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DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 1

RIN 2900-AO45

Disclosures to Participate in State Prescription Drug Monitoring Programs

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its regulations concerning the sharing of certain patient information in order to implement VA's authority to participate in State Prescription Drug Monitoring Programs (PDMPs). Participation in PDMPs will allow the VA patient population to benefit from the reduction in negative health outcomes.

DATES: Effective Date: This rule is effective on [Insert date of publication in the FEDERAL REGISTER].

Comment Date: Comments must be received on or before [Insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted by e-mail through <http://www.regulations.gov>; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue, NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to "RIN 2900-AO45, Disclosures to

Participate in State Drug Monitoring Programs.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, 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 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: Stephania Griffin, Director, Information Access and Privacy Office (10P2C1), Veterans Health Administration, 810 Vermont Avenue, NW., Washington, DC 20420, 704-245-2492. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On December 23, 2011, the President signed into law the Consolidated Appropriations Act, 2012 (the Act), Public Law 112-74. Section 230 of the Act amended 38 U.S.C. 5701, which governs the confidential nature of VA claims and information of present and former members of the Armed Forces and their dependents in VA’s possession, by adding a new subsection (l), which reads as follows:

Under regulations the Secretary [of Veterans Affairs] shall prescribe, the Secretary may disclose information about a veteran or the dependent of a veteran to a State controlled substance 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), to the extent necessary to prevent misuse and diversion of prescription medicines.

Section 230 of the Act similarly amended 38 U.S.C. 7332, which governs the confidentiality of VA records relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia, by adding a

subparagraph (G) to subsection (b)(2), which sets forth exceptions to section 7332's privacy protections. Subparagraph (G) authorizes VA to release this protected information:

[t]o a State controlled substance 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), to the extent necessary to prevent misuse and diversion of prescription medicines.

State controlled substance monitoring programs, as named in the Act, are commonly referred to as State prescription drug monitoring programs or PDMPs. States implement and maintain the PDMP databases on controlled substances prescribed and filled by pharmacies within their borders to achieve public health and law enforcement objectives.

Sections 5701 and 7332 are VA statutes that afford privacy protections to the information of veterans and their dependents, as well as active-duty servicemembers under section 5701, and to VA patients with certain medical conditions. The Act authorizes new exceptions to the limitations on disclosures in sections 5701 and 7332 that permit VA to disclose information to PDMPs on veterans and their dependents about prescriptions of controlled substances.

The two statutory exceptions created in the Act do not by themselves authorize VA to disclose information to PDMPs. In addition to sections 5701 and 7332, VA's authority to disclose information to PDMPs is subject to the Privacy Act of 1974 (5 U.S.C. 552a) and the Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule, 45 CFR Parts 160 and 164). Before releasing information to PDMPs, under the Privacy Act, VA must publish a Federal Register notice establishing a routine use for the relevant system of records from which the

information will be disclosed. VA will publish the required notice separate from this rulemaking. VA's authority to disclose the information to PDMPs under the HIPAA Privacy Rule is contained in 45 CFR 164.512(b), which allows disclosures to an agency or authority responsible for public health matters as part of its official mandate. The combination of these four authorities allows VA to disclose information pertaining to the prescriptions for controlled substances to veterans and their dependents.

VA will participate in PDMPs by both disclosing and obtaining information from States about VA patients. By contributing to and reviewing PDMP databases, VA health care providers will be able to identify at-risk individuals and trends that will assist in the prevention of the accidental or intentional misuse of prescribed medication by veterans and their dependents. By both disclosing information to and acquiring information from PDMPs, VA would improve the public health benefits already realized by PDMPs and obtain vital information that will reduce the number of emergency room visits and overdoses attributable to prescription drug misuse and identify patients at risk of negative health outcomes associated with the misuse of prescribed controlled substances. Episodes of care associated with the abuse or misuse of controlled substances can be costly and VA anticipates a significant aggregate benefit by providing data to States with PDMPs. Controlled substances, when used appropriately, have proven to significantly improve the overall health of patients. However, these substances present serious health risks when they are not used strictly in accordance with prescribed instructions or when used along with other contraindicated prescription drugs. Although patients have the right to control their health information, and respecting this right is at the heart of professional ethics and patient-centered care,

overriding the confidentiality of certain health information can be ethically justified to protect the health and safety of the public. Sharing the necessary information to participate in PDMPs supports this ethical justification.

