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November 14, 2017

The Honorable Jefferson B. Sessions III
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530–0001

Dear Attorney General Sessions:

President Trump's recent declaration of the opioid crisis as a public health emergency represents a positive step forward in the country's ability to reduce the widespread suffering wrought by this unparalleled opioid epidemic. In Massachusetts, we have seen a 450% increase in opioid-related deaths over 16 years. In 2016, more than two thousand Massachusetts residents died of an opioid-related overdose. Currently, we estimate that 265,000 or 4% of Massachusetts residents have an opioid use disorder. Opioids are having a profound societal, economic, and human impact in the commonwealth.

The Commonwealth, like other states, requires all of the tools necessary to confront this epidemic and the federal government, through administrative action, can increase treatment capacity and afford practitioners the flexibility to prescribe the most effective treatment available. Towards this end, I urge you to take swift action in approving the following steps to strengthen states' abilities to carry out effective and comprehensive approaches to treating those suffering from a substance use disorder (SUD):

1. **Interchange of Abuse-Deterrent Formulations:** The Drug Enforcement Agency (DEA) should allow states the flexibility to require pharmacists to interchange abuse deterrent formulations of opioid drug products in accordance with state law, without demonstrating the chemical equivalency of the two drugs.
2. **Access to Medication-Assisted Treatment:** The DEA should increase flexibility for states to expand access to medication-assisted treatment.

1. Access to Abuse-Deterrent Formulations

Drug manufacturers have recently developed and brought to market innovative abuse-deterrent drug products as an alternative to traditional pain medications, including opioids classified as Schedule II by the DEA. Massachusetts and several other states have enacted laws promoting abuse deterrent formulations, which are crush resistant and more difficult to inhale or inject, based on the opportunity these new drugs present to further combat the current opioid epidemic. I respectfully request that the DEA take immediate steps to update its guidance to prescribers and pharmacists to allow essential elements of any prescription to be modified consistent with state substitution or interchange laws.

Massachusetts General Law Chapter 112, Section 12D requires interchange of certain abuse deterrent formulations of opioid drugs for non-abuse deterrent formulations, similar to automatic generic substitution for equivalent brand name medications, unless "no substitution" is indicated on the prescription. [1] However, current DEA regulations and guidance do not allow for automatic interchange – in particular for Schedule II medications – without an updated prescription from the prescriber.[2]

This incongruity between state and federal policies creates a situation in which pharmacists are required to interchange abuse deterrent formulations for non-abuse deterrent drug products, but are unable to dispense the abuse deterrent formulation without a new prescription from a practitioner.

This update would afford states the flexibility to require pharmacists to interchange abuse deterrent formulations of opioid drug products in accordance with state law, similar to current policies requiring automatic substitution of generic medications.

2. Access to Medication-Assisted Treatment

As the President's Commission reported, medication-assisted treatment is a proven method of treating opioid use disorder by reducing overdose deaths, improving treatment outcomes, and preventing the spread of infectious disease. Expansion of access to MAT is an essential component of addressing the ongoing opioid crisis.[3]

Currently, Federal Drug Enforcement Agency (DEA) regulations significantly limit provider flexibility to treat a patient experiencing acute withdrawal symptoms when the provider is not specially licensed with the DEA as a narcotic treatment program.[4] Under 21 C.F.R. § 1306.07, a physician can treat a patient experiencing withdrawal symptoms with methadone or buprenorphine for up to a maximum of 3 days. As withdrawal symptoms may last for more than 3 days, this leaves many patients without access to appropriate treatment for their substance use disorder.

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[1] https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12D

[2] 21 CFR 1306.11 prohibits pharmacists from dispensing a Schedule II medication without a written prescription, while language in DEA Final Rule 72 FR 64921 indicates "the essential elements of the CII prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed)…may not be modified orally," except for generic substitution as permitted by state law.

[3] President's Commission on Combatting Drug Addiction and the Opioid Crisis, Report available here https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

[4] https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_07.htm

This regulation should be revised in two ways. First, this regulation should authorize other primary care providers with prescribing authority, such as advanced practice registered nurses and physician assistants, to administer methadone or buprenorphine to manage withdrawal symptoms. Second, this regulation should be revised to extend the dispensing limit from three days to seven days, helping mitigate access barriers to community-based methadone and buprenorphine treatment.

These changes, along with several changes that I requested in a separate letter to Acting Secretary of Health and Human Services Eric D. Hargan, would provide the Commonwealth additional tools to confront this epidemic. Thank you again for your continued support for Massachusetts' efforts to address the opioid crisis.

Sincerely,

Charles D. Baker
Governor

cc: The Honorable Eric D. Hargan
Acting Secretary of Health and Human Services