



Physician Office Management of Pain Medication Usage

By Emily Grey, Breazeale Sachse & Wilson LLP, and Elizabeth Hein, Post & Schell PC

National statistics on opioid pain medication show an alarming increase in prescribing and usage in recent years, and physician offices are on the front lines of the opioid addiction crisis. This article provides a brief background followed by an explanation of state law changes impacting physician practices; federal enforcement activities; developments in hospital, pharmacy, and payer practices; and key pointers for physician offices.

The Centers for Disease Control and Prevention (CDC) provides extensive information on the pervasive nature of the opioid problem. CDC research indicates that “sales of prescription opioids in the United States nearly quadrupled from 1999 to 2014.”¹ In some states, more prescriptions have been dispensed for opioid pain pills than there are people in the state.² The rates of opioid overdose deaths closely track prescribing rates,³ and the prescription opioid addiction crisis plays a significant part in fueling heroin addiction.

In recent years, opioid prescribing has levelled off, particularly high-dose prescribing, which suggests that physicians are responding to the crisis by being more cautious in prescribing.⁴ Nevertheless, prescribing rates remain high, with over 61 million patients receiving at least one opioid prescription in 2016, and retail pharmacies dispensing more than 214 million opioid prescriptions annually.⁵ CDC data released on March 6, 2018 show that suspected opioid overdoses still increased 30% between July 2016 and September 2017, highlighting the continuing need for prevention and treatment efforts.⁶

While widespread, PDMPs vary in effectiveness, primarily because their use is not mandatory in every state.

State Law Changes

States have set in motion numerous initiatives to roll back the epidemic, focusing on increasing use of Prescription Drug Monitoring Programs (PDMPs), aligning prescribing activity and payment for prescriptions with the *CDC Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline)*⁷ and other best practices, and disciplining or prosecuting individuals and companies responsible for overprescribing.

All states have now enacted legislation authorizing PDMPs, electronic databases that track prescribing and dispensing of controlled substances and can serve as essential resources for physicians and their practices. While widespread, PDMPs vary in effectiveness, primarily because their use is not mandatory in every state. States with the most comprehensive mandates require that all prescribers query the PDMP when initially

prescribing opioids or benzodiazepines, and perform subsequent checks of the database at three-month intervals if prescribing continues.⁸ However, some states require PDMP queries based only on subjective criteria, such as a prescriber’s judgment of possible misuse. Other states only require PDMP queries in certain contexts, such as opioid treatment programs, workers’ compensation programs, or pain clinics.⁹ Increased utilization of PDMPs is associated with declines in opioid prescribing.¹⁰ PDMPs are an important tool in evaluating the appropriateness of prescribing opioids for individual patients.

A number of states have worked to align prescribing activity and payment for opioid prescriptions with the *CDC Guideline* or other best practices.¹¹ For instance, several states have imposed quantity limits on initial opioid prescriptions for acute pain.¹² These laws often exclude prescriptions for pain associated with cancer treatment and palliative care, and include exceptions based on medical judgment. Other states have adopted quasi-regulatory or advisory treatment guidelines.¹³

Some states have taken steps to modify formulary policies and drug plan management for formularies subject to state control, such as Medicaid or workers’ compensation formularies, to reinforce prescribing guidelines and minimize use of opioids. For instance, the Texas Department of Insurance created a closed formulary beginning in September 2011, and saw an 81% reduction in prescriptions for opioids on the “not-recommended” drug list; use of other opioids fell by 8%.¹⁴ The Centers for Medicare & Medicaid Services (CMS) also has urged state Medicaid agencies to require step therapy or prior authorization to limit access to particular opioids.¹⁵

Some states also have passed pain management clinic laws, requiring physician practices that meet certain thresholds for pain management activities to register or obtain a state license or certificate. For instance, in Louisiana, a facility that “primarily engages in the treatment of pain by prescribing narcotic medications” must be state-licensed and is subject to the Health Department’s minimum standards on quality of care, prescription limits, and personnel.¹⁶

With respect to enforcement, state medical boards have stepped up disciplinary activity. While traditionally state professional boards have taken action only in response to complaints received, recently some states have granted state boards access to the state PDMP to monitor prescribing patterns.¹⁷

Finally, many state medical, nursing, and pharmacy boards have expanded access to professional continuing education on safe prescribing practices, increasingly imposing mandatory requirements. The increased availability of education is designed to inform physicians about the challenges with opioids and how to address abuse.

