CME

The US Opioid Crisis: Current Federal and State Legal Issues

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The United States is in the midst of a devastating opioid misuse epidemic leading to over 33,000 deaths per year from both prescription and illegal opioids. Roughly half of these deaths are attributable to prescription opioids. Federal and state governments have only recently begun to grasp the magnitude of this public health crisis. In 2016, the Centers for Disease Control and Prevention released their Guidelines for Prescribing Opioids for Chronic Pain. While not comprehensive in scope, these guidelines attempt to control and regulate opioid prescribing. Other federal agencies involved with the federal regulatory effort include the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), and the Department of Justice.Each federal agency has a unique role in helping to stem the burgeoning opioid misuse epidemic. The DEA, working with the Department of Justice, has enforcement power to prosecute pill mills and physicians for illegal prescribing. The DEA could also implement use of prescription drug monitoring programs (PDMPs), currently administered at the state level, and use of electronic prescribing for schedule II and III medications. The FDA has authority to approve new and safer formulations of immediate- and long-acting opioid medications. More importantly, the FDA can also ask pharmaceutical companies to cease manufacturing a drug. Additionally, state agencies play a critical role in reducing overdose deaths, protecting the public safety, and promoting the medically appropriate treatment of pain. One of the states' primary roles is the regulation of practice of medicine and the insurance industry within their borders. Utilizing this authority, states can both educate physicians about the dangers of opioids and make physician licensure dependent on registering and using PDMPs when prescribing controlled substances. Almost every state has implemented a PDMP to some degree; however, in addition to mandating their use, increased interstate sharing of prescription information would greatly improve PDMPs' effectiveness. Further, states have the flexibility to promote innovative interventions to reduce harm such as legislation allowing naloxone access without a prescription. While relatively new, these types of laws have allowed first responders, patients, and families access to a lifesaving drug. Finally, states are at the forefront of litigation against pharmaceutical manufacturers. This approach is described as analogous to the initial steps in fighting tobacco companies. In addition to fighting for dollars to support drug treatment programs and education efforts, states are pursuing these lawsuits as a means of holding pharmaceutical companies accountable for misleading marketing of a dangerous product. (Anesth Analg 2017;125:1675–81)

Over the past decade, opioid prescription drug abuse has grown into a national crisis. In the early 2000s, with support from the Veterans Health Administration hospitals and strong backing from the Joint Commission, pain became the "fifth vital sign."[1–3] This new requirement to monitor and assess pain led inevitably to much more aggressive treatment of pain by physicians, with a concomitant dramatic increase in prescribing of opioids. From 2000 to 2010, the number of opioid prescriptions written increased from 164 million to over 234 million.[4] Emergency department visits related to prescription opioids climbed between 150% and 200% between 2004 and 2011. In the face of this overwhelming crisis, states have been the incubator of many creative solutions not only to reduce the volume of controlled substances within their borders but also to provide care and assistance to a vulnerable population.

Perhaps most disturbing, overdose deaths from prescription drugs grew from 16,651 patients in 2010 to an astonishing 18,893 patients in 2014.[5,6] Moreover, in 2015, there were 33,091 overdose deaths involving all opioids including heroin, and the *New York Times* recently reported data from 2016 demonstrating nearly 65,000 deaths.[7] This unrelenting opioid crisis is occurring against the backdrop of a heavily regulated pharmaceutical industry.

Responding to these concerning trends, both federal and state governments have enacted policies and regulations to control opioid prescribing, reduce the risk from overdose, and increase resources for treatment. The federal government holds broad powers over the health care industries, while the states exercise insurance oversight and retain authority for medical licensure. Much of federal authority is exercised through regulatory agencies that interpret and implement laws passed by Congress. The federal agencies

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pertinent to this discussion fall into 2 general categories—those that are primarily enforcement agencies and those whose primary activity is not enforcement. Enforcement agencies within the Department of Justice include the Drug Enforcement Administration (DEA), the Federal Bureau of Investigation, and the US Attorney's Offices (1 for each federal judicial district). The Food and Drug Administration (FDA is the major enforcer of regulations outside the Department of Justice. Other agencies, such as the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health, have more varied roles, including collection of data, advancement of scientific knowledge, and distribution of federal funds.

