

Physician Organizations

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Course Correction: The Opioid Crisis, Regulatory Efforts, and the Role of Physicians

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By all accounts, the opioid addiction epidemic is one of the most profound tragedies and public health challenges of our time. Each day, the news is replete with stories about the significance and wide-ranging impact of the opioid crisis in the United States. The overwhelming flow of addictive pain medications is a topic at the forefront of our national awareness. This article provides an overview of key statistics that show historical trends culminating in the current crisis, a summary of recent regulatory efforts to deal with the epidemic, and practice points on the central role physicians have to fill in addressing the crisis.

The Bad News: Startling Statistics and Scary Truths

The increase in the prescription of opioids over time is startling. Between 1999 and 2015, the amount of opioids prescribed per person *tripled*.¹ By 2015, Americans were being prescribed enough opioids for every American to be medicated 24/7 for three weeks.² In some states, more prescriptions have been dispensed for opioid pain pills than there are people in the state. The rates of opioid prescribing are important because, not surprisingly, the rates of opioid overdose deaths have been shown to closely track these prescribing rates.³

The significance and result of the extensive prescription of opioids cannot be overstated. The current statistics tell a harrowing tale of the tremendous cost of the opioid crisis in the form of economic losses, a corresponding heroin epidemic, and in deaths. First, from a purely financial perspective, it is estimated that in a single year, prescription opioid misuse and



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overdose cost the United States over \$78 billion for substance abuse treatment, criminal justice, productivity losses, and increased health care expenses.⁴ Additionally, clinicians and law enforcement recognize that the overuse of opioids has, in turn, contributed to a heroin epidemic. As one physician explained: “up to 80 percent of the heroin users we see started off on prescription opioids.”⁵

Finally, and most tragic of all, are the deaths attributable to this epidemic. Opioid overdoses kill 91 Americans each day,⁶ and over 165,000 Americans died from a prescription opioid overdose between 1999 and 2014.⁷ In 2015 alone, more than 15,000 people died from overdoses involving prescription opioids.⁸

Physicians have questioned the appropriateness of “pain as the fifth vital sign”⁹ and the use of a pain scale due to its subjective nature and some suggest that it has contributed to the opioid epidemic.¹⁰ Commenters have also suggested that pain management questions in patient satisfaction surveys “created pressure on hospital staff to prescribe more opioids in order to achieve higher scores on this dimension.”¹¹ The intense attention on the crisis has brought the opportunities to address these problems into focus.

The Good News: Wide-Ranging Regulatory Efforts

For a number of years, regulators took little or no action to address the problem of overprescribing of opioid pain medications. Fortunately, now state and federal regulators are focused on the issue and have taken a number of overlapping steps to limit inappropriate prescribing, prosecute “pill mill” practitioners, and expand the capacity of the health care system to screen and treat opioid use disorders. These guidelines and new requirements can be helpful tools for physicians who find themselves on the front lines of the battle against opioid abuse.

CDC Guidelines

In March 2016, the CDC published *Guidelines for Prescribing Opioids for Chronic Pain (CDC Guidelines)*.¹² While the CDC Guidelines have no force of law, the document has been foundational for much of the state and federal legislative activity that has occurred in the past 18 months. The guidelines can also be especially helpful for practicing physicians. Key points from the CDC Guidelines are briefly summarized as follows:

- **Indication:** Opioids are not first-line or routine therapy for chronic pain.
- **Initial Prescription Decision:** Before starting opioid therapy, clinicians should establish treatment goals; discuss with patients known risks and realistic benefits of opioid therapy; and clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to safety.
- **Prescribe lowest effective dose and no more than needed:** When opioids are started, clinicians should prescribe the lowest effective dose. Clinicians should reassess evidence of individual benefits and risks when increasing dosage to > 50 MME/day, and avoid increasing dosage to > 90 MME/day or carefully justify such a decision. When opioids are needed for acute pain, prescribe no more than needed (three days or less is often sufficient, rarely more than seven days will be needed).
- **Monitoring and follow-up:** Clinicians should evaluate benefits and harms with patients within one to four weeks of starting opioid therapy for chronic pain or dose escalation; clinicians should evaluate benefits and harms with patients every three months or more frequently. If benefits do not outweigh harms, clinicians should taper and discontinue.
- **Use available risk mitigation tools:** Check Prescription Drug Monitoring Programs (PDMPs) for high doses and prescriptions from other providers.

State Activity

States have set in motion numerous initiatives intended to roll back the epidemic, focusing on increasing use of PDMPs, aligning prescribing activity and payment for prescriptions with the CDC Guidelines and other best practices, and identifying and disciplining or prosecuting individuals and companies responsible for overprescribing. Currently, all 50 states and the District of Columbia have 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 any opioid or benzodiazepines, and perform subsequent checks of the database at three month intervals if prescribing continues.¹³ However, some states require PDMP queries based only on subjective criteria, such as a prescriber's judgment of possible inappropriate use, and other states only require prescribers to query the PDMP in certain contexts, such as opioid treatment programs, workers' compensation programs, or pain clinics.¹⁴ Increased utilization of PDMPs is associated with declines in opioid prescribing.¹⁵ PDMPs are an important tool for physicians 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 CDC Guidelines or other best practices.¹⁶ For instance, several states have imposed quantity limits on initial opioid prescriptions for acute pain.¹⁷ These types of laws often exclude initial prescriptions for chronic pain, prescriptions for pain associated with cancer diagnosis or treatment and palliative care, and include exceptions when the prescriber determines that the patient's condition requires a greater dose than that permitted by law. Other states have adopted quasi-regulatory or advisory treatment guidelines.¹⁸

Some states have taken steps to modify the formulary policies and drug plan management for formularies subject to state control, such as Medicaid or workers' compensation formularies, to reinforce prescribing guidelines and to 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 prescription for opioids on the "not-recommended" drug list; use of other opioids fell by 8%.¹⁹ The Centers for Medicare and Medicaid Services (CMS) has also urged state Medicaid agencies to require step therapy or prior authorization to limit access to particular opioids.²⁰

With respect to enforcement, state medical boards have stepped up disciplinary activity. While traditionally state professional boards have only taken action in response to complaints received, recently some states have granted medical boards access to the state PDMP for the purpose of monitoring prescribing patterns.²¹ State attorneys general have also formed partnerships with other state and federal agencies to leverage investigatory resources and enforcement efforts against prescribers as well as against opioid manufacturers and distributors.²² Forty-one attorneys general are now participants in a national investigation of the companies responsible for manufacturing and distributing the majority of the nation's opioids, recently serving Civil Investigative Demands and information demand letters as part of their coordinated effort.²³

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 on this subject is designed to inform physicians about the challenges with opioids and how to address abuse.

