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Drug Scheduling & Monitoring

Introduction

Prescription Drug Monitoring Programs (PDMPs) are databases that collect information on prescriptions for controlled substances in a state. PDMPs collect data on providers and pharmacies distributing controlled substances and on patients receiving prescriptions. PDMPs help providers identify patients who may be “doctor shopping” for an opioid prescription, and/or have been prescribed other substances, such as benzodiazepines.¹

Drug Scheduling

Drugs are regulated based on their schedule. Schedule I drugs include those without an accepted medical use, and with a high potential for abuse.² Schedule I drugs include marijuana, lysergic acid diethylamide (LSD), and 3,4-methylenedioxymethamphetamine (ecstasy).³ Schedule II drugs are those that have a high potential for abuse, which can lead to psychological or physical dependence.⁴ Schedule II includes drugs with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), methamphetamine, methadone, meperidine (Demerol), oxycodone (OxyContin), fentanyl, Adderall, and Ritalin.⁵ Schedule III drugs are those that have a moderate to low potential for dependence, and drugs with less than 90 milligrams of codeine per dosage unit.⁶ This includes drugs such as Tylenol with codeine, anabolic steroids, and testosterone.⁷ Schedule IV drugs have a low potential for abuse and a low risk for dependence.⁸ Xanax, Soma, Darvon, Valium, and Tramadol are Schedule IV drugs.⁹ Schedule V drugs have an even lower potential for abuse than Schedule IV drugs and may have a limited quantity of certain narcotics.¹⁰ This includes cough preparations with less than 200 milligrams of codeine per 100 milliliters (Robitussin AC), and Lyrica.¹¹

Currently, all states, the District of Columbia, Puerto Rico and Guam track Schedules II, III, and IV drugs.¹² Thirty-nine states, D.C., Puerto Rico and Guam track Schedule V drugs.¹³ Nebraska is the only state that tracks all prescriptions.¹⁴ Drug scheduling varies from federal to state level. For example, particular states may schedule drugs that the Drug Enforcement Agency (DEA) has not scheduled federally, and some states schedule drugs at a higher level than they are scheduled federally by the DEA.¹⁵

Select Drugs Monitored by PDMPs

The following controlled substances are monitored by PDMPs in certain states, in addition to all Schedule II, III and IV drugs, due to their common misuse beyond prescribed purposes.

Butalbital: Butalbital is a sedative that decreases anxiety and results in sleepiness.¹⁶ Butalbital is not regulated under federal law. However, some of its compounds are prescribed to treat tension headaches and are regulated. Physicians have known for many years that butalbital has the potential for abuse, dependency, and withdrawal. However, it is still frequently prescribed for

migraines.¹⁷ In many European countries, butalbital products have been banned due to causing intoxication, as well as their potential for abuse and dependence.¹⁸

→ Alabama, Kansas, Louisiana, Minnesota, Utah and the District of Columbia track butalbital through their PDMPs.¹⁹ Some states track butalbital specifically when combined with other substances that risk increasing its unwanted effects and/or its potential to become habit-forming. Utah tracks butalbital products when combined with acetaminophen, and Kansas tracks butalbital combined with both acetaminophen and caffeine. Alabama tracks any butalbital products and combinations.²⁰

Gabapentin: Gabapentin is a drug used to treat seizures, pain, hot flashes and restless leg syndrome.²¹ Although it does not present a high risk of fatal overdose, long-term effects have not been well researched.²² The drug can avert opioid withdrawals and can stop the effects of medications used for addiction treatment.²³ Lawmakers are becoming more concerned about gabapentin because there has been an increase in prescriptions and it is increasingly involved in overdoses.²⁴ CDC reported that in opioid-related overdoses in 11 states from July 2016 to June 2017, gabapentin was identified in approximately one in five deaths resulting from prescription opioids.²⁵ One study demonstrated that when pharmaceutical representatives visited physicians, the representatives promoted nonapproved uses, which resulted in an increase of physicians prescribing the drug.²⁶ In addition, gabapentin has a black market value and is often abused.²⁷