Although the Act provides authority in 38 U.S.C. 5701 and 7332 for VA to disclose information to PDMPs, it requires VA to promulgate regulations to implement the authority only under section 5701. However, we are promulgating regulations to implement the authority under both sections 5701 and 7332 for clarity. VA implements sections 5701 and 7332 through separate bodies of regulations dedicated to each statute.

The body of regulations for section 5701 is published in part 1 under the undesignated center heading “Release of Information From Department of Veterans Affairs Claimant Records.” We are establishing a new section, 38 CFR 1.515, under the heading “Disclosure of information to participate in state prescription drug monitoring programs.” We note that current § 1.515 is titled “To commanding officers of State soldiers’ homes.” This rulemaking reassigns that section to reserved § 1.523. This new § 1.515 implements the authority created under 38 U.S.C. 5701(l) and explains the extent to which VA will disclose information to PDMPs. We are adding a reference to new § 1.515 in the regulation that implements the authority created under 38 U.S.C. 7332(b)(2). We are adding an authority citation to the end of § 1.515 that reflects the statutory authorities relied upon in this rulemaking. These authorities are discussed throughout the preamble.

The body of regulations for section 7332 is published in part 1 under the undesignated center heading “Release of Information from Department of Veterans

Affairs (VA) Records Relating to Drug Abuse, Alcoholism or Alcohol Abuse, Infection with the Human Immunodeficiency Virus (HIV), or Sickle Cell Anemia.” Under that heading, this rulemaking creates a new § 1.483 under the undesignated center subheading “Disclosures Without Patient Consent.” The new section cross-references new § 1.515.

This rulemaking creates new § 1.515 to implement VA’s authority to disclose information contained in a claimant’s records to PDMPs and details the information that will be provided to PDMPs under all statutory and regulatory authorities. In new § 1.515(b), we define a “[c]ontrolled substance” as a substance identified by United States Drug Enforcement Administration (DEA) regulations (21 CFR part 1308) as a Schedule II, III, IV, or V controlled substance. We note that the Act only authorizes the specific disclosure of information pertaining to what is commonly understood within the medical profession to be controlled substances. Although some States occasionally expand their definition of which substances may be considered controlled substances, the DEA regulatory list is the most universally accepted list of such substances. DEA is the recognized authority for establishing the list of controlled substances and updates the list as necessary. VA will rely on DEA’s expertise in choosing to use these schedules to define the controlled substances that we will report to PDMPs.

We specifically exclude Schedule I substances under 21 CFR part 1308 because these substances are not dispensed by VA due to their lack of medical value.

Therefore, VA has no data to share regarding these substances.

In paragraph (b), we define a PDMP as “a State controlled substance 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).” This definition encompasses all existing PDMPs and will allow for VA to share information with any States that develop PDMPs in the future. This definition is derived directly from the Act.

In paragraph (c), we state that VA may disclose to PDMPs information that falls under specified categories of information.

Paragraphs (c)(1) through (3) describe the three categories of information that will be disclosed to PDMPs under the regulation and provide examples of these categories of information. The Act does not require, nor can VA at this time provide, a definitive list of the individual data elements within each category that will be shared with PDMPs by VA due to variances in the requirements of PDMPs. Based on VA’s review of PDMP requirements, we believe that the information VA must provide to participate with the PDMPs will fall into one of these general categories of information, and the examples provided represent the specific information that will be shared with the majority of PDMPs.

The examples provided under paragraphs (c)(1) through (c)(3) are derived from section 399O of the Public Health Service Act (42 U.S.C. 280g-3). Under section 280g-3, the U.S. Department of Health and Human Services (HHS) authorizes grants to States that operate PDMPs according to the requirements set forth in the statute. Although the grant program is voluntary and the statute allows States some flexibility to require reporting of information not in the statute, VA will use these examples as a baseline for reporting data to PDMPs. This list of reporting elements was created by Congress when it established the HHS grant program. We believe this indicates that

Congress finds these elements to be the most effective in meeting the public health goals of PDMPs. However, as stated, the elements within each category of information in § 1.515(c) are examples. To better collaborate with States, VA requires flexibility to identify additional reporting requirements and to determine whether VA is capable of providing such information. VA may provide an element of information that falls within one of the categories even if it is not named as an example; however, without further rulemaking, VA will not provide information to PDMPs that does not fall within one of the three listed categories of information.