Federal Activity

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

CMS published an *Opioid Misuse Strategy*, which identified four priority areas of focus in CMS' efforts to combat opioid misuse and promote treatment and recovery supports: (1) implement more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion; (2) expand naloxone use, distribution, and access, when clinically appropriate; (3) expand screening, diagnosis, and treatment of opioid use disorders with an emphasis on increasing access to medication-assisted treatment; and (4) increase the use of evidence-based practices for acute and chronic pain management.²⁴

The United States Drug Enforcement Administration (DEA) has taken administrative and criminal action against all participants in the distribution chain of controlled substances, including prescribers, pharmacies, distributors, and manufacturers.²⁵ DEA is charged with enforcing the Controlled Substances Act (CSA), 21 U.S.C. 801 and accompanying regulations, which prohibit practitioners from dispensing controlled substances except "for a legitimate medical purpose" and "in the usual course of professional practice."²⁶ Practitioners who fail to comply with the CSA and accompanying regulations are subject to administrative action, including revocation of their DEA registration, and can be criminally prosecuted if they knowingly or intentionally prescribe not for a legitimate medical purpose or outside the usual course of professional practice.²⁷ DEA, which also regulates manufacturers of controlled substances, has additionally proposed cutting the amount of controlled substances to be manufactured in 2018 by 20% compared to 2017.²⁸

The United States Department of Justice (DOJ) has vigorously prosecuted opioid overprescribers under the CSA, as well as under federal fraud and abuse statutes. On July 13, 2017, Attorney General Sessions and former 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.²⁹ The focus of the enforcement was on billing for medically unnecessary drugs. Attorney General Sessions also announced a pilot Opioid Fraud and Abuse Unit, composed of 12 prosecutors designated to focus on investigating and prosecuting individuals contributing to the opioid epidemic in 12 federal districts in Florida, Michigan, Alabama, Tennessee, Kentucky, Maryland, Pennsylvania, Nevada, Ohio, California, North Carolina, and West Virginia.³⁰

Also this summer, the HHS Office of Inspector General (OIG) released a Data Brief, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, which identified about 400 prescribers with questionable opioid prescribing patterns.³¹ OIG identified the prescribers by (1) identifying beneficiaries receiving extreme amounts of opioids (> 240 mg daily MED for 12 months), (2) identifying beneficiaries who appear to be doctor

shopping, and (3) identifying the prescribers who ordered opioids for the highest numbers of beneficiaries at serious risk. The Data Brief observes that nurse practitioners and physician assistants make up about one third of the 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, at least with respect to federal health care beneficiaries, and suggests that outlier prescribers are likely targets for enforcement.

Finally, CMS has worked to align Medicare plans, including Part D, with the CDC Guidelines.³²

Private Sector Activity

Even the private sector appears to be joining efforts to limit access to prescription opioid medications. On September 21, 2017, CVS announced that beginning in February 2018, it would limit opioid prescriptions to seven days or less for certain patients with acute pain who hadn't previously taken an opioid prescription.³³ It will also limit patients with chronic pain to a maximum daily dose of 90 morphine milligram equivalents, or MMEs. It remains to be seen whether other national pharmacy chains will follow suit.

The Role Of Physicians

Physicians' role of helping and protecting their patients is at the heart of the practice of medicine. Focused rules and guidelines from many sources are aligning to provide support to physicians as they work to prevent opioid misuse and to detect and address opioid abuse in their patients.

- Physicians should get educated on the issues. Continuing education on these issues has become more available and, in some states, even mandatory.
- Physicians should be alert and attentive to the changing standard of care, complying with legal limits on opioid prescriptions which are newly enacted in many states.
- Physicians and their practices can look to the CDC Guidelines which, while voluntary, help direct parameters for initial prescriptions, dosages, and monitoring. These can serve as the basis for the implementation of internal policies relating to opioids.
- Available PDMPs should be used to their fullest extent. Although these are not mandatory in every state, they are an important tool to inform medical judgment and help identify patients with opioid problems, including those who may be doctor-shopping.
- Physicians can use legal limits on prescriptions, payment limits from private and government payers, and dosage limits imposed by pharmacies like CVS as additional support to bolster their limitation on opioid prescriptions for patients.

For physicians and their practices, the risks of over-prescription of opioids are significant. They can face non-payment, discipline from their state Board of Medical Examiners, or scrutiny from

CMS or the OIG. They can even be subject to criminal prosecution for knowingly prescribing opioids where there is no legitimate medical need or for fraud in prescribing opioids. In contrast, the benefits of using available tools to fight this opioid crisis dovetail with the very reasons many went into the medical profession in the first place: physicians have the opportunity to help their patients and save them from becoming another heartbreaking statistic.

