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POLICY FORUM

Shared Responsibility: Massachusetts Legislators, Physicians, and An Act Relative to Substance Use Treatment, Education, and Prevention

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Abstract

Recent passage of the Massachusetts law, An Act Relative to Substance Use, Treatment, Education, and Prevention, represents an admirable public health approach to substance use disorder (SUD), a stigmatized chronic disease that affects some of society's most vulnerable people. With its seven-day supply limit on first-time opioid prescriptions, this legislation takes an unusual approach to state government involvement in health care. By intervening in individual physicians' practices, state legislators have entered a space traditionally reserved for clinical teams. The seven-day supply limit and the process through which it was developed highlight competing priorities and dialogue between physicians and legislators, limits of physician self-regulation, and standards of evidence in policy making and health care. Addressing these issues requires both physicians and legislators to recognize and fulfill new responsibilities in order to better assist the populations they serve.

Shared Responsibility: Legislators, Physicians, and Massachusetts' An Act Relative to Substance Use, Treatment, Education, and Prevention

SUD is a stigmatized chronic disease that affected some 20.2 million adults in the United States during 2014 and carries with it a substantially increased risk of morbidity and death [1, 2]. In Massachusetts, opioid misuse, in particular, has been on the rise. In 2015, the estimated rate of unintentional opioid-related overdose deaths rose to 22.6 deaths per 100,000 residents, representing a more than 400 percent increase from the rate of 5.3 deaths per 100,000 residents in 2000 [3]. The rising death rate has captured the attention of many, including Governor Charlie Baker and the Massachusetts state legislature, which, in March 2016, passed An Act Relative to Substance Use, Treatment, Education, and Prevention in an effort to control the epidemic [4].

The causes of and potential policy responses to the opioid epidemic are myriad. A central part of the act—and this commentary—is the decision to limit opioid supply by regulating physician practice. It is noteworthy, however, that the act also allows patients to request smaller quantities of opioids than were prescribed, mandates substance use evaluations for patients who present to the emergency department after an overdose,

implements education and screening programs in public schools, and improves treatment conditions for women who are committed for substance use treatment [5].

A closer look at one of the more controversial elements of bill—a seven-day supply limit on first-time opioid prescriptions—highlights several challenges that arise with legislative involvement in health care. Because this policy focuses on physician prescribing behavior, rather than on the behavior of the public, it differs from most government-led, population-level chronic disease prevention efforts. With nutrition labels and higher cigarette taxes, for example, legislators become part of a broader public health care team; however, with limits on prescribing, they join the clinical care team.

The seven-day supply limit and the process through which it was developed highlight several issues: the competing priorities of and dialogue between physicians and legislators, limits of physician self-regulation, and standards of evidence and priorities in policy making and medicine. Ultimately, it illustrates the importance of legislators understanding clinical practice and physicians advocating for evidence-based policies that address patient needs.

Evolution of An Act Relative to Substance Use, Treatment, Education, and Prevention

An Act Relative to Substance Use, Treatment, Education, and Prevention was developed through a two-year dialogue among legislators, community members, and physicians. In February 2015, the governor appointed a working group, including three physicians and one nurse, to make policy recommendations to reduce opioid misuse. In June 2015, the group released recommendations on prevention, intervention, treatment, and recovery [6]. Four months later, the governor introduced his proposed bill, which limited first-time opioid prescriptions to a 72-hour supply. The focus on prescribing came in the wake of data revealing a strong correlation between opioid prescription sales and prescription opioid overdoses [7]. Nationally, both sales of opioid pain relievers and opioid overdose deaths nearly quadrupled between 1999 and 2008 [8], causing officials at the Centers for Disease Control and Prevention (CDC) to claim "we now know that overdoses from prescription opioid pain relievers are a driving factor in the 15-year increase in opioid overdose deaths" [9]. Coupled with evidence of prescriptions leading to addiction and illegal drug use, this data offered a compelling story illuminating the roles of physicians in the opioid epidemic [10, 11].

While sharing the legislature's concern about the growing opioid epidemic, physicians had a different risk-benefit analysis. Some felt the 72-hour supply limit would decrease access to opioids for patients with pain and harm patient-physician relationships [12]. In his testimony before the legislature, President Dennis Dimitri of the Massachusetts Medical Society (MMS) raised concerns about physicians' capacity under the proposed legislation to "address the individual needs of our patients" [12]. He also emphasized important practical implications: since opioid prescriptions cannot be phoned in, older,

poorer, or sicker patients' pain could be left untreated or undertreated. The MMS instead recommended a seven-day supply limit [12]. Citing lack of evidence that any supply limit would reduce substance use or improve health outcomes, the MMS also called for a "sunset provision" to re-evaluate the seven-day limit after a trial period [12].