While much of the oversight, regulation, and enforcement occur under federal guidance, individual states have dealt with the brunt of the current crisis and responded with unique solutions. In Oregon, during 2013, 918,000 individuals received an opioid prescription, representing 24% of the population.[8] The numbers are even more concerning in other areas of the United States. During 2009 to 2010 in Tennessee, more than 1 opioid prescription was written for every individual in the state—142.5 prescriptions/100 individuals.[9]

This article will examine federal and state regulations of controlled substances. We will discuss both federal- and state-level regulatory and enforcement powers currently available to help slow this crisis. Finally, we will highlight several examples of creative approaches to safeguarding citizens from opioid misuse, addiction, or death.

FEDERAL OVERSIGHT

Most federal regulatory bodies are created by Congress but function under the auspices of the Executive Branch. Oversight of these agencies derives from the Executive Branch, but the Judicial Branch is the final arbiter of the lawfulness of the activities of each. While outlining the entire range and capabilities of each federal agency is well beyond the scope of this article, it is worth noting that the executive branch agencies have critical roles in rulemaking, statutory interpretation and implementation, and enforcement of federal law.

Food and Drug Administration

The federal government began what is considered modern regulation over medications and prescriptions at the turn of the 20th century. For several decades prior, Congress had been considering and trying to pass legislation that would establish legislative authority to regulate pure foods and drugs. However, it took Upton Sinclair's investigative journalism into the business practices of the time in both the food and medication industries to force Congress's hand. Specifically, his moving account of the horrible conditions of modern meatpacking plants led to a public uproar, and, in turn, to federal intervention and oversight.

The original 1906 law, the Pure Food and Drug Act, forbade interstate shipments of adulterated food products and misbranded drugs.[10] It also gave the federal government the power to seize these adulterated items. Additionally, for the first time, the federal government provided that false or misleading claims on the labels of food or a drug by industry would constitute misbranding and would be subject to intervention. Finally, the 1906 Act required products containing alcohol or specific narcotic drugs to disclose this inclusion on the label.[11]

The 1906 Act gave the federal government its first regulatory power over interstate shipment and manufacture of medications. Previously, the Bureau of Chemistry oversaw this role, but with this new act, the Food and Drug Agency, now known as the FDA, was officially formed. In contrast to today, the regulatory focus at that time was the proper labeling of medications rather than premarket approval for safety and efficacy.

In 1938, in response to deaths caused by sulfanilamide, the Food, Drug, and Cosmetics Act was passed, giving the FDA some of the regulatory powers we associate with the present agency: prohibiting false and misleading claims for medications, regulating cosmetics and medical devices, and, perhaps most important, providing the statutory responsibility to perform safety visits at manufacturing sites.[12] Further legislation in the 1960s through the 1990s provided increased authority and responsibility.

Considering the opioid epidemic, the FDA initially followed closely the pathway created by the Secretary of Health and Human Services in consultation with the White House Office of National Drug Policy. This comprehensive plan is multifaceted and brings many federal agencies to the table. The Health and Human Services guidance carved out a primary role for the FDA, which included educating professionals about questionable prescribing practices, advising the pharmaceutical industry of new requirements for stronger labeling, both in advertising and package inserts for medications, and making possible the rapid expansion of the use of naloxone for first responders. Subsequently, the FDA studied the possibility of using abuse deterrent formulations (ADFs) of long-acting/extended-release opioids to reduce intranasal and intravenous abuse.[13,14] Moreover, in consultation with industry, the FDA published guidance on manufacturing standards and the testing of efficacy of these new formulations. This activity, the creation of essentially a new class of drugs, ADFs, has occupied the already inadequate resources of the agency for more than 5 years now. Limited postmarketing data concerning ADFs have not revealed whether the effect of this effort has been to reduce the numbers of deaths or addictions, or has simply produced the movement of established users to heroin and fentanyl. The continued rise in opioid mortality rates would suggest the latter.

