House Committee on Energy and Commerce

Subcommittee on Health

Hearing titled, "Combating the Opioid Crisis: Prevention and Public Health Solutions"

March 21, 2018

Written testimony on behalf of

Christopher M. Jones, PharmD., M.P.H.
Director, National Mental Health and Substance Use Policy Laboratory
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services

Chairman Burgess, Ranking Members Green, and Members of the Committee. Thank you for the opportunity to discuss the opioid crisis in the United States and the Federal response. From the start of his Administration, President Trump has made addressing the opioid epidemic a top priority, and at the Substance Abuse and Mental Health Services Administration (SAMHSA) we share the President's commitment to bringing an end to this crisis, which is exacting a heavy toll on individuals, families, and communities across the country.

Over the past 15 years, communities across our Nation have been devastated by increasing prescription and illicit opioid abuse, addiction, and overdose. According SAMHSA's National Survey on Drug Use and Health (NSDUH), in 2016, over 11 million Americans misused prescription opioids, nearly 1 million used heroin, and 2.1 million had an opioid use disorder due to prescription opioids or heroin. Over the past decade, the U.S. has experienced significant increases in rates of neonatal abstinence syndrome (NAS), hepatitis C infections, and opioid-related emergency department visits and hospitalizations. Most alarming are the continued increases in overdose deaths, especially the rapid increase since 2013 in deaths involving illicitly made fentanyl and other highly potent synthetic opioids. Since 2000, more than 300,000 Americans have died of an opioid overdose. Opioids were involved in 42,249 deaths in 2016, and opioid overdose deaths were five times higher in 2016 than 1999.

The opioid epidemic in the United States can be attributed to a variety of factors. For example, there was a significant rise in opioid analgesic prescriptions that began in the mid-to-late 1990s. Not only did the volume of opioids prescribed increase, but also well-intentioned healthcare providers began to prescribe opioids to treat pain in ways that we now know are high-risk and have been associated with opioid abuse, addiction, and overdose, such as prescribing at high doses and for long durations. One additional factor is a lack of health system and healthcare provider capacity to identify and engage individuals with opioid use disorders, and to provide them with high-quality, evidence-based opioid addiction treatment, in particular the full spectrum of medication-assisted treatment (MAT). It is well-documented that the majority of people with opioid addiction in the United States do not receive treatment, and even among those who do, many do not receive evidence-based care. Accounting for these factors is paramount to the development of a successful strategy to combat the opioid crisis. Further, there is a need for more rigorous research to better understand how existing programs or policies might be contributing to or mitigating the opioid epidemic.

In April 2017, HHS outlined its five-point Opioid Strategy, which provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. The comprehensive, evidence-based Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;

- Target the availability and distribution of overdose-reversing medications to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;
- Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves;
- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and
- Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

As HHS's lead agency for behavioral health, SAMHSA's core mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA supports a portfolio of activities that address all five prongs of HHS's Opioid Strategy.

Improving Access to Prevention, Treatment, and Recovery Support Services

SAMHSA administers the Opioid State Targeted Response (STR) grants, a two-year program authorized by the 21st Century Cures Act (P.L. 114-255). By providing $485 million to states and U.S. territories in fiscal year (FY) 2017, this program allows states to focus on areas of greatest need, including increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of the full range of prevention, treatment and recovery services for opioid use disorder. The President's Budget for SAMHSA in FY 2019 proposes an initial allocation of $1.2 billion to SAMHSA for a variety of new and expanded efforts to fight the opioid crisis. Of that amount, $1 billion is included to expand STR grants, an increase of $503 million above the FY 2018 Continuing Resolution amount for these activities.

In November 2017, SAMHSA announced that it was accepting applications for $1 million in grants for Opioid State Targeted Response (STR) Supplements. The purpose of this program is to expand and enhance prevention, treatment, and recovery support efforts in the states hardest hit by the nation's opioid epidemic. The purpose of the supplemental funding is to bolster efforts already being made through the STR grant program. One Monday, SAMHSA awarded grants to three states that are among those with the highest overdose death rates and rate of increase in death rates. This funding follows the STR grants which SAMHSA distributed to states and territories based on number of overdose deaths and the number of people needing treatment.

Following the nationwide public health emergency declaration on October 26, SAMHSA announced a new Technical Assistance (TA) effort to focus on the specific needs of states and local jurisdictions to address the opioid crisis in their areas. In January, SAMHSA released $12

million in funding to the American Academy of Addiction Psychiatry to begin the effort to utilize local expertise to provide TA and training on scientifically based evidence-based practices to combat the nation's opioid crisis. The Opioid State Targeted Response TA program aims to provide technical assistance on evidence-based practices across the spectrum of prevention, treatment and recovery. The technical assistance and training program will ensure that Americans suffering with opioid use disorders will gain access to the life-saving evidence-based medication-assisted treatment and psychosocial services they need.