- 1 Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention. *Prescription Opioid Overdose Data*, citing *Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration*; 1999 and *QuintilesIMS Transactional Data Warehouse*; 2015. Available at <https://www.cdc.gov/vitalsigns/opioids/infographic.html> (last visited Oct. 12, 2017).
- 2 *Id.*
- 3 The Healthcare Fraud Prevention Partnership Whitepaper. *Healthcare Payer Strategies to Reduce the Harms of Opioids*, p. 10 (Jan. 2017). Available at <https://downloads.cms.gov/files/hfpp/hfpp-opioid-white-paper.pdf> (last visited Oct. 12, 2017).
- 4 *Id.* at p. 9.
- 5 John W. Mitchell, *Opioids: Addressing the Epidemic*. HEALTHCARE JOURNAL OF BATON ROUGE (July/August 2017) at p. 33. (Quoting Stephen Mette, MD, Chief Medical Officer at the University of Arkansas for Medical Sciences).
- 6 Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention. *Prescription Opioid Overdose Data*. Available at <https://www.cdc.gov/drugoverdose/data/overdose.html> (last visited Oct. 12, 2017).
- 7 The Healthcare Fraud Prevention Partnership Whitepaper, *supra* note 3 at p. 10.
- 8 *Supra*, note 6.
- 9 In 1996, the American Pain Society introduced "pain as the 5th vital sign." See National Pharmaceutical Counsel Whitepaper on *Assessment of Pain*. Available at http://americanpainsociety.org/uploads/education/section_2.pdf (last visited Oct. 12, 2017).
- 10 See *Practical Pointers for Hospitals Handling the Opioid Crisis*. AMERICAN HEALTH LAWYERS ASSOCIATION. Webinar (Sept. 9, 2007). See also John W. Mitchell, *Opioids: Addressing the Epidemic*. HEALTHCARE JOURNAL OF BATON ROUGE (July/August 2017) at p. 33. (Quoting Beau Clark, MD, East Baton Rouge Parish Coroner and emergency room physician).
- 11 Quality Data Reporting Requirements for Specific Providers and Suppliers, CMS Final Rule, 82 Fed. Reg. 38322, 38329 (Aug. 14, 2017).
- 12 See Centers for Disease Control, *CDC Guidelines for Prescribing Opioids for Chronic Pain – United States*, 2016 (March 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.
- 13 See *PDMP Prescriber Use Mandates: Characteristics, Current Status, and Outcomes in Selected States*, Prescription Drug Monitoring Program Center of Excellence at Brandeis (May 2016), http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/COE%20briefing%20on%20mandates%203rd%20revision.pdf.
- 14 *Id.*
- 15 *Id.*
- 16 The Federation of State Medical Boards (FSMB) has published a Model Policy, *Guidelines for the Chronic Use of Opioid Analgesics, Treatment Guidelines*, which may be incorporated by state legislatures or state medical boards as criteria for use in evaluating a clinician's management of a patient with pain. See Federation of State Medical Boards, *Guidelines for the Chronic Use of Opioid Analgesics* (Apr. 2017), https://www.fsmb.org/Media/Default/PDF/Advocacy/Opioid%20Guidelines%20As%20Adopted%20April%202017_FINAL.pdf. The Guidelines expressly state that the focus is to promote safe and evidence-based prescribing of opioids without creating any specific standard of care.
- 17 See, e.g. CONN. GEN. STAT. 20-140(b) (7 day limit for initial prescriptions for outpatient use); 32 MRSA 2210(1)(D) (7 day limit for treatment for acute pain); MASS GEN. LAWS Ch. 94C Sec. 19D (7 day supply for initial opioid prescriptions in outpatient setting); N.J. STAT. 24:21-15.2 (5 day limit on initial prescriptions for acute pain); 35 PS. 873.3(a) (7 day limit for opioid prescriptions in ED or urgent care center).

- 18 See, e.g., Medical Board of California, *Guidelines for Prescribing Controlled Substances for Pain* (Nov. 2014), http://www.mbc.ca.gov/licensees/prescribing/pain_guidelines.pdf; Pennsylvania Department 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*, <http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Pages/Prescribing-Guidelines.aspx#.WcUhcVtSyUk> (last visited Sept. 22, 2017).
- 19 See Texas Department of Insurance, *Texas Reduces Costs, Opioid Use With Closed Formulary* (Aug. 16, 2016), <https://www.tdi.texas.gov/news/2016/dwc08162016.html>.
- 20 U.S. Department of Health and Human Services, CMCS Informational Bulletin, *Best Practices for Addressing Prescription Opioid Overdoses, Misuse, and Addiction* (Jan. 28, 2016), <https://www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf>.
- 21 See North Carolina Medical Society, *Medical Board Launches New Program to Monitor Opioid Prescribing* (Apr. 20, 2016), <http://www.ncmedsoc.org/medical-board-launches-new-program-to-monitor-opioid-prescribing/>.
- 22 See generally, National Association of Attorneys General, *Attorney General Programs and Initiatives Listed by State*, <http://www.naag.org/publications/papers-briefs-and-other-research/nagtri-prescription-opioid-projects/prescription-opioid-education-toolkit-for-consumer-education/attorney-general-program-and-initiatives-listed-by-state.php>.
- 23 41 States to Investigate Pharmaceutical Companies Over Opioids, NPR (Sept. 19, 2017), <http://www.npr.org/sections/thetwo-way/2017/09/19/552135830/41-states-to-investigate-pharmaceutical-companies-over-opioids>.
- 24 CMS, *Opioid Misuse Strategy* (Jan. 5, 2017), <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf>.
- 25 See, e.g., *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). DEA was criticized recently by Mr. Rannazzisi, now former Deputy Assistant Administrator, for not being aggressive enough and for being derailed by pressure from Congress and the drug industry in enforcing drug control laws. See 60 Minutes: *The Whistleblower* (CBS television broadcast Oct. 15, 2017), available at <https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/>; see also Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph over the DEA*, THE WALL STREET JOURNAL (Oct. 15, 2017).
- 26 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 who is licensed to administer and/or dispense such drugs under applicable state law and is registered with the DEA is exempt from this broad prohibition. 21 U.S.C. 353(B), 802(21), 829(b). However, a practitioner 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).
- 27 See, e.g., *United States v. Moore*, 423 U.S. 122, 134 (1975); *United States v. Hurwitz*, 459 F.3d 463 (4th Cir. 2006);
- 28 See Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2018, 82 Fed. Reg. 36830-34.
- 29 United States Department of Justice, 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), <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-over-412-individuals-responsible>.
- 30 United States Department of Justice Press Release, *Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit* (Aug. 2, 2017), <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit>.
- 31 HHS OIG, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, <https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf> (last visited Sept. 27, 2017).
- 32 CMS, Press Release, *CMS finalizes 2018 payment and policy updates for Medicare Health and Drug Plans, and releases a Request for Information* (Apr. 3, 2017), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-04-03.html>.
- 33 CVS Health Moves to Limit Access to Opioid Painkillers, THE WALL STREET JOURNAL (Sept. 21, 2017).



How Will the United States Pay for the Opioid Epidemic?

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According to the Centers for Disease Control and Prevention (CDC), overdose deaths involving opioids have more than quadrupled since 1999. This development was “driven by increasing deaths from prescription opioids”¹ during a time when the prescribing of opioids to treat chronic pain increased dramatically. In 2015, the CDC estimated that more than two million people in the United States had a substance use disorder (SUD) involving prescription pain relievers—nearly four times the agency’s estimated number of people addicted to heroin.² Opioid prescribing rates have slowly declined since 2012, suggesting that widespread efforts to change prescribing practices have had an impact.³ However, the average length of an opioid prescription increased from 13 days in 2006 to 18 days in 2015.⁴ Anne Schuchat, a former Acting Director of the CDC, found this trend “concerning,” noting that the longer a person has access to opioids, the greater are that person’s chances of becoming addicted.⁵

As the escalation in the number of opioid overdose deaths nationwide continues, much of the response to the crisis has focused on educating physicians and individuals about the risks and potential harms of prescribing and taking opioids to alleviate pain. For those already suffering from addiction, however, access to effective and affordable SUD treatment, including medication-assisted treatment (MAT), will be a key factor in their recoveries and in slowing the overdose epidemic. Despite ongoing efforts at both the federal and state levels to assure the availability of insurance coverage for mental health and SUD treatment that is equivalent to coverage for medical and surgical treatment, the goal of achieving true parity remains elusive and requires further attention.