Concurrently, the FDA made an attempt to influence prescribing practices by producing a blueprint for provider education through the creation of Risk Evaluation and Mitigation Strategies (REMS). This program, including comprehensive training in the appropriate use of opioids, was to be funded by opioid manufacturers and initially involved only long-acting/extended-release opioid analgesics. REMS was a voluntary program from the outset. There was and is no penalty for nonparticipation, and clinicians with the highest rate of opioid prescription writing are not tracked. A 2016 evaluation of efficacy by the FDA Advisory Committee on Anesthetic and Analgesic and Drug Products revealed that less than a third of those targeted to obtain this training availed themselves of the opportunity. Further, recent evaluations of the use of short-term training to affect

prescribing behaviors have demonstrated little effect. The effectiveness of REMS and medication guides remains in doubt.[15,16] Whether this is due to a failure of the educational offerings or of physicians to participate is unclear. The FDA has the ability to mandate provider education through the REMS program given current statutory law. However, the American Medical Association and the American Board of Family Medicine, among other organized medicine associations, have been adamant in their opposition to any mandatory provider education.[17]

Additionally, on June 8, 2017, the FDA asked Endo Pharmaceuticals (Malvern, PA) to stop manufacturing Opana ER due to concerns of increasing numbers of people crushing, snorting, and injecting the drug. Injection abuse of the reformulated drug had been associated with an outbreak of human immunodeficiency virus and hepatitis C and cases of thrombotic microangiopathy. The FDA action came after advisers, who reviewed the safety of Opana ER at a March 2017 hearing, voted 18 to 8 that the benefits of the reformulated drug no longer outweigh its benefits.[18]

Naloxone Access

The FDA retains the regulatory authority to convert medications from prescription status to over-the-counter (OTC) status.[19] Despite the current public health crisis, the FDA has been slow to use this authority to convert naloxone to OTC status. The FDA's inaction has led states to take the lead on increasing naloxone access. States are now at the forefront of getting naloxone into the hands of the people who need it most: opioid users, school nurses, and other first responders. More than 35 states have passed legislation allowing pharmacists to dispense naloxone without a prescription.[20] While the content of these laws varies from state to state, they typically allow a third party, whether a patient, parent, friend, school nurse, or other likely first responder, to receive naloxone directly from a pharmacist without requiring a prescription. Some states require the party obtaining naloxone first to take an online safety course that teaches signs of overdose and the proper administration of the drug. These state laws allow opioid users access to a lifesaving drug without the added hurdle and burden of a doctor's visit to obtain a prescription.

A secondary critical component of these laws is broadening current "Good Samaritan" laws to mitigate professional liability when dispensing naloxone. Additionally, these laws can and should encourage bystanders to seek help by providing greater protection for individuals who intervene when someone has overdosed.

It is still too early to determine whether the liberalization of access laws has had an impact on opioid overdose mortality rates. The FDA has raised concerns whether current naloxone dosing regimens are appropriate given the increased use of fentanyl and carfentanyl. Recent internal data suggest that an increased naloxone dose would be necessary to provide adequate opioid antagonist effect to reverse an overdose. Nonetheless, if the data show a positive correlation on overdose mortality, as one would expect, the FDA can and should take the additional step of changing the status of naloxone and making the drug available OTC nationwide. Such a change would provide even greater access to naloxone. Presently, the FDA indicates a dialog surrounding the appropriateness of moving naloxone to OTC status. However, the FDA has yet to issue a rule for public comment.

Centers for Disease Control and Prevention

The CDC was established after World War II in 1946. Formed out of the Office of Malaria Control in War Areas and initially named the Communicable Disease Center, the Center was established to support state and local health authorities in controlling the spread of communicable disease. Over time, the Center's mission expanded to addressing injury, environmental health, occupational health, and noncommunicable diseases.[21]

It was with this eye to improving population health that in 2016 the CDC released their Guidelines for Prescribing Opioids for Chronic Pain.[22] As stated in their summary, the Guidelines are aimed at primary care physicians prescribing opioids for chronic noncancer pain. The Guidelines were not intended to address issues with pediatric populations, nor cancer pain or end-of-life treatment. While many hospitals had opioid-prescribing policies in place, many states and local hospital systems are now updating existing opioid guidelines to bring them into line with the more stringent 2016 CDC recommendations.