SAMHSA also has several initiatives aimed specifically at advancing the utilization of or MAT for opioid use disorder, which is proven effective but is highly underutilized. SAMHSA's Medication Assisted Treatment for Prescription Drug and Opioid Addiction (MAT-PDOA) program expands MAT access by providing grants to states with the highest rates of treatment admissions for opioid addiction. Twenty-two states are currently funded by MAT-PDOA, and in September 2017, SAMHSA awarded $35 million dollars over three years in additional MAT-PDOA grants to six states. The President's Budget for SAMHSA for FY 2019 maintains $56 million for the MAT-PDOA program.

SAMHSA also provides critical funding for MAT for specific high-risk and vulnerable populations, such as those involved with the criminal justice system and pregnant and postpartum women. SAMHSA's criminal justice grantees can use up to 20 percent of their grant awards for the purchase of FDA-approved medications for treatment of opioid and alcohol addiction. Since 2013, SAMHSA has seen a steady increase in the number of drug courts integrating MAT into their programs with 57 percent of active programs currently doing so. The President's Budget for SAMHSA for FY 2019 expands the use of drug courts.

Under SAMHSA's Pregnant and Postpartum Women's (PPW) program, which serves women with opioid or other substance use disorders who are pregnant and/or newly parenting, grantees are encouraged to ensure access to MAT for opioid addiction, which has been shown to improve birth outcomes. Last month SAMHSA awarded $9.8 million over three years for new State Pilot PPW grants authorized by the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198) and $49 million over five years in new PPW service grants to support the recovery of pregnant and postpartum women struggling with substance abuse, including opioid addiction. The President's Budget for SAMHSA for FY 2019 expands these services to pregnant and postpartum women and their children.

Last month, SAMHSA released a new publication "Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants." SAMHSA's Clinical Guidance comes at a time of great need for effective opioid use disorder (OUD) treatment. In 2016, over 20,000 pregnant women reported using heroin or misusing pain relievers in the past month. Newborn babies of mothers who used opioids while pregnant are at risk of neonatal abstinence syndrome--a syndrome of physical and neurobehavioral signs of withdrawal. The Clinical Guidance offers standard approaches to a range of real-world scenarios faced by healthcare

professionals working with mothers and infants. For each scenario, the guidance offers clinical action steps and supporting evidence. The action steps reflect the best available treatment, including medication-assisted treatment for the mother and infant and appropriate types of social supports and follow-up services.

A well-documented challenge to improving access to opioid use disorder treatment is a lack of providers who can provide MAT. SAMHSA supports a number of training initiatives to increase the number of qualified healthcare providers who can provide treatment for opioid addiction. In the last four years, more than 62,000 medical professionals have participated in online or in-person trainings on MAT for opioid addiction through SAMHSA's Provider's Clinical Support System (PCSS)-MAT. This program is a national training and clinical mentoring project that provides the DATA waiver training necessary for physicians, nurse practitioners, and physician assistants to provide office-based treatment of opioid use disorders and provides mentoring of newly trained physicians by experienced specialists, and maintains a library of evidence-based practice materials for continuing education.

SAMHSA regulates opioid treatment programs (OTPs), which dispense methadone and may also dispense and prescribe buprenorphine and administer extended-release naltrexone. In coordination with the Drug Enforcement Administration (DEA) and states, territories, and the District of Columbia, SAMHSA reviews new and renewal applications for OTPs through an accreditation process that ensures programs have sound risk management practices in place and are using evidence-based treatments. SAMHSA also oversees physicians, nurse practitioners (NPs), and physician assistants' (PAs) ability to prescribe buprenorphine in office-based outpatient treatment settings. On July 8, 2016, SAMHSA published a final rule, which allows certain qualified physicians who have obtained a waiver to prescribe buprenorphine for up to 100 patients for at least a year, to request and receive approval to treat up to 275 patients. The regulation provides that these licensed physicians can become eligible for the patient limit of 275 either by being board certified in Addiction Medicine or Addiction Psychiatry or by practicing in a qualified practice setting.

These physicians are required to complete a SAMHSA reporting form each year to ensure that physicians prescribing at the new, higher level are in compliance with the regulatory requirements for the increase in the patient limit. As of March 3, 2018, 3,992 physicians have been provided a waiver to prescribe up to 275 patients. Most recently, SAMHSA began processing waivers to allow NPs and PAs to prescribe buprenorphine in accordance with the requirements of CARA. As of March 3, 2018, 4,863 nurse practitioners and 1,276 physician assistants have received waivers to prescribe buprenorphine. Now that TIP 63: *Medications for Opioid Use Disorders* has been released, SAMHSA will ensure that currently waivered practitioners receive this document which includes information about the appropriate use of all FDA-approved medications for the treatment of opioid use disorders consistent with the requirements of CARA.