The Road to Mental Health and SUD Treatment Parity

Private health insurers and publicly-funded health care programs have a long history of providing less robust coverage for mental health and SUD treatment than for physical ailments. In 1996, Congress attempted to address this discrepancy by enacting the Mental Health Parity Act (MHPA). The MHPA prohibited health plans from applying different aggregate lifetime and annual dollar limits for mental health services than for medical and surgical services. However, the MHPA only applied to group health plans of employers having 50 or more employees, and it did not apply to SUDs. Significantly, it did not require such plans to offer mental health benefits; it merely required those plans that did so to apply

lifetime and annual dollar limits no higher than the limits applicable to medical and surgical benefits.⁶

The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) ushered in a new attempt to end the inequity in payment for mental health services.⁷ Like the MHPA, the MHPAEA only applied to large group health plans (over 50 employees), and it also didn’t mandate coverage for mental health conditions, but the parity requirements now specifically applied to treatment for SUDs. Thus, if a plan offered mental health and SUD coverage, it was required to offer such coverage with no greater dollar limits than the limits imposed on covered medical and surgical services. The MHPAEA also prohibited covered plans from placing financial limitations (such as deductibles and copayments) or treatment limitations (such as caps on the number of outpatient visits or days of inpatient treatment covered) on mental health conditions and SUDs that were more restrictive than the limitations imposed on medical and surgical benefits. Before federal agencies could draft regulations implementing the MHPAEA, however, the Affordable Care Act (ACA) revisited parity once again.⁸



Under the ACA, mental health and SUD benefits were included as two of the ten “essential health benefits” (EHBs) that most health plans (except for grandfathered plans)—including those offered through the individual and small employer market—were now required to offer. Whereas the MHPAEA only required parity in mental health and SUD coverage if a health plan offered those types of benefits, the ACA now required health plans to offer such benefits **and** to pay for them in a manner equivalent to the plans’ payment for medical and surgical benefits.

The ACA authorized the Department of Health and Human Services (HHS) to define each EHB, setting the parameters of what must be covered. Instead of establishing a single uniform set of minimum benefits or limitations, HHS elected to have the EHBs defined by a benchmark plan selected by each state.⁹ As a result, the extent to which insurers cover mental health and SUD treatment varies widely among the states. For example, two-thirds of the states place no limit on the number of days an individual may receive inpatient SUD treatment, but the remaining states have placed caps on inpatient days of care ranging from seven to 90 days a year.¹⁰ Similar coverage variances exist for outpatient care.¹¹ In addition to limiting the number of days of coverage,

several states have limited detoxification services and excluded coverage for services provided at residential treatment centers or for court ordered SUD treatment.¹² Even with these state-specific EHB variances, however, health plans that are subject to MHPAEA’s parity requirements still cannot adopt more stringent benefit minimums and limitations for SUD treatment than those that apply to medical and surgical care.

In November 2013, HHS adopted final rules implementing the MHPAEA.¹³ Courts had already recognized the difficulty of trying to determine the equivalency of physical health services and behavioral health services, particularly in residential treatment settings.¹⁴ To assist with this analysis, the MHPAEA final rule established six broad categories of benefits (inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drug) and required health plans to list, in a consistent manner, the covered physical and behavioral health services within these categories.

This categorization made it much easier to compare co-pays and caps on the number of covered days or visits (referred to as “quantitative treatment limitations”). However, for “non-quantitative treatment limitations” (NQTLs), such as medical necessity standards or prior authorization requirements, comparing medical and behavioral health benefits remains very difficult, and is sometimes impossible. For example, there is no medical or surgical equivalent to the intensive outpatient programs used to treat some mental health issues and SUDs. In other words, adopting medical necessity standards or step therapies (which require use of more conservative, lower-cost therapies before resorting to higher-cost therapies) may still have a disparate impact upon mental health and SUD benefits.

The 21st Century Cures Act’s Focus on Parity Enforcement

Congress again revisited the mental health and SUD treatment parity issue as part of the 21st Century Cures Act (Cures Act). A far-reaching and ambitious law, the Cures Act sought to improve access to mental health treatment, improve mental health and SUD care based upon best practices and evidence-based protocols, and coordinate mental health and physical health treatment and records.¹⁵ It also addressed prescribing practices, prevention and education about opioid prescribing and use, and other ways to combat opioid abuse.

Title XIII of the Cures Act provided for enhanced oversight and enforcement of the MHPAEA’s mental health and SUD parity requirements. It required the Departments of HHS, Labor, and Treasury to develop Compliance Program Guidance (Guidance) by December 13, 2017 (and update it every two years thereafter) to alert group health plans about MHPAEA compliance requirements.¹⁶ Such Guidance must provide illustrative, de-identified examples of previous findings of MHPAEA compliance and noncompliance based upon agency investigations. It also must include recommendations for plans to implement internal controls to monitor their compliance, along with examples of compliant and non-compliant NQTLs.¹⁷



Additionally, Title XIII required the Secretary of HHS to convene a public meeting of specified stakeholders to develop an action plan to improve federal and state coordination of mental health parity enforcement, including an implementation timeline. The action plan was required to include educational information for patients; centralized collection, monitoring, and response to patient complaints and inquiries; a single toll-free number; and a website to help consumers find the appropriate federal or state agencies for assistance, and the plan must be published on HHS' website within six months of the public meeting.¹⁸

The Cures Act also required HHS and the Government Accountability Office (GAO) to study parity compliance and enforcement. If a federal agency determines that a plan sponsor or health insurance issuer has violated parity requirements at least five times, the applicable Secretary of HHS, Labor, or Treasury must audit relevant plan documents in the subsequent plan year to help improve compliance.¹⁹ Further, the Employee Benefits Security Administration must summarize specific data on all closed investigations in which serious violations of the MHPAEA were found in the preceding 12-month period. The first report is due by December 13, 2017, and the agencies must submit annual compliance reports for the next five years.²⁰ On or before December 13, 2019, the GAO must issue a compliance report that addresses whether health plan NQTLs are complying with parity requirements, how federal agencies are ensuring compliance, and enforcement progress. The GAO also must provide recommendations for additional enforcement, education, and coordination.²¹

