improve that analysis. We thus follow the same basic approach here.

The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 1) and at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses.*

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that: ''* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) * * *.'' The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Pub. L. 101–535, 104 Stat. 2353, 2364 (1990)). If this proposed rule is made final, the final rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act.

VIII. References

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. United States Department of Health and Human Services. United States Food and Drug Administration. Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis for Proposed Rule on ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Extension of Compliance Dates.'' September 2017. Available from *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses.*

Dated: September 26, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21019 Filed 9–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ06

Authority of Health Care Providers To Practice Telehealth

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its medical regulations by standardizing the delivery of care by VA health care providers through telehealth. This rule would ensure that VA health care providers provide the same level of care to all beneficiaries, irrespective of the State or location in a State of the VA health care provider or the beneficiary. This proposed rule would achieve important Federal interests by increasing the availability of mental health, specialty, and general clinical care for all beneficiaries.

DATES: Comments must be received on or before November 1, 2017.

ADDRESSES: Written comments may be submitted through *http://www.Regulations.gov* by mail or hand-delivery to: Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1063B, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll-free telephone number.) Comments should indicate that they are submitted in response to ''RIN 2900–AQ06-Authority of Health Care Providers to Practice Telehealth.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free telephone 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: Kevin Galpin, MD, Executive Director Telehealth Services, Veterans Health Administration Office of Connected Care, 810 Vermont Avenue NW., Washington, DC 20420. (404) 771–8794. (This is not a toll-free number.) *Kevin.Galpin@va.gov.*

SUPPLEMENTARY INFORMATION: Section 7301 of title 38, United States Code (U.S.C.), establishes the general functions of 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 [of Veterans Affairs (Secretary)] pursuant to this title.'' 38 U.S.C. 7301(b). In carrying out this function, VHA must ensure that patient care is appropriate and safe and its health care providers meet or exceed generally accepted professional standards for patient care. In addition, because VA is a national health care provider, VHA must ensure that beneficiaries receive the same high level of care and access to care no matter where, in a State, a beneficiary or health care provider is located at the time the health care is provided.

The Secretary is responsible for the proper execution and administration of all laws administered by the Department and for the control, direction, and management of the Department, including agency personnel and management matters. See 38 U.S.C. 303. To this end, Congress authorized the Secretary ''to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department and are

consistent with those laws.'' 38 U.S.C. 501(a). The Under Secretary for Health is directly responsible to the Secretary for the operation of VHA. 38 U.S.C. 305(b). Unless specifically otherwise provided, the Under Secretary for Health, as the head of VHA, is authorized to ''prescribe all regulations necessary to the administration of the Veterans Health Administration,'' subject to the approval of the Secretary. 38 U.S.C. 7304.

To allow VA to carry out its medical care mission, Congress also established a comprehensive personnel system for certain VA health care providers, independent of the civil service rules. See 38 U.S.C. chapters 73–74. Congress granted the Secretary express statutory authority to establish the qualifications for VA's health care providers, determine the hours and conditions of employment, take disciplinary action against employees, and otherwise regulate the professional activities of those individuals. 38 U.S.C. 7401–7464.

To be eligible for appointment as a VA employee in a health care position covered by section 7402(b) of title 38, U.S.C. (other than a medical facility Director appointed under section 7402(b)(4)), a person must, among other requirements, be licensed, registered, or certified to practice his or her 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, section 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.'' Such authority is necessary to ensure the viability of our national health care system, which is designed to ensure the well-being of those who have ''borne the battle.''

Just as it is critical to ensure there are qualified health care providers on-site at all VA medical facilities, VA must ensure that all beneficiaries, specifically including beneficiaries in remote, rural, or medically underserved areas, have the greatest possible access to mental health care, specialty care, and general clinical care. Thus, VA has developed a telehealth program as a modern, beneficiary- and family-centered health care delivery model that leverages information and telecommunication technologies to connect beneficiaries with health care providers, irrespective of the State or location within a State where the health care provider or the beneficiary is physically located at the time the health care is provided. Telehealth enhances VA's capacity to deliver essential and critical health care services to beneficiaries located in areas where health care providers may be unavailable or to beneficiaries who may be unable to travel to the nearest VA medical facility for care because of their medical conditions. Telehealth increases the accessibility of VA health care, bringing VA medical services to locations convenient for beneficiaries, including clinics in remote communities and beneficiaries' homes. By providing health care services by telehealth from one State to a beneficiary located in another State or within the same State, whether that beneficiary is located at a VA medical facility or in his or her own home, VA can use its limited health care resources most efficiently.

