State Laws Regulating Prescribing of Controlled Substances: Balancing the Public Health Problems of Chronic Pain and Prescription Painkiller Abuse and Overdose

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Introduction
According to the Institute of Medicine, chronic pain affects at least 116 million adults in the United States (U.S.), which is more than the total affected by heart disease, cancer, and diabetes combined. Pain costs the nation up to $635 billion each year in medical treatment and lost productivity. It has been conceptualized as a public health problem due to its prevalence, seriousness, disparities, vulnerable populations, the utility of population health strategies, and the importance of prevention at both the population and individual levels. For many patients, treatment of pain is inadequate due to uncertain diagnoses, societal stigma, the lack of effective treatments, and inadequate patient and clinician knowledge about the best ways to manage pain. This article explores the inadequate treatment of pain in the U.S. and the subsequent rise of prescription painkiller abuse, misuse, and overdoses. This is followed by a review of the actions taken by states to regulate the prescribing of controlled substances.

Inadequate Treatment of Pain
In the late 1990s and early 2000s, there was a heightened focus on the under-treatment of pain. Health care providers were seen as having inaccurate and exaggerated concerns about addiction and opioid side effects. Coupled with the fear of being sanctioned by regulatory boards for over-prescribing, providers also faced concerns of being deemed overly cautious about the use of these drugs. In 1999, the Oregon Board of Medical Examiners disciplined a physician for not prescribing enough medication to alleviate pain in six of his patients. This was the first time a medical board had taken such an action. At the time, the decision was seen as underscoring the “medical community’s changing attitudes about how doctors should help patients deal with severe and chronic pain.”

In 2000, the Veterans Health Administration (VHA) launched a National Pain Management Strategy with the goal of preventing pain in persons receiving care in the VHA system. One element of that strategy was recognizing pain as the fifth vital sign to establish routine screening and assessment of pain. The VHA toolkit suggests that health care providers could be barriers to pain care due to fear of patient addiction as well as concerns regarding the side effects of analgesics. On January 1, 2001, the Joint Commission’s pain management standards went into effect for accredited ambulatory care facilities, behavioral health care organizations, critical access hospitals, home care providers, hospitals, office-based surgery practices, and long-term-care providers. The standards addressed pain assessment and management and required organizations to recognize the right of patients to appropriate assessment and management of pain.

At that time, it was suggested that treatment and management of pain could also be improved by the threat of tort litigation that would spotlight providers’ failures to comply with an emergent standard of proper pain management and incentivize a change in practice. In 2001, a California case brought against a physician for failing to prescribe prescription drugs strong enough to relieve a patient’s pain gained significant attention. The jury found that the physician committed elder abuse by failing to adequately treat his patient’s pain. While the case hinged on the state’s
elder abuse law, not on professional negligence, the outcome meant that under-prescribing for pain could be just as legally risky as over-prescribing.

In 2004, the Federation of State Medical Boards passed a model policy on the use of controlled substances to treat pain. The policy encouraged state medical boards to consider under-treatment of pain just as serious of a violation of the standard of care as over-treatment. It also provided that physicians should not fear disciplinary action from state boards if they treat pain for a legitimate medical purpose.9 Over time, medicine’s philosophy on the treatment of pain has shifted, and patient’s subjective reports of pain have taken precedence over other potentially competing considerations, such as addiction.10

Rise of Prescription Painkiller Abuse, Misuse, and Overdose

Today, opiate-based prescription painkillers account for significant morbidity and mortality in the U.S. According to the Centers for Disease Control and Prevention, prescription painkiller overdose has reached epidemic proportions over the past decade.11 The rise of prescription painkiller overdoses has paralleled the rise in supply of these drugs. In 2010, the quantity of prescription painkillers sold to pharmacists, hospitals, and doctors’ offices was four times larger than in 1999. It is estimated that prescription painkiller overdoses killed nearly 15,000 people in the U.S. in 2008, which is more than three times the number in 1999.12

Increased opioid prescribing has also resulted in a rise of diversion and nonmedical use of these medications. In 2010, about 12 million Americans aged 12 or older reported that they used prescription painkillers for nonmedical reasons within the last year.13 The rise in abuse, misuse, and diversion of opioids is associated with increases in emergency department visits for nonmedical prescription drug use, opioid addiction treatment, and neonatal abstinence syndrome rates.14 Nonmedical prescription drugs. The purpose of such programs is to help prescribers avoid drug interactions and identify drug-seeking behaviors, as well as to help regulators identify clinicians with inappropriate prescribing and dispensing patterns. Currently, 49 states have authorized the creation of prescription drug monitoring programs. Missouri is the lone state without an authorized program, and the state considered, but did not pass, authorizing legislation (House Bill 1193) in 2012. Legislation, B19–966, is also pending in the District of Columbia. Prescription drug monitoring programs vary greatly by state. Differences include: the schedules of drugs reported to the database, where the database is housed within the state, which prescribers and dispensers are required to report data, how often data must be reported (i.e., monthly, weekly, or in real time), who has access to the database, and whether data can be shared with

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other states. These provisions all play a role in determining the effectiveness of a state’s prescription drug monitoring program.