Cures Act and Other Funding to Combat Opioid Use Disorders

The Cures Act appears to have spurred a wave of funding initiatives to address different facets of the opioid crisis. Section 1003 of the Cures Act directed the Department of the Treasury to transfer \$500 million each in fiscal years 2017 and 2018 to an account from which the HHS Secretary may award grants to states having a high incidence or prevalence of opioid use disorders to address the opioid abuse crisis within those states. Such grants may be awarded for a variety of public health activities, including: (1) improving state prescription drug monitoring programs (PDMPs); (2) implementing and evaluating prevention activities to identify effective strategies for preventing opioid abuse; (3) best practices training for practitioners that focus on prescribing opioids, pain management, recognizing signs of substance abuse, referral of patients to treatment programs, and preventing overdoses; (4) supporting access to health care services, including services offered by federally certified opioid treatment programs (OTPs) and other health care providers who appropriately may treat SUDs; and (5) other public health-related activities determined appropriate by the applicable state for addressing the state's opioid abuse crisis.²²

On April 19, 2017, then-HHS Secretary Tom Price announced that a total of \$485 million in grants authorized by the Cures Act would soon be issued to the states and territories to help combat opioid addiction. California, Texas, Florida, Pennsylvania, Ohio, and New York were the largest grant recipients (each state

received well over \$20 million), but all states received at least \$2 million in funding.²³

In addition to the funding provided by the Cures Act, on May 31 HHS announced the availability of more than \$70 million to assist communities and health care providers in obtaining naloxone (the opioid overdose reversal drug) and training on its use to prevent overdose deaths, and in providing SUD treatment, including MAT, to those suffering from addiction.²⁴

Most recently, the Department of Justice announced in September an award of approximately \$59 million to support various programs in fighting the opioid epidemic. The funds will be distributed among cities, counties, public health departments, state court systems, boards of pharmacy, and other agencies to connect overdose survivors with SUD treatment services, establish effective alternatives to incarceration, enhance PDMP databases, and support and increase the number of and services offered by adult drug courts and Veterans Treatment Courts.²⁵

Current State of SUD Insurance Coverage

Medicare covers SUD treatment when the services are “reasonable and necessary.”²⁶ However, Medicare coverage focuses on professional services, including inpatient and outpatient treatment based upon services recognized by Medicare (counseling, individual or group psychotherapy, occupational therapy), and screening, brief intervention, and referral to treatment services performed in physician offices and outpatient hospitals. Although Medicare Part D sponsors must include drugs to treat opioid dependence, Part D drugs by definition are those that “may be dispensed only upon a prescription.”²⁷ Accordingly, although buprenorphine (available as Subutex or Suboxone in sublingual tablet and film forms) and naltrexone (available as Revia or Vivitrol in tablet or extended-release injection forms) can be Part D drugs, methadone—arguably the most widely-used medication for treatment of opioid addiction—is not covered by Part D when used to treat opioid dependence because it is typically dispensed at an outpatient OTP, not through a prescription sent to a retail pharmacy.²⁸

TRICARE covers a wide variety of substance use disorder treatment, including emergency inpatient hospitalization, partial hospitalizations, intensive outpatient programs, and MAT in the medical office or OTP setting, but limits and conditions apply to such coverage.

State Medicaid programs typically cover at least one of the three types of drugs to treat opioid dependence, and 31 states and Washington, D.C. cover all three.²⁹ Accordingly, Medicaid beneficiaries in most states can be treated in OTPs with methadone.

On March 30, 2016, CMS published a final rule extending the application of mental health and SUD parity rules to Medicaid managed care organizations (MCOs), Alternative Benefit Plans, and the Children's Health Insurance Plan (CHIP). The final rule's compliance deadline was October 2, 2017.³⁰ The final rule is quite complex and requires both MCOs and states to perform a parity analysis under certain circumstances to assure compliance with the rule in the applicable state. Because Medicaid MCOs and CHIP plans must make medical necessity criteria for mental

health and SUD services available to enrollees only upon request, the rule places the burden on consumers to research and identify covered mental health and SUD services before they are needed.

Criticism of Current Parity Enforcement

In June 2017, the newly-formed Addiction Solutions Campaign (ASC)—a collaboration among the National Center on Addiction and Substance Abuse, the Legal Action Center, Partnership for Drug-Free Kids, and the Treatment Research Institute—described its campaign to make mental health and SUD treatment parity a reality.³¹ The ASC studied publicly-available documents for major health plans offered in 2015 and 2016 in New York and Maryland. The collaboration concluded that requiring consumers to notify regulators about potential parity violations and to appeal mental health and SUD coverage denials unfairly burdens the consumer. Health plan document details about quantitative and qualitative limitations on coverage typically are far from clear, and consumers generally do not receive notice of their parity rights under the MHPAEA or instructions about filing a parity complaint.

To overcome the barriers to enforcement of the MHPAEA, the ASC offers several recommendations for state insurance regulator activity, including that regulators should: (1) require health plans to submit data showing that their coverage complies with parity requirements and highlight any limitations on benefit scope or access to services; (2) evaluate each plan's scope of prescription drug coverage and utilization management requirements for mental health and SUD treatment; (3) develop model agreements that clearly describe mental health and SUD benefits and inform consumers of their legal parity rights; and (4) educate providers about potential MHPAEA violations and advocate for plan compliance with parity requirements through network adequacy and rate setting standards.³²

Conclusion

The recent spate of funding suggests that Congress and policy-makers recognize the importance of providing access to, and paying for, SUD treatment as part of the effort to curb the opioid epidemic. However, until more government and private insurers offer coverage for SUD treatment, including MAT, that is equivalent to coverage for medical and surgical treatment—and until effective parity enforcement mechanisms are implemented—reducing the supply of prescription opioids and using naloxone may reduce the number of deaths, but it will not address the underlying problem as more addicted individuals turn to heroin and other opiates to stave off withdrawal.

1 CDC, *Annual Surveillance Report of Drug-Related Risks and Outcomes – United States 2017*, Surveillance Special Report 1, pp. 6, 26 (Aug. 31, 2017), available at <https://www.cdc.gov/drugoverdose/pdf/pubs/2017-cdc-drug-surveillance-report.pdf>.

2 CDC Annual Surveillance Report – U.S. 2017 at 13.

3 *Id.* at 8.

