DEPARTMENT OF HEALTH AND HUMAN SERVICES

Combatting an Epidemic: Legislation to Help Patients with Substance Use Disorder

March 3, 2020

Witnesses Appearing Before the
House Subcommittee on Health of the Committee on Energy and Commerce

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Introduction

Thank you Chair Eshoo, Ranking Member Burgess, and distinguished Members of the Committee. It is a privilege to be before you today to discuss how the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), has advanced the work of the Department of Health and Human Services (HHS) to combat the opioid crisis. From the start of his administration, President Trump has made addressing the opioid crisis a top priority, and our Department is ensuring that the Administration is delivering on that commitment: to reduce deaths and disability from overdoses, to enhance and ensure opportunities for Americans to achieve long-term recovery, and to prevent future generations from suffering with the chronic brain disease of addiction.

Together, We are Making Progress

Our nation's drug overdose crisis has been one of the most pressing public health challenge of our time. Countless communities across the United States have been devastated by substance misuse, use disorders, and overdose mortality. Since 1999, over 770,000 people died due to drug overdose, the majority of these deaths involved opioids.[1] In 2018 alone, over 68,500 Americans died of a drug overdose, and over 47,600 of these deaths were caused by opioids. The latest National Survey on Drug Use and Health found that approximately 2 million Americans had an opioid use disorder (OUD).[2] We also know that approximately 10.3 million Americans over the age of 12 years, have misused opioids in the past year, with 808,000 people reporting heroin use.

While combatting the opioid crisis continues to be a highly complex and daunting challenge, there is evidence that the Administration, with the support of Congress, has made significantprogress. Most notably, between 2017 and 2018, drug overdose deaths fell by 4.1 percent, and age adjusted mortality fell by 4.6 percent. These figures represented the first year-to-year decreases in almost 3 decades. We have also led a nationwide decrease in opioid prescribing and use. Specifically, from January 2017 to September 2019, there has been a 32 percent reduction in total morphine milligram equivalents dispensed monthly by retail and mail order pharmacies.[3]

In addition, more Americans are receiving the treatment they need. Medication-assisted treatment (MAT) is the use of medications approved by the Food and Drug Administration (FDA), in combination with counseling and behavioral therapies and holistic recovery services, to treat OUD or alcohol use disorder). Compared to treatment for OUD that does not include an FDA-approved medication, MAT is associated with greater treatment retention, reduced illicit drug use, reduced transmission of HIV and HCV and improved adherence to treatment for these conditions, reduced overdose and related

[1] https://www.cdc.gov/nchs/pressroom/podcasts/20190911/20190911.htm

[2] Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

[3] IQVIA National Prescription Audit. Retrieved October 2018 and October 2019. Note: These data are for the retail and mail service channels only and do not include the long-term care channel

mortality, and reduced criminal justice system involvement.[4,5 6,7,8,9,10,11,12,13,14] Data suggest that in 2016, about 920,000 Americans were receiving MAT for OUD. As of January 2020, about 1.3 million Americans were receiving a form of FDA-approved medication for the treatment of OUD; this is a 41 percent increase in individuals receiving the recommended treatment for OUD.[15] From January 2017 to September 2019, the number of patients receiving buprenorphine and naltrexone monthly increased by 31 percent and 58 percent respectively. Availability of naloxone, an opioid agonist that is used to temporarily reverse the effects of an opioid overdose, has increased dramatically, as evidenced by a 405 percent increase in the number of naloxone prescriptions dispensed monthly by retail and mail order pharmacies since 2017.[16] This is in addition to the millions of naloxone doses that are directly distributed to clients, first responders, health professionals, and other stakeholders.

From 2016 to 2019, HHS awarded $9 billion in grant funding to states, tribes, and local communities to increase access to prevention, treatment, and recovery services, including the State Opioid Response (SOR) grants administered by the Substance Abuse and Mental Health Services Administration (SAMHSA). The SOR grants provide a high degree of flexibility to states, along with an unprecedented newly restructured program of technical assistance led by SAMHSA; but require that funds be spent based on the best scientific evidence and medical practice.

