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**BILLING CODE 8320-01**

## **DEPARTMENT OF VETERANS AFFAIRS**

### **38 CFR Part 1**

### **RIN 2900-AS73**

### **Expanding Access to State Prescription Drug Monitoring Programs**

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend its regulation that governs disclosure of information to and querying of State prescription drug monitoring programs (PDMPs). The rule would clarify certain statutory definitions, including the definition of delegate and licensed health care provider. In doing so, VA would eliminate confusion as to who VA would allow to query the PDMP and would better protect these individuals from any possible adverse action by a State, as long as they are acting within the scope of their VA employment or, if applicable, scope of their contract. The rule would also mandate that VA disclose the specified information to State PDMPs to the extent necessary to prevent misuse and diversion of prescription medicines. This proposed rule would promote safe and effective prescribing of controlled substances to covered individuals and patients who receive VA health care.

**DATES:** Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments through *www.regulations.gov* under RIN 2900-AS73. That website includes a plain-language summary of this

rulemaking. Instructions for accessing agency documents, submitting comments, and viewing the rulemaking docket, are available on *www.regulations.gov* under “FAQ.”

**FOR FURTHER INFORMATION CONTACT:** Friedhelm Sandbrink, MD, National Program Director for Pain Management, Opioid Safety and Prescription Drug Monitoring Programs, Veterans Health Administration, (202) 745-8145.

**SUPPLEMENTARY INFORMATION:**

**Background/Statutory Authority**

Broadly speaking, this rulemaking would codify in a single regulation and amend 38 Code of Federal Regulation (CFR) 1.515 to include: (1) the general rules and definitions applicable to all activities described in this section; (2) the rules on mandated disclosures of information to PDMPs required by 38 United States Code (U.S.C.) 5701(l) to the extent necessary to prevent misuse and diversion of prescription medicines; and (3) the rules governing querying of State PDMPs under 38 U.S.C. 1730B for covered patients to support the safe and effective prescribing of controlled substances.

These amendments to section 1.515 are driven by relatively recent laws. First, VA proposes to amend section 1.515 to accord with the amendment made to Subsection 5701(l) by section 914 of Title IX, of Public Law 114-198, July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016. Section 901 of Title IX establishes the short title for this Act to be the Jason Simcakoski Memorial and Promise Act and this short title will be used herein. Specifically, section 914 of the Jason Simcakoski Memorial and Promise Act changed the

permissive authority in 5701(l), added in December 2011, to require, under regulations to be prescribed, VA to disclose information about a covered individual to a State PDMP, including a program approved by the Secretary of Health and Human Services under section 399O of the Public Health Service Act (42 U.S.C. 280g-3) to the extent necessary to prevent misuse and diversion of prescription medicines. VA would amend current section 1.515 to reflect that disclosures are required, not just permissive, if they meet the terms of Subsection 5701(l). Mandated disclosures, like ones done under VA's prior discretionary authority, include information needed for PDMPs to document the prescriptions of controlled substances and include demographic information of the individual who was prescribed the controlled substance, information about the prescribed controlled substance, and prescriber information.

It is also worth noting that records of the identity, diagnosis, prognosis, or treatment of any patient or subject that are maintained in connection with the performance of any program or activity (including education, training, treatment, rehabilitation, or research) relating to drug abuse, alcoholism or alcohol abuse, infection with human immunodeficiency virus, or sickle cell anemia, which is carried out by or for VA, are protected as confidential by 38 U.S.C. 7332, except as provided in subsections (e) and (f) of that section, and (section 5701 to the contrary notwithstanding) such records may be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of section 7332. Section 7332(b)(2)(G) authorizes VA to disclose such records, without the consent of the respective patient or subject, to a State PDMP to the

extent necessary to prevent misuse and diversion of prescription medicines. While disclosure of information authorized pursuant to subsection 7332(b) is usually permissive, the mandatory nature of subsection 5701(l) requires the disclosure of information that falls within the purview of both subsections.

Section 2 of Public Law 115-86, enacted on November 21, 2017, also amended subsection 5701(l) by replacing the reference to a veteran or the dependent of a veteran with the term covered individual. It further added a definition of covered individual to mean an individual who is dispensed medication prescribed by an employee of the Department or by a non-Department provider authorized to prescribe such medication by the Department. This rulemaking would make these conforming amendments.