SAMHSA also recently released a fact sheet, "Finding Quality Treatment for Substance Use Disorders." This fact sheet provides individuals and families with some of the right questions to ask when looking for quality treatment, including whether the treatment program is licensed or certified by the state, whether the program offers FDA approved medications, whether the program includes family members in the treatment process, and whether the program provides other supports in addition to treatment. The fact sheet is on SAMHSA's website: https://store.samhsa.gov/shin/content//PEP18-TREATMENT-LOC/PEP18-TREATMENT-LOC.pdf.

In January, SAMHSA issued a final rule related to the regulation of substance use disorder treatment records (Part 2) that takes steps to further modernize Part 2 to better address new models of integrated care and the use electronic health records. This rule is one way to strengthen the nation's efforts to ensure safe and effective care of all who seek treatment for opioid addiction. The rule also reflects an effort to better align Part 2 requirements with those of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). As required by the 21st Century Cures Act (section 11002), SAMHSA held a public meeting on January 31, 2018, to obtain input about the impact of Part 2 on "patient care, health outcomes, and patient privacy." The vast majority of those who spoke at the listening session expressed their support for further aligning Part 2 and HIPAA and acknowledged that to achieve many of their goals Congress would need to take action on legislation. While the Administration has not taken a position on any particular bill related to Part 2, I want to assure you that SAMHSA supports further consideration of the benefits of aligning the statute governing Part 2 with HIPAA.

The President's Budget for SAMHSA for FY 2019 proposes additional funds that will help States provide services to reduce injection drug use and related HIV/AIDS and Hepatitis C infection rates related to opioid use.

SAMHSA also promotes recovery through targeted grants, such as last month's award of $4.6 million over three years in Building Communities of Recovery (BCOR) program grants, created by CARA. The purpose of this program is to mobilize resources within and outside of the recovery community to increase the availability and quality of long-term recovery supports for individuals in or seeking recovery from addiction. These grants are intended to support the development, enhancement, expansion, and delivery of recovery support services as well as promotion of and education about recovery. Programs will be principally governed by people in recovery from substance abuse and addiction who reflect the community served. The President's Budget for SAMHSA for FY 2019 maintains funding for the BCOR program.

Targeting Overdose-Reversing Drugs

SAMHSA has been a leader in efforts to reduce overdose deaths by increasing, through funding and technical assistance, the availability and use of naloxone to reverse overdose. SAMHSA's "Opioid Overdose Prevention Toolkit," first released in 2013, is one of SAMHSA's most downloaded resources. The Toolkit provides information on risks for opioid overdose, recognition of overdose, and how to provide emergency care in an overdose situation. The

Toolkit is intended for community members, first responders, prescribers, people who have recovered from an opioid overdose and family members, as well as communities and local governments.

SAMHSA provides a number of funding streams that can be used to expand access to naloxone. States are able to use Opioid STR funds to purchase and distribute naloxone, and some states are also using a portion of their SABG funds for opioid overdose prevention activities. SAMHSA is currently providing $11 million per year in Grants to Prevent Prescription Drug/Opioid Overdose Related Deaths to 12 states. These grants are also being used to train first responders on emergency medical care to be rendered in an overdose situation and how to administer naloxone as well as how to purchase and distribute naloxone. In September 2017, SAMHSA awarded funding for grants authorized by CARA, including almost $46 million over five years to grantees in 22 states to provide resources to first responders and treatment providers who work directly with the populations at highest risk for opioid overdose. The President's Budget for SAMHSA for FY 2019 proposes additional funding to allow communities to purchase the overdose-reversing drug naloxone for first responders.

Strengthening Public Health Data and Reporting

SAMHSA's National Survey on Drug Use and Health (NSDUH) provides key national and state level data on a variety of substance use and mental health topics, including opioid misuse. NSDUH is a vital part of the surveillance effort related to opioids, and the data from NSDUH has been used to track historical and emerging trends in opioid misuse, including geographic and demographic variability.

The President's Budget for SAMHSA for FY 2019 includes $15 million to re-establish the Drug Abuse Warning Network, a national public health surveillance system that will improve emergency room monitoring of mental and substance abuse crises, including those related to opioids. This will be an important tool in tracking substance misuse and related toxicities nationally and will help in addressing these issues as they evolve.

Thank you again for inviting me to testify today. I look forward to answering your questions.