These CDC recommendations are another element in the federal plan to limit patients' initial exposure to and potential dependence on opioid medications. The Guidelines achieve this by promoting nonopioid therapies as the first line of treatment of pain and limiting the dose and duration when prescribing opioids. Shah et al[23] demonstrated that the probability of long-term opioid use, defined as >1-year duration, increased sharply after the fifth day of prescription opioid use in opioid-naïve patients receiving a first-time opioid prescription after surgery. The risk of long-term opioid use again rises sharply when prescription opioids are used for >30 days. Furthermore, this same study found similar increases in long-term opioid use when patients received a total of 3 or more prescriptions for opioids or a cumulative total dose of >700 morphine milligram equivalents. Accordingly, limiting the initial opioid dose, both in terms of total morphine milligram equivalents and number of prescription days, may be critical in preventing long-term opioid use for noncancer pain.[24]

Although the CDC has limited enforcement powers relating primarily to infectious disease outbreaks, it has no enforcement power concerning the opioid epidemic. Despite these limitations, the CDC Guidelines gain more political force at the state level, as medical boards educate prescribers; at the hospital level, with provider credentialing and privileging requirements; and at the national level, with the CDC's ability to educate patients, the public, and providers regarding the harms of long-term opioid use.[25] In addition, the FDA and CDC operate under the auspices of the Secretary of Health and Human Services and the President. Given the gravity of the current situation, and their responsibility for oversight, these officials have the capacity to intervene and force communication and response.

Drug Enforcement Agency

In 1968, the Bureau of Narcotics and Dangerous Drugs was formed from the Federal Bureau of Narcotics, then under

the Treasury Department, and the Bureau of Drug Abuse Control. President Nixon then established the DEA in 1973 after signing the Controlled Substances Act (CSA) into law in 1970.[26]

The DEA merged the newly founded Bureau of Narcotics and Dangerous Drugs, the Office of National Narcotics Intelligence, the Office of Drug Abuse Law Enforcement, the Narcotics Advance Research Management Team, and parts of the US Customs Service. The mission of this new agency was to enforce the CSA and other drug laws of the United States.

Undoubtedly, the DEA has the farthest reach and enforcement power of any federal agency when it comes to US drug laws. The DEA works to reduce supply, whether at the source of illegal "pill mills" or in foreign countries producing and manufacturing drugs such as cocaine, heroin, and fentanyl. Specifically, the DEA enforces the CSA by regulating the production and distribution of controlled substances, and the DEA, indeed, exercises the authority to limit the manufacture of opioid analgesics in the United States. Because the DEA has both rulemaking and enforcement powers, strong oversight by the Executive Branch and the Judicial Branch is critical to ensure proper use of the DEA's powers.[27] The decision as to which portions of the CSA are enforced, how the government views the prosecution of thousands of Americans, and the balance between incarceration versus referral for medical treatment lies almost entirely in the Executive Branch, specifically the White House Office of National Drug Control Policy.

Prescription Drug Monitoring Programs and Electronic Prescribing

At the state level, reducing supply means, among other things, modifying prescriber behavior. While the DEA may be able to investigate and close illegal "pill mills," states have other powers available to them. One of the most prominent state-level interventions has been the creation of prescription drug monitoring programs (PDMPs). A PDMP is an online database that collects information on any prescription drug: prescriber, patient, and dispensing pharmacy.[28] The data collected in each state differ because of variations in state law. One state, Missouri, had vigorously fought against the formation of a PDMP (however, the Missouri State Senate recently passed legislation that would implement a PDMP). Additionally, the real-time capabilities of each system differ. In some states, data are updated daily; in other states, they are updated much less frequently. Many states have PDMPs but do not require participation for all prescribers.

Studies have shown mixed evidence of a consistent decrease in use of schedule II or III medications after the implementation of PDMPs. Meara et al[29] reviewed 6 types of state-specific laws surrounding prescription opioids: prescription limits, PDMPs, tamper-resistant prescriptions, patient ID requirements, doctor-shopping restrictions, and pain clinic regulations. This study did not find any meaningful reductions in the number of opioid prescriptions written in states adopting the studied measures. Contrasting these findings, Dowell et al[30] looked at the combination of mandated review of PDMPs and pain clinic laws noting a reduction in both the number of prescribed opioids and in opioid overdose death rates. Bao et al[31] also found reductions in prescriptions written for schedule II opioids after implementation of state PDMPs. However, while Bao et al[31] found a decrease in the number of schedule II and III medications prescribed, the overall number of pain medications and nonopioid prescriptions remained constant.

