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Chairman Pitts and Ranking Member Green, thank you for this opportunity to talk with you about addressing the misuse and abuse of opioids. The President has made addressing this important public health issue a priority and we at HHS share this commitment to doing what it takes to turn this public health crisis around. Secretary Burwell has made addressing the opioid crisis a top priority; she is keenly aware of the toll it is taking on communities across the Nation.

The terrible consequences of opioid misuse and abuse have no regard for demographic, economic or geographic distinctions: they affect us all. At HHS, we are encouraged by the momentum building in communities and across party lines on both sides of the Capitol and in state and local governments to take action to halt the crisis and save lives.

The data on the crisis are stark. In 2014, over 10 million people reported nonmedical use of prescription opioids and nearly one million reported heroin use. Further, more than two million people have an opioid-use disorder.[1] This disrupts families, creates disability and produces criminal activity. This costs American society in money and lost human potential. Most alarming, thousands of families are losing loved ones to opioid overdoses and many more struggle to overcome the shame and social consequences of opioid use disorder.

When Secretary Burwell arrived at HHS, a little over a year ago, one of the first things she did was direct our senior leadership team to develop and carry out an initiative to address opioid

[1] Jones CM et al. National and State Treatment Need and Capacity for Opioid-Agonist Medication Assisted Treatment. Am J Public Health. 2015

misuse and abuse. She insisted that we identify targeted, strategic investments to promote evidence based solutions and partner with states, communities and the Congress to find common ground. She also asked us to track our progress and evaluate our work as we go, so that we can know what's working and make midcourse corrections if our efforts aren't having the intended outcomes. Based on a review of the evidence and clinical science, our plan focuses on the actions that existing evidence suggests would produce the most impact on three specific areas: (1) improving opioid analgesic prescribing practices; (2) expanding the use of medication-assisted treatment and recovery services for individuals with an opioid-use disorder; and (3) expanding the use and distribution of naloxone.[2]

We are taking important steps on all three fronts:

- First, on the prescribing issue, as part of the Centers for Disease Control and Prevention (CDC)'s Prescription Drug Overdose: Prevention for States program, HHS has invested $20 million in Fiscal Year (FY) 2015 to stand up comprehensive, multi-sector prevention programs in 16 states to combat the prescription drug overdose epidemic on multiple fronts, including improving state prescription drug monitoring programs (PDMPs), enhancing insurer and health system practices, and reaching the hardest hit communities. This builds on previous work of the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office of the National Coordinator for Health Information Technology (ONC). The President's FY 2016 Budget includes $68 million to expand CDC's program to all 50 states and $10 million for a related SAMHSA initiative.

[2] The evidence we uncovered showed that utilization of PDMPs and prescribing guidelines change prescribing behavior, that naloxone in the hands of first responders reduces overdose death and that MAT is effective in treating opioid use disorder. For more background information, please refer to the ASPE Issue Brief, Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths, http://aspe.hhs.gov/basic-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths .

The FY 2016 Budget also includes $5.6 million to support CDC's efforts to address the troubling rise in overdose deaths from illicit opioids such as heroin and $5.0 million to expand electronic death-reporting to provide faster, better-quality data on deaths of public health importance, including Prescription Drug Overdose deaths.

- Also, related to prescribing, in January, just a few months from now, the CDC, in partnership with the National Institute on Drug Abuse (NIDA), SAMHSA, ONC, and the Food and Drug Administration (FDA), and the Office of National Drug Control Policy, will release suggested guidelines for providers on safer, more effective use of opioids to treat chronic pain outside of end-of-life care.
- Regarding the distribution of naloxone, the National Institute on Drug Abuse (NIDA) is supporting a number of research trials exploring the efficacy of prescribing take-home naloxone and FDA is supporting the development of new opioid overdose treatments by using its expedited review programs. In addition, the Health Resources and Services Administration (HRSA) is awarding $1.8 million in grants to support rural communities in reducing opioid overdose and death. And, the President's FY 2016 Budget includes $12 million for SAMHSA to fund "Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths," which will provide states with funds to purchase and distribute naloxone.
- In July, we released a $100 million funding opportunity to expand substance abuse treatment, including medication-assisted treatment (MAT) for opioid misuse and abuse, at community health centers. I will go into greater detail on MAT later in this statement.

