CRNAs. Thus far in 2023, no bills have been enacted that would remove physician involvement.

Independent literature points to the risk to patients of providing anesthesia without appropriate physician clinical oversight, including studies finding that:

- Patients undergoing general or orthopedic surgery were eight percent more likely to die if anesthesia was not provided by a physician anesthesiologist.[2]
- Patients who had their anesthesia solely provided by a CRNA, rather than an anesthesiologist, were 80 percent more likely to have an unexpected disposition, such as admission to the hospital or death.[3]

Additionally, the VA's Quality Enhancement Research Initiative concluded that there was no evidence to support the safe implementation of CRNA-only models of anesthesia for the VA especially for complex surgeries and in small or isolated VA hospitals.[4]

Moreover, there is no evidence that access to care has increased in those states that have chosen to remove the Medicare physician supervision requirement for CRNAs. As such, the AMA believes that the VA should maintain current Directive 1123 which was the product of extensive discussions and multiple rounds of comments over several years.

Optometrists

The majority of eye-related care is delivered through a collaborative team-based approach, with each team member bringing forth an important but distinct skill set. Optometrists are vital members of the health care team, providing routine eye care services to patients, while ophthalmologists provide advanced care including laser and other types of invasive surgical procedures. However, in multidisciplinary settings, ophthalmologists, due to their extensive training and clinical experience, are the leaders of the clinical team. This team-based approach enables ready access to basic eye care needs including routine eye checks, glasses and contact lenses, and swift detection of eye diseases which may need invasive surgical procedures, including laser eye surgery. Moreover, this physician-led structure encourages effective communication and rapid care transitions between optometrists and ophthalmologists and improves patient outcomes.

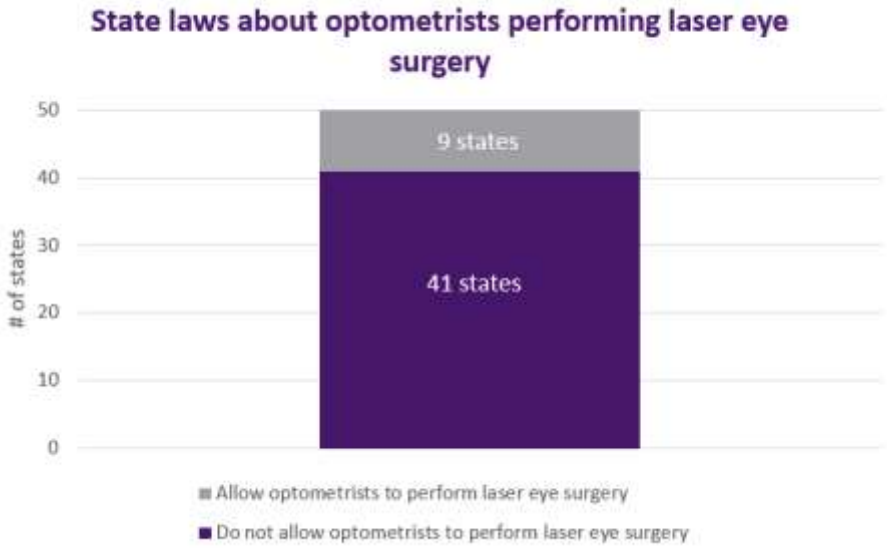
The different roles on the eye care team are extremely important because students of optometry rarely complete postgraduate education and are not exposed to standard surgical procedure, aseptic surgical technique, or medical response to adverse surgical events. Acknowledging the vastly different education and training of optometrists and ophthalmologists, 41 states do not allow optometrists to perform laser surgery.

---

[2] Silber JH, Kennedy SK, Even-Shoshan O, et al. Anesthesiologist direction and patient outcomes. Anesthesiology. 2000;93(1):152-163. doi:10.1097/00000542-200007000-00026.

[3] Memtsoudis SG, Ma Y, Swamidoss CP, Edwards AM, Mazumdar M, Liguori GA. Factors influencing unexpected disposition after orthopedic ambulatory surgery. J Clin Anesth. 2012;24(2):89-95. doi:10.1016/j.jclinane.2011.10.002.