In addition to these two laws, section 134 of public law 115-182, June 6, 2018, the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018 (VA MISSION Act of 2018) added new section 1730B to title 38, United States Code. It deems, by operation of law, VA licensed health care providers and delegates to be authorized recipients or users (herein referred to as authorized users) for purposes of querying and receiving data from State-based PDMPs, or any individual State or regional prescription drug monitoring program, to support the safe and effective prescribing of controlled substances to covered patients.

Under section 1730B, the grant of authorized user status is irrespective of any State law, rule, or regulation that would otherwise restrict such access,

thereby reducing current impediments to VA access. Without this status, States could deny VA licensed health care providers and their delegates access to their PDMPs based upon individual state-imposed requirements, which may include the need for licensure in the State, even though VA health care providers are not restricted to practice only in the State of their licensure. Section 1730B surmounts this operational hurdle by deeming VA licensed health care providers and their delegates to be authorized users with a right of access, notwithstanding State imposed requirements that would otherwise apply. States are, in turn, obligated to grant access to VA licensed health care providers and their delegates.

Section 1730B also provides that no State may deny or revoke the license, registration, or certification of a licensed health care provider or delegate who otherwise meets that State's qualifications for holding the license, registration, or certification on the basis that the provider or delegate queried or received data or attempted to query or receive data for a covered patient from the national network of State-based PDMPs, or any individual State or regional PDMP, under this section.

Further, although VA licensed health care providers and delegates deemed to be authorized users for covered patients are not subject to an individual State's PDMP requirements insofar as the State requirements conflict with section 1730B, Federal standards still apply to VA's use of State's PDMPs. VA licensed health care providers and delegates would be required by subsection 1730B(a)(2)(A) to query PDMPs, including an individual State or

regional prescription drug monitoring program, in accordance with applicable VA regulations and policies. This is in line with VA's previously implemented regulation, 38 CFR 17.419(b)(ii), which states that if a State law or license, registration, certification, or other requirement prevents or unduly interferes with a health care professional's practice within the scope of their VA employment, the health care professional is required to abide by their Federal duties even when a State law, registration, certification, or other requirement conflicts or unduly interferes with such standard.

Subsection 1730B(a)(2)(A) also serves as a check on potential misuse or abuse by providers or delegates of State PDMPs, as VA is only authorized, by 38 CFR 17.38(b), to provide care that is in accord with generally accepted standards of medical practice and needed to promote, preserve, or restore health, and VHA regulations and policies align with these requirements. Therefore, licensed health care practitioners and their delegates could only rely on their authorized user status under section 1730B to check PDMPs when consistent with the standards of section 17.38(b).

Lastly, although section 1730B(b)(2) excludes individuals receiving palliative care or enrolled in hospice care from the definition of covered patients, this authority does not prevent VA licensed health care providers and delegates from accessing State PDMPs for such patients, so long as States allow VA licensed health care providers and delegates access. VA licensed health care providers or delegates would continue to perform this clinical activity for this population, when reasonably possible, as they have previous to the enactment of

1730B on VA's general treatment authority to provide necessary medical care to veterans enrolled in VA's health care system (38 U.S.C. 1710, 1705).

## **Section 1.515**

### *Short Title*

To reflect the inclusion of additional authorities and consequent expanded scope, the short title of 38 CFR 1.515 would be amended to read: Disclosure of Information to and Querying of State Prescription Drug Monitoring Programs.

### *Section 1.515(a) Definitions*

The proposed rulemaking would renumber current paragraph (b) as new paragraph (a) and provide the definitions applicable to proposed section 1.515.

VA would define the term controlled substance to retain the same definition as found in current section 1.515(b), with no edits.

VA proposes to use the term covered individual to apply to disclosures of information to PDMPs. Covered individual would be assigned the same definition as in 38 U.S.C. 5701(l)(2), upon which the term's usage in this proposed rulemaking is based, as discussed above in the Background/Statutory Authority section.

