



# Rx Gatekeeper: Looking at the Opioid Crisis from the Pharmacy Perspective

By Darshan Kulkarni, Synchrogenix; Ashley Thomas, Baker Donelson; and Andrea Tunnard

Cancer advocates cite the phrase, “everyone knows someone” to remind people of the prevalence of cancer. Unfortunately, the epidemic proportions of people suffering from opioid addiction suggest that “everyone [may indeed] know someone” affected by the opioid epidemic. The National Institutes of Health reports that 90 Americans die from opioid overdose deaths daily, and that half of those deaths involve prescription opioids.<sup>1</sup> The severity of the opioid crisis has prompted intervention from the federal government including President Trump calling the crisis a public health emergency.<sup>2</sup> Pharmacists can play a key role in the fight against the opioid crisis. This article focuses on the epidemic through the lens of the pharmacy and pharmacists in monitoring opioid prescription practices.

## Fixing the Problem

Because the opioid problem is complex, it will require a multi-faceted approach as governments, health care providers, and advocates struggle to make progress. Initial steps have been taken to address the ongoing problem.

## Federal Government

Prior to designating the opioid crisis as a “public health emergency,” the President created the Commission on Combating Drug Addiction and the Opioid Crisis (Commission) in March 2017, to study and identify the ways the government can reduce opioid abuse.<sup>3</sup> The Commission’s Final Report was released on November 1, 2017 outlining direct recommendations for government agencies and pharmacy associations to help support pharmacies in monitoring opioid prescriptions. The Commission recommended better training in evaluating the legitimacy of opioid prescriptions and to stop penalizing pharmacists for denying inappropriate prescriptions. The Commission cited a study from Wisconsin finding that a not insignificant minority of pharmacists did not understand federal and state laws about evaluating the legitimacy of a controlled substance prescription.<sup>4</sup> According to the Commission, 36% of these pharmacists considered extended prescribing of opioids to be a violation of law or unacceptable medical practice. A pharmacist’s main responsibility is to dispense valid prescriptions and to recognize illegitimate prescriptions. Pharmacists are not well equipped to provide safe care to the patient if a number of pharmacists cannot distinguish between acceptable and unacceptable prescribing practices.

## Controlled Substances Act (CSA) and Drug Enforcement Administration (DEA)

The CSA establishes federal requirements for importing, manufacturing, and dispensing controlled substances and requires all businesses operating in this area to register with the DEA.<sup>5</sup> When the CSA was passed in 1970 it created a closed system of distribution of controlled substances and established a regulatory framework to control every facet of handling these substances, from manufacture to consumption. The CSA was designed to prevent abuse or diversion of controlled substances while also ensuring an adequate supply of controlled substances for legitimate medical needs.

The DEA is charged with enforcing controlled substances laws, including the CSA, and holding responsible those organizations and individuals that violate the law. Tackling the opioid crisis is a top priority of the DEA, which is actively cracking down on medical offices acting as “pill mills” and curbing the import of fentanyl and other controlled substances. The 2017 National Drug Threat Assessment released by the DEA in October 2017 showed the opioid crisis continues to be a vexing challenge, and the DEA will continue to focus its attention in this area.<sup>6</sup> The DEA has increased its enforcement efforts against pharmacies suspected of diverting controlled substances.

Because pharmacists are the gatekeepers between patients and drugs, it is imperative that pharmacists understand and follow the requirements of the CSA. Failure to do so can have severe medical consequences for the patient, as well as legal consequences for the pharmacist. Pharmacies and pharmacists are obligated by the CSA to:

- » Fulfill their “corresponding responsibility”
- » Verify DEA registration or licensure
- » Be attentive to “red flags” and verify questionable prescriptions

Under the CSA, pharmacists have a “corresponding responsibility,” meaning the individual pharmacists have an obligation to ensure the controlled substance she is dispensing is for a legitimate medical reason and written by a medical professional in the usual course of professional practice. This corresponding responsibility does not mean the pharmacist has to stand in the shoes of the medical professional prescribing the controlled substance, but rather pharmacists have an obligation to exercise



their professional judgment in scrutinizing the prescriptions the pharmacist receives and dispenses. In practice, pharmacists should be on the lookout for so called “red flags.” Red flags are warning signs that a controlled substance is not being obtained for a legitimate medical purpose but rather for diversion or abuse. Some examples of red flags include:

- » Patient has multiple controlled substances prescription from multiple physicians
- » Patient receives multiple controlled substances that treat the same symptoms
- » Patient seeks early refills
- » Patient travels long distances to see physician and pharmacist
- » A significant number of prescriptions are paid for in cash
- » Pharmacist learns that patient’s prescription refill has been denied by another pharmacist

