



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

May 27, 2014

The Honorable Edward J. Markey
United States Senate
Washington, DC 20510

Dear Senator Markey:

Thank you for your letter in which you shared the success of the Massachusetts Department of Public Health's (DPH) programs designed to provide naloxone to those most likely to witness or be first on the scene to an overdose. The Department of Health and Human Services (HHS) recognizes the important role that prompt use of naloxone can have in preventing a death due to opioid overdose. As a part of ongoing efforts to support the effective use of naloxone, HHS approved a new way to deliver naloxone using an auto injector. For family members and caregivers, the product is potentially easier to use than existing technologies and can be carried in a pocket or stored in a medicine cabinet. Combined with the important work being done by trained medical personnel, this could save lives by facilitating earlier use of naloxone in emergency situations.

HHS is working to support the best uses of naloxone. Enclosed is a summary of the most relevant efforts related to naloxone distribution and availability undertaken by various agencies within HHS. This is not an exhaustive description, but it should provide you with an indication of the importance HHS has placed on this critical public health matter.

HHS remains committed to supporting programs and activities to address the serious problem of prescription drug and heroin abuse. This support will be through science-based education and information, ongoing surveillance, regulatory oversight and adoption of sound public health strategies in partnership with states, territories and tribes and communities.

Thank you again for your support and interest.

Sincerely,

Kathleen Sebelius

Enclosure

Expansion of naloxone in the prevention of opioid overdose

1. a) *What funding and resources does HHS have available to help states and local community naloxone programs?*

The Substance Abuse and Mental Health Services Administration (SAMHSA) administers the formula-based Substance Abuse Prevention and Treatment Block Grant (SABG) which is funded in Fiscal Year (FY) 2014 at \$1.82 billion and provides funding to states, territories, and one tribe. State substance abuse agencies may use SABG funding for opioid education and safety training consistent with primary prevention objectives. SAMHSA has ensured that SABG recipients know that there is no explicit restriction in the statute or implementing regulation that would prevent the expenditure of funds to purchase and distribute naloxone. SAMHSA is conducting a review of all current non-formula discretionary grant programs to determine which programs may allow grantees to support overdose prevention efforts as well.

- b) *How are these funds distributed and utilized to support training, technical assistance and evaluation?*

The Substance Abuse Prevention and Treatment Block Grant (SABG) is distributed to the eligible grantees, e.g., states, territories and the tribe based on a statutory formula (42 USC 300x-33). The grantees may obligate and expend SABG funds to plan, carry out and evaluate activities to prevent and treat substance abuse. The SABG has both set-asides, e.g., primary prevention (42 USC 300x-22(a)), early intervention services for HIV (42 USC 300x-24(b)), and performance requirements, e.g., substance using pregnant women and women with dependent children (42 USC 300x-22(b); 42 USC 300x-27), intravenous drug users (42 USC 300x-23), tuberculosis services (42 USC #300x-24(a)) and continuing education (42 USC 300x-28(b)) related to how grantees must utilize SABG funds; however, grantees have some flexibility to determine the best use of its SABG funds within the broad parameters of the SABG statute (42 USC 300x-21-66) and regulation (45 CFR 96.120-137). Targeted technical assistance provided by SAMHSA's Center for Substance Abuse Prevention and Center for Substance Abuse Treatment is available to states. States also have the flexibility to utilize SABG funds for resource development activities which include (1) planning, coordination and needs assessment; (2) quality assurance; (3) training (post-employment); (4) education (pre-employment); (5) program development; (6) research and evaluation; and (7) information systems.

For non-formula based grant programs, the funds are distributed to the appropriate type of grantee based on a competitive, peer-reviewed basis. States and grantees will determine the appropriate use of current dollars to address overdose risk in their respective populations.

- c) *To what extent can these funds be used to offset the cost of purchasing naloxone?*

As noted above, SABG grantees can use allocated dollars for the purchase of naloxone and it is up to each SABG grantee how many of its allocated dollars will be used for the purchase of naloxone. For SAMHSA's non-formula based substance abuse related grant programs, whether

funds can be used for overdose prevention related services or specifically for the purchase and distribution of naloxone or both is dependent on the authorizing statute and on the specific grant Request for Application language.

2. a) *What tools and assistance does HHS have available to help states and localities project and prepare for the cost of expanded naloxone distribution programs for emergency responders and law enforcement officials?*

Recently, SAMHSA released an Opioid Overdose Prevention Toolkit (available at: SAMHSA (<http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742>)). The Toolkit serves as a foundation for education and training of communities, prescribers of opioid pain medications, first responders, patients who are prescribed opioid medications and individuals and family members who have experienced an opioid overdose. SAMHSA has undertaken a series of efforts to disseminate the Toolkit to state public health and substance abuse officials, law enforcement agencies and other affected parties. SAMHSA's Center for Substance Abuse Treatment has informed over 25,000 community based addiction treatment providers of the Toolkit.