- 4 Guy GP Jr., Zhang K, Bohm MK, et al., *Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015*, MMWR Morb Mortal Wkly Rep 2017, 66:697–704, available at <http://dx.doi.org/10.15585/mmwr.mm6626a4>.
- 5 Rob Stein, *Opioid Prescriptions Falling But Remain Too High*, CDC Says, NPR (Jul. 6, 2017), available at <http://www.npr.org/sections/health-shots/2017/07/06/535656477/opioid-prescriptions-falling-but-remain-too-high-cdc-says>.
- 6 Mental Health Parity Act, Pub. L. No. 104-204, 110 Stat. 2944, 2874 (1996).
- 7 Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act, in the Emergency Economic Stabilization Act, Pub. L. No. 110-343, 122 Stat. 3756, 3881 (2008).
- 8 Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010).
- 9 CMS, Center for Consumer Information and Insurance Oversight, *Essential Health Benefits Bulletin* (Dec. 16, 2011), available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.
- 10 Kathleen G. Noonan, Stephen J. Boraske, *Enforcing Mental Health Parity through the Affordable Care Act's Essential Health Benefit Mandate*, 24 ANNALS HEALTH L. 252, 280-285 (2015).
- 11 *Id.*
- 12 *Id.*
- 13 78 Fed. Reg. 68, 240, 68, 240-96 (Nov. 13, 2013).
- 14 See, e.g., *Harlick v. Blue Shield of Cal.*, 686 F.3d 699, 721 (9th Cir. 2012).
- 15 21st Century Cures Act, Pub. L. No. 114-225, 130 Stat. 1033 (Dec. 16, 2016).
- 16 *Id.* § 13001.
- 17 *Id.*
- 18 *Id.* § 13002.
- 19 *Id.* § 13001.
- 20 *Id.* § 13003.
- 21 *Id.* § 13004.
- 22 *Id.* § 1003(c)(2).
- 23 HHS Press Office, *Trump Administration Awards Grants to States to Combat Opioid Crisis* (Apr. 19, 2017), available at <https://www.hhs.gov/about/news/2017/04/19/trump-administration-awards-grants-states-combat-opioid-crisis.html>.
- 24 HHS Press Office, *HHS Announces Over \$70 Million in Grants to Address the Opioid Crisis* (May 31, 2017), available at <https://www.hhs.gov/about/news/2017/05/31/hhs-announces-over-70-million-in-grants-to-address-the-opioid-crisis.html>.
- 25 DOJ, Office of Public Affairs, *Department of Justice Awards Nearly \$59 Million to Combat Opioid Epidemic, Fund Drug Courts* (Sep. 22, 2017), available at <https://www.justice.gov/opa/pr/departments-justice-awards-nearly-59-million-combat-opioid-epidemic-fund-drug-courts>.
- 26 CMS, *Medicare Coverage of Substance Abuse Services*, MLN Matters Number SE1604, p. 1 (rev. Jul. 24, 2017).
- 27 *Id.* at 5.
- 28 See *id.*
- 29 Kaiser Family Foundation, *Medicaid's Role in Addressing the Opioid Epidemic* (Sep. 15, 2017), available at <https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/>.
- 30 Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans, 81 Fed. Reg. 18,390 (Mar. 30, 2016), available at <https://www.federalregister.gov/documents/2016/03/30/2016-06876/medicaid-and-childrens-health-insurance-programs-mental-health-parity-and-addiction-equity-act-of>.
- 31 Josie Feliz, *Addiction Solutions Campaign Forms against Backdrop of Healthcare Policy Debates, National Opioid Epidemic* (Jun. 20, 2017), available at <https://drugfree.org/newsroom/news-item/addiction-solutions-campaign-forms-against-backdrop-of-healthcare-policy-debates-national-opioid-epidemic/>.
- 32 *Id.*

Arizona Prescription Monitoring Program – A Rapidly Evolving Response to the Opioid Crisis

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The United States is in the midst of a public health crisis that impacts all physicians and health care workers, professionally and legally. Opioid overdoses and addiction are straining families, the economy, health care infrastructure, and public budgets. Currently, six states, Massachusetts, Virginia, Alaska, Maryland, Florida, and Arizona have enacted public health states of emergency in response to opioid epidemics. On October 26, 2017, President Trump declared the opioid crisis a national public health emergency and indicated it was a crisis of epic proportions impacting every community in all 50 states.¹ The designation as a state of emergency or a national emergency includes providing authority and funding for increased government surveillance and oversight of the prescribing of opioids. These designations also initiate emergency rulemaking provisions, and various agencies and lawmakers have been tasked with implementing guidelines and rules with the goal of reducing opioid-related overdoses and deaths, but those goals can have significant impacts on medical providers.²

Prescription Drug Monitoring Systems Become Critical To Combating Opioid Crisis

One key component of the nationwide response to opioid abuse is the tracking and monitoring of the use of controlled substances. Ostensibly to assist law enforcement in identifying illegal activity related to prescribing, dispensing, and consumption of controlled substances, the Controlled Substance Prescription Monitoring Program (PMP) database also provides invaluable information to medical practitioners regarding patient care. The information allows for informed clinical decisions, increased patient safety, and minimizes professional liability risks. All states now have a statewide version of a PMP. This monitoring system is vitally important in combating the opioid crisis and it creates legal obligations for providers.³

According to information derived from the Arizona PMP, there were over 205 million opioid pills prescribed to Arizonans from January 2017 to July 2017.⁴ Using Arizona as an example and focusing on its PMP highlights the significance of rapid changes that can occur once a state of emergency is declared. Arizona Governor Doug Ducey declared a state of emergency due to the opioid overdose epidemic on June 5, 2017.⁵ This placed authority and responsibility for emergency opioid prescribing, surveillance, and treatment rules squarely in the hands of the Arizona Department of Health Services (ADHS). By July 28, 2017, the Emergency Opioid Rule Package regarding the prescribing and monitoring of controlled substances was promulgated and in effect.⁶



Each state designates a state agency to oversee its PMP—in Arizona it is the State Board of Pharmacy (ASBP). Over the last year, numerous revisions to regulations and laws related to opioid use, dispensing, and related overdoses and deaths have been enacted, including several major changes to the controlled substance PMP-mandated reporting requirements.⁷ The ASBP began collection of dispensing pharmacy data in October 2008 and practitioner data in October 2009 following the passage of H.B. 2136 and A.R.S. 36-2602, which required a computerized central database tracking system for the prescribing, dispensing, and consumption of controlled substances in Arizona.⁸ Originally, the requirement was applicable to Schedule II, III, and IV controlled substances but as of August 9, 2017 the requirement was expanded to include Schedule V controlled substances. This revision also expanded the scope of use and release of patient and provider information contained in the PMP to include ADHS “regarding persons who are receiving or prescribed controlled substances in order to implement a public health response to address opioid overuse or abuse.”⁹

