

Prescription Drug Monitoring Program

Summary of 2020 Bills and Regulations Related to PDMPs

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Summary of 2020 Bills and Regulations

Legislative and regulatory efforts in 2020 were impacted by the COVID-19 pandemic, which caused the early termination of many state legislative sessions, abbreviated sessions in other states, and implementation of emergency rulemaking to effect temporary rules crafted to address state issues with utilization of prescription drug monitoring programs (PDMPs) during the pandemic.

General Summary

2020 saw the introduction of 144 state and federal bills related to PDMPs and the proposal of 125 regulations related to PDMPs. Of the bills and regulations introduced, 37 state bills were enacted and 52 state regulations were adopted. Bills not passed in 2020 because of the short legislative session due to COVID-19 may return as refiled bills for the states' 2021 sessions. Included in this summary is a selection of bills and regulations highlighting significant actions related to PDMPs.

Federal Actions

There were two bills and five federal regulations related to PDMP in 2020. One of the regulations, 42 CFR Part 2 (including 42 CFR Part 2 SAMHSA 4162-20 Sections 2.34 & 2.36), was updated by the Substance Abuse and Mental Health Services Administration (SAMHSA), effective August 14, 2020. Among the several changes, the revision addresses PDMPs and allows nonopioid treatment programs and noncentral registry providers to query PDMP to determine whether a patient is already receiving opioid treatment through a member program. Each opioid treatment program is permitted to enroll in a state PDMPD and to report data into the PDMP when prescribing or dispensing Schedule II to V medications, consistent with the state's law. For more information on changes beyond PDMP impact, see <https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html>.

Significant State Regulatory or Statutory Actions Include:

Alabama's Board of Medical Examiners adopted by regulation the "Lorazepam Milligram Equivalency" daily standard for calculating sedative dosing when using Alabama's PDMP. Dosage thresholds are stated requiring PDMP utilization, and follow-up review of one's prescribing history is required. Nursing home and hospice patients are exempted from the PDMP requirements. (See: AL ADC 540-X180.15.)

Arkansas defined exceptions to PDMP use include “in conjunction with surgery in a healthcare facility or at the scene of an emergency, in an ambulance or hospital ICU, palliative administration in nursing home or hospice facility, or when access to PDMP is not accessible due to technological or electric failure.” Arkansas also extended access to PDMP information by outside entities or extended obligations to disclose to outside entities (PDMP data may be provided to the Medicaid prescription drug program and to the Medicaid Inspector General for investigations; AR ADC 007.07, 4IV, V).

California adopted an extensive regulation related to its Controlled Substance Utilization Review and Evaluation System (CURES) Database at 11 CA ADC 820 through 828. An extensive list of definitions is provided. Section 821 extensively details access to CURES for in-state and out-of-state prescribers; Section 822 details access to in-state and out-of-state pharmacists; Section 823 addresses access by interstate prescribers and pharmacists. Section 824 addresses CURES access by regulatory agencies; Section 825 addresses access by law enforcement; and Section 826 defines when researchers may access CURES data (mainly de-identified data) and how such data may be used. Access by individual requestors is addressed at Section 827, and Section 828 defines eligibility and operational obligations for participation in and submission of information to the state’s Information Exchange Web Service.

The **District of Columbia** enacted a rule (DC 22B ADC 1003) as authorized by DC LB 269 mandating that all practitioners be registered with the PDMP to receive a controlled substance registration.

Idaho required that specified data on controlled substances be reported by the end of the next business day by all drug outlets that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans (ID ADC 27.01.600).

Maine (ME ADC 02383, Ch. 121, § 5) obligates each clinician to “deal with persons” who use a clinician to perpetrate illegal acts and allows reporting such actions to law enforcement.