Congress has required other Departments and agencies to conduct telehealth programs. *See, e.g.,* Public Law 114–328, sec. 718(a)(1) (''the Secretary of Defense shall incorporate, throughout the direct care and purchased care components of the military health system, the use of telehealth services''). While VA does not have an analogous mandate, several statutes confirm that Congress intends for VA to operate a national health care system for beneficiaries including through telehealth. Congress has required the Secretary ''to carry out an initiative of teleconsultation for the provision of remote mental health and traumatic brain injury assessments in facilities of the Department that are not otherwise able to provide such assessments without contracting with third-party providers or reimbursing providers through a fee basis system.'' 38 U.S.C. 1709A(a)(1). Congress has authorized the Secretary to ''waive the imposition or collection of copayments for telehealth and telemedicine visits of veterans under the laws administered by the Secretary.'' 38 U.S.C. 1722B. And, as recently as December 2016, Congress required VA to initiate a pilot program to provide veterans a self-scheduling, online appointment system; this pilot program must ''support appointments for the provision of health care regardless of whether such care is provided in person or through telehealth services.'' Public Law 114–286, sec. 3(a)(2).

As noted above, VA only has legal authority to hire health care providers who are licensed, registered, or certified in a State. To continue practicing in VA, providers must maintain those credentials in accordance with their health care specialty as stated in 38 U.S.C. 7402(b).

In an effort to furnish care to all beneficiaries and use its resources most efficiently, VA needs to operate its telehealth program with health care providers who will provide services via telehealth to beneficiaries in States in which they are not licensed, registered, certified, or located, or where they are not authorized to furnish care using telehealth. Currently, doing so may jeopardize these providers' credentials, including fines and imprisonment for unauthorized practice of medicine, because of conflicts between VA's need to provide telehealth across the VA system and some States' laws or licensure, registration, certification, or other requirements that restrict or limit the practice of telehealth. A number of States have already enacted legislation or regulations that restrict the practice of interstate telehealth, as discussed below in the Administrative Procedure Act section.

To protect VA health care providers from potential adverse actions by States, many VA medical centers (VAMC) are currently not expanding some critical telehealth services if the health care service is provided outside Federal property (such as when the beneficiary is receiving telehealth care in his or her home or when the VA provider is delivering telehealth care from his or her home) or across State lines. In addition, many individual VA health care providers refuse to practice telehealth because of concerns over States taking action against the health care provider's State license, State laws, or the shifting regulatory landscape that creates legal ambiguity and unacceptable State licensing risk. The current disparities between VA health care practice in telehealth and State laws have effectively stopped or inhibited VA's expansion of telehealth services to certain locations, thereby reducing the availability and accessibility of care for beneficiaries.

This proposed rulemaking would clarify that VA health care providers may exercise their authority to provide care through the use of telehealth, notwithstanding any State laws, rules, or licensure, registration, or certification requirements to the contrary. In so doing, VA would exercise Federal preemption of State licensure, registration, and certification laws, rules, regulations, or requirements to the extent such State laws conflict with the ability of VA health care providers to engage in the practice of telehealth while acting within the scope of their VA employment. Preemption would be the minimum necessary action for VA to

furnish effectively telehealth services because it would be impractical for VA to lobby each State to remove its restrictions that impair VA's ability to furnish telehealth services to beneficiaries and then wait for the State to implement appropriate changes. That process would delay the growth of telehealth services in VA, thereby delaying delivery of health care to beneficiaries. It would be costly and time-consuming for VA and would not guarantee a successful result. We note that, apart from the limited action of authorizing telehealth across and within jurisdictions in furtherance of important Federal interests, this rulemaking would not expand the scope of practice for VA health care providers beyond what is statutorily defined in the laws and practice acts of the health care provider's state of licensure. That is, this rulemaking does not affect VA's existing requirement that all VA health care providers adhere to restrictions imposed by their State license, registration, or certification regarding the professional's authority to prescribe and administer controlled substances.