Practices must be alert to changing policies in the private sector, how they impact prescribing, and potential impact to patients.

Federal Activity

The federal government also has unleashed its financial, regulatory, and prosecutorial resources to fight the opioid epidemic.

The Drug Enforcement Administration (DEA) has taken administrative action against each participant in the distribution chain of controlled substances, including prescribers, pharmacies, distributors, and manufacturers.¹⁸ DEA enforces the Controlled Substances Act (CSA),¹⁹ which prohibits practitioners from dispensing controlled substances except “for a legitimate medical purpose” and “in the usual course of professional practice.”²⁰ Non-compliant practitioners can be subject to administrative action, including revocation of their DEA registration, as well as civil penalties and criminal prosecution for knowing or intentional violations.²¹

The Department of Justice (DOJ) has vigorously prosecuted opioid over-prescribers and prescribers who allegedly engage in diversion under the CSA and federal fraud and abuse statutes. On July 13, 2017, Attorney General Jeff Sessions and then Department of Health and Human Services (HHS) Secretary Tom Price announced the largest-ever health care fraud enforcement action, which included 120 defendants charged for their roles in prescribing and distributing opioids.²² The focus of the enforcement was on billing for medically unnecessary opioid prescriptions. Attorney General Sessions also announced a pilot Opioid Fraud and Abuse Unit, with 12 prosecutors focused on investigating and prosecuting individuals contributing to the opioid epidemic in Florida, Michigan, Alabama, Tennessee, Kentucky, Maryland, Pennsylvania, Nevada, Ohio, California, North Carolina, and West Virginia.²³

In 2017, the HHS Office of Inspector General (OIG) released a Data Brief that identified about 400 prescribers with questionable prescribing patterns.²⁴ The OIG focused on the prescribers by identifying (1) beneficiaries receiving extreme amounts of opioids, (2) beneficiaries who appear to be doctor-shopping, and (3) prescribers who ordered opioids for the highest numbers of beneficiaries at serious risk. The Data Brief observes that nurse practitioners and physician assistants comprise about one-third of prescribers with questionable prescribing patterns for beneficiaries at serious risk. The Data Brief demonstrates that the government has access to fairly sophisticated data mining tools that enable it to identify outlier prescribers and suggests that outlier prescribers are likely enforcement targets.

Hospitals, Pharmacies, and Payers

Practices must be alert to changing policies in the private sector, how they impact prescribing, and potential impact to patients. Many hospitals are creating or updating opioid policies to ensure state law compliance and based on a renewed focus on guidance such as that from The Joint Commission.²⁵

Pharmacies also are implementing policies to limit opioid prescriptions. For instance, CVS Health announced that, starting in February 2018, its pharmacies would limit opioid prescriptions to a seven-day supply or less for certain patients with acute pain who had not previously taken an opioid prescription.²⁶ Additional limits apply for patients with chronic pain.

Private payers are introducing similar new policies, limiting both initial prescriptions and refills.²⁷ In treating patients who require opioid prescriptions, physicians should be mindful of the payer policies and the patient’s potential payment obligations.

Pointers for Physician Practices

- » Set policies on opioid prescriptions based on applicable state law for practice physicians and mid-level practitioners with prescriptive authority.
- » Ensure prescribers obtain education on drug addiction, abuse, and treatment, particularly where mandated by state law.
- » Ensure prescribers review the state PDMP before prescribing opioids.
- » Monitor changing policies of hospitals, pharmacies, and payers and their impact on the practice and its patients. 