Maryland adopted extensive revisions to its regulation in MD COMAR 10.47.07. Defines “authorized user” as a prescriber, a pharmacist, their delegates, and licensed health care practitioners registered with another state’s PDMP; defines what items must be reported to the PDMP; mandates that the PDMP program monitor data for indications of possible misuse or abuse of a monitored drug and violation of laws or professional standards (duty previously was discretionary); and describes signage a pharmacist “may” post conspicuously where the prescription is delivered to the pharmacist. Section 10.47.07 subsection .07 indicates that PDMP data are NOT subject to discovery, subpoena, or other means of legal compulsion in *civil* litigation and are not public records; it defines standards to keep the information confidential; and it defines a penalty of not more than \$500 for each failure by a dispenser to submit information as required by the PDMP, while indicating that knowing disclosure, use, obtaining, or attempts to obtain is a first-degree misdemeanor subject to imprisonment not exceeding one year or a maximum \$10,000 fine, or both. The rule also requires disclosure of PDMP information to an authorized user of another state’s PDMP or an authorized user with any other authorized local, state, territorial, or federal agency in connection with the provision of medical care. The rule allows the PDMP to provide data to the medical director of a health care facility in connection

with the provision of medical care or the dispensing of a monitored prescription drug. Upon request of the Office of the Chief Medical Examiner, the PDMP shall disclose decedent-specific PDMP data. Disclosure of PDMP data is also required upon receipt of a subpoena that meets certain specified requirements to an administrative licensing entity or to the Office of the Attorney General for the purpose of furthering an existing bona fide investigation. Maryland also allows the PDMP to disclose data about a possible violation of law or a breach of professional standards by a prescriber or dispenser. Section 10.47.07 subsection 09 (general provisions) prohibits fees or other assessments on prescribers or dispensers to support the PDMP; indicates a prescriber or pharmacist is not required or obligated to access PDMP data; and provides immunity for acting or failing to act on the basis of prescription monitoring data. The PDMP must retain monitoring data for five years upon receipt.

Nebraska (NE LB 1183) requires any prescription drug dispensed in Nebraska to be entered into the PDMP by the dispenser (or delegate) no less frequently than daily after such prescription drug is delivered, rather than dispensed.

Ohio (OH ADC 4729:5-5-08) mandates review of a PDMP report if a new or different controlled substance dangerous drug is added to a patient's therapy, if 12 or more months have passed since a report has been reviewed, if the prescriber is outside the usual pharmacy geographic area, if the patient is from outside the usual pharmacy geographic area, or if the pharmacist has reason to believe that the patient has received prescriptions for controlled substance dangerous drugs from more than one prescriber in the preceding three months or the patient is exhibiting signs of abuse or diversion. Another Ohio rule (OH ADC 4729:7-3-03) requires a prescriber to comply with the drug database reporting requirements for personally furnishing drugs. Additional rules (OH ADC 4730401 and 47313302) require a physician assistant (PA) or physician, prior to providing ambulatory detoxification, to conduct a biomedical and psychosocial evaluation of the patient that includes requesting and documenting a review of a PDMP report on the patient as well as requiring the PA or physician to take steps to reduce the chances of medication diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of PDMP. An Ohio emergency rule (OH ADC 5122-40-07, 09) requires each opioid treatment facility to have policies and procedures for addressing Ohio's PDMP. A permanent rule was proposed on 8/28/2020 making similar changes. The proposed permanent rule requires that an individual client record for each client contain documentation of a PDMP check. The proposed permanent rule also requires that each person admitted to an opioid treatment receive an explanation of the PDMP system and how the reports are used to treat and monitor a patient and that such reports be maintained in the patient files.

Utah (UT HB 423) requires two options for a pharmacist to submit required information to the PDMP database: real-time submission or the batch submission over the last 24 hours daily or next business day, whichever is later.