Paragraph (c)(1) authorizes the disclosure of demographic information “of veterans and dependents of veterans who are prescribed a controlled substance.” The Act amends 38 U.S.C. 5701 and 7332, which only apply to certain patient, veteran, or veteran dependent information maintained by VA. VA will also disclose any additional information necessary to meaningfully participate in PDMPs, to the extent that such disclosures are authorized under the Privacy Act of 1974 and HIPAA Privacy Rule requirements, as well as the amendments to sections 5701 and 7332.

Paragraph (c)(2) authorizes sharing information about the prescribed controlled substance, including the substance’s national drug code number, quantity dispensed, number of refills ordered, whether the prescription was a refill or for first-time use, and the date of origin of the prescription. Such information is critical to the proper use of PDMP databases to prevent misuse and protect the health of patients. Merely reporting a prescription of a particular substance will not provide the context necessary to determine if the prescription is appropriate in relation to the patient’s condition and other prescriptions.

Paragraph (c)(3) explains that certain prescriber information will be shared with PDMPs. Such information identifies where an individual is receiving care and the identity of the provider, which may facilitate communication between providers when necessary to prevent negative health outcomes. Such information is also required by PDMPs in order to regulate the quality of contributions to their databases and prevent fraudulent or erroneous reporting.

As a technical matter, we note that one section previously reserved by VA in the CFR is no longer reserved. Title 38 of the CFR currently contains a specific reservation for §§ 1.480 through 1.483. This rulemaking creates new § 1.483 and intends for this section to be published under the undesignated center subheading “Disclosures Without Patient Consent.” The CFR should be updated to correctly reserve §§ 1.480 through 1.482.

Effect of Rulemaking

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

Administrative Procedure Act

In accordance with 5 U.S.C. 553(b)(B), the Secretary of Veterans Affairs finds good cause to issue this interim final rule without prior notice and comment. This

interim final rule implements VA's authorized participation in State PDMPs to identify and prevent potential misuse of prescription drugs and assist in avoiding negative health outcomes for VA patients, including emergency treatment and accidental overdose. As increasing numbers of veterans return from active duty with complex, catastrophic injuries for which pain must be controlled in part by the use of controlled substance medications, VA clinicians require the most complete patient information available. The misuse of prescription medication has reached epidemic levels nationwide, and the veteran population is at a heightened risk for negative health outcomes associated with the improper use of controlled substances. Veterans are subject to unique risk factors involving the misuse of prescribed controlled substances. Karen H. Seal et al., "Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan," 307 JAMA 940 (2012). The conflicts in Iraq and Afghanistan have led to a sharp increase in the number of servicemembers and veterans returning with serious injuries that present symptoms associated with severe pain. Recent studies indicate that almost half of veterans who served in Operation Enduring Freedom and/or Operation Iraqi Freedom, and entered VA health care from 2005 through 2008 received at least one pain-related diagnosis, and of those who received such diagnosis, 66 percent received more than one pain diagnosis. Other risk factors present in the veteran population such as increased rates of homelessness, suicide attempts, and alcohol and other substance-abuse disorders increase the likelihood that an individual will misuse prescribed controlled substances and suffer negative health outcomes. Karen H. Seal et al.,

“Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan,” 307 JAMA 940 (2012).

In addition to promoting the health and safety of VA’s patient population, there are exigent public health reasons not to delay implementation of this rule. The abuse of prescription drugs is growing rapidly throughout the United States. Controlled substances prescribed for pain are misused by patients and often result in negative health outcomes including emergency hospital visitations and overdose. The U.S. Department of Health and Human Services estimates that in 2009 more than 1 million emergency department visits nationwide involved the non-medical use of pharmaceuticals, more than doubling in number compared to 2004. Substance Abuse & Mental Health Servs. Admin., U.S. Dep’t of Health & Human Servs., Drug Abuse Warning Network, 2009: Nat’l Estimates of Drug-Related Emergency Dep’t Visits (2011). In 2009 alone, more than 37,000 Americans died from drug overdoses, with 15,500 deaths being attributable to opioids. Ctrs. for Disease Control & Prevention, U.S. Dep’t of Health & Human Servs., Underlying Cause of Death 1999-2009, CDC WONDER Database (2012). Pain-relief medications, including controlled substances, are the most frequent form of medication used in suicide attempts via overdose.