SAMHSA's Center for Substance Abuse Prevention and the Centers for Disease Control and Prevention's (CDC) National Center for Injury Prevention and Control have been working with the National Association of State Alcohol and Drug Abuse Directors, the National Governors Association and the Association of State and Territorial Health Officials on strategies to increase state effectiveness in addressing overdose issues. Later this year, SAMHSA will convene a state policy academy with officials from a wide range of state agencies to assist them in developing strategies to address prescription drug abuse, with a focus on prevention, treatment and recovery, including the use of naloxone as an intervention.

- b) *What tools does HHS have available to assist states in determining appropriate training and distribution protocols for naloxone?*

Several components of HHS are assisting states in determining the appropriate training and distribution protocols for naloxone. CDC provides information on naloxone through its phConnect website (<http://www.phconnect.org>) to state partners to inform their prevention efforts. PhConnect is an online collaboration tool built to support geographically dispersed professionals working in the field of public health. PhConnect provides an environment for collaborative work, professional networking, and moving public health forward.

SAMHSA will develop a compendium of resources covering best practices for education, training and implementation strategies targeting the five stakeholder populations identified in the Overdose Prevention Toolkit: prescribers, first responders, community members, persons at risk for overdose their families, and persons having survived overdose.

3. *What additional resources would HHS need to assist states in expanding naloxone programs so that local law enforcement and emergency responders are trained and equipped with naloxone for administration? Please provide any estimates or data that you may have available.*

The President's Budget request for FY 2015 includes new and expanded funding for SAMHSA and CDC as part of a strategic effort to address non-medical use of prescription drugs, including opioid overdoses. CDC will expand its Core Violence and Injury Prevention Program to provide basic injury and violence prevention infrastructure to additional states with a high burden of prescription drug overdose while SAMHSA proposes to dedicate \$10 million to a new program, Strategic Prevention Framework Prescription Drug Abuse and Overdose Prevention (SPF Rx), that will provide funding to develop a comprehensive prevention approach and implement evidence-based practices aimed at reducing prescription drug abuse and misuse, potentially including naloxone administration interventions. The budget also provides funding for continuing dissemination of the SAMHSA Opioid Overdose Prevention Toolkit; coordinating with our partners at the federal, state, and local levels; and continuing work with our federal partners to develop both short- and long-term strategies for addressing opioid overdose prevention through targeted activities and programs. In addition, HHS and SAMHSA are committed to ensuring states are well informed about the appropriate use of the Substance Abuse Prevention and Treatment Block Grant dollars in regard to naloxone.

4. a) *Has HHS explored ways to expand naloxone availability to include training and distribution to public bystanders, such as the families of opioid users?*

In April 2012, the FDA convened a meeting specifically focused on naloxone. The purpose of the meeting was to: support a public discussion of wider use of naloxone in non-medical settings to reduce overdose deaths; discuss regulatory, social, ethical and legal issues that might be limiting wider non-medical use of naloxone; and discuss future research needs. In addition to the FDA, several other HHS components participated in the meeting including CDC, NIDA, SAMHSA, and the Office of the Assistant Secretary of Health. The Office of National Drug Control Policy also participated in the meeting.

FDA continues to work with other parts of the federal government to explore how naloxone may be delivered safely in other ways that are potentially easier to use and do not require needles or syringes. FDA is providing priority regulatory assistance to manufacturers who are working on new ways of giving naloxone, such as intranasally, that would be easier to use in non-medical settings.

On April 3, 2014, FDA took a significant step with the approval of Evzio (naloxone auto-injector), the first opioid overdose treatment specifically designed so it can be administered by family members or caregivers. Evzio will be available by prescription with directions appropriate for use by a lay person, which can help save lives in emergency situations. FDA reviewed Evzio under the agency's priority review program, which provides for an expedited review of drugs for serious conditions that, if approved, would provide a significant improvement compared to

marketed products. The product was granted a fast track designation, a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

The National Institute on Drug Abuse (NIDA) recently entered into an agreement with a pharmaceutical company to conduct the dosing studies needed to obtain FDA approval for an intranasal formulation of naloxone.

- b) *Has the Department evaluated whether such naloxone training and distribution programs could be incorporated as a part of broader health programs, such as community health center services, Ryan White services or addiction treatment programs?*

The Department has not evaluated the feasibility of incorporating naloxone training and distribution programs into other health service programs, but such evaluation could be conducted in the future by HHS.