West Virginia (WV HB 4102) addresses reporting of opioid antagonists by amending §16466 to provide that the distribution of an opioid antagonist by a governmental or nongovernmental entity, granting institution, medical provider, or pharmacy whose software cannot automatically report to the PDMP database be reported to the Office of Drug Control Policy on a monthly basis. The law also provides that the report be generated and submitted by the tenth day of each month for the opioids dispensed or distributed in the previous month and provides that the following information be reported: (1) the name and address of the entity dispensing or distributing the opioid antagonist; (2) the name and national drug code for each formulation of opioid antagonist dispensed or distributed; and (3) the total quantity of each formulation of opioid antagonist dispensed or distributed. It requires that data related to dispensing of opioid antagonists be included in the monthly reports submitted to the Office of Drug Control Policy. Also amends §60A94 to delete opioid antagonists from the list of substances required to be reported by a medical services provider and adds Schedule V substances to the list of substances required to be reported by all dispensers. Rule amendments (WV ADC 15-8-1 through 8) add Schedule V controlled substances to the PDMP requirements. W. Va. Code §60A-212 defines Schedule V substances to include (among other items) "Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid in limited quantities as set forth below, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone."

Wisconsin (WI AB 647, 2019 Wisconsin Act 121) reschedules expiration of mandatory PDMP reviews until April 1 and October 30, 2025. Typically, a "sunset provision" such as this is added to promote legislative review of practices and is not a statement of true intent to eliminate mandatory review.

Wyoming (WY HB 85) authorizes developing rules to specify requirements and procedures for practitioners, pharmacists, and any other authorized person using the state's PDMP and sets a standard that queries to the PDMP are to be based on the best-practice guidelines for the profession except that when opioids are prescribed, PDMP queries must occur every three months as long as the opioids remain part of the treatment. Senate File Bill SF77 authorizes data sharing agreements with other states to support the purpose of the PDMP, including release of Wyoming PDMP data when of assistance in preventing or avoiding inappropriate use of controlled substances.

PDMP Mandatory Query Before Specified Action:

Arkansas (AR ADC 007.07.4IV, V) requires a PDMP query every time an opioid from Schedule II or III is prescribed and when benzodiazepine is prescribed the first time; and from oncologists when prescribing on an initial malignant diagnosis and each three months thereafter.

Idaho (ID SB 1348) requires prescribers to review a patient's drug history for the prior 12 months before issuing a prescription for outpatient use of an opioid analgesic or Schedule II, III, or IV benzodiazepines.

Kentucky (201 KAR 25:090) requires podiatrists to review PDMP data for 12 months prior to prescribing a controlled substance; (KAR 9:016) requires licensees to review PDMP for 12 months prior to prescribing amphetamine and amphetamine-like anorectic controlled substances; (KAR 9:260) brings licensees who are "administering" as well as "prescribing and dispensing" under the requirement of a PDMP review; (201 KAR 9:270 and 201 KAR 20:065) requires a PDMP review for the prior 12 months before prescribing or dispensing Buprenorphine-Mono-Product or buprenorphine with naloxone; and (908 KAR 1:374) requires PDMP review to ensure that a patient is compliant with prescribed dosing in office-based opiate treatment services.

Louisiana (LAC 40:1:2104, 2109, 2111) requires PDMP queries by physicians treating patients for chronic pain; it also requires that prescription information for opioid treatments reported by patients be checked against the PDMP and that patient refill records be evaluated using the PDMP.

Maine (ME ADC 02383) indicates that office-based opioid treatment clinicians shall register with the PDMP and comply with laws regarding reporting on dispensed controlled substances and shall query the PDMP prior to initiating office-based opioid treatment and at least every 90 days thereafter, or more frequently when clinically indicated, as well as (ME ADC 10144, Ch. 11 §65) requiring all prescribers of medication-assisted treatment with methadone to consult the PDMP system prior to initial treatment, changes in dosages, and otherwise as clinically indicated.

New Mexico (NMAC 16.11.2.10) requires a practitioner to review a prescription monitoring report for a patient for the preceding 12 months before the practitioner prescribes or dispenses, for the first time, a controlled substance in Schedule II, III, IV, or V to a patient for a period greater than four days, or if there is a gap in prescribing the controlled substance for 30 days or more. When they are available, the practitioner shall review similar reports from adjacent states. The practitioner shall document the receipt and review of such reports in the patient's medical record. A prescription monitoring report shall be reviewed a minimum of once every three months during the continuous use of a controlled substance in Schedule II, III, IV, or V for each patient. The practitioner shall document the review of these reports in the patient's medical record.