[4] McCleery E, Christensen V, Peterson K, Humphrey L, Helfand M. Evidence Brief: The quality of care provided by advanced practice nurses. In: VA Evidence Synthesis Program Evidence Briefs. Washington (DC): Department of Veterans Affairs (US); September 2014.



This restriction aligns with long-standing VA policy, which also does not permit optometrists to perform laser surgery in veterans' health facilities—regardless of their state licensure. Therefore, it is crucial to recognize that the prevailing norm in optometry practice across all 50 states does not encompass performing surgical procedures.

However, the AMA is concerned that in developing the national standard of practice for optometrists the VA may choose to deviate from the vast majority of states and allow these mid-level providers to perform eye surgery, including laser eye surgery, at the VA. Eye surgery is delicate and is approached with the utmost care and caution by ophthalmologists after extensive residency training and years in clinical practice. Expertise in managing serious complications is achieved through eight plus years of medical school, surgical residency, fellowship training, and hands-on clinical training. Physician trainees do not complete their residency in ophthalmology until faculty is confident in their surgical abilities and judgment. Ophthalmologists must also pass a series of licensure examinations testing everything from general medical knowledge, as well as the ability to perform surgery safely and competently. In contrast, optometry training primarily focuses on the correction of refractive error—glasses and contact lenses—and on primary eye care. While the curriculum includes some didactic education on surgical topics, meaningful hands-on surgical training is not included. In states where optometrists have been granted limited surgical privileges, training often consists of a condensed, 32-hour certification course. This certification course often includes no hands-on patient surgical experience, which is crucial for competent, safe and successful eye surgery. An optometrist trained under these circumstances may in fact attempt their first unsupervised laser surgery on a patient having never before used the equipment on a human eye.

Evidence suggests that patients who receive surgical procedures from optometrists experience poorer outcomes. A 2016 study published in *JAMA Ophthalmology* found that there was nearly triple the likelihood of repeat laser treatment in the same eye when the surgery was performed by optometrists

compared to the same surgery done by ophthalmologists.[5] In addition, a study published in *JAMA Ophthalmology* this year found that expansion of laser privileges to optometrists in Oklahoma, Kentucky, and Louisiana, has not resulted in a statistically significant increase in patient access to laser procedures.[6] Therefore, the AMA does not believe that allowing VA optometrists to perform laser eye surgeries can be justified based on an increased access to care.

For the reasons outlined above, the AMA urges the VA to maintain its long-standing policy that only ophthalmologists shall perform laser eye surgery. Furthermore, we strongly encourage the VA to carefully consider the vast differences in education and training between optometrists and ophthalmologists and the safety of veterans' eye health when drafting the NSP for optometrists and not include privileges for eye surgeries in such standards.

Pharmacists

Pharmacists play a crucial role in the health care system, including dispensing medication, monitoring medication efficacy and adverse events, educating patients on the safe and effective use of medications, counseling patients on health topics, and looking for and alerting patients and physicians to possible drug-to-drug interactions. Pharmacists and physicians have a long history of working together to provide optimal patient care—pharmacists as clinical medication experts and physicians as the clinician leads uniquely trained in the full spectrum of medicine including diagnosing and treating patients.

Pharmacists are well-trained as medication experts within an interprofessional team; however, their training in patient care is limited. Most of the Doctor of Pharmacy (PharmD) curriculum across the country consists of instruction in applied sciences and therapeutics. Residency is not required, and the overwhelming majority of pharmacists working in the community setting have not undergone residency training. While pharmacy students do engage in a modest amount of "practice experiences" during their education, the training is not focused on providing medical care to patients. In fact, the practice experiences in the PharmD curriculum do not include performing a physical examination, making a diagnosis, triaging severity, or prescribing. Moreover, pharmacists, though trained in the chemical components and clinical aspects of medications, do not have the holistic or comprehensive medical knowledge and approach of physicians.