The final version of An Act Relative to Substance Use, Treatment, Education, and Prevention was a compromise measure. It extended the supply limit to seven days on first-time opioid prescriptions for adults and on all opioid prescriptions for children, with exceptions for those with chronic pain or cancer and those receiving palliative care. The sunset provision—strongly opposed by Governor Baker—was not included.

This dialogue between the MMS and Massachusetts legislature, with compromises on both sides, mirrors the type of productive debate that occurs among members of a successful interdisciplinary health care team. While the medical community does not traditionally think of legislators as part of patient care teams, through this policy, legislators gain a voice in clinical decision making. By conceptualizing legislators' and clinicians' interactions—and their interchanges of ideas and disagreements—as exchanges within a care team, physicians and legislators may better care for the populations they serve.

Time for Legislative Involvement

Although the MMS was willing to compromise, some physicians in this debate oppose legislative involvement of prescribing practices and call for preservation of self-regulation in medicine, asserting that physicians are uniquely equipped to understand and respond to the needs of their patients and that legislative involvement would limit the breadth of their clinical decision making [13]. The discussion highlights long-standing tensions about the degree to which physicians ought to govern themselves and to which legislatures ought to govern professionals to protect the public health. These tensions are similarly present in conversations about the relationship between physicians and industry, the role of governments and lay people in medical practice, and strategies for managing disciplinary action against physicians [14]. Medicine is, largely, a self-regulating profession. Physicians are allowed autonomy in their practice, and in return are expected to use their knowledge and expertise to act in the best interest of patients and the public.

A complicating factor in professional self-regulation that needs to be acknowledged, however, is that incentives can make it difficult for physicians to self-regulate opioid prescribing. In the 1990s, patient and physician advocacy groups called for more aggressive treatment of pain with opioid analgesics [15]. The American Pain Society introduced a campaign for assessment of pain as a "fifth vital sign" [15], and bodies like the Joint Commission created new standards for pain control [16]. This led the pharmaceutical industry to develop and aggressively market new opioid formulations

like oxycodone, which then became widely available for non-cancer pain [17, 18]. Today, for example, a physician who prescribes an opioid to a postoperative patient is motivated to ensure that the patient has adequate pain relief and to build a trusting, therapeutic relationship with a patient who requests good pain control. But the physician might try to minimize additional appointments for medication refills not only because they can be inconvenient for people who have recently had surgery (and family members who typically accompany them), but also because there is monetary gain in reserving clinic time for new patients' appointments instead of follow-up appointments for existing patients. Physicians are also increasingly expected to obtain high patient satisfaction scores, which are used as quality-of-care metrics and, at times, attached to reimbursements. For example, as part of the Patient Protection and Affordable Care Act, the Centers for Medicare and Medicaid Services (CMS) allocates funds in Medicare payments based on hospitals' performance on patient satisfaction surveys, which include questions about pain control [19]. Finally, though the incidence of opioid dependence varies [20], the vast majority of patients given opioids for acute pain benefit from them and use them responsibly, despite the associated risks [21].

While physicians should ideally use their knowledge of population health to inform and regulate their practice, behavior change takes time, even with educational resources on opioid prescribing [22]. Government involvement—through policy changes implemented via regulation or legislation—can create or counter incentives, expedite or inhibit behavior change, and help catalyze physicians' responsiveness to public health issues that necessitate immediate attention. As MMS President Dimitri stated in his testimony, "In an ideal world we really think that physicians should be allowed to apply their clinical judgment, their expertise, their learning. But we realize there's also a very specific crisis situation that we're in right now so we are willing to be open-minded and somewhat compromising on this and put a number out there to make physicians stop and think" [23].

The Right Legislative Solution?

We must consider, however, whether proposed legislative solutions to reduce opioid misuse and mortality adhere to the values of the clinical community. Physicians are taught to practice evidence-based medicine. While responsible policy making in all areas should be evidence based, physicians—as clinicians, researchers, and patient advocates—can play special roles in ensuring that legislation governing clinical practice is grounded in data.