North Dakota (ND ADC 61120103 and 04) requires dispensers who dispense a controlled substance to request and review a PDMP report covering at least a one-year period, or another state's report, or both reports (when applicable) prior to initially dispensing a prescription, with the exception of prescriptions for a patient in a skilled long-term care facility or a hospice patient. Further reports must be requested and reviewed if specifically listed conditions or factors become known to the dispenser. The rule provides that, for purposes of compliance with the mandatory query requirements, a report could be obtained through a board-approved aggregate too (to include NARxCARE).

Oregon (OR OAR 855-020-0300) mandates that a pharmacist review the PDMP prior to issuing a prescription for pseudoephedrine products for patients 18 years of age and older, not to exceed 3.6 grams, or a 60-count quantity per prescription, whichever is less, or a total of three prescriptions in a 12-month period and retain documentation of PDMP review.

Rhode Island (rule RI 216 RICR 20204.4) mandates that prior to initially prescribing any opioid and regardless of how the prescription is issued, prescribers review the PDMP and recheck the PDMP at least every three months.

Texas (rule TX 22 TAC 170.2, .3, .9) makes review of the prescription monitoring program (PMP) mandatory rather than optional prior to issuing each and every prescription for opioids, and documentation of each PMP check must be maintained in the patient's medical record. Physicians may allow other qualified individuals to check the PMP. A mandatory PMP check is not required before or during an inpatient stay, such as a hospital admission, or during an outpatient encounter in settings, such as an emergency department or ambulatory surgical center visit. Another Texas rule (TX 22 TAC 170.3) amends regulations concerning minimum requirements to treat chronic pain and requires physicians to review the PDMP prior to prescribing opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic pain. A new rule (TX 22 TAC 170.9) titled "Prescription Monitoring Program Check" indicates that before a prescription for opioids, benzodiazepines, barbiturates, or carisoprodol will be issued to a patient, a mandatory PMP check of the patient's controlled substance prescription history is required. The review of the patient's PMP prescribing history must be completed prior to and each time a prescription is issued to a patient for opioids, benzodiazepines, barbiturates, or carisoprodol for (1) take-home use, upon leaving an outpatient setting such as doctor's office, or ambulatory surgical center; or (2) upon discharge from an inpatient setting, such as a hospital admission or discharge from an emergency department visit. A mandatory PMP check is not required before or during an inpatient stay, such as a hospital admission, or during an outpatient encounter in settings such as an emergency department or ambulatory surgical center. The review of the patient's PMP prescribing history must be documented in the patient's medical records. The PMP check and documentation required by this section may be done by the physician or a delegate of the physician.

Virginia rules (VA 12 VAC 301305050 and VA 12 VAC 301305060) require that opioid treatment program risk management and office-based opioid treatment be documented in each individual's record and include a check of the PDMP prior to initiation of buprenorphine products or naltrexone products and at least quarterly for all individuals thereafter.

States Extending or Strengthening PDMP Access to Specified Practitioners:

Advanced Practice Registered Nurses (APRNs): **Arkansas** requires registration, or addressed access to and use of PDMP information, by specified persons, including APRNs (AR ADC 067.004VIII and ADC 007.34.1.4VIII & XII). **Kentucky** also addressed APRNs' access to and use of PDMP (201 KAR 20:057); as well as anyone else "administering" controlled substances. (201 KAR 9:230). **Ohio** addressed APRNs' access to, review, and documentation of PDMP information (OH ADC 4723-9-14).

DEA Registered Licensees: **Oregon** rule (OR OAR 8470100120) requires new licensees with an active DEA registration to register with the PDMP within 30 calendar days of Oregon licensure or DEA registration, whichever is later.

