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October 14, 2014

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Burwell:

I write to urge HHS to review a report I released today that outlines a comprehensive list of strategies that can be utilized by the federal government to address the prescription drug and heroin abuse epidemic, and develop a multi-agency plan of action that includes both immediate and long term goals for stemming the tide of prescription drug abuse and deaths from opioid overdoses. The treatment and prevention of prescription drug and heroin abuse is one of the most important and difficult public health challenges facing our country. In this report (attached) are several actions that can be swiftly taken by the Department of Health and Human Services (HHS) and its operating divisions.

Accidental drug overdose has become the leading cause of preventable injury death for individuals under the age of 65 in the United States. Nationwide, it is estimated that more than 100 people die every day from an overdose, a number that surpasses motor vehicle accidents. According to data recently released from the Centers for Disease Control and Prevention (CDC), deaths from overdoses have nearly quadrupled between 1999 and 2011 and deaths from heroin, typically fueled by prescription opioids, doubled in the last two years. Within the legal and budgetary constraints imposed by Congress, federal agencies and the White House have been developing solutions and redirecting resources to address the prescription drug epidemic, but there is still much more immediate work that needs to be done.

I understand that there is no silver bullet for a disease as complex as opioid addiction. It will require a broad range of actions that must all work in unison. The current crisis demands strategic planning that thoughtfully brings together science, medicine, public health and law enforcement in a multi-faceted solution that encompasses all branches of our federal government. The foundation of a comprehensive approach must integrate policy changes that focus on prevention, treatment and enforcement. With the expertise of your agencies there are several measures described in my report that could be taken in the realm of prevention and treatment that would significantly help address this ongoing crisis:

- HHS should develop effective educational materials for patients that can be distributed with every opioid prescription drug that addresses the appropriate use of prescription drugs, the risks and signs of addiction and abuse, seeking treatment for addiction, the importance of secure storage, and the need for safe disposal of unwanted or unused pills.
- Centers for Medicare and Medicaid Services (CMS) should prioritize coverage determinations for any FDA-approved non-narcotic treatment for pain management, so that patients can access these alternatives without concern about cost reimbursement.
- CMS should encourage and allow FDA-approved tamper proof formulations of opioid pain pills to be substituted by a pharmacist for equivalent medications when available under the prescription drug benefits of Medicare and Medicaid.
- CMS should immediately conduct a review to determine whether the questions in hospital patient satisfaction surveys regarding pain management are influencing patient and physician behavior related to the provision of prescription opioids.
- To improve data collection and better support and expand access to treatment, Health Resources and Services Administration (HRSA) should immediately begin determining which Federally Qualified Health Centers (FQHCs) and FQHC look-alike facilities are offering substance abuse services, whether these services are offered directly at the health center or if they are managed through an ancillary community provider, whether these services include the option of medication assisted therapies, and what the geographical coverage is for these services in every state.
- In the future, all newly designated Federally Qualified Health Centers (FQHC) or FQHC look-alike facilities should be required to offer screening for opioid dependency and if unable to provide direct services within the health center, have a program in place to formally link patients to evidence-based treatment seems like a noun is missing with a qualified medical professional.
- To increase treatment capacity and improve the ability of FQHCs to provide outpatient treatment for opioid dependency according to best practices, HRSA should provide specific grant funding to help health centers implement innovative programs that provide comprehensive addiction care services of MAT define combined with behavioral therapy.
- In order to support the provision of high quality patient care, HRSA should require FQHCs to report measures of how many individuals are screened for opioid addiction and are provided clinical services for treatment.
- With a focus on expertise and quality, HHS should work within its current authority to eliminate the arbitrary caps placed on providers for the treatment of opioid addiction with office-based medication assisted therapies (MAT?).
- FDA should prioritize and actively engage with the National Institute on Drug Abuse and the private sector to rapidly develop clinical tools that can be used in the treatment of addiction and in reducing the harms associated with addiction.

- CMS should convene an expert panel for the medical treatment of opioid addiction to determine whether the current reimbursement rates for inpatient and outpatient treatment are sufficient.
- CMS should, with the assistance of an expert panel, determine best practices for pharmacy benefits management of medications used in the treatment of substance use disorders, including the need for standardized and non-burdensome authorizations.
- HHS should convene an expert panel of providers, including those with expertise in addiction medicine and in the care pregnant women, infants and children to develop best practice guidelines for the diagnosis and treatment of neonatal abstinence syndrome (NAS).
- HHS should identify barriers to the identification and treatment of pregnant mothers with opioid dependency and areas where additional research is needed on addressing the care needs of pregnant women and girls with substance use disorders. A report of these findings should be provided to Congress.
- CDC should provide technical assistance to the States to improve the availability and quality of data collection and surveillance regarding neonatal abstinence syndrome and opioid dependency in youth.
- To support community and state based efforts to increase the availability of naloxone, HHS should allocate funding for the dissemination of overdose prevention and management education, including naloxone distribution to potential bystanders.
- HHS should explore with relevant partners and stakeholders, the usefulness of co-prescribing naloxone with opioid painkillers and if warranted develop guidance regarding this practice.
- As existing naloxone programs scale up and new communities adopt measures to expand distribution of naloxone, the FDA should closely monitor supply and demand for this drug and be prepared to address any indications of a drug shortage as needed within the limits of their authority.
- SAMHSA spell out, in coordination with other relevant federal agencies, should create and disseminate training and toolkit materials on overdose prevention tailored to specific settings and populations, including chronic pain management, addiction treatment facilities and emergency departments. In developing such materials, the agencies should discuss the value in developing best practice guidelines for the prescription of naloxone in conjunction with opioid painkillers.
- To improve data collection associated with overdoses, the CDC should issue guidelines to states on the surveillance data that should be routinely and systematically collected on overdoses, including those overdoses that did not result in death.

I thank you for your attention and leadership on this important issue and for your review of these recommendations. I respectfully request that you respond with your plan on administratively adopting these enclosed measures and any legal or other barriers that may exist preventing their implementation, as well as any other actions you intend on taking to address the ongoing opioid abuse crisis by October 31, 2014.

Sincerely,

A handwritten signature in blue ink that reads "Edward J. Markey". The signature is written in a cursive style with a large, prominent "E" and "M".

Edward J. Markey