→ Eight states (Kentucky, Massachusetts, Minnesota, Ohio, North Dakota, Virginia, and West Virginia) track gabapentin.²⁸

Pseudoephedrine: Pseudoephedrine is a decongestant used to provide temporary relief from symptoms caused by sinus infection or other breathing illnesses, and is a precursor to the illegal drug, methamphetamine. The Combat Methamphetamine Epidemic Act was passed in 2006 due to the increase in the illicit production of methamphetamine utilizing pseudoephedrine as a precursor chemical. This act requires that pseudoephedrine should only be available in locked cabinet doors at stores, or be kept behind the pharmacy counter.^{29,30}

→ Four states (Indiana, Minnesota, Mississippi and Oregon) track pseudoephedrine.³¹ Pseudoephedrine is a Schedule III drug in Mississippi and Oregon, and a Schedule V drug in Arkansas, Iowa, Kansas, Missouri and New Mexico, requiring a prescription in those states.³² Pseudoephedrine products in solid dosage forms are Schedule V drugs in Missouri, but liquid products are not scheduled.³³ The National Precursor Log Exchange (NPLEx), a real-time electronic logging and compliance system, tracks national sales of over-the-counter cold and allergy medications containing pseudoephedrine.³⁴

Other monitored drugs: Some state PDMPs monitor additional drugs in addition to opioids, all Schedule II, III and IV drugs, and the drugs noted above.³⁵ Ephedrine is tracked in multiple states including Indiana, Louisiana and Mississippi. Human growth hormones are tracked in Minnesota and New Jersey. Alabama currently tracks codeine cough syrups, anabolic steroids, and chlorthalidone and its combinations. Arkansas and Kentucky track nalbuphine. The District of Columbia tracks

cyclobenzaprine. Kansas tracks fioricet, prescription pseudoephedrine products, and promethazine with codeine. New York tracks chorionic gonadotropin, which is used in combination with anabolic steroids. West Virginia, the state with the highest opioid overdose mortality,³⁶ is the only state that tracks opioid antagonists, which includes drugs such as Suboxone, Narcan and Naltrexone.

¹ Ctrs. for Disease Control and Prevention, Prescription Drug Monitoring Programs (PDMPs), Department of Health and Human Services, https://www.cdc.gov/drugoverdose/pdf/pdmp_factsheet-a.pdf.

² 21 U.S.C.S. § 812.

³ Drug Enforcement Administration, Drug Scheduling, Department of Justice, <https://www.dea.gov/druginfo/ds.shtml>.

⁴ 21 U.S.C.S. § 812.

⁵ See Drug Enforcement Agency, *supra* note 3.

⁶ 21 U.S.C.S. § 812.

⁷ See Drug Enforcement Agency, *supra* note 3.

⁸ 21 U.S.C.S. § 812.

⁹ See Drug Enforcement Agency, *supra* note 3.

¹⁰ 21 U.S.C.S. § 812.

¹¹ See Drug Enforcement Agency, *supra* note 3.

¹² Prescription Drug Monitoring Program Training and Technical Assistance Ctr., Drug Schedules Monitored, <http://www.pdmpassist.org/content/drug-schedules-monitored>.

¹³ *Id.*

¹⁴ National Alliance for Model State Drug Laws (NAMSDL), The Future of Prescription Drug Monitoring Programs (PMPS): Highlights of 2017 State Bills, June 22, 2017, https://www.asapnet.org/files/June2017/Presentations/ASAPJune17_Presentations03_Green.pdf.

¹⁵ *Id.*

¹⁶ WebMD, Butalbital-Acetaminophen, <https://www.webmd.com/drugs/2/drug-6218/butalbital-acetaminophen-oral/details>.

¹⁷ William B. Young and Hua Chiang Siow, Should butalbital-containing analgesics be banned? Yes. *Current Pain and Headache Reports*, 6(2), 151-155.

¹⁸ *Id.*

¹⁹ See Prescription Drug Monitoring Program Training and Technical Assistance Ctr., *supra* note 12.

