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November 14, 2017

The Honorable Eric D. Hargan
Acting Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW.
Washington, DC 20201

Dear Acting Secretary Hargan:

I am writing in response to the President's declaration of the opioid crisis as a United States public health emergency. As the President's Commission on Combating Drug Addiction and the Opioid Crisis, on which I was honored to serve, demonstrated the nation is in the throes of an unparalleled opioid epidemic. Since 1999, opioid-related overdoses have quadrupled in the United States, with almost two-thirds of all overdoses in 2015 linked to opioids.[1] The devastating trend is similar in Massachusetts, which has 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. Not since the AIDS epidemic of the 1980s and 1990s has Massachusetts seen such a sharp increase in a single category of disease deaths.

While these statistics on opioid-related deaths serve to quantify the final stage of this horrible disease, they do not take into account the estimated 4%, or 265,000, of Massachusetts residents who currently have an opioid use disorder,[2] nor can they quantify the societal, economic, and human impacts this epidemic has had on these individuals, their families and our state.

I have heard countless stories of desperation and suffering from those battling this disease and from their loved ones. Curbing and eliminating the current opioid epidemic's devastating toll on Massachusetts families is a top priority of my Administration. Our strategy is a public health approach, from prevention to recovery, along with increased penalties for drug trafficking.[3] We have

[1] President's Commission on Combatting Drug Addiction and the Opioid Crisis, Interim Report available here https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf
[2] https://www.mass.gov/service-details/chapter-55-overdose-report.
[3] https://www.mass.gov/service-details/governors-opioid-addiction-working-group

increased state spending for substance misuse prevention and treatment by more than 50 percent, implemented a nation-leading package of statutory reforms known as the STEP Act,[4] and obtained federal approval to expand Medicaid coverage for addiction treatment. We have reduced prescriptions of Schedule II opioid drugs by 29% since the first quarter of 2015 and have worked closely with our academic institutions to ensure that future clinicians and prescribers will be better trained to address this epidemic on the front lines.[5]

Massachusetts has seen some promising signs over the past several months, however, this is a problem that will take years of sustained hard work and creative thinking to solve. Towards this end, I urge you to take swift action to approve the following administrative steps to afford states additional tools to address this public health crisis:

1. **Access to Fentanyl Testing:** The Food and Drug Administration (FDA) should take the steps to classify rapid urine Fentanyl tests as CLIA-waived to expand availability and use in clinical settings.
2. **Naloxone Access:** Health and Human Services, using the Secretary's statutory authority to exempt drugs from requiring a prescription, should take the steps to allow states the flexibility to make naloxone, a lifesaving antidote that reverses opioid overdose, available over the counter, if states so choose.
3. **Substance Use Disorder Data Sharing:** The Office for Human Research Protections (OHRP) should take the steps to issue guidance that clarifies the ability of states to continue to receive and share de-identified SUD claims data for the purpose of public policy research, and for the Substance Abuse and Mental Health Services Administration (SAMHSA) to clarify that data submitted to a statistically de-identified database under HIPAA standards is not subject to 42 CFR Part 2 restrictions.
4. **Access to Medication Assisted Treatment:** Health and Human Services should take the steps to revise patient cap restrictions for buprenorphine treatment, amend federal regulations to permit office-based opioid treatment with methadone and allow states to apply for wholesale DATA 2000 waivers for all state practitioners.

1. Access to Fentanyl Testing

Fentanyl, a synthetic opioid that is 50 to 100 times more potent than morphine, is being detected in an increasing proportion of postmortem toxicology screens for opioid-related overdose deaths. In Massachusetts, fentanyl was detected in 81% of opioid-related deaths during the first quarter of 2017, while heroin or likely heroin was present in approximately 39% of these deaths.[6]

While these data indicate fentanyl availability and use is on the rise, most treatment providers cannot readily access rapid urine fentanyl tests due to the federal classification of the tests. Without this important diagnostic tool, clinicians are unnecessarily hamstrung in their ability to assess individuals battling opioid addiction at the point of care. This can lead to delayed treatment that

[4] Chapter 52 of the Acts of 2016 (STEP Act): https://malegislature.gov/Laws/SessionLaws/Acts/2016/Chapter52

[5] Massachusetts Core Competencies for the Prevention and Management of Prescription Drug Misuse: https://www.mass.gov/service-details/prescriber-education-core-competencies

[6] These statistics relate to opioid-related deaths during the first quarter of 2017 where a toxicology screen was also available. For full information, see: https://www.mass.gov/files/documents/2017/08/31/data-brief-overdose-deaths-aug-2017.pdf

could potentially result in patients choosing to forego treatment altogether. For this reason I ask that you designate rapid urine fentanyl tests as waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Under CLIA, treatment sites often seek a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS) when they only perform diagnostic laboratory tests categorized by the FDA as waived and not subject to most CLIA requirements. The FDA categorizes these tests as CLIA-waived because they are simple to use and there is little chance they will provide incorrect information or cause harm if done incorrectly.

With no current CLIA-waived fentanyl tests, health care and substance use disorder treatment providers that currently use similar tests to screen for other drugs at the point of care must send samples to offsite CLIA-certified laboratories for fentanyl testing. Due to added transport and processing time, referring these tests to offsite laboratories can cause a delay of more than 24 hours before providers have this critical diagnostic information. This delay can lead to challenges in initiating the appropriate substance-specific treatment option for an individual suffering from opioid addiction.

Therefore, I urge the FDA to work with laboratory testing manufacturers to review and approve CLIA-waived diagnostic rapid urine tests for the presence of fentanyl.