Any one of these red flags taken alone or together should send signals to a pharmacist to conduct further investigate before filling the prescription. The pharmacist has the obligation to exercise reasonable due diligence when investigating a prescription the pharmacist believes is not for a legitimate medical purpose. In addition, pharmacists have the obligation to verify the validity of the prescribing physician’s DEA registration. Determining red flags is a fact-based analysis that requires the pharmacist to know the patient’s medical needs and the prescribing practices of the physician. If the pharmacist encounters a red flag, the pharmacist should check with the state prescription drug monitoring program (PDMP), or contact the prescribing physician to confirm the prescription.

When a pharmacist registers with the DEA, the pharmacist certifies that he or she will maintain accurate records. Diligent recordkeeping ensures the intended closed system under the CSA functions effectively and will let providers and law enforcement know when diversion issues arise because it will be easy to identify such abuse from the records. This means pharmacists should be monitoring their drug inventory to make sure the records are accurate and labeling is appropriate. If a pharmacist discovers a theft or loss of controlled substances, the pharmacist should immediately follow up with the DEA within one business day.<sup>7</sup> This is an area where pharmacists should be cognizant of state laws or state pharmacy board obligations because some states may have a more stringent reporting deadline. If a pharmacy falls victim to a theft or loss of controlled substances, the pharmacy should critically evaluate their policies and procedures to determine where the security breakdown occurred and use the situation as an opportunity to develop better practices to ensure compliance with CSA requirements.

When pharmacies fail to fulfill these responsibilities, there can be penalties under the CSA. For example, in March 2017, Rite Aid paid \$834,200 in civil monetary penalties for alleged violations of the CSA.<sup>8</sup> According to the government, Rite Aid pharmacies allegedly violated the CSA by dispensing

and recording controlled substances using a medical practitioner’s incorrect or invalid DEA registration number and failing to maintain an accurate internal database monitoring and tracking this activity. The government found multiple occasions where Rite Aid dispensed prescriptions written by a medical practitioner whose DEA registration number had been previously revoked by the DEA for good cause. In addition to the settlement, Rite Aid implemented a registration validation program created to verify and monitor DEA registration numbers from medical practitioners who submit prescriptions to Rite Aid.

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## Food and Drug Administration (FDA)

Like the DEA, the FDA also is looking to curb the ongoing opioid crisis, and has taken proactive steps to assist drug companies in the approvals process for abuse deterrent opioids, or drugs that treat addiction. In its guideline titled *Abuse-Deterrent Opioids—Evaluation and Labeling*, the agency calls on drug companies to make painkillers harder to manipulate for abuse (through crushing for snorting or injecting).<sup>9</sup> The FDA helped to make Naloxone (an overdose reversal drug) an over-the-counter product and hence improve access.<sup>10</sup> Nevertheless, there have been challenges. While the FDA has expressed a sense of urgency in dealing with the opioid crisis, it must balance the need for new drugs with the need for efficacy and safety.

Additionally, the FDA has developed Risk Evaluation and Mitigation Strategies (REMS) to guide prescriber decisions and educate patients. The Opioid REMS is composed of 72 strategies for improving patient safety, communication, and knowledge about FDA-approved medication. REMS guidelines for opioid drugs include training for prescribers about risks of abuse and addiction.<sup>11</sup> On January 30, 2018, the FDA released a revised Blueprint for REMS education providing training information on pain management including the principles of acute and chronic pain management, non-pharmacologic treatments for pain, and pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic).

## State Oversight of Pharmacies & Pharmacy Wholesalers

Like the federal government, the states have worked to help their residents avoid and address addiction to prescription medications. States have helped establish PDMPs that use “state-run electronic databases to track the prescribing and dispensing of controlled prescription drugs to patients.”<sup>12</sup>



These programs are an important tool in monitoring potential drug abuse since they help detect problems like pharmacy and prescriber hopping and early refills.<sup>13</sup> PDMPs can be highly effective; as an example, overdose deaths from OxyContin in Florida dropped 25% within one month of implementation.<sup>14</sup>

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In an unprecedented settlement in Georgia, a federal court ordered two individual pharmacists to pay \$5 million in “community restitution” damages for supplying a well-known “pill mill” pain clinic. According to the Department of Justice, the community restitution damages are the first of its kind in the United States. The settlement is intended to recognize the public harm of drug diversion, and the money will go directly to state agencies that provide victim assistance and substance use treatment services.<sup>15</sup>