As VA's telehealth program expands and successfully provides increased access to high quality health care to all beneficiaries, it is increasingly important for VA health care providers to be able to practice telehealth across State lines and within states free of restrictions imposed by State law or regulations, including conditions attached to their State licenses. For fiscal year (FY) 2016, VA health care providers had 2.17 million telehealth episodes of health care (meaning a clinical encounter or a period of time in which care was monitored), which served over 702,000 veterans (approximately 12 percent of the total patient population), with 45 percent of those veterans living in rural communities. By increasing VA's capabilities to provide telehealth services, VA would be able to expand these services.

Eliminating veteran suicide and providing access to mental health care is VA's number one clinical priority, and this proposed rulemaking would improve VA's ability to reach its most vulnerable beneficiaries. Some mental health patients suffer from conditions, such as anxiety and agoraphobia, which make it incredibly difficult to leave their houses to receive necessary mental and general health care. Furthermore, some of our beneficiaries live in areas that are Federally designated as mental health provider shortage areas. Therefore, even if beneficiaries feel comfortable leaving their home to seek care, there may not be sufficient mental health care providers at a VA medical facility or in the community to address their health care needs. Given the difficulty in providing mental health care under these circumstances, the most practical way to consistently provide all VA beneficiaries with access to high-quality mental health care is through the telehealth program. The data collected in FY 2016 demonstrates that telehealth, particularly in the mental health context, improves patient care and improves patient outcomes. In FY 2016, there was a 31 percent decrease in VA hospital admissions for beneficiaries enrolled in the Home Telehealth monitoring program for non-institutional care needs and chronic care management. Also, beneficiaries who received mental health services through synchronous video telehealth in FY 2016 saw a reduction in the number of acute psychiatric VA bed days of care by 39 percent.

In addition, monitoring general medical conditions in the beneficiaries' home empowers beneficiaries to take a more active role in their overall health care without adding the stress of commuting to a medical facility to receive the same type of care. Telehealth is particularly important for beneficiaries with limited mobility, or for whom travel to a health care provider would be a personal hardship. For example, beneficiaries who have conditions such as a history of stroke, traumatic brain injuries, seizure disorders, and amyotrophic lateral sclerosis (ALS) may find it difficult to leave their home in order to receive much-needed health care. VA also is able to provide health care services to more beneficiaries in localities that are more convenient for them, which may lead to the beneficiary taking a more proactive approach to their care, thereby increasing the likelihood of positive clinical outcomes.

Other benefits of expanding VA telehealth include serving as a recruitment incentive for VA health care providers and allowing VA to address recruitment shortages in various parts of the country. For example, the Charleston, South Carolina VAMC serves as one of the VA's National TeleMental Health Hubs and provides mental health services to beneficiaries across eight States with a team of approximately 30 full-time health care providers. There are currently multiple vacancies for TeleMental Health psychiatrists at the Charleston Hub, and in the past six months, applicants have only expressed interest in telework positions. Several VA health care providers have also left their positions within the past year because they were seeking telework positions. If the health care providers were able to practice telehealth while working from VA-approved alternate worksites and still deliver the telehealth services where needed, the Charleston TeleMental Hub would be able to fill its vacancies and retain needed health care professionals.

These are just some examples of how expanding telehealth, and thereby expanding the locations where VA provides health care services, would allow VA to reach underserved areas or beneficiaries who are unable to travel, improving health outcomes for beneficiaries and allowing VA to better utilize its health care resources. For these reasons, VA proposes to establish a new regulation, 38 CFR 17.417 that would authorize VA health care providers to treat beneficiaries through telehealth irrespective of the location, in a State, of the VA health care provider or the beneficiary.

Proposed paragraph (a) of § 17.417 would contain the definitions that would apply to the new section. We would define the term ''beneficiary'' to mean ''a veteran and any other individual receiving care under title 38 of the United States Code.'' We would use this definition because VA provides health care to veterans, certain family members of veterans, servicemembers, and others. This is VA's standard use of this term.

We propose to define the term ''health care provider'' consistent with the qualifications of appointees within the Veterans Health Administration under 38 U.S.C. 7402(b). We would incorporate the licensure, registration, or certification requirement from section 7402(b) and would state that health care providers must maintain ''credentials (*e.g.,* license, registration, or certification) in accordance with the requirements of their health care specialty as identified under 38 U.S.C. 7402(b).'' This standard would ensure that VA health care providers are qualified to practice their individual health care specialty and also ensure patient safety. A health care provider as defined in this regulation cannot be a VA-contracted employee. Contract health care providers would be required to adhere to their individual State license, registration, or certification requirements.