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[15] IQVIA National Prescription Audit; SAMHSA Opioid Treatment Program Self-Report; N-SSATS.
[16] IQVIA National Prescription Audit. Retrieved October 2018 and October 2019. Note: These data are for the retail and mail service channels only and do not include the long-term care channel

In May of 2019, the Pain Management Best Practices Inter-Agency Task Force issued a final report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations.[17] This report promotes an individualized and multimodal approach to pain management, and centers on five major treatment approaches and four cross-cutting topics that need to be addressed to ensure best practices. In October 2019, SAMHSA launched FindTreatment.gov, a newly designed website that will help connect persons seeking treatment facilities for substance use/addiction and/or mental health problems. Also in October 2019, HHS issued the Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics.[18] This guide focuses on a patient-centered process, and informs clinicians on considerations and evidence-based practices for opioid tapering.

We are proud of the progress we have made, but clearly understand that there is an extraordinary amount of work to do. The public health crisis of substance use disorders and overdose deaths continues to evolve and take the lives of far too many Americans. Unfortunately, while many states are experiencing decreases in deaths, deaths in some states continue to rise. In addition, although our most recent data demonstrate a significant decrease in deaths from prescription opioids, deaths involving synthetic opioids increased 10 percent (2017-2018), deaths involving cocaine increased by 5 percent (2017-2018), and deaths involving psychostimulants with abuse potential (drugs such as methamphetamine) increased by over 20 percent (2017-2018). These trends are continuing into mid-2019 as well, according to our provisional data. However, we must not forget that national trends can mask state or local trends. For example, while the rate of drug overdose deaths in 15 states was lower in 2018 than in 2017, the rate increased from 2017 to 2018 in 5 states.[19] We are also witnessing new and highly dangerous patterns of use, including polysubstance use of both methamphetamines and illicit fentanyl or fentanyl analogs – a particularly dangerous and deadly combination. These disturbing trends show that the opioid crisis is evolving and other substances may threaten the overall progress we have made against prescription opioids and heroin. The Department understands and is committed to expanding and adapting our efforts to best address the dynamic drug overdose epidemic, working collaboratively with our partners throughout government.

HHS Five-Point Strategy

In April 2017, HHS launched a Five-Point Strategy (Strategy) to combat opioid abuse, misuse, and overdose. The Strategy, founded on robust, scientific evidence, provides the overarching framework for our Department, so that we can work in a unified manner to address our nation's overdose crisis. The comprehensive, evidence-based strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with substance use disorders and to help individuals to achieve long-term recovery;
- Strengthen public health data collection and reporting to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves;

[17] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
[18] https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf
[19] Hedegaard, H., Minino, A.M., Warner, M. (2020). Drug Overdose Deaths in the United States, 1999–2018. NCHS Data Brief No. 356, January 2020. Centers for Disease Control and Prevention.

- 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.
- 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;
- 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 drug-related health harms.

In March of 2018, HHS Secretary Azar asked Dr. Brett Giroir to assume the role of Senior Advisor for Opioid Policy, in addition to his regular responsibilities as the Assistant Secretary for Health. In this role, Dr. Giroir is responsible for coordinating efforts across the Department, and serving as the primary HHS liaison to other departments and external stakeholders. He also seeks to understand gaps and evolving trends, and to assure that the department anticipates and responds to emerging threats.

Kim Brandt has been helping to lead the Centers for Medicare and Medicaid Services' (CMS's) opioid response efforts since the fall of 2017. As part of that role, Ms. Brandt oversees all opioids policies undertaken by the agency, engages with other federal partners, and works with the Department to achieve results.

Overview of the Department's Role - Coordination and Tracking of Implementation Efforts

To date, the Department has taken significant steps to carry out provisions in the SUPPORT Act while advancing the goals of our Strategy. This statement addresses the Department's role in implementing a few key provisions of the SUPPORT Act, highlighting a number of efforts taking place across multiple agencies. The SUPPORT Act, Pub. L. 115-271 (Oct. 24, 2018), has already been an essential enabler of HHS efforts to confront the opioid crisis. Through new and expanded authorities granted by the SUPPORT Act, we have been able to expand the scope and effectiveness of our programs across nearly the entire department in order to deliver meaningful results related to the substance use crisis.

To coordinate HHS implementation of the law and ensure accountability, the Department established a SUPPORT Act Implementation Leadership Committee (Committee) and undertook a concerted approach. Under Dr. Giroir's leadership as Senior Advisor for Opioids Policy, and with the coordination of the Office of the Assistant Secretary for Planning and Evaluation, the Committee tracks the implementation of HHS-related provisions, and meets regularly to discuss progress on a subset of targeted provisions.