Dentists: **Alaska** (AK 12 AAC 28.940 & .953); and **Kentucky** (201 KAR 8:540) require review of a patient's drug history for prior 12 months before issuing a prescription for a Schedule II controlled substance and a new PDMP report if treatment extends beyond 3 months. **Maryland** (MD HB 663) indicates that the Board of Dentistry may deny a general license to practice dentistry, a limited license to practice dentistry, or a teacher's license to practice dentistry to any applicant; reprimand any licensed dentist; place any licensed dentist on probation; or suspend or revoke the license of any licensed dentist if the applicant or licensee fails to comply with the requirements of the PDMP. **Oregon** (OR OAR 3330230820) adds dental directors to the list of individuals allowed to access PDMP information.

Licensee: **Maryland** (MD HB 663) authorizes a disciplinary panel to reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee fails to comply with the requirements of the PDMP.

Nurse-Midwife Practitioners: **New Mexico** (NMAC 16.11.2.10) requires use of PDMP information.

Optometrists: **Louisiana** (LAC 46:LI:303) when prescribing any opioid and any uses for more than 90 days each 90 days so continued. **Ohio** (OH ADC 4725-16-04) requires use of the Ohio Automated Rx Reporting System by "licensed" (the added word) optometrists.

Physician Assistants: **West Virginia** (WV ADK 111B2) physician assistants must register in the WV Controlled Substance Monitoring Program. **Maryland** (MD HB 663) indicates that a disciplinary panel may reprimand any physician assistant, place any physician assistant on probation, or suspend or revoke a license if the physician assistant fails to comply with the requirements of the PDMP. **Ohio** (OH ADC 4730-1-06) relates to physician assistants renewing their licenses with a valid prescriber number and states that if the physician assistant prescribes opioid analgesics or benzodiazepines, the applicant for renewal shall certify having been granted access to PDMP unless specified exemptions are applicable.

Podiatrists: **Alabama** (AL ADC 730X3.12) and **Kentucky** (KAR 25:090).

Practitioners, Pharmacists, Pharmacist Delegates, Interns, or Technicians: **Oregon** (OR OAR 3330230820) authorizes practitioners and pharmacist delegates to have access to the PDMP, and **Utah** (UT HB 423) authorizes PDMP data to be provided to a licensed pharmacist having authority to dispense a controlled substance, or a licensed pharmacy intern or pharmacy technician working under the general supervision of a licensed pharmacist, to the extent the information is provided or sought for specified purposes in the statute.

Veterinarians: **Alaska** (AK 12 AAC 68.930), and **Iowa** (IA SF 2120).

States Expanding PDMP Access for Specialized Purposes:

Idaho (ID 27.02.02.600.03) defines the process by which authorized persons without online access may obtain a PDMP profile.

Indiana (IN HB 1182) authorizes Suicide and Overdoses Fatality Review Teams to have access to PDMP records within the scope of their reviews.

Iowa legislation (IA SF 2120) requires that all Schedule II, III, and IV controlled substances and Schedule V substances, including when dispensed by a pharmacist without a prescription except for the sales of pseudoephedrine, be reported to the PDMP, as well as opioid antagonists and other prescription substances that the advisory council and board determine can be addictive or fatal if not taken under the proper care and direction of a prescribing practitioner.

Louisiana (LA LAC 46:LIII.2457 and HB 819) requires use of the PDMP before prescribing medicinal marijuana and requires medical marijuana-dispensing pharmacies to record dispensed marijuana in the PDMP.

Mississippi (MS HB 688) authorizes the director (or the designee) of the Mississippi Bureau of Narcotics to access the PMP for investigative purposes and allows the State Board of Pharmacy to provide PMP statistical data for research or educational purposes. It requires that any pharmacist licensed by the Mississippi Board of Pharmacy be a registered user of the PMP and requires all licensed practitioners holding active DEA numbers to register as users of the PMP.

Nebraska (NE Legislative Bill 1183) authorizes the department or the statewide health information exchange to release data collected for quality measures as approved or regulated by state or federal agencies, as well as data for statistical, research, public policy, or educational purposes or patient quality improvement initiatives approved by the Health Information Technology Board and deletes the requirement that such data have personal identifiers removed.