Unfortunately, the quality of evidence supporting state interventions to decrease opioid use and deaths from overdose is low [24]. For example, in Massachusetts, multiple interventions are being implemented simultaneously, making it difficult to assess causality. Researchers have studied prescription drug monitoring programs (PDMPs), insurer and pharmacy benefit manager strategies, state legislation, clinical guidelines,

naloxone distribution, safe storage and disposal, and provider and patient education [24]. PDMPs, which track a patient's prescriptions for controlled substances across multiple prescribers and pharmacies, are one of the more promising strategies for reducing prescription opioid misuse and diversion [25-27]. In 2012, Kentucky mandated PDMP use by prescribers and, in one year, saw an 8.6 percent decrease in opioid prescriptions and a 25 percent decrease in prescription opioid deaths [26, 28]. New York, Tennessee, and Ohio have all seen decreases in opioid prescriptions and rates of "doctor shopping," or use of multiple prescribers, with mandated PDMP use [28]. While the seven-day supply limit focuses on opioids prescribed for acute pain and applies to all patients, PDMPs aggregate data on opioid prescriptions, which can help clinicians identify patients who may be misusing prescription opioids.

Other promising examples of approaches for reducing opioid misuse include state legislation that regulates pain clinics and enforces clinical guidelines [26]. Starting in 2010, Florida enacted laws regulating pain clinics and mandating PDMP use, and it also conducted statewide raids of pain clinics known as "pill mills" for the large quantities of prescription pain medications prescribed. From 2010 to 2012, overdose deaths from prescription opioids declined by 27 percent [29-31]. In Washington, state agencies and pain clinicians collaborated on new guidelines for chronic pain. These included referral to a pain specialist for patients taking more than 120 morphine milligram equivalents (MME) per day without substantial improvement, based on evidence that the risk of overdose increases with higher doses [32]. After initial decreases in doses and overdose deaths among worker's compensation patients [33], legislators required medical boards to implement rules on dosing, referral, and clinical monitoring with similar statewide results [32]. In August 2015, the Massachusetts state medical board also approved guidelines that included a 100 MME dosing threshold [34]. These state experiences are highly context-specific; they add to our evidence base, but we sorely need more studies to identify the most effective interventions.

Data on the effects of supply-limited first-time opioid prescriptions on opioid misuse and other health outcomes are lacking. The absence of such data, however, does not necessarily mean limiting first-time supply is a poor policy option. Given the scanty evidence base for prevention of opioid use disorders, we must develop and test new strategies.

The seven-day supply limit, based on common sense and the correlation between prescription opioid sales and overdose deaths, appears to be a strategy that *could* work, but it must be accompanied by efforts to assess whether it *does* work. Researchers must examine not only effects on overdose deaths, but also pain control, substance use disorder diagnoses, and quality of life. If the seven-day supply limit is ineffective, the legislature should modify or repeal the law and try other solutions. Provisions for evaluation and iterative modification to improve outcomes—standards to which new

clinical interventions are held—are not part of the existing legislation. If legislators are to join the clinical care team, physicians should hold them to the same standard they would hold other colleagues.

Physicians should also ask why the legislature is choosing to limit first-time prescriptions (the supply side), rather than the demand side (those factors that make people want to continue taking their pain medications after their pain has ended or to continue using opioids once they have become addicted). Many factors beyond opioid prescriptions have been correlated with increased substance use, including mental health disorders, job availability, perceived minority discrimination, and level of education [35-38]. Targeting physician behavior is easier and less costly than creating programs that improve schools, create jobs, or provide evidence-based addiction treatment, such as buprenorphine and methadone. Physician behavior also fits within a neat, linear narrative: a physician prescribes 30 oxycodone pills for a patient with a broken arm who required, perhaps, 10 pills. The patient keeps taking the oxycodone after the pain from the fracture has ended. The patient becomes addicted and starts buying heroin on the street. In this story, the physician is a clear actor, introducing the patient to medications that carry risks of misuse, abuse, overdose, and death. The physical, social, economic, or mental health challenges in the patient's life, which caused her to continue taking the pills after acute pain has resolved, are less concrete, yet no less important.

Physicians should welcome legislators as colleagues in promoting public health. Legislators can help catalyze physician responsiveness to public health issues and are particularly important colleagues in addressing social determinants of health. While physicians can refer patients to social service programs, legislators can create and support social service infrastructure and provision. Physicians, therefore, should push policymakers to implement evidence-based policy and to see patients as individuals who exist within broader social contexts that help to determine their health and well-being. Just as legislators have looked to physicians as colleagues in enacting public health solutions to the opioid epidemic, so the clinical community should see legislators as allies in combating the poverty, inequality, and social exclusion that exacerbate public health threats. These groups must continue working together, each bringing ideas and suggestions to the table, to improve the lives of patients and communities affected by opioid use.

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