The SUPPORT Act enhances our work across all five elements of our 5-Point Strategy, allowing HHS to continue to invest resources in expanding opportunities for evidence-based prevention, treatment and recovery support services, surveillance and data collection, and research on pain, new non-addictive pain medications, and to enhance our understanding of addiction and overdose.

HHS Five-Point Strategy –Improving Access to Prevention, Treatment, and Recovery Services

To address the opioid crisis, we must continue to improve our prevention, treatment, and recovery services, addressing the barriers that impede someone from accessing the services they need. The Support Act includes numerous provisions that will strengthen our efforts. As a payers, CMS is critical to

HHS' efforts. CMS works diligently to protect the safety of all 140 million Medicare, Medicaid, and CHIP beneficiaries by ensuring they have access to the treatment they need.

As the agency implements the SUPPORT Act, Congress has provided CMS a number of important tools,. CMS is focused on three major areas as it contributes to the fight against the opioid crisis:

- preventing and reducing OUD by supporting access to pain management using a safe and effective range of treatment options that rely less on prescription opioids, including non- pharmacological approaches;
- increasing access to evidence-based treatment for OUD; and
- leveraging data to target prevention and treatment efforts and to support fraud, waste, and abuse detection.

CMS is taking a number of steps to identify and stop inappropriate prescribing to help prevent the development of new cases of OUD that originate from opioid prescriptions while balancing the need for continued access to prescription opioids to support appropriate, individualized pain management.

The SUPPORT Act expanded authorities of CMS that addressed both Medicaid and Medicare programs. Section 1003 of the SUPPORT Act authorized CMS to increase the capacity of Medicaid providers to deliver SUD treatment or recovery services in a two-phase demonstration. Phase 1 provides planning grants to ten or more states, and in Phase 2, five of those states will be selected for enhanced federal matching funds for treatment services. We are pleased to report that in September 2019, under Phase 1, CMS awarded approximately $48.5 million to 15 state Medicaid agencies: Alabama, Connecticut, Delaware, District of Columbia, Illinois, Indiana, Kentucky, Maine, Michigan, Nevada, New Mexico, Rhode Island, Virginia, Washington, and West Virginia. These 18-month planning grants are being used to assess needs for SUD states' treatment, provider recruitment and training and improved reimbursement for and expansion of the provider treatment capacity and to plan for improvements in these areas. The states will next apply under Phase 2 for a 36-month demonstration project in which five selected states would be eligible for an enhanced matching rate for opioid treatment services provided above their baseline.

Additionally, section 2005 of the SUPPORT Act established a new Medicare benefit for OUD treatment services provided at opioid treatment programs (OTPs). Starting January 1, 2020, for the first time, Medicare covers methadone for MAT, which can only be furnished by OTPs. In addition to methadone, the new benefit will cover other OUD treatment services in a bundled payment: dispensing and administration of MAT, individual and group therapy, toxicology testing, and periodic assessments. The coverage also includes in-person and virtual delivery of counseling and therapy services furnished by OTPs, broadening access to these critical services, particularly for those living in rural areas who are often the hardest hit by the opioid crisis.

CMS is using its demonstration authority under section 1115 of the Social Security Act to expand states' options for treatment of beneficiaries with SUD. This opportunity allows states to receive federal matching funds for the continuum of services to treat OUD or other SUDs, including services provided to Medicaid enrollees served through residential treatment facilities. In November 2017, CMS announced that it was using this authority to provide a streamlined process for states interested in covering these services. States are expected to take certain steps to improve the quality of care for individuals with SUD, including OUD, particularly in residential treatment settings, by requiring these settings to offer MAT as a treatment option. In addition to being budget neutral, demonstrations must include a rigorous

evaluation based on goals and milestones established by CMS. Information on the progress and outcomes of these demonstrations and evaluations will be made public on Medicaid.gov so that other states can learn from these programs; this cycle of evaluation and reporting will be critical to informing CMS's evolving response to the national opioid crisis. As of the end of 2019, CMS has approved such demonstrations in 26 states and the District of Columbia.