Covered patient would be clarified with respect to both prongs of its definition in section 1730B. Subsection 1730(b)(1) partially defines a covered patient as one who receives a prescription for a controlled substance. VA proposes to broadly interpret the phrase receives a prescription because, in clinical practice, the prescribing of a medication may refer to the ordering of a medication or to a recommendation for the use of a medication. Before a

licensed health care provider orders or recommends the use of any medication, the provider is required by applicable clinical standards of care to determine, based on the exercise of clinical judgment, that the subject medication would not be unsafe or contraindicated for the patient or duplicative of other medications that have been prescribed for the patient outside the VA health care system. Data needed to inform these decisions is particularly important when clinically evaluating the need or dosage of any controlled substance. VA, therefore, proposes to define covered patient to mean a patient who is prescribed, is dispensed, or receives a prescription for a controlled substance, or is being considered for a prescription of a controlled substance when their care satisfies the additional restrictions in 38 U.S.C. 1730B(b)(2). VA does not believe that Congress intended an interpretation in which a patient would not be covered until after a licensed health care provider had already decided to initiate a prescription and such prescription had already been dispensed to the patient, as that would defeat the statute's purpose of facilitating safe and effective prescribing of controlled substances. See, for example, 164 Cong. Rec. H4014-01 (May 16, 2018) (Rep. Dunn stating that "my legislative initiative increases transparency in opioid prescribing at the VA by allowing doctors to identify high users of controlled drugs who are therefore at risk for addiction. My language in the VA MISSION Act instructs the VA to do what most private doctors already do: connect to the prescription drug monitoring databases nationwide so that no one slips through the cracks.")

Section 1730B(c)(2) defines the term delegate to mean a person or automated system accessing the national network of State-based prescription monitoring programs, or any individual State or regional prescription drug monitoring program, at the direction or under the supervision of a licensed health care provider. VA sometimes relies on licensed independent prescribers to deliver care to our patients pursuant to contractual and other arrangements. Because these individuals are not VA employees, they do not meet the definition of licensed health care providers under section 1730B(c)(3). However, they act at the direction of licensed health care providers, such as the VA medical facility chief of staff. Veterans should benefit from receiving the same high standard of care regardless if delivered by a VA employee or these contracted providers, who practice health care throughout our system. This requires their access to all vital data and systems, including PDMPs. VA provides specific care through contract that VA does not include in the definition of contract providers because such care is neither at the direction nor under the supervision of a VA licensed health care provider in the same manner as the individuals discussed above. Examples include, but are not limited to, 38 U.S.C. 1703 (Veterans Community Care Program), 1720J, and Pub. Law 118-42 Div. A, Sec. 234 (In vitro fertilization and other fertility counseling and treatment for covered veterans and their spouse).

VA proposes to clarify the statutory definition of the term delegate to mean any of the following, when acting at the direction or under the supervision of a licensed VA health care provider: a VA clinical associate; a VA administrative

associate who is involved in technical troubleshooting, quality control, or quality improvement activities; scientific investigators who are investigating issues to support the safe and effective prescribing of controlled substances, and to support the assessment for safe and effective care delivery to covered patients; an individual who conducts research with respect to administering, using in teaching, or chemical analysis a controlled substance in the course of their research as a VA employee; an individual who is contracted by VA to provide health care, and is practicing or researching under their contractual agreement with VA (other than individuals operating pursuant to VA's authority in 38 U.S.C. 1703); or a VA automated system accessing the national network of State-based prescription monitoring programs, or any individual State or regional prescription drug monitoring program. This approach would allow contractors who are licensed independent health care providers to access PDMPs at the direction of a VA licensed health care provider, such as the VA medical facility chief of staff, and to conduct queries in the same manner as their equivalent VA employee counterparts.

VA would further clarify that the term clinical associate includes, but is not limited to, registered nurses, licensed practical nurses, health care technicians, licensed social workers, researchers, and psychologists. VA would also clarify that the term administrative associate includes, but is not limited to, administrative officers, program analysts, and technical support specialists. Lastly, VA would clarify that an automated system accessing a PDMP includes, but is not limited to, automatic queries triggered by the system (such as

scheduled appointments, check-ins to emergency rooms) and queries to generate a report on a cohort of covered patients who receive controlled substances (including, but not limited to, patients who are enrolled into a specific primary care panel or other clinical care teams or clinics). VA believes that these clarifications would eliminate confusion as to who VA considers a delegate and thus allows for better protection of the associate from any possible adverse action by a State, provided the delegate is acting within the scope of their VA employment or, if applicable, the scope of their contract.