- c) *What additional resources would be needed to assist in the expansion of bystander naloxone distribution programs?*

Given the need to develop formulations of naloxone that are better suited for use by bystanders, no determination related to additional resources has been made at this time.

5. a) *How does HHS work with the various agencies that comprise HHS, such as the Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA) to support expansion of naloxone programs?*

The Department has established, under the leadership of Assistant Secretary for Health Koh and SAMHSA Administrator Hyde, a Behavioral Health Coordinating Committee (BHCC). The BHCC has formed a Prescription Drug Abuse Subcommittee, headed by the FDA Acting Associate Commissioner for Policy and Planning Lurie and Deputy Director of NIDA Compton which includes a working group on naloxone. The naloxone working group meets approximately monthly and has representation from all relevant agencies in HHS. The working group provides updates on agency activities related to naloxone and seeks to enhance coordination between the agencies. For example, the naloxone working group organized the April, 2012 public meeting on naloxone noted above.

- b) *How does HHS work across other departments and offices outside HHS, such as the Department of Justice, and the White House Office of National Drug Control Policy?*

The Department and its Operating Divisions are actively engaged with other federal agencies both in terms of day to day staff level interaction and through frequent formal committee meetings. ONDCP and HHS leadership meet periodically on a wide-range of important issues associated with misuse and abuse of prescription opioids and heroin. The Treatment Coordination Group (TCG) and ONDCP Rx Abuse Interagency Workgroup are two examples of regular meetings which involve many HHS Operating Division senior staff in collaboration and information sharing with other federal agencies on issues of overdose prevention and naloxone.

- c) *What more is needed to promote inter-departmental planning and engagement?*

We feel that there is sufficient collaboration at both the senior leadership and staff levels to ensure adequate coordination and information sharing with other federal agencies.

- d) *What roles do non-HHS entities play in supporting expansion of naloxone?*

Non-governmental organizations, community health centers, HIV service providers, substance abuse treatment providers, the medical community and public health organizations play a critical role in educating health care consumers and the general public about the risks associated with opioid misuse and abuse including overdose and the use of naloxone. The Department continues to support efforts to reduce barriers to the use of naloxone and opioid overdose prevention activities. State and local governments play a critical role through the public health system in preventing overdose deaths. We have reached out to them to provide technical assistance and to help them strategize on best practices in overdose prevention and naloxone use.

6. a) *On a national level, what data collection systems exist to monitor and evaluate the implementation and impact of increased naloxone availability and use?*

We are undertaking an analysis of the data collection systems within the Department to better understand how data on the use of naloxone is, or can be, captured and analyzed. CDC funded one evaluation of naloxone programs in Massachusetts during 2009-2011. The results were published in the *British Medical Journal* (BMJ) in 2013 (Walley A. *Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis*. BMJ 2013; 346:f174.) CDC has no resources currently available for supporting state or local naloxone programs.

- b) *What additional tools or resources are needed to track progress and impact from these programs?*

New efforts are needed to track both the progress and the outcomes of these programs. One strategy would be to begin with an implementation study to understand how this type of program is best developed and deployed and what barriers exist to implementation. Following that, a well-developed evaluation of this type of program would specifically examine the outcomes of

distributing naloxone. This can be expected to be a complex evaluation requiring follow up with programs; clients who receive naloxone; and law enforcement personnel in order to understand the outcomes from many perspectives. Such an evaluation may require study of 'hot spots' where there appears to be higher levels of trafficking and use, as well as mortality, in order to clearly identify the optimal timing of implementation and volume of naloxone distribution programs. The FY 2015 Budget includes funding in CDC and SAMHSA related to prescription drug abuse that could begin to inform this effort.

7. a) *Has HHS evaluated whether there exist state or local laws that may serve as a barrier for expansion of naloxone programs for emergency responders and law enforcement officials?*

CDC worked with EMS providers to identify state and local policies that permit/restrict naloxone use by certain types of paramedics/EMTs and first responders and to identify the primary barriers to the expansion of naloxone access among first responders.

- b) *What about expansion for distribution to public bystanders?
Please describe.*

CDC has completed a scan of state immunity from prosecution ("Good Samaritan") laws that provide immunity from prosecution or mitigation at sentencing for individuals who seek assistance during an overdose. These laws are sometimes connected with a provision for naloxone. The CDC Public Health Law Program will soon publish a menu of legal strategies states can use to provide immunity to bystanders in the event of an overdose. Such immunity might remove one barrier to naloxone use by members of the public.