States generally cover some form of MAT. Section 1006(b) of the SUPPORT Act requires state Medicaid programs to provide coverage for all forms of MAT for OUD beginning October 1, 2020, and ending September 30, 2025. In addition, section 5022 of the SUPPORT Act makes behavioral health coverage a mandatory benefit for children and pregnant women covered under the CHIP and requires that child health and pregnancy related assistance "include coverage of mental health services (including behavioral health) necessary to prevent, diagnose, and treat a broad range of mental health symptoms and disorders, including substance use disorders."

CMS has also leveraged its Innovation Center authority to launch payment and service delivery models to address the opioids crisis. Under the Maternal Opioid Misuse (MOM) model, CMS entered into cooperative agreements with ten states in December 2019 to foster coordinated and integrated care delivery, and strengthen capacity and infrastructure. This effort will build states' organizational capacity to serve mothers and their infants affected by opioid use disorder. Pursuant to the SUPPORT Act section 6042, CMS will further use its Innovation Center authority to test whether a care management fee and a performance-based incentive, coupled with treatment services will reduce hospitalizations and emergency room visits, among other things.

The SUPPORT Act also expanded the Department's capacity to increase funding across the continuum and patient access to providers. As the lead HHS agency for behavioral health, SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. SAMHSA administers the SOR grants to provide flexible funding to state governments to increase access to MAT, reduce unmet treatment needs, and reduce opioid overdose-related deaths through the provision of prevention, treatment and recovery activities for OUD in the ways that meet the needs of their state. In FY 2018, a total of $1.4 billion (including a 15 percent set-aside for the ten states with the highest mortality rate related to drug overdose deaths) was awarded among all 50 states and seven territories. In FY 2019, SAMHSA awarded an additional total of $1.5 billion in supplemental and continuation funds, including over $1.4 billion to states and territories, and $50 million for tribal communities under the Tribal Opioid Response grant program.

Through successful implementation of section 3201 of the SUPPORT Act, SAMHSA increased the number of waivered health care providers that can prescribe or dispense MAT by broadening eligibility requirements needed to prescribe buprenorphine.[20] By allowing other qualified practitioners to apply for or increase their waiver to practice opioid dependency treatment with approved buprenorphine medications, we are able to provide greater access to treatment for individuals with OUD. To further increase our provider capacity and access to MAT, SAMHSA provided 28 grants in FY 2018 to universities

[20] DEA Requirements for DATA Waived Physicians: https://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm

to support the training of waived providers. By implementing section 3202, we are able to ensure that physicians who have recently graduated in good standing from an accredited school of allopathic or osteopathic medicine, and who meet other specified training requirements, can qualify to obtain a waiver to prescribe MAT.

In order to improve care for individuals with SUD who are in need of recovery-oriented transitional housing, SAMHSA issued Recovery Housing: Best Practices and Suggested Guidelines to better assist individuals living with SUD in achieving and maintaining recovery.[21] This resource, mandated by section 7031, includes Ten Guiding Principles to guide recovery house operators, stakeholders and states in enacting laws designed to provide the greatest level of resident care and safety possible.

Expanding our workforce programs is critical to our approach for ensuring that the structure and capacity of our health care systems are responsive to the evolving drug overdose epidemic. The Health Resources and Services Administration's (HRSA) investments in community health centers, rural communities, and workforce programs establish, enhance, and expand access to opioid and other substance use disorder services. These programs work toward integrating behavioral health services into primary care to better meet the needs of communities across the country. HRSA workforce programs also expand SUD, including OUD, treatment and recovery workforce. In FY 2019, HRSA awarded over $87 million in funding for programs that, over the course of the three-year project period, will add approximately 7,860 behavioral health professionals and paraprofessionals working in the provision of OUD/SUD prevention, treatment, and recovery services. These workforce investments support training across the behavioral health provider spectrum including community health workers, social workers, psychology interns and post-doctoral residents. Central to these programs is an approach to training that builds on both academic and community partnerships, enabling clinicians to provide integrated behavioral health care and treatment services in underserved communities.