Criticizing PDMPs does not require a significant amount of imagination. Interstate sharing of information is minimal to nonexistent and thus severely limits their overall efficacy. Without interstate collaboration, prescribers and pharmacists have essentially no objective source of key information regarding an individual patient's history of prescription opioid use.

Furthermore, too little information is collected—for example, data regarding patient diagnosis or payment method. Collecting additional data could benefit not only efforts to reduce unnecessary opioid use by individual patients but also could allow further meaningful epidemiological studies of diversion.

Moreover, physicians and pharmacists have little ability to see data in real time, and obtaining information at the time providers are making decisions is vital. A functional PDMP system, therefore, requires a nationwide database, updated in real time and including recent information regarding individual patients' receipt of prescription opioids. Physicians, other prescribers, and pharmacists could then use this information to make decisions regarding prescribing and dispensing opioid analgesics. Concurrently, the patchwork of state laws requiring identification at the time of obtaining opioid medication at a pharmacy would need to be replaced by a more a consistent approach. Requiring an ID to get opioids would be politically unpopular, however, as cancer patients and those with the long-standing need for analgesia would see this for what it is, an attempt to limit opioid prescribing and use. The political ramifications of a requirement for ID may prevent widespread adoption. Developing this type of comprehensive national PDMP would require overcoming many hurdles and would certainly require strong leadership from the Executive Branch.

Because states regulate the practice of medicine and the licensure of physicians within their borders, each state has tremendous control over the requirements for any physician to practice within that state, and it is this statutory authority that will provide the most leverage in changing prescribing behaviors. Thus, 1 potential solution to the shortcomings of PDMPs would be to require physicians to sign up for the state PDMP as part of the medical licensure process. States could streamline this process by integrating the PDMP registration into the physician licensure application. Indeed, to ensure PDMP use (and not merely an initial sign-up), prescribers could be required to provide all opioid analgesic prescriptions electronically, and writing such a prescription would require consultation of the PDMP before prescribing.

Requiring electronic prescribing has additional advantages, and the DEA could rely on its gatekeeper regulatory and enforcement authority to realize these benefits and positively alter prescribing behavior. Any provider or institution that prescribes controlled substances must obtain a license from the DEA. If the DEA were to require

electronic prescribing (e-prescribing) for all schedule II and III medications,[32] physicians, hospitals, and pharmacies could achieve better record keeping. Additionally, requiring electronic prescribing would provide accurate real-time information that could be cross-linked to states' PDMPs and used by pharmacies and physicians when prescribing and dispensing medications.[33] The added real-time information, in conjunction with incentives for prescribers to use PDMPs consistently, could produce significant changes both in prescriber behavior and patient use of opioid analgesics. There are significant privacy concerns having the DEA oversee this role. Many health care organizations would argue, and the authors would support, that the DEA must have a judicial subpoena to access PDMP data. This provides necessary privacy protections to both patients and prescribing physicians.

Furthermore, e-prescribing may reduce the duration of initial opioid prescriptions. As discussed above in the Shah et al[23] study, a major risk factor for long-term opioid use is taking prescription opioids for >5 days. Under current regulations, patients are required to have a written prescription for schedule II or III medications.[34] Practically speaking, this requirement entails an additional doctor's office visit if additional pain medicine is needed. A shift to electronic prescribing would allow physicians to write prescriptions for shorter periods of time and thereby avoid the current tendency to write (unnecessary) 14- or 30-day prescriptions for patients[35] who might otherwise seek longer-term prescriptions out of fear of needing medication and being unable to obtain a new prescription. Moreover, dispensing less medication at any 1 time has the potential to eliminate millions of unused pills sitting in medicine cabinets throughout the country or entering the street market.[36] Requiring an electronic prescription for any schedule II or III controlled substance would also help solve the problem of stolen or counterfeit prescriptions. Together with minimizing the length of prescriptions and the amount of medication dispensed, electronic prescribing has great potential to stem the supply of nonmedically used prescription opioids.[35]

STATE AND LOCAL INITIATIVES

States ultimately deal with the end results of the burgeoning prescription drug abuse epidemic—overdose deaths, increased emergency department usage, increased law-enforcement demands, and broken communities. As discussed above, states have been at the forefront of creative solutions to help stem the tide of prescription and illegal opioid deaths.