Pharmacists and physicians often enter into a formal collaborative practice agreement (CPA) such as a collaborative drug therapy management agreement (CDTM). Under such an agreement, a pharmacist—alongside and as directed by a physician—can play a critical role in managing patients' medication therapies using an evidence-based approach to care. The AMA supports this model of physician-led, team-based care with pharmacists, as do the at least 43 states with existing laws in place supporting collaborative drug therapy management.

While CDTM laws vary by state, the strongest models have three qualities in common: 1) they establish a formal agreement between an individual physician and a pharmacist, 2) they include clear treatment protocols that are individualized to a patient's needs, and 3) they require patient notification or consent. Strong collaborative drug therapy management agreements allow pharmacists to play a key role in comprehensive medication management and have proven effective in improving patient outcomes,

[5] Stein JD, Zhao PY, Andrews C. Comparison of Outcomes of Laser Trabeculoplasty Performed by Optometrists vs Ophthalmologists in Oklahoma. JAMA Ophthalmol, 2016.
[6] Shaffer J; Rajesh A; Stewart MW; Lee AY; Miller DD; Lee CS; Francis CE. Evaluating Access to Laser Eye Surgery by Driving Times Using Medicare Data and Geographical Mapping. JAMA Ophthalmol, 2023.

including patients with chronic diseases like diabetes. The AMA encourages the VA to consider this model as part of the pharmacist NSP.

During the listening session focused on pharmacists, pharmacist organizations encouraged the VA to include independently initiating treatment for opioid use disorder (OUD) and test and treat for other illnesses in the VA NSP for pharmacists. The AMA believes eliminating a physician would be a mistake. Allowing pharmacists to independently diagnose and treat OUD without physician supervision ignores the complexity of OUD as well as the complexities involved with designing a treatment plan and medical follow-up and management. While OUD is a chronic disease requiring comprehensive medication management over time, similar to diabetes and hypertension, this is best done within a physician-led, team based care where the pharmacist has a critical role. Test and treat laws that would allow pharmacists to independently diagnose and prescribe medications to patients based only on the results of a CLIA waived test, ignoring the importance of a physical examination, knowledge of patient history, and other factors that are part of a differential diagnosis and of which pharmacists are not trained to perform. It is important to note that very few states allow pharmacists to perform either of these functions outside of a formal collaborative drug therapy management agreement as described above. While all 50-states allow pharmacists to administer opioid antagonists such as naloxone, we understand allowing pharmacists to independently diagnose and treat OUD without physician supervision to be virtually unheard of. Likewise, only about seven states allow pharmacists to treat patients for conditions such as strep throat and the flu based on the results of a CLIA waived test. Notably, legislatures in 11 states considered pharmacist test and treat legislation so far this year and decided not to pass legislation in their respective state.

We urge the VA to take into account this current state legislative landscape when considering the pharmacist NSP and not including medication treatment for OUD or test and treat without any physician involvement in the NSP for pharmacists; however, we would encourage the VA to continue to support strong CPA and CDTM agreements between pharmacists and physicians, including for treating OUD.