The November 5, 2017 Draft Arizona Opioid Prescribing Guidelines require a health care provider or institution to develop a system for opioid stewardship, i.e. monitoring opioid prescribing practices, outcomes, and provider alignment with guidelines and best available evidence.¹⁰ The first step for any provider in Arizona is to review the patient report and information contained in the PMP in order to determine what controlled substances the patient has been prescribed or is currently using to assess potential risks, adverse outcomes, and complications should opioids be prescribed, and to explain in a meaningful way the risks associated with opioid use to the patient in order to obtain informed consent. A key component of any prescribing or course of treatment involving the use of an opioid is the reporting of any prescription to the PMP database. The accuracy of information contained in the PMP database depends on accuracy of information reported by providers and pharmacies.

Revisions to Arizona regulations have directly impacted the prescribing of opioids and the role of the PMP. For instance, A.R.S. 36-2606 now requires all medical practitioners who are licensed under Title 32 or Title 36 and who possess a United States Drug Enforcement Agency (DEA) license or an active registration under the Controlled Substances Act¹¹ to register with the ASBP for access to the PMP. Each DEA license must have an associated registration, and each DEA licensed provider in the practice must have an individual PMP registration.¹²

Clinical Flow and Practical Use of the PMP

Providers can, and should, also query their own controlled substance prescribing history to make certain that they are not listed as the prescriber for non-patients and that their DEA license has not been compromised. If there is a discrepancy or mistake the provider should reconcile the information to ensure both provider and patient information in the database is accurate.¹³ The PMP is a

valuable tool for ensuring patient care and provider safety but, in order to be effective, it must be accurate and well utilized. Pursuant to federal law, “all prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.”¹⁴ This information is contained in the PMP and providers who monitor their own prescriber information or “report card” and identify incorrect information can correct mistakes. The first step is to contact the dispensing pharmacy and verify the details. If the information is indeed incorrect, the pharmacy needs to correct the information and resubmit their data to the ASBP. If the inaccuracy is larger in scope, the provider can contact the PMP administrative staff at ASBP directly for assistance.¹⁵

Each provider can designate a “delegate” (an employee or person to act on the provider’s behalf) who can access the PMP, query a patient record, and put the patient PMP report in front of the treating provider for review. In a multi-provider practice, providers can have the same delegate but it is important for the delegate to ensure they are properly logging in as a delegate under the provider who will be treating that patient so that PMP information is accurate as to which provider queried and reviewed patient PMP data. This is an often misunderstood function because in some practices the medical director or a sole provider has an account, but doesn’t designate a delegate or require all providers in a practice to register for their own separate account. Sometimes, the medical assistant or practice manager will query the patients on the schedule for the next day in the account of the medical director or registered provider for the treating provider to review. When this happens, the PMP will only reflect the fact the medical director or sole registered provider queried the patient PMP, though the patient was treated by a different provider. While the provision of care may be proper and the PMP is being reviewed and patients are being counseled accordingly, the information contained in the PMP is incorrect. This specific example can lead to the medical director or registered physician account in a multi provider practice being used to query excessive numbers of patients. Due to the incorrect use of a single ID login the data can falsely indicate that other providers in the practice are not properly reviewing patient reports or accessing the database at all, despite prescribing controlled substances to those patients. This type of practice error can lead to skewed and inaccurate PMP data that can in turn be referred to various licensing boards and investigative agencies for review and investigation.¹⁶

In order for the data contained in the PMP to be accurate and reliable, every provider must be registered separately and the delegate must use the proper login for the provider PMP access. This maintains the integrity within the database of each provider’s account, accessing history, prescribing history, and patient records and it avoids the appearance of overprescribing.

Physician Organizations

Arizona PMP Requirements Change Rapidly Under State of Emergency

In Arizona, the latest mandate for all providers to use the PMP database became effective October 16, 2017.¹⁷ Each medical practitioner's regulatory board will notify its respective licensees of the mandate. A medical practitioner may be granted a one-year waiver from the mandated PMP registration requirement due to technological limitations that are not reasonably within the control of the practitioner or other exceptional circumstances demonstrated by the practitioner pursuant to a process established by the ASBP. Despite the possible exception, the rapid rule-making and focus on the opioid crisis has led to a situation where the rule became effective before there was a process in place for providers to seek the waiver.¹⁸ As of the date of this writing, there are no rules or process yet in place for obtaining such a waiver, which means those physicians not registered and using the PMP are not in compliance.

The impact of these recent changes will be to require that before beginning a new course of treatment that includes prescribing an opioid analgesic or benzodiazepine controlled substance listed in schedule II, III, IV and now V for a patient, a medical practitioner must obtain a PMP patient utilization report regarding that patient for the preceding 12 months and that the patient PMP report must be updated at least quarterly while that prescription remains part of the patient's treatment plan. With patients on long term controlled medications, it is advisable that the prescribing

provider, often a pain management specialist, review the current PMP at each visit. This practice enables a provider to ascertain whether the patient is properly utilizing the prescription(s); has other contradictory substances such as alcohol or illegal drugs or even no trace of the prescribed medications in their system through use of recommended urine screening. The morphine equivalency dosing (M.E.D.) information contained in the PMP can provide prescribers and pharmacists the ability to ensure the patient is receiving the proper dosage(s) or treatment. These key factors can serve as red flags to providers and can significantly impact treatment and the identification of possible opioid abuse.

The PMP database in Arizona is now also used to track dispensing of Naloxone, a non-addictive drug that reverses the excessive central nervous system depression and respiratory distress that can be caused by opioid use. Under the state of emergency orders, Naloxone has been made more readily available. On June 19, 2017, a standing order, signed by the Director of the ADHS, authorized any Arizona licensed pharmacist to dispense naloxone hydrochloride or any other opioid antagonist that is approved by the United States Food and Drug Administration (FDA) to any individual without requiring a physician's prescription.¹⁹ It also allowed prescribers to dispense Naloxone to law enforcement, jails, social workers, and laypeople. This also supports pain management providers who have implemented practice protocols for prescribing Naloxone to chronic pain sufferers who substantially benefit from long term opioid therapy. The dispensing of Naloxone now requires mandatory reporting to the PMP database.