Section 1730B(c)(3) defines the term licensed health care provider to mean a health care provider employed by VA who is licensed, certified, or registered within any State to fill or prescribe medications within the scope of his or her practice as a VA employee. VA would clarify in proposed paragraph (a) that a licensed health care provider means (a) a physician, dentist, nurse practitioner, physician assistant, or pharmacist employed by VA; or (b) another person licensed, registered, certified, or otherwise permitted by the United States or the jurisdiction in which the individual practices to prescribe or fill a controlled substance in the course of their practice as a VA employee.

Prescription Drug Monitoring Program in proposed paragraph (a) would mean a State or regional prescription drug monitoring program, including a program approved by the Secretary of Health and Human Services under section 399O of the Public Health Service Act (42 U.S.C. 280g-3), or an interconnected nation-wide system that facilitates the transfer of State prescription drug monitoring program data across State lines. This definition is consistent with the

inclusive authority in section 1730B(a) that extends the protection and requirements of that subsection to licensed health care providers and delegates accessing State or regional PDMPs. This definition is also inclusive of the current definition of the term PDMP in section 1.515(b), which is based upon the statutory authority set forth in 38 U.S.C. 5701(l)(1) and 7332(b)(2)(G) to disclose information to such PDMPs. While section 5701(l)(1), section 7332(b)(2)(G), and the current definition of PDMP in section 1.515(b) explicitly mention State controlled substance monitoring programs, their references to section 399O of the Public Health Service Act (42 U.S.C. 280g-3), which specifically provides for support of States and localities in establishing, implementing, maintaining, and improving PDMPs, reasonably implies that local (regional) PDMPs are also intended to be included in the statutory authority to disclose information to State PDMPs. This interpretation is also supported by the definition of the term State in section 1730B(c)(5), which specifically includes a political subdivision of a State. It would not make sense from either a policy or practical standpoint that Congress intended for VA to request and receive information from regional PDMPs, but not to share such information with those same PDMPs. Similarly, whereas statutory authority exists to request and receive information from, and to disclose information to, State and regional authorities individually, it logically follows that such authority would also exist to disclose information to a national network made up of those programs.

*Section 1.515(b) Disclosure to PDMPs*

The proposed rulemaking would combine current paragraphs (a) and (c) and renumber them as new proposed paragraph (b). It would also replace in the new proposed subsection (b) the permissive nature of disclosures to State PDMPs with a requirement (replacing may with will) that VA disclose the specified information to the extent necessary to prevent misuse and diversion of prescription medicines, reflecting the statutory amendments to subsection 5701(l)(1) described in the Background/Statutory Authority section above.

*Section 1.515(c) Access to PDMPs*

Proposed paragraph (c) would incorporate the authority granted by and the requirements contained in section 1730B. Proposed paragraph (c)(1) would restate 38 U.S.C. 1730B(a)(1) in declaring that any licensed health care provider or delegate is considered an authorized recipient or user for the purpose of querying and receiving data from PDMPs to support the safe and effective prescribing of controlled substances to covered patients.

Proposed paragraph (c)(2) would clarify what VA means by querying and receiving data. VA would state that querying and receiving data includes, but is not limited to, viewing, accessing, processing, and storing the data according to VA's need in a format that is most appropriate to providing the highest quality clinical care. Different States have implemented different PDMP protocols for their usual transactions with non-Federal entities, and VA wants to be inclusive of all accessing methods. It is worth noting that VA does not manipulate or change the data in the PDMP database. VA would access the PDMP databases to obtain the information on the covered patient. Currently, VA receives a report with the

PDMP query results and then documents the relevant data into its own records per applicable Federal law and regulations.