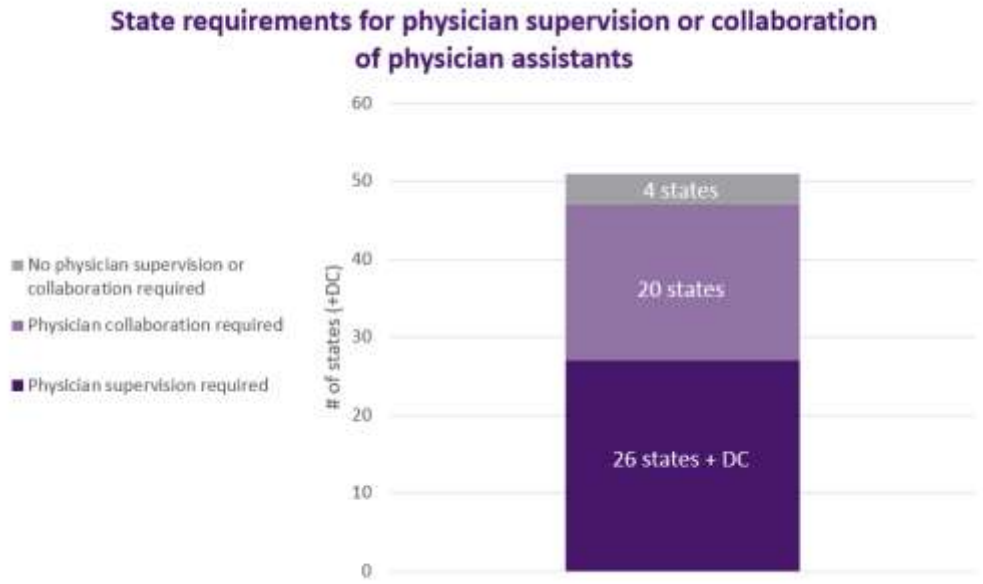
Moreover, expanding pharmacists' scope of practice is unlikely to result in increased access to care. Pharmacists in the community setting said they already have so much work to do that everything cannot be done well. The problem appears systemic: 71 percent of all pharmacists and 91 percent of pharmacists working in community pharmacies rated their workload as high or excessively high. Moreover, pharmacists reported that the "three most common 'highly stressful' job aspects were 'having so much work to do that everything cannot be done well' (43 percent reporting 'highly stressful'), 'working at current staffing levels' (37 percent reporting 'highly stressful'), and 'fearing that a patient will be harmed by a medication error' (35 percent reporting 'highly stressful')."[7] Scope expansions only add further responsibilities to an overburdened pharmacist workforce and threaten patient safety due to their insufficient training in these activities. Therefore, it is inappropriate to authorize pharmacists to diagnose, prescribe, or assume the role of a physician.

Physician Assistants

Likewise, we strongly encourage the VA to review and consider existing state laws when drafting the NSP for physician assistants. Currently, 46 states require physician supervision of or collaboration with physician assistants, with the majority of states (26) plus the District of Columbia requiring physician supervision. Of the 20 laws requiring physician collaboration, a few states only require collaborative

[7] https://www.aacp.org/sites/default/files/2020-03/2019_NPWS_Final_Report.pdf.

agreements for a certain number of hours or years of practice, typically ranging from 4,000-10,000 hours. These states may also limit the practice environment in which the physician assistant can practice after acquiring these hours. Understanding that unlike physicians who complete a residency program and obtain board certification in a specific specialty, physician assistants can switch specialties without any additional formalized education or training, several of these states often require additional hours if the physician assistant changes specialties. Of note, in 2023 more than two dozen states considered physician assistant scope expansion, only a few passed such bills, and many of these were amended to preserve physician-led care. The trend at the state level for scope of practice of physician assistants continues to be requiring physician assistants to practice with physician supervision or collaboration.



According to numerous studies, expanding the scope of practice of physician assistants will increase the cost of care due to inappropriate prescribing, unnecessary referrals to specialists, unnecessary orders for diagnostic imaging studies, and performing more biopsies compared to physicians:

- Hattiesburg Clinic, a multispecialty clinic and top-rated accountable care organization with 17 locations across Mississippi, found that care provided by nonphysicians, including physician assistants, working on their own primary care patient panels led to higher costs, more referrals, higher emergency department use, and lower patient satisfaction than care provided by physicians. The Hattiesburg Clinic findings are unique because they are a pragmatic analysis or self-assessment of the cost and quality of care provided to patients across their clinics, using cost and quality data from the Centers for Medicare & Medicaid Services and patient surveys. Based on Medicare cost data, the clinic found that the Medicare ACO patient spend was nearly $43 higher per member per month for patients with a primary care non-physician compared to those with a primary care physician. These additional costs could translate to an additional $10.3 million in spending annually for the system. The findings from the study were used to shift the Clinic's approach to team-based care, recognizing

that advanced practice providers, including physician assistants, are a crucial part of the care team; however, based on the data, they should not function independently.[8]