HHS believes that addressing this problem is an area of common ground and there are a number of bills introduced in the Congress that touch on some of the same issues. While the

Administration does not have a formal position on any of the bills discussed below, we look forward to working with the Committee on these proposals and welcome the opportunity to provide technical assistance to you and your staff on these topics. For example, one of the bills we are discussing today, the Heroin and Prescription Opioids Abuse Prevention, Education and Enforcement Act (H.R. 2805), touches upon the themes of provider education, bolstering PDMPs, and increasing access to naloxone to prevent overdose death. The Overdose Prevention Act (S. 1654), and Stop Overdose Stat Act (H.R. 2850), focus on increasing access to naloxone and improving surveillance and research. Several bills address the need for better training for providers to safely prescribe opioids; the Administration supports mandatory training as part of the National Drug Control Strategy. In addition, earlier this year, the National All Schedules Prescription Electronic Reporting Reauthorization Act (H.R. 1725), and the Protecting Our Infants Act (H.R. 1462), were passed by this Committee and then the full House of Representatives.

In the remaining time I have with you today I would like to describe our efforts related to improving access to high quality treatment for the estimated more than two million people with opioid use disorders. We have effective treatments for opioid use disorders. MAT is the combination of medication supported by behavioral interventions and recovery support services, as well as careful patient monitoring that has been shown by the best science to reduce cravings for opioids and morbidity. MAT also prevents relapse to unwanted drug use and has been shown to reduce risk behaviors associated with the transmission of HIV.[3] Yet, despite the established

[3] Kresina TF, Lubran R. Improving Public Health Through Access to and Utilization of Medication Assisted Treatment. International Journal of Environmental Research and Public Health. 2011;8(10):4102-4117. doi:10.3390/ijerph8104102.

clinical and cost-effectiveness of this therapy, MAT is underutilized. Fewer than half of those diagnosed with opioid use disorders receive MAT.[4] We are committed to changing that.

MAT for opioid use disorders can make use of one of three types of FDA-approved medications, including those containing: buprenorphine, methadone, and injectable long-acting naltrexone. Depending on the medication used, MAT may be delivered in different treatment settings. Provision of MAT faces unique barriers to patient access including the application of stringent medical management techniques like prior-authorization requirements and time-in-treatment limitations.[5]

Furthermore, in the case of office-based buprenorphine, that only physicians can prescribe, the number of opioid use disorder patients a physician can treat is limited to no more than 100 at any one time.[6] Additionally, methadone can be dispensed for substance-use disorder only in Federally-regulated opioid-treatment programs, which often are subject to local zoning regulations that prevent them from opening in many communities. Injectable, long-acting naltrexone requires complete abstinence for 7-10 days prior to administration. All of these factors complicate expanding access to MAT.

Our approach to expanding use of MAT is guided by: (1) the recognized need to expand the use of MAT; (2) the fact that effective use of MAT means delivering the full package of pharmaceuticals, counseling, recovery support, and monitoring of patient adherence with treatment; and (3) the goal that capacity be expanded in a way that minimizes the risks of drug

[4] Volkow ND, Frieden TR, Hyde PS, Cha SS. Medication-assisted therapies: tackling the opioid-overdose epidemic. *N Engl J Med*. 2014;370(22):2063-2066.
[5] We are examining these issues in the context of parity implementation.
[6] It is well known that methadone, which is also used to treat addiction, faces stringent conditions regarding providers permitted to dispense and conditions of use.

diversion.[7] This approach is supported by national clinical guidelines including SAMHSA's Treatment Improvement Protocols and the American Society of Addiction Medicine's recently issued guidelines on the appropriate use of MAT in treating opioid use disorders. [8] These guidelines include recommendations regarding the proper diagnosis, withdrawal-management, and treatment protocols for the use of MAT in treating opioid-use disorders. Moreover, the guidelines include steps physicians should take to reduce the chance of buprenorphine diversion, including frequent office visits, urine drug-testing, and recall visits for pill counts.

I want to share with you the steps we are taking to expand our capacity to deliver MAT, which touch on similar issues as certain proposed bills, such as the TREAT Act (H.R. 2536), currently under consideration in the Congress. As with the other proposals under consideration, we look forward to working with the Committee on this topic and providing additional technical assistance as needed.

Just a few weeks ago, at her 50 State convening on the opioid crisis, Secretary Burwell announced that we will be engaging in rulemaking to address buprenorphine prescribing as enumerated in the Federal Drug Addiction Treatment Act of 2000, as amended. Under current regulations, physicians certified to prescribe buprenorphine for MAT are allowed to prescribe up to 30 patients initially, and then after one year can request authorization to prescribe up to a

[7] According to the National Forensic Laboratory Information System data (DEA), buprenorphine is the 4th most commonly diverted prescription opioid. However, recent studies have indicated that motivations for buprenorphine diversion differ from those associated with other prescription opioids. For example, according to a 2013 study published in the journal, Addictive Behaviors, nearly 75% of participants reporting use of street-obtained buprenorphine, reported using the drug to manage withdrawal symptoms (as opposed to getting intoxicated).