Proposed paragraph (c)(3) would state how a licensed health care provider or delegate would access PDMPs and how the data contained within PDMPs would be used by VA. VA wants to ensure that VA is as inclusive as possible with respect to accessing PDMPs for clinical care. Some methods of accessing PDMPs are more automated and technologically driven, as opposed to a clinician manually performing a query. As a result, VA wants to ensure that these options are within the scope of VA's regulations. VA would state that a licensed health care provider or delegate can access PDMPs through manual access to the individual PDMPs or through integrated automated data processing systems, which include, but are not limited to, health information exchanges, electronic health records systems, and e-prescribing. Health information exchanges allow health care providers a secure and sharable access to a patient's health care information electronically. Electronic health records are a real-time digital version of a patient's paper chart that make information available instantly and securely to authorized users. E-prescribing allows a health care provider the ability to electronically generate and send a prescription order directly to a pharmacy. VA would also state that VA information technology systems may have interoperability with other data systems and integrated automated queries. These data systems can be incorporated into clinical workflow to improve the use of such data and analytics by licensed health care providers and delegates. VA would clarify that interoperability means: (a) the

integration of PDMP data within electronic health records and health information technology infrastructure; or (b) linking of a PDMP to other data systems within the State, including, but not limited to, the State's Medicare and Medicaid program, workers' compensation programs, medical examiners or coroners, and any other relevant State, national, or regional database. VA would also clarify that clinical workflow includes the physical and mental tasks that are performed in the clinical setting to deliver care to patients. Improvements to workflow can be achieved through the integration of automated queries for PDMPs' data and analytics into health information technologies such as electronic health record systems, health information exchanges, or pharmacy dispensing software systems.

VA understands that certain States generally do not allow delegates to access PDMPs in the same manner as licensed health care providers when such access is across State lines; however, section 1730B(a)(2)(B) expressly authorizes VA delegates to access PDMPs in the same manner as licensed health care providers. For this reason, VA would state in proposed paragraph (c)(4) that delegates would receive the same access to shared data to the same extent as licensed health care providers, including when PDMP data sharing is across State lines. This paragraph would ensure the protection granted to a delegate by section 1730B from any adverse action by a State when such delegate is accessing the PDMP while acting within the scope of the delegate's VA employment or contractual agreement with VA, if applicable.

*Section 1.515(d) Preemption of State law*

Proposed paragraph (d) would expressly state the intended preemptive effect of section 1.515, to ensure that conflicting State and local laws, rules, regulations, and requirements related to VA licensed health care providers or delegates who query or receive data from PDMPs would have no force or effect on such providers or delegates. 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). This language has been similarly used in other VA regulations asserting Federal supremacy where there is a conflict between State and Federal law. See sections 17.417 and 17.419. VA would state that notwithstanding any general or specific provision of law, rule, or regulation of a State, no State may restrict the querying process or limit the data contained within the query for VA health care providers or delegates acting in accordance with this section. VA would also state that no State will deny or revoke the license, registration, or certification of a licensed health care provider or delegate who otherwise meets that State's qualifications for holding the license, registration, or certification on the basis that the licensed health care provider or delegate queried or received data, or attempted to query or receive data, from the national network of State-based prescription drug monitoring programs, or from any individual State or regional prescription drug monitoring program, under this section. The Supremacy Clause of the U.S. Constitution bars States and State officials from penalizing government personnel for performing their Federal functions, whether through State criminal prosecution, license revocation proceedings, or civil litigation unless authorized

by Federal law. All suspected improper usage of PDMPs should be reported to VA for investigation and appropriate action. This paragraph is in alignment with the preemptive intent of section 1730B.

### **Executive Order 13132, Federalism**

Executive Order 13132 provides the requirements for preemption of State law when it is expressly stated in rulemaking. While 38 U.S.C. 1730B expressly preempts State law, VA's regulations based on section 1730B must be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to the regulations that are promulgated. In this rulemaking, VA licensed health care providers and their delegates may access State PDMPs irrespective of any State law, rule, or regulation that would otherwise restrict such access only to the extent such State laws interfere with the ability of VA health care providers and delegates to access the State PDMPs. Therefore, VA believes that the rulemaking is restricted to the minimum level necessary to achieve the objectives of the Federal statute.

The Executive Order also requires an agency that is publishing a regulation that preempts State law to follow certain procedures. These procedures include: that the agency consult with, to the extent practicable, the appropriate State and local officials in an effort to avoid conflicts between State law and federally protected interests; and that the agency provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.