We propose to define the term ''State'' consistent with 38 U.S.C. 101(20), and including political subdivisions of such States. We include political subdivisions in the definition because subdivisions of a State are granted legal authority from the State itself, so it would make sense to include entities

created by a State, or authorized by a State in the definition.

Last, in proposed paragraph (a)(4) of § 17.417, we would define the term ''telehealth'' to mean ''the use of electronic information or telecommunications technologies to support clinical health care, patient and professional health-related education, public health, and health administration.'' This definition would be consistent with other statutory definitions, such as a provision in the Public Health Service Act regarding mental health services delivered by telehealth in 42 U.S.C. 254c–16(a)(4).

As we have mentioned in this rulemaking, currently, individual States can restrict and limit where a health care provider can practice under a State license, certification, or registration. This proposed rulemaking would authorize VA health care providers to furnish telehealth services without regard to any State restriction that would prevent the provider from delivering care via telehealth. Proposed paragraph (b)(1) of § 17.417 would state that VA health care providers could provide ''telehealth services, within their scope of practice and in accordance with privileges granted to them by the Department, irrespective of the State or location within a State where the health care provider or the beneficiary is physically located.'' This would authorize VA health care providers to furnish care, consistent with their employment obligations, through telehealth, without fear of adverse action by any State. A health care provider's practice within VA, however, would continue to be subject to the limitations ''imposed by the Controlled Substances Act, 21 U.S.C. 801 *et seq.,* 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.'' This would ensure that providers would still be in compliance with critical laws concerning the prescribing and administering of controlled substances. We would also state that this rulemaking ''only grants health care providers the ability to practice telehealth within the scope of their VA employment and does not otherwise grant health care providers additional authorities that go beyond the scope of the health care providers' State license, registration, or certification.''

In proposed paragraph (b)(2)(i) through (vii) of § 17.417, we would provide situations where a health care provider's practice of telehealth could be inconsistent with a State law or State license, registration, or certification requirements while engaging in the practice of telehealth in VA. These examples would be consistent with the reasons VA is proposing to take this rulemaking action, as described above.

Proposed paragraph (c) would expressly state the intended preemptive effect of § 17.417, to ensure that conflicting State and local laws, rules, regulations, and requirements related to health care providers' practice would have no force or effect when such providers are practicing telehealth while working within the scope of their VA employment. In circumstances where there is a conflict between Federal and State law, Federal law would prevail in accordance with Article VI, clause 2, of the U.S. Constitution (Supremacy Clause).

Executive Order 13132, Federalism

Section 4 of Executive Order 13132 (Federalism) requires an agency that is publishing a regulation that preempts State law to follow certain procedures. Section 4(b) 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(c) states ''Any regulatory preemption of State law shall be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated.'' Section 4(d) requires that when an agency ''foresees the possibility of a conflict between State law and Federally protected interests within its area of regulatory responsibility, 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) requires that when an agency ''proposes to act through adjudication or 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) states that ''To the extent practicable and permitted by law, 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 proposed rule would preempt certain State laws, VA consulted with State officials in compliance with sections 4(d) and (e), as well as section 6(c) of Executive Order 13132. VA sent a letter to the National Governor's Association, Association of State and Provincial Psychology, National Council of State Boards of Nursing, Federation of State Medical Boards, Association of Social Work Boards, and National Association of State Directors of Veterans Affairs on July 12, 2017, to state VA's intent to allow VA health care providers to practice telehealth irrespective of the location of the health care provider or beneficiary in any State and regardless of State telehealth restrictions. In addition, the Director of the Federation of State Medical Boards solicited comments and input from the nation's State Medical Boards. The Wisconsin Medical Examining Board unanimously passed a motion in support of the rule. The Rhode Island Board of Medical Licensure & Discipline (BMLD) responded to our letter by stating that BMLD considers physicians employed by VA to be exempt from license requirements as long as such physician maintains a valid license in another U.S. jurisdiction. BMLD also indicated that the exemption does not necessarily extend to prescribing controlled substances without an appropriate DEA registration. In response to this caveat, we have stated in this proposed rule that, if finalized, VA health care providers would be subject to ''the limitations imposed by the Controlled Substances Act, 21 U.S.C. 801, *et seq.,* 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.'' The State of Utah Department of Commerce also stated that the Utah Occupations and Professions Licensing Act exempts from licensure requirements in Utah