2. Naloxone Access

Naloxone is a lifesaving antidote that, if available and administered quickly, can reverse an opioid overdose while it is occurring. Over the past several years, Massachusetts has taken a number of steps to make naloxone more available, including grant programs for first responders and bystanders, the establishment of a bulk purchasing system for municipalities to purchase naloxone at a reduced price, and the ability of individuals to purchase naloxone at pharmacies via standing order. In 2016, more than 13,000 people were trained in naloxone administration, pushing the total number of people trained statewide to more than 56,000. It is estimated that more than 2,800 opioid overdoses were reversed by bystander administration of naloxone in Massachusetts in 2016. Each one of these naloxone reversals saved a life, and offered someone suffering from a substance use disorder a potential path to treatment and recovery. In an effort to further expand access to this lifesaving drug, I respectfully request that you use your authority to adopt emergency regulations that exempt naloxone from requiring a prescription, where a state has authorized over the counter use.

The United States Secretary of Health and Human Services has the regulatory authority to exempt drugs from the requirement that they require a prescription to be dispensed, if doing so would not pose a risk to public health. *See* 21 USC c. 9 §353(b)(3). Allowing states the flexibility to choose whether to make naloxone available over the counter by exempting it from this requirement would pose little to no risk to public health because naloxone has nearly no side effects at the dose necessary to reverse an opioid overdose. On the contrary, doing so would significantly benefit public health by increasing the availability of this lifesaving antidote, thereby providing individuals with a second chance at life and recovery.

3. Substance Use Disorder Data Sharing

The United States Department of Health and Human Services (HHS) recently issued a final rule to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2.[7] Effective March 21, 2017, the updated rule includes changes that govern how data related to services rendered by SUD treatment providers may be shared among SUD providers and other lawful holders of data. We believe the rule change continues to authorize insurers to submit de-identified SUD claims data to the Massachusetts' all payer claims database (APCD) because 42 CFR Part 2 only prohibits the re-disclosure of information that would identify an individual as having been diagnosed with or treated for a substance use disorder. However, there remains uncertainty among some insurers about whether this is still permissible under the new rule. Therefore, we seek guidance clarifying that insurers may continue to submit SUD claims data that is de-identified under HIPPA standards, including statistically de-identified claims data, to state all payer claim databases under 42 CFR Part 2.

This guidance will ensure that Massachusetts is able to continue crucial work that is underway to protect the public health. Massachusetts, using the APCD, has developed a first in the nation data-linkage process where we are able to connect multiple siloed datasets for the purpose of public health research.[8] This aggregate, de-identified information is then analyzed and used to target resources. For example, through this data set we are able to identify that rates of opioid-related overdose decrease during pregnancy and are lowest during the second and third trimesters, but significantly increase in the postpartum period, with the highest rates being 6 months to 1 year after delivery. This information allows us to target resources to post-partum mothers with an opioid use disorder in the first year after birth.

As good stewards of public resources we need to continue to use data to inform the way limited resources are allocated. I respectfully request that the Office for Human Research Protections (OHRP) issue immediate guidance that clarifies states' abilities to receive and share SUD data for the purpose of public policy research without the need for institutional review board approval, and for the Substance Abuse and Mental Health Services Administration (SAMHSA) to clarify that data submitted to a statistically de-identified database under HIPAA standards is not subject to 42 CFR Part 2 restrictions.

4. Access to Medication Assisted Treatment

Medication assisted treatment (MAT) is an effective treatment of substance use disorder that has successfully treated many struggling with this disease. Medications utilized in this treatment include methadone, buprenorphine, and naltrexone, which are prescribed and dispensed to patients through opioid treatment programs or clinical offices, in accordance with federal law and regulations. Massachusetts data from 2011-2015 indicates that individuals who engaged in buprenorphine or methadone MAT following a nonfatal opioid-related overdose had half the risk of dying from a subsequent opioid-related overdose than those who did not engage in buprenorphine

[7] 42 CFR Part 2: https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records.
[8] https://www.mass.gov/service-details/chapter-55-overdose-report.

or methadone MAT.[9] The evidence base for MAT continues to grow and we ask that you remove federal barriers that constrain expanded access.

MAT should be regulated more similarly to other chronic disease treatments and available within traditional health care settings in order to increase access and reduce stigma. There are two key changes that would help integrate MAT into traditional health care settings. First, amending 42 CFR part 8 to allow office-based opioid treatment with methadone. Second, allowing states to apply for wholesale DATA 2000 waivers for all state practitioners.

Additionally, in July 2016, federal HHS issued a final rule outlining a process for providers to request approval from SAMHSA to increase the maximum number of patients provided buprenorphine MAT from 100 to 275.[10] The rule stipulates providers must provide buprenorphine MAT to 100 patients for at least one year prior to requesting a waiver to increase the patient cap. The final rule establishes a process for physicians to increase to 275 on an emergency basis for a period of up to six months. To expand access to this critical treatment, the rule should be revised so that providers may request such an increase after providing six months of buprenorphine treatment, versus one year.

These reforms along with changes that I have requested in a separate letter to the Honorable Jefferson B. Sessions III would significantly increase access to medication assisted treatment. Thank you for your continued support for Massachusetts' efforts to address this epidemic.

Sincerely,

Charles D. Baker
Governor

cc: The Honorable Jefferson B. Sessions III
Attorney General of the United States

[9] Legislative Report: Chapter 55 Opioid Overdose Study - September 2016: https://www.mass.gov/files/documents/2017/08/31/chapter-55-opioid-overdose-study-data-brief-9-15-2016.pdf.

[10] https://www.law.cornell.edu/cfr/text/42/8.610; https://www.samhsa.gov/medication-assisted-treatment/qualify-nps-pas-waivers.