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 State PDMP administrators on September 14, 2020. The letter generally advised the States of VA's proposed approach to implementing 38 U.S.C. 1730B, drawing special attention to: allowing for an exception to the restriction on the definition of covered patients concerning patients receiving palliative care or enrolled in hospice care when clinically appropriate and necessary to ensure the safety of the patient or to prevent unlawful diversion (an approach that VA has now reconsidered in favor of pursuing a legislative fix); including a broad interpretation of receives a prescription within the definition of covered patients; and including local, municipal, and regional PDMPs within the definition of State PDMPs. VA received two comments in response to this letter.

The Commonwealth of Virginia Department of Health Professions responded to VA's letter on September 29, 2020. The commenter responded to the four key elements in VA's letter. First, the commenter stated that Virginia's PDMP does not restrict the use of PDMP by health care providers treating or dispensing to patients in palliative care or enrolled in hospice. The commenter added that they believe that access to PDMP information for all patient types is essential so health care providers can make the most informed clinical treatment/dispensing decision possible for their patients. Virginia's PDMP supports allowing for an exception to the restriction on the definition of covered patients.

Second, the commenter stated that Virginia's PDMP does not restrict the use of the PDMP by health care providers who are not prescribing a controlled substance. The commenter cited the State laws pertaining to the requirements of the prescriber and the requirements for the dispenser and supported the allowing for a broad interpretation of receives a prescription within the definition of covered patient.

Third, the commenter indicated that Virginia's PDMP is aware that Missouri does not have a statewide PDMP, but a cooperative collection of cities and counties has created a Prescription Monitoring Program (PMP), which covers around 80 percent of patients. VA notes that Missouri transitioned to a Statewide PDMP in December 2023. The commenter added that Virginia's PDMP supports including local/municipal/regional PDMPs within the definition of state PDMPs.

Lastly, the commenter stated that Virginia's PDMP has the ability to cover costs associated with VHA facilities connecting to Virginia's PDMP and granting access to authorized health care providers. Also, Virginia's PMP vendor, Appriss Health, (now Bamboo Health) reports there is no additional cost to the State for this implementation.

VA also received a letter from the State of Hawaii Department of Public Safety on October 13, 2020. The commenter was in support of increasing access and usage of Hawaii's PDMP information because it is an effective tool towards addressing the nationwide opioid epidemic. However, the commenter had two concerns. The commenter's first concern was that although they appreciate the

importance of protecting the privacy of the prescription information contained in the Hawaii PDMP, any effort to mandate that Hawaii's PDMP information be shared with VA should include safeguards to protect confidential medical information and allow for data to be shared only for VA's official purposes. The commenter stressed that Hawaii's confidential PDMP information must not be shared by VA with other entities.

VA agrees with the commenter in that the confidential medical information contained in the PDMP needs to be safeguarded. Federal law and regulations require confidentiality and security of any such records. The Privacy Act (PA) (5 U.S.C. 552a), 38 U.S.C. 5701, and the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules (45 CFR Part 160 and subparts A, C, and E of Part 164), are applicable. Additionally, 38 U.S.C. 5705 and 7332 would protect information that falls within their purview. VA will continue to abide by these Federal laws and regulations to continue to protect the privacy of veterans' medical information. VA will only share such information as authorized by those laws and regulations.

The commenter's second concern was regarding the potential costs that the State Narcotics Enforcement Division (NED) may incur to make the required connections between the Hawaii PDMP and VA, especially given the drastic budget crisis facing Hawaii's Department of Public Safety. The commenter added that VA's letter does not describe what the potential costs might be and that VA's independent efforts may create an unfunded mandate that the State NED may

incur as a one-time, or worse yet, an ongoing, recurring cost that cannot be absorbed by their agency.

VA agrees that States could incur IT development and connection costs associated with connecting to VA if they were not previously using PMP InterConnect. However, according to Appriss Health, Hawaii is currently connected to the system known as PMP InterConnect, and there are no costs to the State so long as it maintains connectivity to PMP InterConnect. PMP InterConnect is provided by the National Association of Boards of Pharmacy/Appriss Health at no cost to the State. Therefore, it is anticipated that Hawaii will incur no additional cost, as it is already a member of the required network.

