Bureau of Justice Assistance
U.S. Department of Justice

PDMP TTAC
Prescription Drug Monitoring Program Training and Technical Assistance Center

Prescription Drug Monitoring Program

Summary of Selected 2021 Bills and Regulations

March 2022

This document was prepared by the Institute of Intergovernmental Research (IIR) for distribution by the Bureau of Justice Assistance.

This project was supported by Grant No. 2019-PM-BX-K003 awarded by the Bureau of Justice Assistance (BJA). BJA is a component of the U.S. Department of Justice's Office of Justice Programs, which also includes the Bureau of Justice Statistics, the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, the Office for Victims of Crime, and the Office of Sex Offender Sentencing, Monitoring, Apprehending, Registering, and Tracking (SMART). Points of view or opinions in this document are those of the author and do not necessarily represent the official position or policies of the U.S. Department of Justice.

General Summary

Last year, 2021, saw the introduction of at least 91 state and federal bills related to prescription drug monitoring programs (PDMPs) and the proposal of at least 52 regulations related to PDMPs. Of the bills and regulations introduced, 38 state bills were enacted, 51 state regulations were adopted, and 1 federal regulation was adopted. The primary topics of the enacted bills or adopted regulations include mandatory registration (12), mandatory use (16), authorized recipients (15), opioid treatment programs (2), penalties and sanctions (4), and substances reported (3). Included in this summary is a selection of bills and regulations highlighting significant actions related to PDMPs.

Significant Federal Action

Registration requirements for narcotic treatment programs with mobile components was addressed in 21 CFR Parts 1300, 1301, and 1304. As stated in the Drug Enforcement Agency (DEA) published rule's summary (summary linked below), this final rule revises "existing regulations for narcotic treatment programs (NTPs) to allow the operation of a mobile component associated with a DEA-registered NTP to be considered coincident activity permitted under the NTP's registration. Based on these revisions, NTP registrants that operate or wish to operate mobile components (in the State in which the registrant is registered) to dispense narcotic drugs in schedules II-V at remote location(s) for the purpose of maintenance or detoxification treatment do not need a separate registration for such mobile component. This final rule waives the requirement of a separate registration at each principal place of business or professional practice where controlled substances are dispensed for those NTPs with mobile components that fully comply with the requirements of this rule. These revisions to the regulations are intended to make maintenance or detoxification treatments more widely available, while ensuring that safeguards are in place to reduce the likelihood of diversion."

The Drug Enforcement Agency published rule's summary can be found at the following link:
https://www.deadiversion.usdoj.gov/fed_regs/rules/2021/fr0628_3.pdf

A more detailed summary on 21 CFR Parts 1300, 1301, and 1304 can be found at the following link:
https://www.pdmpassist.org/pdf/TTAC_Summary_21CFR1300_1301_1304_final_20210921.pdf

Significant State Regulatory or Statutory Actions

Alabama allowed authorized representatives of the Board of Nursing to access the controlled substance database to receive information concerning the licensee of the Board of Nursing who is the subject of an investigation or disciplinary activity. Any certifying board, state or federal law enforcement agency, or other individual or entity authorized to access the information from the controlled substance database pursuant to this article may share information with the Board of Nursing concerning a licensee who is the subject of an investigation or disciplinary activity. See, 2021 AL Senate Bill 186 (Act #2021-383).

Arizona imposed a restriction upon sharing controlled-substance-PDMP information with health care insurers, requiring that the information will be provided only if the health care insurer states

in writing that the information is necessary for an open investigation or complaint or for performing a drug utilization review for controlled substances that supports the prevention of opioid overuse or abuse and the safety and quality of care provided to the insured. It also provides that persons or entities authorized to prescribe or dispense controlled substances must deactivate a delegate within five business days after an employment status change, the request of the delegate or the delegate's inappropriate use of the PDMP's central database tracking system. See, 2021 AZ Senate Bill 1091 (Chapter 239).

Colorado law requires the PDMP to track all controlled substances prescribed in Colorado. The Board of Pharmacy (Board) is to determine if all prescriptions should be tracked in the PDMP. If the Board determines that all prescription drugs should be tracked, the Board must promulgate rules to that effect. If the Board determines one or more prescription drugs should not be tracked in the PDMP, the Board must publicly note the justification for why it is excluded. See, 2021 CO House Bill 1012.