- A 2020 study in the *Journal of Internal Medicine* found that 8.4 percent of physician assistants prescribed opioids to more than 50 percent of their patients compared to just 1.3 percent of physicians. In addition, the study found that from 2013 to 2017, when almost every medical specialty decreased opioid prescribing, nurse practitioners and physician assistants significantly increased opioid prescribing.[9]
- A 2013 study by the Mayo Clinic found that inappropriate referrals to tertiary referral centers by nurse practitioners and physician assistants could offset any potential savings from the increased use of both health care professionals.[10] In a study comparing the accuracy of dermatologists with physician assistants in diagnosing skin cancer, researchers found that physician assistants performed more skin biopsies per case of skin cancer diagnosed and diagnosed fewer melanomas in situ, suggesting that the diagnostic accuracy of physician assistants may be lower than that of dermatologists.[11]
- Another study using Medicare data from 2005 - 2020 found that the presence of non-physician providers, including physician assistants, in emergency departments (ED) resulted in 5.3 percent more imaging studies per ED visit.[12] Notably, this is consistent with a November 2022 study that found that nurse practitioners practicing independently in the VA Emergency Department respond "to lower skill in their clinical decision-making by ordering more tests and consults in order to gather information from other sources, compared to physicians."[13]

Physician assistants are valued members of physician-led teams, but they are not physicians and should not function independently. Physicians go to medical school for four years—physician assistants complete only two to 2.5 years of graduate-level education. Physicians must complete three to seven years of additional residency training—physician assistants have no residency training requirements. Physicians must complete 12,000 - 16,000 hours of advanced clinical training—physician assistants must complete 2000 hours of clinical training. Moreover, it is important to note that the physician assistant education model assumes that in practice physician assistants will be supervised by or collaborating with a physician. Scope of practice for any health care professional should be based on standardized, adequate

---

[8] "Targeting Value-Based Care with Physician-Led Care Teams," Bryan N. Batson, MD, Samuel N. Crosby, MD, and John Fitzpatrick, MD, Journal of the Mississippi State Medical Association, Jan. 2022.

[9] Lozada MJ, Raji MA, Goodwin JS, Kuo YF. Opioid Prescribing by Primary Care Providers: A Cross-Sectional Analysis of Nurse Practitioner, Physician Assistant, and Physician Prescribing Patterns. J Gen Intern Med. 2020 Sep;35(9):2584-2592. doi: 10.1007/s11606-020-05823-0. Epub 2020 Apr 24. PMID: 32333312; PMCID: PMC7459076.

[10] Lohr RH, West CP, Beliveau M, Daniels PR, Nyman MA, Mundell WC, Schwenk NM, Mandrekar JN, Naessens JM, Beckman TJ. Comparison of the quality of patient referrals from physicians, physician assistants, and nurse practitioners. Mayo Clin Proc. 2013 Nov;88(11):1266-71. doi: 10.1016/j.mayocp.2013.08.013. Epub 2013 Oct 9. PMID: 24119364.

[11] Anderson AM, Matsumoto M, Saul MI, Secrest AM, Ferris LK. Accuracy of Skin Cancer Diagnosis by Physician Assistants Compared With Dermatologists in a Large Health Care System. JAMA Dermatol. 2018 May 1;154(5):569-573. doi: 10.1001/jamadermatol.2018.0212. Erratum in: JAMA Dermatol. 2018 Jun 1;154(6):739. PMID: 29710082; PMCID: PMC6128496.

[12] Christensen EW, Liu C, Duszak R, Hirsch JA, Swan TL, Rula EY. Association of State Share of Nonphysician Practitioners With Diagnostic Imaging Ordering Among Emergency Department Visits for Medicare Beneficiaries. JAMA Netw Open. 2022;5(11): e2241297. doi:10.1001/jamanetworkopen.2022.41297.