In addition, VA met with 82 of the State PDMP administrators and the Technical Training and Assistance Center to address both outgoing PDMP data from VA to the States and the VA new query access. Many of the questions presented at the meeting were regarding VA delegate access to the PDMP. Because VA received so many questions regarding delegates and the related definitions, VA has provided a comprehensive definition in this rulemaking that would clearly state who VA would consider a delegate for purposes of querying the PDMP.

Another question posed was whether the VA provider had to register with the PDMP of the State where they are practicing. VA notes that VHA Directive 1306 requires VA users to register with the PDMP of the State in which their VA medical facility (or more specifically where their assigned Veterans Health

Information Systems and Technology Architecture (VistA) division) is located and to remain active within that State.

### **Executive Orders 12866, 13563, and 14192**

VA examined the impact of this rulemaking as required by Executive Orders 12866 (Sept. 30, 1993) and 13563 (Jan. 18, 2011), which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. The Office of Information and Regulatory Affairs has determined that this rulemaking is not a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. This proposed rule is expected to be an Executive Order 14192 deregulatory action.

*Economic Impact:* The proposed amendments clarify statutory definitions and ensure VA health care providers and delegates can query PDMPs nationwide regardless of State restrictions. The proposed amendments also require disclosure of specified information to PDMPs to prevent misuse and diversion of controlled substances. The rule imposes no new costs or transfers. Qualitative benefits resulting from this rule include reductions in administrative burden through automating PDMP queries and enhancements in clinical decision-making for veteran care.

### **Regulatory Flexibility Act**

The Secretary hereby certifies that this proposed rule would 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. The provisions

associated with this rulemaking are not processed by any other entities outside of VA. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking would be exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

### **Unfunded Mandates**

This proposed rule would not 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.

### **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).

### **List of Subjects in 38 CFR Part 1**

Administrative practice and procedure, Archives and records, Cemeteries, Claims, Courts, Crime, Flags, Freedom of information, Government contracts, Government employees, Government property, Infants and children, Inventions and patents, Parking Penalties, Privacy Reporting and recordkeeping requirements, Seals and insignia, Security measures, Wages.

### **SIGNING AUTHORITY**

Douglas A. Collins, Secretary of Veterans Affairs, approved this document on April 21, 2026, 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.

**Gabriela DeCuir,**

*Alternate Federal Register Liaison Officer, Department of Veterans Affairs.*

For the reasons set forth in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 1 as set forth below:

## PART 1 – GENERAL PROVISIONS

1. The authority citation for part 1 continues to read as follows:

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

\* \* \* \* \*

Section 1.515 is also issued under 38 U.S.C. 1730B, 5701, and 7332.

\* \* \* \* \*

### **Section 1.515 [Amended]**

2. Revise and republish section 1.515.

### **Section 1.515 Disclosure of Information to and Querying of State**

#### **Prescription Drug Monitoring Programs.**

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

*Controlled substance* means any substance identified in 21 CFR part 1308 as a schedule II, III, IV, or V controlled substance.

*Covered individual* has the same meaning as defined in 38 U.S.C. 5701(l)(2).

*Covered patient* includes a patient who is prescribed, is dispensed, or receives a prescription for a controlled substance, or is being considered for a prescription of a controlled substance by a licensed health care provider, when their care satisfies the additional restrictions in 38 U.S.C. 1730B(b)(2).

*Delegate* means any of the following, when acting at the direction or under the supervision of a licensed VA health care provider:

(a) A VA clinical associate (including, but not limited to, registered nurses, licensed practical nurses, health care technicians, licensed social workers, and psychologists);

(b) A VA administrative associate (including, but not limited to, administrative officers, program analysts, and technical support specialists);

(c) Scientific investigators who are investigating issues to support the safe and effective prescribing of controlled substances, and to support the assessment for safe and effective care delivery to covered patients (unless the investigator is a licensed health care provider, as defined in this regulation);

(d) An individual who conducts research with respect to administering, using in teaching, or chemical analysis a controlled substance in the course of their research as a VA employee (unless the researcher is a licensed health care provider, as defined in this regulation);

(e) An individual who is contracted by VA to provide health care and is practicing or researching under their contractual agreement with VA. This provision does not include individuals with whom VA contracts directly or indirectly pursuant to 38 U.S.C. 1703; or

(f) A VA automated system accessing a PDMP, including, but not limited to, automatic queries triggered by the system (e.g., scheduled appointments, check-ins to emergency rooms) and queries to generate a report on a cohort of covered patients who receive controlled substances (including, but not limited to, patients who are enrolled in a specific primary care panel or other clinical care teams or clinics).