²⁰ *Id.*

²¹ Omudhome Ogburu and Jay W. Marks, Gabapentin (Neurontin, Gralise, Horizant, Fa natrex FusePag) Side Effects, Dosage, and Abuse), MedicineNet, November 11, 2016, <https://www.medicinenet.com/gabapentin/article.htm>.

²² Carmen Heredia Rodriguez, New on the Streets: Gabapentin, a Drug for Nerve Pain, and a New Target of Misuse, STAT, July 6, 2017, <https://www.statnews.com/2017/07/06/gabapentin-opioid-abuse/>.

²³ *Id.*

²⁴ Renatta Signorini, West Virginia begins tracking gabapentin after related overdose deaths increase, December 6, 2017, TribLive, <http://triblive.com/state/pennsylvania/13040424-74/west-virginia-begins-tracking-gabapentin-after-related-overdose-deaths-increase>; Gabapentin: States must track drug's prescriptions, January 24, 2017, The Parkersburg News and Sentinel, <http://www.newsandsentinel.com/opinion/editorials/2017/01/gabapentin-states-must-track-drugs-prescriptions/>; Eric Eyre, As overdoses climb, gabapentin designated 'drug of concern' in WV, December 5, 2017, Charleston Gazette-Mail, https://www.wvgazette.com/news/health/as-overdoses-climb-gabapentin-designated-drug-of-concern-in-wv/article_1f2c9ef4-09fc-5115-8ac8-d0b9f0cd3c31.html.

²⁵ Christine L. Mattson, Julie O'Donnell, Mbabazi Kariisa, Puja Seth, Lawrence Scholl, R. Matthew Gladden. Opportunities to Prevent Overdose Deaths Involving Prescription and Illicit Opioids, 11 States, July 2016–June 2017. *MMWR Morb Mortal Wkly Rep* 2018;67:945–951. DOI: <http://dx.doi.org/10.15585/mmwr.mm6734a2>

²⁶ Michael A. Steinman, G. Michael Harper, Mary-Margaret Chren, C. Seth Landerfeld, and Lisa A. Bero. Characteristics and Impact of Drug Detailing for Gabapentin, *PLoS Medicine*, 4(4) e134, <http://doi.org/10.1371/journal.pmed.0040134>.

²⁷ Eric Eyre, As overdoses climb, gabapentin designated 'drug of concern' in WV, December 5, 2017, Charleston Gazette-Mail, https://www.wvgazettemail.com/news/health/as-overdoses-climb-gabapentin-designated-drug-of-concern-in-wv/article_1f2c9ef4-09fc-5115-8ac8-d0b9f0cd3c31.html.

²⁸ See Prescription Drug Monitoring Program Training and Technical Assistance Ctr., *supra* note 12.

²⁹ United States Food and Drug Administration, Legal Requirements for the Sale and Purchase of Drug Products Containing Pseudoephedrine, Ephedrine, and Phenylpropanolamine, November 24, 2017, <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm072423.htm>.

³⁰ Drug Enforcement Agency, Diversion Control Division, Procedures for Establishment of Individual Import, Manufacturing, and Procurement Quotas, July 10, 2007, https://www.dea.gov/diversion/usdoj.gov/meth/q_a.htm.

³¹ See Prescription Drug Monitoring Program Training and Technical Assistance Ctr., *supra* note 12.

³² National Association of State Controlled Substances Authorities, State Profiles, October 4, 2018, <http://www.nascsa.org/database/reports/stateProfiles.pdf>.

³³ *Id.*

³⁴ Appriss Health, NPLeX: Helping state agencies reduce methamphetamine production, <https://apprisshealth.com/solutions/nplex/>.

³⁵ See Prescription Drug Monitoring Program Training and Technical Assistance Ctr., *supra* note 12; National Association of State Controlled Substances Authorities, *supra* note 38.

³⁶ In 2016, there were 52 deaths per 100,000 residents in West Virginia. See Christopher Ingraham, CDC releases grim new opioid overdose figures: 'We're talking about more than an exponential increase,' THE WASHINGTON POST, December 21, 2017, https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.1f9889713b52.