Accuracy of Information Is Key for Providers and Patients

Information contained in the database can have significant impacts on providers and patients alike. The ASBP generates a report card for providers based on their prescribing data in the PMP. Each provider can register under one of 31 specialties and their data will be analyzed in relation to the data obtained on similarly situated providers within the same specialty. Thus a pediatrician will not be compared to a pain management specialist. However, the top 25-50 prescribers above the mean per specialty are identified and those with above average controlled substance prescribing numbers are notified by a quarterly report card issued by the ASBP that they are "outliers" in terms of PMP data. The reporting of PMP statistical information to various licensing boards presents

legal issues beyond the scope of this discussion, however it is yet another reason for providers to be especially accurate in terms of PMP reporting.²⁰

Utilizing shared multistate information or accessing the PMP databases of states connected to the continuum of care for patients, is another way for providers to have more information to properly assess and treat patients. Providers in Arizona, for example, often treat winter residents. These patients are often treated by physicians in other parts of the country and it can be difficult to effectively evaluate a patient without prescription data. The American Hospital Association (AHA) in a September 21, 2017 comment letter, responding to an interim report issued in July by the new White House Commission on Combating Drug Addiction and the Opioid Crisis, supported the Commission's efforts to ensure interstate data sharing among prescription drug monitoring programs.²¹ Arizona PMP registered users can select from a list of participating states to obtain multi-state approval for sharing of information between states enrolled in the PMP Clearinghouse, which is a consortium of participating states. The ASBP is a member of the National Association of State Controlled Substances Authorities (NASCSA) and is working diligently to facilitate a national reporting system as well as integrate the Arizona PMP with various electronic health record and pharmacy dispensing systems to make information more comprehensive, accurate, and readily available. Missing or inaccurate information in the database remains an issue and has been identified by providers and investigative agencies as a sound reason for improving both state and national information sharing, provider education on use of the databank, and methods to correct identified mistakes or inaccuracies.²² Recently, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended funding to bolster PMP requirements, including development of a national data sharing hub, mandated PMP queries, PMP data integration into electronic health records, and an increase in electronic prescribing to prevent diversion and forgery.²³

As regulations and laws continue to develop and be implemented, it will be imperative for providers to ensure accurate information is reported to the PMP. The next year will be filled with changes to the controlled substance related monitoring system, but the PMP is emerging as a key resource for addressing the opioid state of emergency in Arizona.

system. S.B. 1283 further requires practitioners to obtain a patient utilization report regarding the patient for the preceding twelve months at the beginning of each new course of treatment; before prescribing an opioid analgesic or benzodiazepine listed in Schedule II, III, IV, and V; and on a quarterly basis if the substance remains part of treatment.

- 4 ADHS Draft Arizona Opioid Prescribing Guidelines, Oct. 5, 2017, available at <http://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf>; 2016 ADHS Arizona Opioid Report, available at <http://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/arizona-opioid-report.pdf>; and President's Commission on Combating Drug Addiction and the Opioid Crisis Chairman's Letter, November 1, 2017.
- 5 https://azgovernor.gov/sites/default/files/related-docs/opioid_declaration.pdf.
- 6 A.A.C. R9-10-Article 1 focuses on health and safety while implementing regulatory consistency for all health care institutions.
- 7 <https://pharmacypmp.az.gov/new-pmp-reporting-mandates-naloxone-and-c-v-0>.
- 8 4 A.A.C. Title 4. Professions and Occupations, Chapter 23, R4-23-501, Board of Pharmacy, Article 5.
- 9 Chapter 283, Senate Bill 1023, amending A.R.S. Sections 36-2602; 36-2604 and 36-2608 became effective on August 9, 2017 and included the required reporting of Schedule V controlled substances prescribed, dispensed, or consumed to the PMP database, available at <https://www.azleg.gov/legtext/53Leg/1R/laws/0283.pdf>.
- 10 Arizona Opioid Prescribing Guidelines, November 5, 2017 available at <http://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/draft-opioid-prescribing-guidelines.pdf>.
- 11 21 U.S.C. § 801-904.
- 12 Arizona Prescription Monitoring Program User Support Manual Section 2.2, available at <https://pharmacypmp.az.gov/sites/default/files/documents/files/Arizona%20-%20PMP%20AWARxE%20Requestor%20User%20Support%20Manual.pdf>.
- 13 Perrone J, Nelson LS, *Medication reconciliation for controlled substances an "ideal" prescription drug monitoring program*, N ENGL J MED. 2012;336(25):2341-2343.
- 14 Title 21 C.F.R. § 1306.05(a).
- 15 https://pharmacypmp.az.gov/sites/default/files/documents/files/Report%20Card%20FAQs_4.pdf.
- 16 State of Arizona, Executive Order 2017-04, Enhanced Surveillance Advisory requires law enforcement, licensing boards, state agencies, and providers to participate in mandatory reporting and sharing of information. See also *Oregon Prescription Drug Monitoring Prog. v. DEA*, No. 14-35402 (9th Cir. June 26, 2017).
- 17 <https://www.azleg.gov/viewDocument/?docName=http://www.azleg.gov/ars/36/02606.htm>.
- 18 A.R.S. 36-2606(F) enumerates the mandate and the exception to the rule, but defers the process for obtaining a waiver to the ASBP.
- 19 <https://pharmacypmp.az.gov/sites/default/files/documents/files/naloxone-standing-order.pdf>.
- 20 Arizona PMP Task Force Meeting 2017 Minutes.
- 21 <http://www.aha.org/advocacy-issues/letter/2017/170921-let-thompson-eop-opioidcrisis.pdf>.
- 22 *How Clinicians Use Prescription Drug Monitoring Programs: A Qualitative Inquiry*, PAIN MED. 2014 Jul; 1179-1186. See Table 2.
- 23 https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

1 Brian Zimmerman, "6 States Fighting Opioid Epidemic with Emergency or Disaster Declarations," Becker's Hospital Review, Aug. 10, 2017, available at <https://www.beckershospitalreview.com/opioids/6-states-fighting-the-opioid-epidemic-with-emergency-or-disaster-declarations.html>.

2 Notice of Emergency Rulemaking, Title 9 Health Services Chapter 4 Arizona Department of Health Services.

3 E.g., A.R.S. 36-2606 mandates each medical practitioner who is issued a license and possesses an Arizona registration under the Controlled Substances Act must have a current PMP registration and access to the database tracking

Resource Corner

Have You Read This Publication?

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