Executive Summary: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths

Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury death in the United States. Prescription drugs, especially opioid analgesics – a class of prescription drugs such as hydrocodone, oxycodone, morphine, and methadone used to treat both acute and chronic pain – have been increasingly implicated in drug overdose deaths over the last decade. From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics nearly quadrupled. Deaths related to heroin have also increased sharply since 2010, including a 39 percent increase between 2012 and 2013.

In response to these recent increases in opioid-related morbidity and mortality, the U.S. Department of Health and Human Services (HHS) has made addressing the opioid abuse problem a high priority and is focused on implementing evidence-based approaches to reduce: 1) opioid overdoses and overdose-related mortality and 2) the prevalence of opioid use disorder.

HHS and Secretary Burwell are focused on three priority areas to reach these goals and to combat opioid abuse:

- Opioid prescribing practices to reduce opioid use disorders and overdose
- The expanded use of **naloxone**, used to treat opioid overdoses
- Expanded use of <u>Medication-assisted Treatment (MAT)</u> to reduce opioid use disorders and overdose

These priority areas were identified through a Department wide effort that tapped all the scientific, analytical and programmatic expertise contained in HHS agencies. The development effort also relied on discussions with states and other stakeholder organizations. The priorities, grounded in the best research and clinical science available, will guide the Department's efforts to implement the most effective and achievable means for addressing the nation's opioid epidemic.

HHS continues to coordinate the activities of agencies across the Department, such as the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH), Office of the National Coordinator for Health Information Technology (ONC), and Substance Abuse and Mental Health Services Administration (SAMHSA), to ensure effective implementation of the initiative's programs and policies. HHS has also prioritized the development of an evaluation to identify the most effective strategies for obtaining the greatest public health impact.

Opioid Prescribing Practices (prescription opioids)

While actions to address prescription opioid abuse must target both prescribers and high-risk patients, prescribers are the gatekeepers for preventing inappropriate access. Interventions to improve safe and appropriate prescribing must balance the need for these drugs for legitimate

purposes with the need to curb dangerous practices. Within this priority area are three objectives:

- Improve clinical decision-making to reduce inappropriate prescribing
- Enhance prescription monitoring and health information technology (health IT) to support appropriate pain management
- Support data sharing to facilitate appropriate prescribing

Some key actions include:

Increased investments in evidence-based state prevention interventions, including PDMPs
Building off the infrastructure of the Prevention Boost and Core Violence and Injury Prevention
programs, CDC received \$20 million in FY 2015 and will launch the Prescription Drug
Overdose Prevention for States program, which will target states with high burdens of
prescription drug overdose morbidity and mortality. This funding will be used to expand statelevel interventions that focus on improving prescribing to prevent overdose, including
enhancements to PDMPs.

Establishing opioid prescribing guidelines for chronic pain and working to ensure effective implementation of guidelines

To improve clinical decision making to reduce inappropriate opioid prescribing, CDC is developing guidelines for opioid prescribing for chronic pain outside the setting of end-of-life care. To ensure effective implementation of guidelines, ONC is exploring opportunities to convert guidelines into standardized, sharable, health IT-enabled clinical decision support interventions.

Naloxone (prescription opioids and heroin)

Naloxone is a life-saving medication that rapidly blocks the effects of opioids when a person first shows symptoms of a prescription opioid or heroin overdose. To support the important role of naloxone in overdose prevention, HHS focuses on three objectives:

- Accelerate the development and availability of new naloxone formulations and products
- Identify and disseminate best practice naloxone delivery models and strategies
- Expand utilization of naloxone

through its expedited review programs.

Some key actions include:

Research trials on implementation and dissemination of overdose prevention programs The National Institute on Drug Abuse (NIDA) within the National Institutes of Health (NIH) is supporting a number of research trials exploring the efficacy of prescribing take-home naloxone for individuals at high risk of prescription opioid or heroin overdose or at high risk of witnessing an overdose. FDA is also encouraging the development of new opioid overdose treatments

Expanding utilization of naloxone through grants program to states

Currently, states may use some of their <u>substance abuse block grant funds to purchase naloxone</u> and the necessary materials to assemble and disseminate overdose kits and increase education/training on the use of naloxone. The FY 2016 President's Budget proposes \$12 million in grants to states to purchase naloxone, equip first responders in high-risk communities, and provide education and the necessary materials to assemble overdose kits, as well as cover expenses incurred from dissemination efforts.

Medication-assisted Treatment (prescription opioids and heroin)

Medication-assisted treatment (MAT) is treatment for addiction that includes the use of medication along with counseling and other support. MAT is the most effective form of treatment for opioid use disorders. Within the MAT priority area are two objectives:

- Support research that informs effective use and dissemination of MAT and accelerates development of new treatment medications
- Increase access to clinically effective MAT strategies

Some key actions include:

Research to support effective MAT strategies

NIDA is currently supporting research on the effects of the Affordable Care Act on MAT implementation and the efficacy of implementation strategies for MAT in medical and criminal justice settings, among other study topic areas. In addition, FDA is also promoting the development of medications for the treatment of opioid use disorders by using its expedited review programs.

Investments in MAT services

In FY 2015, SAMHSA will provide \$12 million through a <u>demonstration grant program</u> to expand treatment services for opioid dependence. Grants will provide accessible, effective, comprehensive, coordinated and evidence based medication assisted treatment and recovery support services including the use of methadone, buprenorphine products, and naltrexone products. The FY 2016 President's Budget proposes an additional \$13 million expansion of this program to increase the number of states that would receive targeted funding to address prescription drug misuse and heroin use through expanded MAT services.

Next Steps

Building upon the Department's existing efforts to address opioid drug-related dependence, overdose, and death, HHS leadership has joined together to aggressively implement the new initiative and monitor progress. Many activities are already underway, and the Department continues to seek opportunities to work with its partners on this public health crisis.