[8] Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP) Series 43.HHS Publication No. (SMA) 12-4214.Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005. http://www.asam.org/docs/default-source/default-document-library/asam-national-practice-guideline-supplement1b630f9472bc604ca5b7ff000030b21a.pdf?sfvrsn=0

maximum of 100 patients. This cap on prescribing limits the ability of some physicians to prescribe to patients with opioid-use disorders. Secretary Burwell is using other tools to encourage broader adoption of MAT in primary care settings, particularly in underserved areas. HRSA has recently announced a competition for $100 million to expand the use of MAT in community health centers nationwide, and SAMHSA recently awarded $11 million to eleven states across the Nation to increase access to comprehensive medication-assisted treatment for opioid use disorders and has requested $25.1 million to expand to 22 states in FY 2016.

Additionally, we are working with states to help them improve the delivery of treatment for substance use disorders. The Centers for Medicare Medicaid Services (CMS) issued a letter to State Medicaid Directors (SMD) this past July describing opportunities and Federal authorities that states can use to provide a continuum of care for beneficiaries with substance use disorders including opioid addiction. CMS also recently launched the Innovation Accelerator Program (IAP) to support states in improving their delivery systems with technical assistance at varied levels of intensity. The first phase of this IAP initiative is focused on helping states transform substance use disorder treatment services including by taking advantage of the new opportunities to pay for a continuum of care for substance use disorders outlined in the recent SMD letter. There are two platforms of technical assistance available to states through the IAP initiative on substance use disorder. The first, called the High Intensity Learning Collaborative, is geared for states that committed to work intensively on designing and implementing SUD delivery system reforms. The second, called the Targeted Learning Opportunities, is geared to states that want peer-based learning series on successful SUD delivery reforms but are not ready to commit to immediate program changes. The seven states participating in the High Intensity Learning Collaborative and receiving strategic support are Washington, Louisiana, Texas, Michigan,

Minnesota, Kentucky and Pennsylvania. So far, 46 states (including the District of Columbia) have participated in the Targeted Learning Opportunities. We are also exploring ways to expand provider understanding of opioid use disorders and ways they can engage in treating them. The Federal Government is committed to providing clinicians with the state of the art in education on the treatment of pain and addiction and in providing screening and clinical decision support tools to facilitate integration of that knowledge into clinical practice. To date, over 60,000 physicians, nurses, and other health care professionals have successfully completed a continuing medical education module developed by NIDA with support from ONDCP managing pain patients who use drugs, and over 50,000 successfully completed a module concerning safe prescribing for pain.

And while clinician engagement is key to improving access to opioid use disorder treatment, HHS recognizes the need to ensure that the care being delivered is of the highest quality and consistent across delivery systems. To that end, HHS and its partners in the quality improvement field are promoting widespread adoption of existing substance use disorder screening and treatment intervention measures as well as refining or developing new provider performance measures. This effort is intended both to assess the quality of care being delivered and to incentivize broader adoption of effective substance use disorder treatment.

Secretary Burwell is doing all she can to get the word out that we need an "all hands" solution to the opioid crisis. I mentioned a while ago the 50 State convening. At this meeting, just a couple of weeks ago, Secretary Burwell hosted representatives from all the states and the District of Columbia to share best practices and discuss solutions to reverse the opioid crisis. The meeting was very well received and added even more energy and support to our efforts to collaborate

with partners in the states to improve opioid prescribing practices, increase access to naloxone and expand the use of MAT.

There is some progress to report. Forty-one states plus the District of Columbia have adopted laws that facilitate the prescribing and/or distribution of naloxone, and, as mentioned, hundreds of community health centers and other community-based programs are poised to receive over $100 million in Federal support for the delivery of addiction treatment, including medication-assisted treatment for opioid use disorders. We are starting to see progress in certain states as well. Florida, Kentucky, Washington State, and Oregon have seen declines in prescription opioid prescribing and opioid-related health outcomes after working across sectors to implement comprehensive policies and programs. These are notable markers of progress but do not suggest that victory is yet in sight.

As you can see, we are fighting this battle on many fronts. We will continue to work with many partners – states, the addiction-treatment community, specialists, general practitioners, private-sector partners, public safety, and state legislators. And of course we are very interested in continuing to work with the Congress to secure funding for the Secretary's Opioid Initiative included in the President's FY 2016 Budget and to provide technical assistance on legislation addressing the priority impact areas we have identified. The Secretary continually reminds us that among our most important partners are people suffering with addiction, people in recovery and the people who love them. At its heart, this is an issue that affects families and communities and we will measure the success of our initiative by the impact it has on them.