*Licensed health care provider* means:

(a) A physician, dentist, nurse practitioner, physician assistant, or pharmacist employed by VA; or

(b) Another person licensed, registered, certified, or otherwise permitted by the United States or the jurisdiction in which the individual practices to prescribe or fill a controlled substance in the course of their practice as a VA employee.

*Prescription drug monitoring program (PDMP)* means a State or regional prescription drug monitoring program, including a program approved by the Secretary of Health and Human Services under section 399O of the Public Health Service Act (42 U.S.C. 280g-3), or an interconnected nation-wide system that facilitates the transfer of State prescription drug monitoring program data across State lines.

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

(b) *Disclosure to PDMPs.* Information covered by section 1.500 through 1.527 of this part will be disclosed to PDMPs, to the extent necessary to prevent misuse and diversion of prescription medicines, subject to the limitations set forth in this paragraph (b). Such information is limited to the following concerning the prescription of controlled substances:

(1) Demographic information of a covered individual. Examples include name, address, and telephone number.

(2) Information about the dispensed controlled substances. Examples include the identification of the substance by a national drug code number, quantity dispensed, number of refills ordered, whether the substances were dispensed as a refill of a prescription or as a first-time request, and date of origin of the prescription.

(3) Prescriber information. Examples include the prescriber's United States Drug Enforcement Administration-issued identification number authorizing the individual to prescribe controlled substances and United States Department of Health and Human Services-issued National Provider Identifier number.

(c) *Access to PDMPs.* (1) Any licensed health care provider or delegate is considered an authorized recipient or user for the purpose of querying and receiving data from PDMPs to support the safe and effective prescribing of controlled substances to covered patients.

(2) Querying and receiving data includes, but is not limited to, viewing, accessing, processing, and storing the data according to VA's need in a format that is most appropriate to providing the highest quality clinical care.

(3) A licensed health care provider or delegate can access PDMPs through manual access to the individual PDMPs or through integrated, potentially automated, information technology solutions. These include, but are not limited to, health information exchanges, electronic health records systems, and e-prescribing. VA information technology systems may have interoperability with other data systems and integrated automated queries. These data systems can

be incorporated into clinical workflow to improve the use of such data and analytics by licensed health care providers and delegates.

(i) Interoperability means:

(A) The integration of PDMP data within electronic health records and health information technology infrastructure; or

(B) Linking of a PDMP to other data systems within the State, including, but not limited to, the State's Medicare and Medicaid program, workers' compensation programs, medical examiners or coroners, and any other relevant State, national, or regional database.

(ii) Clinical workflow includes the physical and mental tasks that are performed in the clinical setting to deliver care to patients. Improvements to workflow can be achieved through the integration of automated queries for PDMPs' data and analytics into health information technologies such as electronic health record systems, health information exchanges, or pharmacy dispensing software systems.

(4) Delegates will receive the same access to shared data as licensed health care providers, including when PDMP data sharing is across State lines.

(d) *Preemption of State law.* To achieve important Federal interests, including, but not limited to, the ability to query or receive data from PDMPs, this section, as provided in 38 U.S.C. 1730B, preempts conflicting State laws relating to health care providers or delegates when they are querying or receiving data from PDMPs. Notwithstanding any general or specific provision of law, rule, or regulation of a State, no State may restrict the querying process or limit the data

contained within the query for VA health care providers or delegates acting in accordance with this section. 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. No State will deny or revoke the license, registration, or certification of a licensed health care provider or delegate who otherwise meets that State's qualifications for holding the license, registration, or certification on the basis that the licensed health care provider or delegate queried or received data, or attempted to query or receive data, from the national network of State-based prescription drug monitoring programs, or any individual State or regional prescription drug monitoring program, under this section.

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