State Continuing Medical Education Requirements

States control the practice of medicine through several avenues. The state legislature is responsible for crafting laws overseeing the practice of medicine. In addition, a critical oversight role falls to independent state medical boards tasked with overseeing medical licensure within their state's borders. While licensure is a primary responsibility, medical boards also play an essential role in defining a local standard of medical care and oversight of the medical profession. Through medical board's oversight, physicians could be required to obtain continuing medical education (CME) credits on opioid abuse and treatment options as part of both the initial and subsequent state licensure.

These CMEs could take several forms: educating physicians and other providers of known risk factors for long-term opioid use, as described above; explaining state-specific laws regarding naloxone prescribing and Good Samaritan exemptions; and teaching effective use of a PDMP in clinical practice. Several state medical boards have already taken this step in recognition that physician and provider education is a fundamental component of restricting the amount of opioids in circulation while also adequately responding to and treating patients' pain.[37] This leadership allows medical boards to foster a culture of safe practice surrounding opioid prescribing and leads to a change in the standard of care. The FDA's and DEA's joint and cooperative support for these initiatives, in conjunction with the DEA's broad authority, could make it possible for state efforts to make substantial headway against the opioid crisis.

State and Local Municipality Lawsuits Against Opioid Manufacturers

Over the past several years, states and local municipalities have filed complaints in the courts to seek redress against opioid manufacturers. State attorneys general allege that opioid manufacturers minimized the dangers of opiates, exaggerated their long-term benefits for noncancer pain treatment, and effectively violated state law.

These lawsuits are interesting on several levels. States and localities are seeking to recoup the increased costs and damages related to treating addiction within their communities. If states and localities prevail, their efforts may increase funding for treatment, enforcement, and prevention. Publicly supported lawsuits could, therefore, provide yet another avenue for stemming the tide of opioid abuse, both by limiting prescriptions and providing increased availability of treatment centers.

However, the most interesting impact of these lawsuits may arise from pretrial discovery, including depositions. State attorneys general could obtain internal corporate documents, including email and other internal communications and discussions. These internal communications may demonstrate marketing practices, detail the science of addiction as known by the drug manufacturers, and reveal other internal processes and decision making. Pretrial discovery would allow the courts to determine what these drug manufacturers knew or suspected about these drugs and addiction, in contrast to what drug manufacturers told state and federal regulators and in contrast to pharmaceutical company statements made while marketing opioids to the public. For good reason, these lawsuits have been compared to the initial stages of litigation against the tobacco industry.

CONCLUSIONS

In summary, while the prescription opioid crisis has shown signs of slowing, heroin and now fentanyl overdoses and opioid deaths have risen considerably over the past 2 years. The federal and state governments have a multitude of regulatory and enforcement powers that, when applied

in force, could have an impact on controlling the present untenable situation. Provider behavior can be changed by a combination of factors: additional education, mandatory use of PDMPs when prescribing controlled substances, and e-prescribing for all controlled substances. These initiatives require the federal and state governments to work together to address this crisis.

At the federal level, the FDA can continue to require strict marketing language for opioids, both within the printed medication insert and for print and media advertising. The FDA should also adopt stringent requirements for any new opioid, short- or long-acting, applying for new drug approval. In general, the FDA has the power to undertake more aggressive regulation of prescription opioid manufacturers and should do so.

The DEA can continue its work against pill mills and physicians inappropriately prescribing opioids while being mindful that most physicians are ethical and hardworking clinicians trying to treat patients' pain appropriately.

The CDC's leadership on opioid abuse has been significant, and the CDC can continue in its role of educating the public and providers. However, more research is needed to determine which of the new guidelines is effective in reducing new opioid prescriptions and in keeping patients from becoming long-term users of opioids. The CDC may be able both to support and perform this research, and in the absence of efforts by other entities, the CDC's approach may prove to be critical. While research on outcomes from governmental interventions directed to more appropriate opioid prescribing is essential, it is also crucial that research studies investigate the effect these proposed interventions have on patients living with chronic pain.

Finally, the states can continue to innovate with their responses to the opioid crisis. Ongoing litigation may reveal valuable information about drug manufacturer knowledge regarding addiction to and marketing of opioid medications. Most importantly, the states have the power to influence provider behavior through measures such as initial and relicensing requirements, mandating use of a PDMP for all controlled substance prescriptions, and working with the DEA to require e-prescribing for all controlled substance prescriptions.

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