New York legislation (NY S07509) requires that practitioners (physicians, physician assistants, and nurse practitioners) review the PDMP prior to making or issuing a certification for medical cannabis and provides that, when dispensing medical cannabis, the registered organization shall not dispense an amount greater than an amount established by the executive director in regulation and shall verify the information by consulting the PDMP.

North Dakota rules (ND ADC 61120103 and 04) authorize the board of pharmacy to allow access to the PDMP to delegates certified by an authorized individual listed in N.D. Century Code § 19-03.5-03 and also authorizes access to controlled substance records to authorized individuals listed in N.D. Century Code § 19-03.5-03 for a period of three years.

Ohio (OH House Bill 341) requires the PDMP to provide PDMP information on receipt of a request from a prescriber or pharmacist who is from or participating with a PDMP operated by a federal agency and approved by the board, but only if there is a written agreement under which the information is to be used and disseminated according to the laws of this state.

Pennsylvania (PA SB 432) authorizes the PDMP to provide data to designated Commonwealth personnel and contracted staff, or personnel of an organization that has an agreement to be paid on a capitated basis to provide services to medical assistance beneficiaries who are engaged in care management, to support the development and evaluation of quality improvement strategies, program integrity initiatives, or internal compliance reviews and data reporting for medical assistance programs. The rule also provides that personnel engaged in the above-listed activities shall notify the Department of Human Services and the Office of the Attorney General if fraud is suspected based on the results of the query and the review of the database. Other county or local level access authorizations are also detailed.

Texas (TX 22 TAC 315.16) authorizes a patient, the patient's parent, or the patient's legal guardian to obtain a copy of the patient's PDMP report, including a list of persons who have accessed that record, by following specified requirements to obtain the information.

Utah (UT HB 285) provides that PDMP information may be provided to a person authorized to obtain that information on behalf of the Utah Professionals Health Program if access is limited to obtaining information regarding the person who is the subject of the division's consideration and the conduct that is the subject of the division's consideration includes a violation or potential violation of law. Utah (UT SB 23) allows a state court to order release of information contained in the PDMP if the court determines good cause has been shown and has ordered the disclosed information be restricted, limited, or restrained from further dissemination as the court determines is appropriate. Utah also allows, upon the motion of a defendant, for the court to issue an order compelling production of PDMP information that pertains to a victim if the court

finds upon notice, and after a hearing, that the defendant is entitled to production of the information under applicable state and federal law. Utah legislation (UT HB 425) requires any qualified medical provider who recommends or renews a recommendation for medical marijuana to review any record related to the patient in the state's electronic verification system and the controlled substance database. Utah rules (UT R15637f203, R15637f301) require the PDMP to collect information regarding the prescription of gabapentin and butalbital.

Virginia legislation (VA HB 648 and VA SB 575) indicate that the PDMP may provide information about a specific recipient to the Emergency Department Care Coordination Program.

West Virginia (WV ADC 69141, 2 & 3) establishes a rule to facilitate exchange of PDMP data with the Office of Drug Control Policy, the Department of Health and Human Resources and its Bureaus, the Department of Military Affairs and Public Safety, the Department of Administration, the Administrator of Courts, the Poison Control Center, and the Board of Pharmacy, as well as law enforcement, local health departments, and emergency medical service agencies in each West Virginia county; and to facilitate reporting of overdoses by law enforcement agencies, including state, county, and local police departments, health care providers, emergency response providers, medical examiners, and hospital emergency rooms.

Wisconsin (WI CSB 4.04, .09, .093 and .11) authorizes a health care professional to access monitored prescription drug history reports for scientific research purposes if a patient is a direct patient of the health care professional and has given informed consent. It allows health care professionals to access PDMP information about a patient for purposes of conducting an overdose fatality review. It allows Department of Safety and Professional Service staff members who are charged with investigations to access audit trails related to PDMP drug history reports and PDMP data disclosed and a log of requests for PDMP information or monitored prescription drug history reports, even when no information was disclosed. Section 4.11(9) allows the board to disclose PDMP data without personally identifiable information for public health and scientific research purposes.