physicians, physician assistants, advanced practice nurses, psychologists or other health care provider who provide telehealth services as part of their VA employment as long as such health care provider is licensed in any State. Utah supports VA efforts to enhance telehealth services to all veterans. The Florida Board of Medicine stated that Florida does not prohibit the practice of telehealth except in certain circumstances and provided as an example that an in-person examination is required each time a physician issues a certification for medical marijuana. This proposed rule would supersede any State requirement regarding the practice of telehealth, such as the in-person examination requirement in Florida, and would maintain the restrictions imposed by Federal law and policy regarding the prescription of controlled substances. The North Carolina Medical Board recognizes the shortage of psychiatric care in rural and medically underserved communities and supports VA's initiative.

The President of the National Association of State Directors of Veterans Affairs (NASDVA) sent an email to all of its State directors informing the directors of the association's intent to fully support VA's initiative. The NASDVA also formally responded to our letter, which fully supports VA's plans to amend its regulations and enhance access to health care via telehealth services. The National Council of State Boards of Nursing (NCSBN) fully supports VA's initiative for health care providers to deliver services via telehealth as long as such providers maintain a valid State license. However, the NCSBN does not support expanding VA State licensure exemptions to personal services contractors who practice telehealth. As stated in this proposed rulemaking, VA contractors would be excluded from providing telehealth services.

The Chief Executive Officer of the Association of State and Provincial Psychology Boards formally responded to our letter and indicated that the proposed rule is in alignment with their current initiatives, specifically, Psychology Interjurisdictional Compact (PSYPACT) legislation, which has been adopted in three jurisdictions and is under active consideration in many more States. The PSYPACT legislation allows psychologists to provide telepsychology services across State lines via a compact without obtaining additional licenses. The Chief Executive Officer further stated that these services will be of assistance in addressing the delivery of telehealth services to veterans.

The Veterans' Rural Health Advisory Committee (VRHAC) formally submitted a letter in support of the proposed rule. The letter stated that although VA leads the way in being the largest provider of telehealth in the country, there are barriers that affect many rural and highly rural areas, which includes limited internet or cellular access with sufficient bandwidth to support the required applications and also State legislations that restrict the practice of telehealth across State lines or into a veteran's home. The commenter strongly supports the proposed rule and further adds that expanding telehealth to rural and highly rural veterans across State lines would strengthen the delivery of care to enrolled veterans who live in rural and highly rural areas and supports the critical need for access to mental health care.

The West Virginia Board of Osteopathic Medicine responded to VA's letter and indicated that West Virginia has made legislative changes to encourage physician participation in the VA system. The commenter stated that W.Va. Code 30–14–12c authorizes the West Virginia licensing boards to issue a license to a physician licensed in another State via reciprocity when the applicant presents proof that they are a VA employee working in a VA medical facility that is located in a county where a nursing home is operated by the West Virginia Department of Veteran's Assistance. Also, W.Va. Code 30–14–12d states the requirements for practicing telemedicine in West Virginia and defines that the practice of medicine occurs where the patient is located and defines what constitutes a physician-patient relationship. The commenter stated that the West Virginia Board of Osteopathic Medicine rarely knows when a VA physician is practicing in West Virginia without a West Virginia State license. However, the commenter cautioned that if a VA physician is licensed in West Virginia and does not follow state law and such action becomes known to the Board, the Board would file a complaint and investigate such action. The commenter stated that their telehealth law was written to protect patients and indicated that veterans deserved the same high quality care. As we have stated in this proposed rule, we are preempting State law as it applies to health care providers who practice telehealth while acting within the scope of their VA employment.

The Pennsylvania State Board of Medicine responded to VA's letter and acknowledged the potential value for telehealth to expand access to health care, especially in rural and underserved areas. The commenter further stated that Pennsylvania law on the Interstate Medical Licensure Compact affirms that the practice of medicine occurs where the patient is located at the time of the health care encounter, which requires the physician to be under the jurisdiction of the State medical board where the patient is located. The commenter indicated that VA has oversight of its health care providers, however, the foundational principle that the physician should be licensed where the patient is located helps to assure the safety, quality, and accountability of the care provided. This proposed rule preempts State law as it applies to health care providers who practice telehealth while acting within the scope of their VA employment.