Emily Grey is the Section Manager of Breazeale Sachse & Wilson LLP’s health care section, one of the largest in Louisiana. She represents health care providers in a wide range of issues including routine operational matters, regulatory compliance, fraud and abuse, licensing, provider enrollment, contracting, joint ventures, and health care transactions including hospital/physician integration. Emily’s clients range from Fortune 500 companies to individual health care professionals and include hospitals and health systems, surgery centers, pharmacies, physicians and their practices, health care management and consulting companies, and other health care providers.



Elizabeth M. Hein is an Associate in Post & Schell’s Health Care Practice Group, providing legal services to the Firm’s health care clients in litigation, regulatory, and compliance matters. Ms. Hein’s litigation practice includes assisting in the defense of complex commercial, regulatory, and antitrust matters, medical staff litigation, and injunctive proceedings. Her health care consulting services include federal and state regulatory compliance; Fraud-and-Abuse and False Claims Act analysis and consultation; not-for-profit governance; licensing; and accreditation; federal and state payment regulation; and EMTALA, HIPAA, HITECH, HCQIA, and ACA statutory and regulatory compliance.

National statistics on opioid pain medication show an alarming increase in prescribing and usage in recent years, and physician offices are on the front lines of the opioid addiction crisis.

Endnotes

- 1 CDC, NAT'L CTR. FOR INJURY PREVENTION AND CONTROL, DIV. OF UNINTENTIONAL INJURY PREVENTION, *Opioid Overdose Data*, available at <https://www.cdc.gov/drugoverdose/data/prescribing.html> (last visited Mar. 8, 2018).
- 2 From 2014–2016, states with the highest opioid prescribing rates per 100 persons were Alabama (121.0), Arkansas (114.6), Tennessee (107.5), Mississippi (105.6), and Louisiana (98.1). See CDC, *Annual Surveillance Report of Drug-Related Risks and Outcomes—United States, 2017*, at 10 (Aug. 31, 2017) available at <https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf>. (hereafter, CDC Surveillance Report).
- 3 Healthcare Fraud Prevention Partnership Whitepaper, *Healthcare Payer Strategies to Reduce the Harms of Opioids*, at 10 (Jan. 2017), available at <https://downloads.cms.gov/files/hfpp/hfpp-opioid-white-paper.pdf>.
- 4 CDC Surveillance Report, *supra* note 2, at 8.
- 5 *Id.* at 9, citing QuintilesIMS Health estimates.
- 6 CDC, Press Release, *Emergency Department Data Show Rapid Increases in Opioid Overdoses* (Mar. 6, 2018), available at <https://www.cdc.gov/media/releases/2018/p0306-vs-opioids-overdoses.html>.
- 7 CDC, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* (Mar. 18, 2016), available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.
- 8 See Prescription Drug Monitoring Program Center of Excellence at Brandeis, *PDMP Prescriber Use Mandates: Characteristics, Current Status, and Outcomes in Selected States* (May 2016), available at http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/COE%20briefing%20on%20mandates%203rd%20revision.pdf.
- 9 *Id.*
- 10 *Id.*
- 11 The Federation of State Medical Boards (FSMB) published a Model Policy that state legislatures or medical boards may be incorporated as criteria for use in evaluating a clinician's management of a patient with pain. See FSMB, *Guidelines for the Chronic Use of Opioid Analgesics* (Apr. 2017), available at https://www.fsmb.org/globalassets/advocacy/policies/opioid_guidelines_as_adopted_april-2017_final.pdf. The Guidelines expressly state that the focus is to promote safe, evidence-based prescribing of opioids without creating any specific standard of care.
- 12 See CONN. GEN. STAT. § 20-14o(b) and LA. REV. STAT. § 40:978 (seven-day limit for initial prescriptions for outpatient use); MASS GEN. LAWS ch. 94C, § 19D (seven-day supply for initial prescriptions in outpatient setting); N.J. STAT. §§ 24:21-15.2 (five-day limit on initial prescriptions for acute pain); 35 PA. STAT. § 873.3(a) (seven-day limit for opioid prescriptions in emergency department or urgent care center).