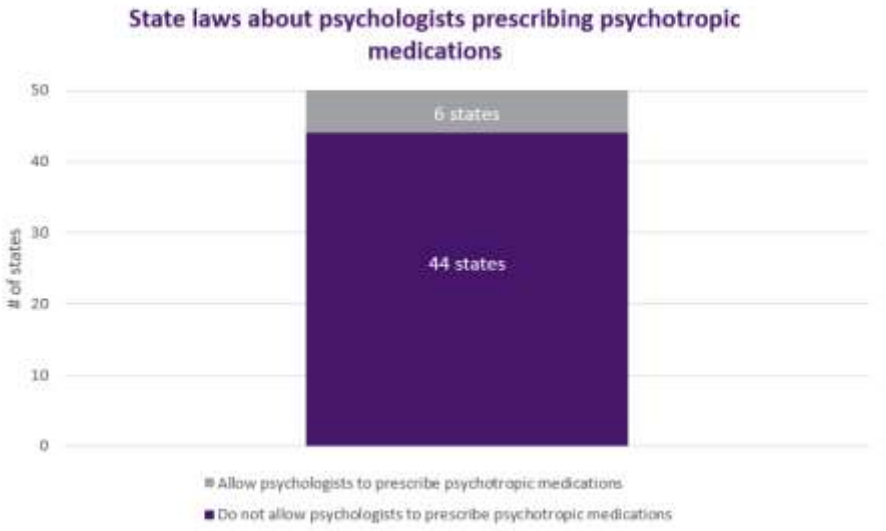
[13] Productivity of Professions: Lessons from the Emergency Department, Chan, David C. and Chen, Yiqun, NBER, Oct. 2022.

training, and demonstrated competence in patient care. As such, we urge the VA to preserve physician-led care and maintain the current standard of practice in the physician assistant NSP.

Psychologists

Ensuring that Veterans have access to high quality mental health care is extremely important and psychologists play a critical role in providing such care; however, the VA should not advance policy that would allow psychologists to prescribe medications. Psychotropic medications are powerful and impact all body systems; as such, safe prescribing, and ongoing maintenance of psychotropics requires a comprehensive medical education.

Psychologists are not allowed to prescribe and manage medication independently without collaborating with a medical doctor in any setting, including the VA, because they do not have the requisite training or medical background to do so. To date, no Federal program including Medicare, Medicaid, TRICARE, or the VA allows psychologists to have independent prescriptive authority. Furthermore, Medicare expressly states that the program does not reimburse for evaluation and management or pharmacologic management by prescribing psychologists, specifically citing psychologists' lack of knowledge and ability.



Only six states currently allow psychologists to prescribe psychotropic medications, although several of these states still require collaboration or supervision with a physician or other medical provider.

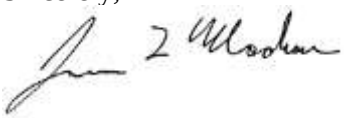
Conclusion

The AMA firmly believes that the Federal Supremacy Project should be rescinded and, instead, the VA should pursue strategies that increase recruitment, training, and retention of physicians in the VA system. We believe that the VA can work towards this goal by enhancing integrated care, further expanding telehealth, ensuring that all physicians are direct hires, streamlining the hiring process for international medical graduates (IMGs) by providing/expanding the exception to the two-year home country return

requirement if an IMG works for the VHA for a designated period of time, increasing the number of residency positions offered by the VA, and providing additional benefits to physician working within the VA to help with retention. At a minimum, physician led team-based care should be maintained and there should be physician representation on all the NSP Work Groups, not just the Physician Work Group. Moreover, if there must be uniform privileging in the VA, then instead of setting practice privileges to align with the least restrictive scope provisions, the VA should ensure that veterans are provided with the best care and adhere to the most conservative state scope requirements.

The AMA looks forward to working with the VA as it moves through the NSP development process. If you have questions or require additional information, please contact Margaret Garikes, Vice President for Federal Affairs, at margaret.garikes@ama-assn.org, or by calling 202-789-7409.

Sincerely,



James L. Madara, MD