Some states also are looking into the actions of wholesale drug distributors. In Kentucky, the state charged McKesson Corporation for its alleged role in fueling the drug epidemic.<sup>16</sup> The lawsuit alleges that McKesson distributed an abnormally high number of opioid pills, and failed to report the suspicious orders to the DEA. In one county in Kentucky, the lawsuit claims that McKesson supplied enough pills for each resident to have received more than 400 pills in a six-year period, a figure significantly higher than the average demand for opioids. Prosecutors argue that by ignoring the red flags associated with such high volumes of opioid orders, McKesson helped supply pill mills rather than working with the proper authorities to initiate an investigation into the orders.

To prevent a situation like the one described in Kentucky, West Virginia and Oregon are requesting pharmacy wholesalers to provide reports of “suspicious orders” of opioids. These reports should enable the wholesalers to proactively investigate unscrupulous activity. West Virginia plans to require wholesale distributors to flag orders “of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency” by filling out paper forms monthly and submitting them to the West Virginia Board of Pharmacy.<sup>17</sup> Additionally, they also plan to implement a “zero reporting” requirement. A zero reporting requirement would require a wholesale distributor that does not encounter a suspicious order in one calendar month, to report such information to the West Virginia Board of Pharmacy within 15 days from the end of the month. Oregon, unlike West Virginia, does not have a zero reporting requirement or provide a timeline of when suspicious orders must be reported but does require that the distributor should provide notice to the Oregon Pharmacy Board “upon discovery.”<sup>18</sup>

## Pharmacies and E-Prescribing

Pharmacies are changing their policies to help address the opioid epidemic. CVS Caremark, the pharmacy benefits management company for CVS pharmacy, has implemented new policies to address the opioid problem such as limiting the number and strength of opioid pills available to first time patients.<sup>19</sup> Walgreens aims to address the opioid problem with its #ItEndsWithUs campaign, while Walmart is giving away free disposal packets to help rid patients of opioids securely. Some states have passed laws empowering pharmacists to prescribe naloxone, the overdose reversal drug, to patients filling opioid prescriptions.<sup>20</sup> The National Community Pharmacists Association has urged Congress to require electronic prescribing (e-prescribing) of opioids, which would make it harder for fraudulent prescriptions to be given to pharmacists.<sup>21</sup>

Because pharmacists have a one-on-one interaction with patients, they have a unique opportunity to recognize and act upon the signs of abuse and addiction. The FDA has called on pharmacists to receive more training in recognizing the signs of addiction. This will hopefully empower pharmacists to intervene when necessary, possibly leading to a conversation about treatment options for addiction. There are limitations to these actions, however. Conversations about drug abuse are sensitive and sometimes unwelcome. Still, the pharmacist has the responsibility to act in the best interest of the patient, and that may require acting upon their suspicions regarding a patient’s drug use.

One way to make pharmacists’ jobs easier with respect to detecting drug abuse in patients is to implement e-prescribing systems. The DEA established this system to help limit the number of fraudulent opioid prescriptions taken to pharmacies, as well as adulteration of the original written prescriptions.<sup>22</sup> Although not mandatory in every state, e-prescribing is used by almost 90% of retail pharmacies.<sup>23</sup> E-prescribing requires that the prescriber is authenticated and registered with the DEA before any controlled substances prescriptions may be written. Because the patient does not have access to a paper “script,” he does not have the opportunity to edit it in any way. In New York, Minnesota, and Maine e-prescribing is mandatory for controlled substances, and similar legislation is being considered in California, Missouri, and Vermont.<sup>24</sup>

## Medicare Part D

On February 1, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a Draft Call Letter announcing that it is considering new strategies to reduce opioid overutilization under Medicare Part D. One strategy contemplates new “hard-formulary levels” for pharmacies in filling opioid prescriptions, as one way to limit opioids prescriptions.<sup>25</sup> The maximum allowable level is 90 morphine milligram equivalent (MME), with a seven-day supply allowance. The plan sponsor can override the amount after consulting the prescribing physician. CMS is proposing to limit initial prescription fills for treatment of acute pain with or without a daily maximum dose.



In addition, CMS is looking to enhance the current opioid utilization monitoring system by adding flags for beneficiaries who use certain drugs in combination with prescription opioids and is considering a new measure on the concurrent use of opioids and benzodiazepines. CMS accepted comments until March 5, 2018.

