Congress of the United States

Washington, DC 20510

July 22, 2015

The Honorable Sylvia Matthews Burwell, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell:

Given the success of naloxone in rescuing tens of thousands of individuals from opioid overdose fatalities, we urge the Department of Health and Human Services (HHS) to explore additional methods for getting this overdose antidote into the hands of more individuals though co-prescribing or distribution with prescription opioid painkillers.

The scourge of prescription painkiller abuse across the nation has been devastating, including the loss of more than 16,000 lives in 2013 due to prescription opioid overdoses. Unintentional opioid-related overdose deaths are now the leading cause of injury death in Massachusetts, far surpassing car crashes and homicides. The Food and Drug Administration-approved opioid antagonist, naloxone, counters the effects of an opioid overdose. When administered in a timely manner, naloxone, a nontoxic, non-addictive drug, reverses the depression of the central nervous system and respiratory system that can lead to a fatal overdose. The Department of Health and Human Services has taken important steps in supporting the development and distribution of this lifesaving drug, especially to emergency responders. However, one additional step that may help reduce the number of deaths associated with prescription opioid overdoses is the provision of naloxone simultaneous with the prescription of an opioid painkiller, a process known as co-prescribing.

Naloxone has been used for more than 40 years by emergency medical personnel to reverse opioid overdose and resuscitate persons who otherwise might have died in the absence of treatment. The drug, which dislodges opioids, such as heroin or prescription painkillers, from their receptors in the brain, thereby quickly reversing an overdose, has increasingly been administered outside of conventional medical settings by community and family members, as well as by first responders such as police and fire departments. In the last few years, primarily in response to the overwhelming number of opioid-related overdoses, there has been an enormous growth in the number of community-based programs that provide naloxone kits and associated training to non-medical laypersons. These small, community-based distribution programs put this life-saving drug in the hands of people at high risk and their families. Results from a recently released survey found that since 2010, there has been a 243 percent increase in the number of local sites providing naloxone, a 183 percent increase in the number of laypersons provided

naloxone kits, and a 160 percent increase in the number of overdose reversals reported.[1] Between 1996 and 2014, more than 26,000 overdoses were reversed because of administration by a layperson, usually a family member, friend or other bystander.

Although the number of organizations providing naloxone and training to laypersons has increased, in 2013, twenty states were reported to have no such community-based naloxone distribution program. Furthermore, nine states had less than one layperson per 100,000 members of the population who had received a naloxone kit.[2] In communities where these programs are located, they typically serve high risk individuals who may not be engaged in the healthcare system and are therefore invaluable to getting naloxone to those at most risk of witnessing or falling victim to an overdose. However, in addition to these vital programs it is important to continue to explore ways in which this naloxone can get to populations who may not be served by these community-based programs. One such group is individuals who are prescribed high-potency or extended doses of opioid painkillers and who may be prone to an accidental opioid overdose. The routine practice of distributing naloxone or co-prescribing naloxone with prescriptions for opioid painkillers may help to get naloxone into households that may otherwise not have easy access to this life-saving antidote.

The potential of naloxone co-prescribing has received increasing attention over the last year, but is in need of more robust implementation and evaluation. The Substance Abuse and Mental Health Services Administration's 2014 Opioid Overdose Toolkit includes a section encouraging providers to consider naloxone co-prescribing upon initiation of opioid treatment.[3] Additionally, a growing number of states have issued recommendations for naloxone co-prescribing, particularly for high-risk patients. For example, the Massachusetts Medical Society recently issued guidelines for its physicians providing opioid therapy, which included the prescription of naloxone for patients that are on opioid therapy for more than 90 days.[4] Furthermore, in 2014, the Veterans Administration released recommendations which outlined a range of clinical circumstances for which providers should consider prescribing naloxone.[5]

Thousands of Americans who are currently taking prescription opioid painkillers, whether legitimately for the treatment of pain or illicitly without doctor supervision, could potentially be saved from accidental overdose by having wider access to naloxone. Furthermore,

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[1] Wheeler, E., et al. Opioid Overdose Prevention Programs Providing Naloxone to Laypersons-United States, 2014. Morbidity and Mortality Weekly Report.

[2] ibid

[3] Substance Abuse and Mental Health Services Administration. SAMHSA Opioid Overdose Prevention Toolkit. HHS Publication No. (SMA) 14-4742. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

[4] Massachusetts citation: Massachusetts Medical Society Opioid Therapy and Physician Communication Guidelines. May 21, 2015. http://www.massmed.org/Patient-Care/Health-Topics/Massachusetts-Medical-Society-Opioid-Therapy-and-Physician-Communication-Guidelines/#.VZ51Pfm6e1k

[5] Naloxone Kits and Naloxone Autoinjectors: Recommendations for Issuing Naloxone Kits and Naloxone Autoinjectors for the VA Overdose Education and Naloxone Distribution (OEND) Program May 2015

wider discussion about and distribution of naloxone may help further educate patients and providers alike on prescription opioid safety and responsible consumption. Evidence from community naloxone distribution programs has demonstrated that providing naloxone and appropriate training to laypersons is clearly an effective way to address the opioid overdose epidemic and save lives from overdose deaths.

The Department of Health and Human Services could take a number of actions that would help support broader access to naloxone through co-prescribing, including establishing demonstration programs, encouraging federally-funded health centers to adopt policies for co-prescribing, and reducing payment barriers for naloxone coverage and reimbursement. Additionally, the Department should consider issuing recommendations that could be used to institute best practices for co-prescribing naloxone with opioid painkillers throughout the country. We encourage HHS to promptly explore these and other potential activities that encourage broader access to naloxone through co-prescribing.

Sincerely,

Edward J. Markey
United States Senator

Elizabeth Warren
United States Senator

Richard E. Neal
Member of Congress

James P. McGovern
Member of Congress

Michael E. Capuano
Member of Congress

William R. Keating
Member of Congress

Joseph P. Kennedy, III
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Katherine Clark
Member of Congress

Seth Moulton
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