The Michigan Department of Licensing and Regulatory Affairs responded to VA's letter by stating that Michigan law does not require a VA health care provider to hold a Michigan State license in the discharge of official duties. The commenter also stated that telehealth at a VA medical facility would be permitted. However, if the health care provider is delivering care to the beneficiary's home, such provider would need a Michigan State license. As we have indicated in this proposed rule, VA would preempt State law as it applies to health care providers who practice telehealth while acting within the scope of their VA employment.

The Virginia Board of Medicine responded to VA's letter by stating that the Executive Committee of the Board met and supported the enhancement of access to care for veterans. The commenter stated that the proposed rule should benefit many beneficiaries that have little or no access to health care.

The comments provided above will be placed on *Regulations.gov* for public inspection during the comment period. Stakeholders will also have an opportunity to provide comments during the notice and comment period.

This proposed rule complies with Executive Order 13132 by (1) identifying where the exercise of State authority would directly conflict with the rule; (2) limiting preemption to these areas of conflict; (3) restricting preemption to the minimum level necessary to achieve the objectives of the statutes pursuant to which the rule is promulgated; (4) consulting with the external stakeholders listed in this rule; and (5) providing opportunity for all affected State and local officials to comment on this proposed rulemaking.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this proposed

rule, represents VA's implementation of its legal authority on this subject. Other than future amendments to this rule or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rule if possible. If not possible, such guidance is superseded by this rule.

Paperwork Reduction Act

This proposed 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 proposed 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 proposed rule directly affects only individuals who are VA employees and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563, and 13771

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.''

OMB has determined that it is a significant regulatory action under Executive Order 12866 given the policy implications. In addition, under Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs), this proposed rule is expected to be an E.O. 13771 deregulatory action, though VA is not able to quantify any cost savings associated with it. 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.''

Executive Order 12866 also directs agencies to ''include a comment period of not less than 60 days.'' Given the importance of telehealth in providing critical, and potentially lifesaving, access to health care for our beneficiaries, VA must act expeditiously, through this rulemaking, to ensure that it can expand its telehealth program. The primary barrier to the expansion of VA's telehealth program is that States' licensing boards have placed explicit restrictions on the use of telehealth in their States and have not made exceptions for VA providers, which ultimately inhibits VA providers from delivering VA health care to beneficiaries. Five of the States with the largest veteran populations, California, Texas, Florida, New York, and Ohio, have enacted laws and rules that restrict health care providers' ability to practice telehealth across State lines. See, 16 C.C.R. § 1815.5; Cal Bus & Prof Code §§ 2052, 2060; TX Occupation Code § 151.056; TX Admin Code, Title 22, § 172.12; FL Admin Code 64B8–9.0141; FL Admin Code 64B15–14.0081; NY Consolidated Law Service Public Health § 2805–u; OH Revised Code Annotated, Sec. 4731.296(C). As telehealth capabilities continue to expand, new State legislation and regulations across the country are enacted relating to the practice of telehealth. The possibility of sanctions to VA health care providers' State license, including fines and imprisonment for unauthorized practice of medicine has hindered VA's ability to expand its telehealth program. To protect VA health care providers from potential adverse actions by States, many VAMCs are currently not expanding some critical telehealth services if the health care service is provided outside Federal property (such as when the VA provider is delivering telehealth care from his or her home) or across State lines, or the care is delivered in a beneficiary's home. In addition many individual VA health care providers refuse to practice telehealth because of concerns over States taking action against their State license. This rule will supersede State restrictions on the practice of telehealth and allow VA health care providers to practice telehealth anywhere within a State (such as from the residence of the health care provider) and across State lines.