### Telemedicine

When President Trump declared the opioid crisis a public health emergency, he requested expanded access to telemedicine services, including services involving remote prescribing for substance use and mental health treatment.<sup>26</sup> Currently, the Ryan Haight Online Pharmacy Consumer Protection Act (Haight Act) requires a controlled substance to be dispensed via a valid prescription that is issued following an in-person evaluation with a medical professional. Providers are prohibited from dispensing controlled substances to a patient who lacks a valid prescription and in-person medical evaluation, unless one of the narrow telemedicine exceptions set forth in the Haight Act applies. The Act was enacted to reduce the proliferation of online pharmacies selling controlled substances without a valid medical purpose. The Commission recommended the use of telemedicine to assist in expanding access to treatments for patients with opioid dependence disorder and some providers were hopeful that Haight Act requirements would be relaxed after the opioid crisis was declared a public health emergency. In January 2018, several U.S. Senators wrote a letter to the DEA urging the agency to promulgate rules that would allow health care providers to prescribe medication-assisted treatments via telemedicine.<sup>27</sup> However, as of this writing, DEA has not proposed any such regulations.

### Compliance Tips

In January 2017, U.S. Attorney General Jeff Sessions announced the DEA's intent to increase scrutiny of pharmacies and prescribers.<sup>28</sup> According to the Attorney General, the DEA collects around 80 million transaction reports every year from manufacturers and distributors of controlled substances. From this information, the DEA will look for trends and outliers in determining who to investigate. Pharmacies and pharmacists are on notice that more enforcement is coming.

It is imperative that pharmacies and pharmacists evaluate their current policies and procedures and make necessary changes to ensure compliance with applicable federal and state laws. All pharmacists need to be familiar with their state's requirements to operate a pharmacy and dispense controlled substances. Most state pharmacy boards have developed resources educating pharmacists on the regulatory requirements and effective operations and pharmacists should consult these resources.

Some states may require pharmacists to actively consult the local or state PDMP. A pharmacist operating in a state without a mandatory PDMP check requirement that allows the

pharmacist to access PDMP information should nevertheless utilize the PDMP as a tool to help prevent abuse. Pharmacies should consider conducting internal audits to quantify their distribution of controlled substances. This could help them prepare for an investigation, in which the DEA will be looking at the proportion of controlled substances dispensed out of all prescriptions at a pharmacy.

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### Looking Forward

Pharmacists must remain engaged with lawmakers as public policy is created to address the opioid crisis. Additionally, the responsibility of addiction treatment should be delegated among the various professionals best equipped to deal with the problem. While pharmacists certainly have a role to play in preventing addiction, it is important that we do not create policies that expect those professionals alone to treat or cure addiction. Instead, we must work collaboratively with social workers, counselors, and those who study addiction to create the best outcomes for individuals, families, and communities who are coping with this devastating epidemic. 



**Darshan Kulkarni**, Pharm.D, MS, is currently Vice President of Regulatory Strategy at Synchrogenix, a life sciences consultancy and services innovation platform, and is the Principal Attorney at the Kulkarni Law Firm. He is also Visiting Professor in the Biomedical Writing Program at the University of the Sciences.



**Ashley Thomas**, is an Associate in the Washington, DC office of Baker Donelson. Ashley provides counsel to a broad range of health care industry clients on a wide variety of regulatory compliance matters. She currently serves as the Vice-Chair of Research and Website for AHLA's Public Health System Affinity Group.



