PDMP Legal Update

National Meeting for Harold Rogers PDMPs and COAP Grantees

Heather Gray, J.D.
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Legislation and Regulation Update
Enacted Legislation and Regulations

• 186 PDMP-related bills proposed in 44 states, DC, and Congress
• 43 bills in 29 states and DC enacted
  • Mandatory queries, mandatory registration, authorized recipients, integration, interstate sharing
• 53 PDMP-related regulations proposed in 22 states and DC
• 27 regulations adopted in 13 states and DC
  • Mandatory queries, mandatory registration, integration, drugs of concern
Enacted Legislation and Regulations

• AR HB 1627 – allows sharing with federal PDMPs
• FL HB 375 – allows U.S. Department of Veterans Affairs, U.S. Department of Defense, and Indian Health Service to receive PDMP information
• MD HB 466 – for purposes of interstate sharing, can share data with authorized local, state, territorial, or federal agencies in connection with medical care
Enacted Legislation and Regulations

• ME E.O. 2 – establishes system to notify prescribers of patients who have fatally overdosed or have been revived
• SC HB 3728 – notice to practitioners that a patient was administered an opioid antidote
• UT HB 186 – medical examiner’s report of a fatal overdose sent to a practitioner
Enacted Legislation and Regulations

• NE LB 556 – allows interstate sharing
• LA SB 53 – allows sharing with EHRs and pharmacy information systems in other states, territories, federal districts, and federal jurisdictions
• CO HB 1172 – repeals and reenacts PDMP statutes under new chapter
• IN HB 1294 – repeals and reenacts PDMP statutes under new chapter
Enacted Legislation and Regulations

• IA IAC 657-37.1 to -37.23 – rescinds and reenacts regulations
  • Opioid antagonist reporting by first responders
  • Integration
  • Prescriber activity reports

• WA – new regulations related to dentists
  • Mandatory queries
  • Written treatment agreement which shall include authorization for the dentist to release the agreement to other practitioners so those practitioners can report violations of the agreement to the dentist and the PDMP
Pending Federal Legislation

• US HR 2062 – Overdose Prevention and Patient Safety Act
• US S 1012 – Protecting Jessica Grubb’s Legacy Act
  • Changes to confidentiality and disclosure of records relating to HIPAA
  • “It is the sense of Congress . . . that [practitioners] should access the applicable state-based PDMP as a precaution against substance use disorder”

• US SB 516 – Prescription Drug Monitoring Act of 2019
  • Mandatory queries
  • Proactive notifications
  • Reporting within 24 hours
  • De-identified data sets
  • Interstate sharing
Pending State Legislation

• DE SB 34 – “opioid impact fund”
• MA HB 1703 – assessment against manufacturers
• MN HF 2184/SF 2302 – controlled substance registration fee for manufacturers
• OR HB 3192 – manufacturer assessment
Pending State Legislation

• CA AB 528 – changes reporting period to one working day
• CT HB 6152 – requires reporting methadone to PDMP
• IL HB 2587 – to receive reimbursement for worker’s compensation treatment, a physician must query the PDMP
• MA HB 3486/SB 1277 – process to include data regarding administration of opioid maintenance treatment information; consent form
• MN HF 1731/SF 1943 – veterinarian PDMP
Pending State Legislation

• NJ AB 5444/SB 3861 – Alcohol and Drug Use Disorders Treatment Resource Database
  • Nonidentifying information regarding patient treatment
  • May use nonidentifying PDMP information to establish, maintain, implement, and maximize the utilization and functionality of the database

• PA HB 1005 – reporting of opioid overdose agents; submission by first responders

• UT HB 469 – program the PDMP to alert practitioners that a patient is exhibiting high-risk behaviors
PDMP-Related Caselaw
Recent Cases

  • Suit against various manufacturers and distributors of opioids, and pharmacies
  • Allegations include consumer fraud, negligence, nuisance, unjust enrichment, and civil conspiracy
  • Defendants filed various motions to dismiss
  • Court denied motions of Manufacturers and Distributors
  • Court granted motions of Pharmacies
  • Court granted all motions to dismiss claims of nuisance and unjust enrichment
  • Case remanded to lower court for further proceedings
Recent Cases

  • Trade association for pharmaceutical wholesale distributors, association representing generic drug manufacturers, and pharmaceutical company filed suit against New York
  • Assessments against distributors and manufacturers licensed to sell or distribute opioid products in New York
  • Pass-through clause prohibits licensees from passing the cost of the assessment down to purchasers; licensees may incur a penalty if they do so
  • Court found pass-through clause unconstitutional
Recent Cases

- **John Christopher Hull v. Matthew G. Whitaker, et al.**
  - One of multiple cases filed across the country by *pro se* plaintiffs
  - Complaint downloaded from website promoting the repeal of restrictions on the prescription and distribution of opioid painkillers
  - Website refers to the movement as “Operation Starburst” and encourages others to be “warriors” in filing complaints in federal courts across the country
  - Case dismissed without prejudice
Statutes and Regulations Table
### PDMP Resource

- Complete listing of all statutes and regulations related to PDMP topics
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Opioid antagonists, such as naloxone, are drugs used to reverse the symptoms of an opioid overdose. States have begun keeping track of the prescribing, dispensing, and/or administration of opioid antagonists and either reporting that information to the state PDMP or otherwise sharing such data with the PDMP. In some cases, that information is used only for statistical or public health surveillance purposes and is not included with the patient’s PDMP report.

### Opioid Antagonist Reporting to PDMP

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<td>§ 32-1979 R4-23-407.1 R9-4-602</td>
<td>A pharmacist who dispenses naloxone hydrochloride or any other opioid antagonist shall document the dispensing consistent with board rules. Healthcare providers, administrator of a health care institution or correctional facility, EMS/Ambulance personnel, medical examiners, pharmacists, and others, including law enforcement agencies, are required to report certain specific health conditions to the department, including suspected opioid overdoses, suspected opioid deaths, naloxone doses administered in response to either condition, naloxone doses dispensed, and NAS and this information will be shared with the Board of Pharmacy.</td>
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<tr>
<td>Idaho</td>
<td>§ 37-2726</td>
<td>All opioid antagonists dispensed for humans shall be filed with the board electronically.</td>
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<td>Iowa</td>
<td>§ 124.551</td>
<td>The program shall collect from pharmacies dispensing information for controlled substances identified pursuant to section 124.554, subsection 1, paragraph “g”, and from first responders as defined in section 147A.1, subsection 7, with the exception of emergency medical care providers as</td>
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Contact Information and Resources

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