In 2012, several states considered whether providers should be required to query the database prior to prescribing. Kentucky, Massachusetts, New York, Tennessee, and West Virginia passed legislation making consulting the databases mandatory. The New York law provides that “[e]very practitioner shall consult the prescription monitoring program registry prior to prescribing or dispensing any controlled substance listed on Schedule II, III, or IV...for the purpose of reviewing a patient’s controlled substance history.”

However, 10 exceptions were included in the final bill. In Tennessee, prescribers are required to check the database prior to prescribing an initial course of treatment involving opioids or benzodiazepines and annually as long as the patient is being treated with the medication. Exceptions to the mandate include courses of treatment that are seven days or fewer, hospice, and surgical procedures performed in a licensed facility.

Licensing and Regulating Pain Clinics
Regulating pain management clinics is an approach taken by several states, including Florida, Kentucky, Louisiana, Ohio, Tennessee, Texas, and West Virginia, to limit prescribing at high volume pain clinics or “pill mills.” Some characteristics that distinguish a “pill mill” from a legitimate pain management practice include: nonexistent or cursory patient exams, large daily volume of patients, absence of health care providers among clinic owners, cash-only operations, identical prescription cocktails given to each patient, onsite dispensing, and a single facility as source of all patients’ magnetic resonance images. Pain management clinics are defined as prescribing controlled substances to a majority (51 percent) of patients for the treatment of chronic pain. Exceptions to this definition vary, but often include: hospitals, hospice programs, medical schools or training institutions, and ambulatory surgery facilities. The laws provide for state oversight of pain management clinics through registration or licensure, allow or require state inspection of the facilities, and require that they be owned by a licensed physician who meets specific education and training criteria in pain management.

Establishing Dosage Thresholds
On March 25, 2010, Washington Governor Chris Gregoire signed Engrossed Substitute House Bill 2876 into law. Washington’s opioid prescribing law is now considered the strictest in the country, as it goes beyond regulating providers practicing in pain clinics and applies broadly to any provider who prescribes opioids for chronic, non-cancer pain, though acute pain from surgery, hospice, and palliative care are exempt from the law. The bill required five state health care boards — medical, osteopathic, nursing, dental, and pediatric — to adopt new rules, including dosage standards, for chronic, non-cancer pain management. The rules established a dosage threshold mandating that primary care providers consult with board-certified pain specialists prior to prescribing daily morphine-equivalent doses of 120 mg or greater. The criteria to be considered a “pain specialist” are outlined in the rules along with consultation exemptions for exigent circumstances. Providers may also be exempt from the consultation requirement if they have completed continuing education hours on chronic pain management with at least two hours dedicated to long-acting opioids.

Discussion
It is too early to fully understand the impact these laws will have on prescription painkiller abuse, misuse, and overdoses and patient access to pain treatment. A review of peer-reviewed research on prescription drug monitoring programs published between 2001 and 2011 concluded that prescription drug monitoring programs reduce “doctor shopping,” change prescribing behavior, and reduce prescription drug abuse. A 2012 study found that while opioid abuse was increasing over time, the rate of increase was slower in states with prescription drug monitoring programs. However, additional research is needed to determine the effectiveness of new state laws mandating prescriber use of prescription drug monitoring programs.

The Drug Enforcement Administration has indicated that Florida’s laws limiting the ability of doctors to dispense controlled substances at pain clinics has drastically decreased oxycodone purchases by doctors in the state. There are concerns, however, that providers will limit prescribing of controlled substances to treat pain to fewer than 51% of their patients to avoid having to be licensed by the state as a pain clinic. There are also concerns raised regarding access to care as a result of Washington State’s requirement for a consult with a pain specialist above a specified dosage. Primary care providers are often the first line of care for patients with pain. Pain is a fairly new medical specialty, making these specialists difficult to find. This is particularly of concern in rural areas where the number of specialists is especially limited.

Providers want the freedom to use their clinical decision-making to treat patients, and some feel these new requirements are over-regulating the practice of medicine. State medical boards are being encouraged...
to do more to address physicians who over-prescribe. One governor has acknowledged that he is unhappy with his state medical board for not doing more to rein in doctors who contribute to the prescription drug abuse epidemic.24 Physicians in Florida and California are facing criminal prosecution in connection with patient overdoses, leaving some medical professionals in fear that this will have a chilling effect on the legitimate use of pain medication for legitimate reasons.25

Conclusion

Pain affects millions of Americans and contributes greatly to national morbidity, mortality, and disability rates. The pendulum has swung in recent years from a focus on the under-treatment of pain to addressing prescription drug overdose morbidity and mortality through various policy and regulatory approaches. As states continue to explore policy options to address prescription drug abuse and misuse, it will be important to evaluate the impact these approaches are having, both in reducing painkiller abuse, misuse, and overdoses and on legitimate access to pain care.

Note

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Resources


12. Id.

13. Id.