**Andrea Tunnard** is an MS candidate in the Biomedical Writing program at University of the Sciences.

## Endnotes

- 1 CTRS. FOR DISEASE CONTROL & PREVENTION (CDC), Fact Sheet, Prescription Opioid Overdose data, available at <https://www.cdc.gov/drugoverdose/data/overdose.html>.
- 2 Greg Allen & Amita Kelly, *Trump administration declares opioid crisis a public health emergency*, NPR, Oct. 26, 2017, available at <https://www.npr.org/2017/10/26/560083795/president-trump-may-declare-opioid-epidemic-national-emergency>.
- 3 *Id.*
- 4 AM Gilson, *Pharmacists and Controlled Substances Prescriptions*, MEDSCAPE, May 15, 2009, available at <http://www.medscape.com/viewarticle/701794>.
- 5 21 U.S.C. § 811.
- 6 DRUG ENFORCEMENT ADMIN. (DEA), Press Release, *DEA releases 2017 National Drug Threat Assessment*, Oct. 23, 2017, available at <https://www.dea.gov/divisions/hq/2017/hq102317.shtml>.
- 7 21 C.F.R. § 1301.76(b).
- 8 DEP'T OF JUSTICE (DOJ), Press Release, *Rite Aid Corporation Pays \$834,200 to Settle Allegations of Violating the Controlled Substances Act*, Mar. 9, 2017, available at <https://www.justice.gov/usao-cdca/pr/rite-aid-corporation-pays-834200-settle-allegations-violating-controlled-substances-act>.
- 9 80 Fed. Reg. 17765 (Apr. 2, 2015).
- 10 Karen Mahoney, MD, *FDA supports greater access to naloxone to help reduce opioid overdose deaths*, FDA BLOG, Aug. 10, 2016, available at <https://blogs.fda.gov/fdavoices/index.php/2016/08/fda-supports-greater-access-to-naloxone-to-help-reduce-opioid-overdose-deaths/>.
- 11 FOOD AND DRUG ADMIN. (FDA) Database, *Approved risk evaluation and mitigation strategies (REMS)*, available at <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemsData.page>.
- 12 CDC Injury Center, *What states need to know about PDMPs*, available at <https://www.cdc.gov/drugoverdose/pdmp/states.html>.
- 13 Carolyn Heinze, *Prescribed Measures: Identifying and Preventing Prescription Abuse*, PHARMACY TIMES, Sept. 24, 2009, available at <http://www.pharmacytimes.com/publications/issue/2009/september2009/featurefocusprescriptionabuse-0909>.
- 14 C. Delcher et al., *Abrupt decline in oxycodone-caused mortality after implementation of Florida's Prescription Drug Monitoring Program*, DRUG ALCOHOL DEPEND., May 1, 2015.
- 15 DOJ, Press Release, *Two pharmacists sentenced to 19 and 20 years in prison and ordered to pay \$5 million in restitution to the State of Georgia to combat the opioid epidemic*, Oct. 27, 2017, available at <https://www.justice.gov/usao-ndga/pr/two-pharmacists-sentenced-19-and-20-years-prison-and-ordered-pay-5-million-restitution>.
- 16 Jonathan Sperling, *Suit accuses drug distributor McKesson of fueling Kentucky's opioid epidemic*, ASSOCIATED PRESS, Jan. 22, 2018, available at <https://www.nbcnews.com/storyline/americas-heroin-epidemic/suit-accuses-drug-distributor-mckesson-fueling-kentucky-s-opioid-epidemic-n839921>.
- 17 W. VA. ADMIN. R. § 15-2-5.3.
- 18 OR. ADMIN. R. § 855-065-0010.
- 19 Andrew Joseph, *CVS tightens restrictions on opioid prescriptions in bid to stanch epidemic*, Sept. 21, 2017, available at <https://www.statnews.com/2017/09/21/cvs-opioid-prescription-limits/>.
- 20 PRESCRIPTION DRUG ABUSE POLICY SYSTEM (PDAPS), *Naloxone overdose prevention laws*, July 21, 2017, available at <http://pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139>.
- 21 NAT'L COMMUNITY PHARMACISTS ASS'N, *Recommendations for federal response to opioid crisis* 2017.
- 22 DOJ, *Electronic prescriptions for controlled substances* (2010).
- 23 OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., *Electronic prescribing of controlled substances (EPCS)*, available at <https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/#section-4-3>.
- 24 See N.Y. STATE DEP'T OF HEALTH, *Electronic Prescribing*, available at [https://www.health.ny.gov/professionals/narcotic/electronic\\_prescribing/](https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/). See also Pillo, Valerie, *More states require e-prescribing to combat fraud and abuse*, Decision Resources Group, Dec. 23, 2016, available at <https://decisionresourcesgroup.com/drg-blog/health-reform/states-require-e-prescribing-combat-fraud-abuse/>.
- 25 CMS, Fact Sheet, 2019 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter, Feb. 1, 2018, available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-02-01.html>.
- 26 White House, Press Release, *President Donald J. Trump is taking action on drug addiction and the opioid crisis*, Oct. 26, 2017, available at <https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/>.
- 27 Letter from U.S. Senators' Claire McCaskill, Lisa Murkowski, & Dan Sullivan to DEA Acting Administrator, Robert W. Patterson, Jan. 30, 2018, available at <https://www.hsgac.senate.gov/imo/media/doc/2018-01-30%20CMC%20Murkowski%20Sullivan%20ltr%20to%20DEA%20re%20telemedicine.pdf>.
- 28 DOJ, Press Release, *Attorney General Sessions Announces DEA Surge to Combat Prescription Drug Diversion*, Jan. 31, 2018, available at <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-dea-surge-combat-prescription-drug-diversion>.

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