In sum, providing a 60 day public comment period instead of a 30 day public comment period would be against public interest and the health and safety of VA beneficiaries because any restriction from a State or State licensing board on practicing telehealth, within the State or across State lines, could impede beneficiaries' access to health care, which will ultimately impact the health of the beneficiary. For the above reasons, the Secretary issues this rule with a 30 day public comment period. VA will consider and address comments that are received within 30 days of the date this proposed rule is published in the **Federal Register**.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, requires 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 proposed rule will have 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; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; 64.039 CHAMPVA; 64.040 VHA Inpatient Medicine; 64.041 VHA Outpatient

Specialty Care; 64.042 VHA Inpatient Surgery; 64.043 VHA Mental Health Residential; 64.044 VHA Home Care; 64.045 VHA Outpatient Ancillary Services; 64.046 VHA Inpatient Psychiatry; 64.047 VHA Primary Care; 64.048 VHA Mental Health Clinics; 64.049 VHA Community Living Center; and 64.050 VHA Diagnostic Care.

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. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on July 28, 2017 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, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Dated: September 26, 2017.

Michael Shores,

Director, Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set forth in the preamble, we propose to amend 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 is amended by adding an entry for § 17.417 in numerical order to read in part as follows:

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

* * * * *

Section 17.417 also issued under 38 U.S.C. 1701 (note), 1709A, 1712A (note), 1722B, 7301, 7330A, 7401–7403; 7406 (note)).

■ 2. Revise the undesignated center heading immediately after § 17.412 to read as follows:

Authority of Health Care Providers to Practice in the Department

■ 3. Add § 17.417 to read as follows:

§ 17.417 Health care providers.

(a) *Definitions.* The following definitions apply to this section.

(1) *Beneficiary.* The term beneficiary means a veteran or any other individual receiving health care under title 38 of the United States Code.

(2) *Health care provider.* The term health care provider means an individual who:

(i) Is licensed, registered, or certified in a State to practice a health care specialty identified under 38 U.S.C. 7402(b);

(ii) Is appointed to an occupation in the Veterans Health Administration that is listed in or authorized under 38 U.S.C. 7401(1) or (3);

(iii) Maintains credentials (*e.g.,* a license, registration, or certification) in accordance with the requirements of his or her medical specialty as identified under 38 U.S.C. 7402(b); and

(iv) Is not a VA-contracted employee.

(3) *State.* The term State means a State as defined in 38 U.S.C. 101(20), or a political subdivision of such a State.

(4) *Telehealth.* The term telehealth means the use of electronic information or telecommunications technologies to support clinical health care, patient and professional health-related education, public health, and health administration.

(b) *Health care provider's practice.* (1) Health care providers may provide telehealth services, within their scope of practice and in accordance with privileges granted to them by the Department, irrespective of the State or location within a State where the health care provider or the beneficiary is physically located. Health care providers' practice is subject to the limitations imposed by the Controlled Substances Act, 21 U.S.C. 801, et seq., 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. This section only grants health care providers the ability to practice telehealth within the scope of their VA employment and does not otherwise grant health care providers additional authorities that go beyond the scope of the health care providers' State license, registration, or certification.

(2) Situations where a health care provider's VA practice of telehealth may be inconsistent with a State law or State license, registration, or certification requirements related to telehealth include when:

(i) The beneficiary and the health care provider are physically located in different States during the episode of care;

(ii) The beneficiary is receiving services in a State other than the health care provider's State of licensure, registration, or certification;

(iii) The health care provider is delivering services in a State other than the health care provider's State of licensure, registration, or certification;

(iv) The health care provider is delivering services either on or outside VA property;

(v) The beneficiary is receiving services while she or he is located either on or outside VA property;

(vi) The beneficiary has or has not previously been assessed, in person, by the health care provider; or

(vii) Other State requirements would prevent or impede the practice of health care providers delivering telehealth to VA beneficiaries.

(c) *Preemption of State law.* To achieve important Federal interests, including, but not limited to, the ability to provide the same complete medical and hospital service to beneficiaries in all States under 38 U.S.C. 7301, this section preempts conflicting State laws relating to the practice of health care providers when such health care providers are practicing telehealth within the scope of their VA employment. Any State law, rule, regulation or requirement pursuant to such law, is without any force or effect on, and State governments have no legal authority to enforce them in relation to, this section or decisions made by VA under this section.

[FR Doc. 2017–20951 Filed 9–29–17; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2016–0406; FRL–9967–77–Region 6]

Approval and Promulgation of Implementation Plans; New Mexico; Albuquerque and Bernalillo County; Regional Haze Progress Report State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is proposing to approve a revision to a State Implementation Plan (SIP) for the City of Albuquerque and Bernalillo County, New Mexico (the County) submitted by the Governor on June 24, 2016. The SIP revision addresses