State PDMPs are effective in detecting and preventing prescription medication misuse. One of the primary risk factors for individuals who overdose on opioids, controlled substances generally prescribed for pain, is “doctor shopping,” or obtaining multiple prescriptions from different providers. Alan G. White et al., “Analytic Models to Identify Patients at Risk for Prescription Opioid Abuse,” 15 Am. J. Managed Care 897 (2009). PDMPs in States with robust monitoring programs have shown some success

in curbing the rapid growth in opioid consumption occurring nationally. Leonard J. Paulozzi & Daniel D. Stier, "Prescription drug laws, drug overdoses, and drug sales in New York and Pennsylvania," 31 J. of Pub. Health Pol'y 422 (2010). Although many PDMPs are relatively new and data is limited, preliminary data indicates that PDMPs are associated with mitigated risks of abuse and misuse of opioids in the general population over time. Liza M. Reifler et al., "Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse?" 13 Pain Med. 434 (2012). Some states have also noted that reporting individuals to the PDMP has reduced the number of doctors and pharmacies visited. "Nevada's Proactive PMP: The Impact of Unsolicited Reports," Prescription Monitoring Program Ctr. of Excellence, Brandeis Univ. (Oct. 2011), http://www.pmpexcellence.org/sites/all/pdfs/nevada_nff_10_26_11.pdf. In 2002, Congress recognized their value by beginning to provide funding to support these programs and has continued to do so since. Effective PDMPs have also coincided with reductions in the rate of hospital admissions related to the misuse of controlled substances. Leonard J. Paulozzi & Daniel D. Stier, "Prescription drug laws, drug overdoses, and drug sales in New York and Pennsylvania," 31 J. of Pub. Health Pol'y 422 (2010).

For these reasons, the Secretary has concluded that ordinary notice and comment procedures would be impracticable and contrary to the public interest and is accordingly issuing this rule as an interim final rule. In order to ensure timely implementation of the program established by this rule, and for the reasons stated above, the Secretary also finds, in accordance with 5 U.S.C. 553(d)(3), that there is good cause for this interim final rule to be effective immediately upon publication. For

the same reasons detailed above, it is in the public's interest to commence this program as soon as possible, and this will be facilitated by an immediate effective date.

Unfunded Mandates

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

Paperwork Reduction Act

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

Regulatory Flexibility Act

The Secretary hereby certifies that this regulatory action 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. 601-12. This regulatory action affects only individuals and will not affect any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this regulatory action is exempt from the initial and final flexibility analysis requirements of sections 603 and 604.

Executive Orders 12866 and 13563

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

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for this rule are 64.012 Veterans Prescription Service and 64.019 Veterans Rehabilitation-Alcohol and Drug Dependence.

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. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on February 5, 2013, for publication.

List of Subjects in 38 CFR Part 1

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

Dated: February 6, 2013

Robert C. McFetridge,
Director of Regulation Policy and Management,
Office of the General Counsel,
Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 1 as follows:

PART 1 – GENERAL PROVISIONS

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

AUTHORITY: 38 U.S.C. 501(a), and as noted in specific sections.

2. Section 1.483 is added immediately following the undesignated center heading “Disclosures Without Patient Consent” to read as follows:

§ 1.483 Disclosure of information to participate in state prescription drug monitoring programs.

Information covered by §§ 1.460 through 1.499 of this part may be disclosed to State Prescription Drug Monitoring Programs pursuant to the limitations set forth in § 1.515 of this part.

3. Section 1.515 is redesignated as § 1.523 and a new § 1.515 is added to read as follows:

§ 1.515 Disclosure of information to participate in state prescription drug monitoring programs.

(a) General. Information covered by §§ 1.500 through 1.527 of this part may be disclosed to State Prescription Drug Monitoring Programs pursuant to the limitations set forth in paragraph (c) of this section.

(b) Definitions. For the purposes of this section:

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

State Prescription Drug Monitoring Program (PDMP) means a State controlled substance 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).

(c) Participation in PDMPs. VA may disclose to PDMPs any of the following information concerning the prescription of controlled substances:

(1) Demographic information of veterans and dependents of veterans who are prescribed a controlled substance. Examples include name, address, and telephone number.

(2) Information about the prescribed 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.

(Authority: 5 U.S.C. 552a; 38 U.S.C. 5701, 7332; 45 CFR 164.512(b))

[FR Doc. 2013-03001 Filed 02/08/2013 at 8:45 am; Publication Date: 02/11/2013]