- 13 See MED. BD. OF CAL., *Guidelines for Prescribing Controlled Substances for Pain* (Nov. 2014), available at http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf; PA. DEP'T OF HEALTH, *Pennsylvania Guidelines on the Use of Opioids to Treat Chronic Non-Cancer Pain; Pennsylvania Emergency Department Pain Treatment Guidelines, Pennsylvania Guidelines on the Use of Opioids in Dental Practice*, available at <http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Pages/Prescribing-Guidelines.aspx#WuDXkWaZNBx> (last visited Mar. 11, 2018).
- 14 See TEX. DEP'T OF INS., Press Release, *Texas Reduces Costs, Opioid Use With Closed Formulary* (Aug. 16, 2016), available at <https://www.tdi.texas.gov/news/2016/dwc08162016.html>.
- 15 U.S. DEP'T OF HEALTH AND HUMAN SERVS., CMCS Informational Bulletin, *Best Practices for Addressing Prescription Opioid Overdoses, Misuse, and Addiction* (Jan. 28, 2016), available at <https://www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf>.
- 16 See LA. REV. STAT. § 40:2198.12.
- 17 See N.C. MED. SOC'Y, *Medical Board Launches New Program to Monitor Opioid Prescribing* (Apr. 20, 2016), available at <http://www.ncmedsoc.org/medical-board-launches-new-program-to-monitor-opioid-prescribing/>. North Carolina passed a new law in 2017 allowing the Department of Health and Human Services to audit PDMP data. See N.C. STAT. § 90-113.74C(c). The Department of Health and Human Services may report to the North Carolina Medical Board information regarding the prescribing practices of practitioners whose prescribing reaches certain thresholds. See N.C. STAT. § 90-113.74(b2); 21 N.C. ADMIN. CODE 32Y.0101.
- 18 See *Examining the Growing Problems of Prescription Drug and Heroin Abuse: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. On Energy and Commerce*, 113th Cong. (Apr. 29, 2014) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA).
- 19 21 U.S.C. § 801 *et seq.*
- 20 The Controlled Substances Act makes it unlawful for any person, except as authorized by the statute and regulations, to “knowingly or intentionally . . . distribute or dispense, or possess with intent to . . . distribute or dispense a controlled substance.” 21 U.S.C. § 841(a)(1). A practitioner licensed to administer and/or dispense such drugs under applicable state law and registered with the DEA is exempt from this broad prohibition. 21 U.S.C. §§ 353(B), 802(21), 829(b). However, practitioners may only prescribe and/or dispense a controlled substance “for a legitimate medical purpose” and “in the usual course of professional practice.” 21 C.F.R. § 1306.04(a).
- 21 See *United States v. Moore*, 423 U.S. 122, 134 (1975); *United States v. Hurwitz*, 459 F.3d 463 (4th Cir. 2006).
- 22 DOJ, Press Release, *National Health Care Fraud Takedown Results in Charges Against Over 412 Individuals Responsible for \$1.3 Billion in Fraud Losses* (July 13, 2017), available at <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-over-412-individuals-responsible>.
- 23 DOJ, Press Release, *Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit* (Aug. 2, 2017), available at <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit>.
- 24 HHS OIG, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, available at <https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf> (last visited Mar. 11, 2018).
- 25 The Joint Commission issued new and revised standards related to Pain Assessment and Management for Hospitals, effective January 1, 2018. See Standard LD.04.03.13 and MS.05.01.01. The new standards require that safe opioid prescribing be an organizational priority for the hospital. See also The Joint Commission, *Safe Use of Opioids in Hospitals*, SENTINEL EVENT ALERT, Issue 49 (Aug. 8, 2012).
- 26 Jeanne Whalen, *CVS Health Moves to Limit Access to Opioid Painkillers*, WALL ST. J., Sept. 21, 2017.
- 27 See, e.g., Jay Greene, *Blue Cross To Limit Opioid Scripts To 30-Day Supply*, MODERN HEALTHCARE, Dec. 11, 2017.