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Opioids: Part II of III
Legislation and Regulation Combat Epidemic

The opioid epidemic poses a significant threat to the public health, such that, to date, six states have issued emergency declarations in response to opioid misuse (i.e., addiction).[1] In an attempt to hinder prescription opioid misuse, regulatory and legislative authorities, as well as the courts, have taken action by tracking prescriptions, controlling the supply of opioids, and policing the marketing of these drugs, among other enforcement activities.

In an attempt to combat prescription drug misuse, states have developed and implemented *Prescription Drug Monitoring Programs* (PDMPs). A PDMP is a statewide electronic database that collects data on certain drugs dispensed throughout the state and distributes this data to individuals authorized under law to receive this information.[2] Data collection and reporting vary across states, but by tracking prescription and patient histories, PDMPs may help to identify patients who may be diverting or abusing opioids and other drugs.[3] State reports on the success of PDMPs have indicated that PDMPs have had a positive impact by reducing the number of patients receiving prescriptions from multiple physicians simultaneously, also known as "*doctor shopping.*"[4] Currently, PDMPs are implemented in every state (including Washington, D.C.), with the exception of Missouri.[5] In July 2017, Missouri Governor Eric Greitens signed an executive order creating a multi-phase PDMP.[6] Although Missouri's PDMP is not currently in use and has an uncertain launch date, its development is in progress.[7] In addition to PDMPs, states are also moving to mandated *electronic prescribing of controlled substances* (EPCS), in which physicians are prohibited from prescribing opioids in written form.[8] This effort may serve to mitigate the risk both of written prescriptions being stolen or altered, and of multiple physicians writing the same prescription for the same patient.[9] Currently, three states have passed legislation mandating EPCS, and eight states have introduced such legislation.[10] Further, Maine has successfully reduced the prescription of opioids by enacting legislation that restricts physicians from prescribing patients over 100 *morphine milligram equivalents* (MME) per day.[11] This legislation received strong pushback from patients and physicians, but by adding additional exceptions, both patients and physicians has endorsed this legislation.[12]

On the federal level, the *Food and Drug Administration* (FDA), *Drug Enforcement Administration* (DEA), and *Department of Justice* (DOJ) have taken action to restrict access to opioids and combat the fraudulent diversion or dispensation of opioids. The FDA has implemented a comprehensive action plan that, among other efforts, will require the FDA to assemble an expert advisory committee that will review applications for new opioids that lack abuse-deterrent properties.[13] Additionally, on June 8, 2017, the FDA requested that the drug maker Endo Pharmaceuticals halt sales of Opana ER, a powerful opioid, due to public health concerns,[14] and the drug maker voluntarily complied.[15] This was the first time that the FDA had ever sought the removal of an approved opioid from the market.[16] The DEA has also taken regulatory action to fight the opioid epidemic by restricting the manufacture of Schedule II opioids by 25 percent in 2017.[17] In addition, some drugs, such as hydrocodone, have been reduced to 66 percent of the 2016 level.[18] Further, the DOJ has created an opioid fraud and abuse detection unit that will pursue healthcare fraud claims specifically related to opioids.[19] The unit will use data analytics to identify potential opioid-related fraud activities and prosecute the individuals who are believed to be exacerbating the opioid epidemic.[20] For example, the unit's data analytics will be able to identify physicians who are prescribing opioids at a much higher rate than their peers; the unit will then work with other federal and state bodies to determine if fraud or abuse is present, and consequently prosecute the appropriate claim(s).[21]

Although recent Republican efforts to *repeal* and *replace* the 2010 *Patient Protection and Affordable Care Act* (ACA) were unsuccessful,[22] the proposed legislation may indicate future stances on opioid treatment. For example, the revised version of the *Better Care Reconciliation Act of 2017* (BCRA), the (ultimately unsuccessful) Republican Senate bill that attempted to repeal and replace the ACA, proposed an allotment of $45 billion per year to states to combat the opioid epidemic, an increase from the initial $2 billion in state allotment proposed in the original version of BCRA.[23] Originally refusing advice from both *Health and Human Services* (HHS) Secretary Tom Price and the *Commission on Combating Drug Addiction and Opioid Crisis* to declare a national state of emergency on the opioid crisis, President Trump later reversed course and verbally

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declared a national state of emergency,[24] however, no official action has occurred yet.[25] Although President Trump has declined to name specific steps that will be taken under the national emergency declaration,[26] the declaration will allow the executive branch of the federal government to increase funding for the treatment and prevention of opioid addiction, as well as to supply police with *naloxone*, a drug used to treat opioid overdoses.[27]

In addition to state and federal legislative responses to the opioid epidemic, both states and individuals have successfully turned to the court system to regulate the use of prescription drugs, and to seek remedy for the harm suffered due to opioid misuse. In the past, successful malpractice suits have been brought against physicians for the negligent prescription of opioids;[28] however, a new wave of lawsuits specifically targeting drug distributors and manufacturers is underway. In December 2016, two pharmaceutical distributors reached a settlement of $36 million with the West Virginia Attorney General representing the West Virginia Boone County Commission.[29] In June 2017, the Missouri and Oklahoma Attorneys General filed separate lawsuits against pharmaceutical companies, for "*misrepresenting the truth*" and falsely downplaying the risk of opioid addiction.[30] These two suits follow similar lawsuits filed by the states of Ohio and Mississippi against major drug companies with essentially the same allegations.[31]

While the future of opioid regulation is still uncertain, the opioid epidemic has drawn the attention of federal and state authorities, prompting them to take steps to combat the crisis and improve public health.

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