Connecticut amended subsection (j)(1) of Section 21a-254, Connecticut statutes, to include federal Substance Abuse and Mental Health Service Administration certified substance use disorder clinics licensed under Section 19a-495 with CFR 2 to dispensers who should report the dispensation of Schedule II, III, and IV controlled substances to the PDMP. Subsection (j)(13) was also amended and clarified that the provisions of subsection (j) will not apply to any institutional pharmacy or pharmacist's drug room operated by a facility, licensed under 194-945 and regulations adopted pursuant to 194-945, that dispenses or administers to a patient an opioid antagonist for treatment of a substance use disorder, unless the patient has signed a consent to disclose the patient's record to a PDMP that is compliant with 42 CFR 2 Subpart. B. If consent is withdrawn, disclosure must immediately stop. See, 2021 CT Senate Bill 895 and 2021 CT Senate Bill 694.

Illinois extended specified requirements to opioid treatment programs that are licensed or certified by the Department of Human Services' Division of Substance Use Prevention and Recovery and are authorized by the DEA to prescribe Schedule II, III, IV, or V controlled substances for the treatment of opioid use disorders. They require opioid treatment programs to attempt to obtain written patient consent, document attempts to obtain the written consent, and not transmit information without patient consent. Documentation obtained as a result cannot be utilized by law enforcement and treatment of a patient must not be conditioned upon his or her written consent. See, 2021 IL Senate Bill 1842 (Public Act 102-0527).

Missouri established a statewide PDMP with the passage of 2021 MO Senate Bill 63. The "Joint Oversight Task Force of Prescription Drug Monitoring" will supervise the collection and use of patient dispensation information for prescribed Schedule II, III, or IV controlled substances as submitted by dispensers in the state. Beginning August 28, 2023, the contracted vendor must collect data and maintain it in an individual's dispensation information system for a maximum of three years from the date of dispensation. Information must not be provided to local, state, or federal law enforcement or prosecutorial officials or any regulatory board for any purpose other than those set forth in HIPAA and any regulations promulgated. Dispensation information submitted cannot be used to prevent an individual from owning or obtaining a firearm and cannot be used to form the basis for probable cause or to obtain a warrant as part of a criminal investigation. A dispenser who knowingly fails to submit dispensation information or who

knowingly submits incorrect dispensation information will be subject to an administrative penalty of $1,000 for each violation. Any person who unlawfully and purposefully accesses or discloses, or any person who is authorized to have patient dispensation information who purposefully discloses the information or purposefully uses such information in a manner and for a purpose in violation of the statute, is guilty of a class E felony. This bill became law in 2021 but had deadlines occurring in 2023 and 2024 for implementation of required procedures. See, 2021 MO Senate Bill 63.

Wisconsin adopted a regulation which replaces Chapter 75. The adopted regulation includes Section 75.24 (11) related to Wisconsin's community substance abuse services clinical assessment requirements. Part of the assessment must include collateral information, which may include a review of the PDMP. Subsection (19) addresses medical services. A service may offer medication management for treatment of substance use disorders or mental health disorders but must have written policies and procedures for medication management services, which include the prescriber checking the PDMP. Also included is Section 75.59 (25) relating to Opioid Treatment Programs (OTP). The service must develop and maintain a policy and procedure that requires ongoing monitoring of data from the PDMP for each patient. Requirements stated include:

1. Upon admission a patient must be notified in writing that the medical director must monitor the PDMP to review the prescribed controlled drugs a client received.

2. The medical director or the medical director's delegate must review the data from the PDMP before the patient is ordered any controlled substance including medications for maintenance therapy, and subsequent reviews of the PDMP data must occur at least every 90 days.

3. A copy of the PDMP data reviewed must be maintained in the client's file.

4. When the PDMP data contains a recent history of multiple prescribers or multiple prescriptions for controlled substances, the physician's review of the data and subsequent actions must be documented in the patient's file within 72 hours and must contain the medical director's determination of whether the prescriptions place the patient at risk of harm and the actions to be taken in response to the PDMP findings. The provider must conduct subsequent reviews of the PDMP in these circumstances on a monthly basis.

5. If at any time the medical director believes the use of controlled substances places the patient at risk of harm, the service must seek the patient's consent to discuss the patient's opioid treatment with other prescribers and for other prescribers to disclose to the OTP's medical director of the client's condition that formed the basis of the other prescriptions. If the information is not obtained within seven days, the medical director must document whether or not changes to the client's medication dose or number of unsupervised-use doses are necessary until the information is obtained. See, WI ADC DHS 75.59 (25) (2021).

Resources

Additional information regarding all legislation and regulations introduced and enacted in 2021 can be found at https://www.pdmpassist.org/Policies/Legislative. PDMP issue-specific maps and charts can be found on the PDMP Training and Technical Assistance website located at https://www.pdmpassist.org/Policies/Maps.