To address provider shortages in resource-limited settings, section 7071 tasked the HHS Secretary with entering into loan repayment agreements, extending up to six years, with SUD treatment professionals in mental health professional shortage areas (HPSA) or counties that have been hardest hit by drug overdoses. The Further Consolidated Appropriations Act, 2020 includes $12,000,000 for HRSA to establish the Loan Repayment Program (LRP) for Substance Use Disorder (SUD) Treatment Workforce. This program aims to address shortages in the SUD workforce by providing for the repayment of education loans for individuals (professionals and paraprofessionals) working in a full-time SUD treatment job that involves direct patient care in either a HPSA designated for Mental Health or a county where the mean drug overdose death rate exceeds the national average.

HRSA also supports the National Health Service Corps (NHSC), which awards scholarships and loan repayment to primary care providers to pay off their student loan debt in exchange for service to underserved communities. In FY 2019, HRSA established the NHSC Substance Use Disorder Workforce Loan Repayment Program to improve recruitment and retention of providers and expand access to quality opioid and substance use treatment in underserved areas nationwide. HRSA made 1,074 awards under this new initiative that broadened the NHSC to include SUD counselors, pharmacists, and registered nurses. The program provides up to $75,000 in exchange for a three-year commitment; HRSA awarded $66 million through this program. Also in FY 2019, as part of the new NHSC Rural Community Loan Repayment Program, an additional 100 awards were made to providers working to combat the opioid epidemic in the nation's rural communities.

[21] https://www.samhsa.gov/sites/default/files/housing-best-practices-100819.pdf

In addition to these new programs, the NHSC now offers $5,000 incentive awards to practitioners who obtain waivers pursuant to the Drug Abuse Treatment Act of 2000, as amended, and demonstrate that they provide OUD treatment at NHSC-approved clinical sites. Nearly 200 providers received these incentive awards when they continued their service in 2019.

HHS Five-Point Strategy – Strengthening public health data

Advancing our data to further understand the evolving substance use crisis is instrumental because our data informs our policy and programs. Timely, high-quality data are crucial in driving public health action, enabling experts to better understand the problem, focus resources where they are needed most, and evaluate the success of prevention and response efforts. As the nation's public health and prevention agency, the Centers for Diseases Control and Prevention (CDC) is applying scientific expertise to understand the epidemic, conduct surveillance, and use data to inform evidence-based interventions to prevent further harms, including the spread of infectious disease, neonatal abstinence syndrome, and overdose deaths. CDC continues to be committed to the comprehensive priorities outlined in the Strategy and to working together with other HHS agencies to save the lives of those touched by this epidemic. As a component of the HHS strategy, CDC's contributes in the following key areas: (1) conducting surveillance and research; (2) building state, local, and tribal capacity; (3) supporting providers, health systems, and payers; (4) partnering with public safety; and (5) empowering consumers to make safe choices.

With the passage of the SUPPORT Act and continued support from the Administration and Congress, CDC is investing in strengthening the capacity of states to monitor the opioid overdose epidemic and target their prevention activities. Section 7161 does this by authorizing activities aimed at preventing overdoses while section 7162 authorizes CDC's support for states and localities to improve their Prescription Drug Monitoring Programs (PDMPs), collect public health data, and also encourages data sharing between states. In FY 2019, CDC awarded $301 million through Overdose Data to Action (OD2A) cooperative agreements to scale up prevention and response activities in states, cities, territories, and tribes, including enhancements to PDMPs as a form of public health surveillance and as a clinical decision-making tool. OD2A recipients are undertaking PDMP activities to ensure universal use among providers within a state, including more timely data contained within a PDMP, sending proactive (or unsolicited) reports to providers to inform prescribing, ensuring that PDMPs are easy to use and access by providers, and ensuring inter- and intrastate interoperability. These activities are improving safe and effective opioid prescribing, informing clinical practice, and protecting patients at risk.

One key focus of OD2A is requiring funded recipients to collect surveillance information on all drug overdose deaths, including nonfatal overdose data on all suspected drug, opioid, heroin, and stimulant overdoses from 75 percent of a state's emergency departments. CDC is collecting data on more substances and from more facilities, and plans to rapidly disseminate the data in order to inform local prevention and response efforts. These funds further our stakeholders in obtaining high quality, more comprehensive, and timelier data on overdose morbidity and mortality and using those data to inform prevention and response efforts.

The Department has also seen significant advances in data through CMS's November 2019 release of the SUD Data Book, the first nationwide analysis using Medicaid's new data system. As required by section 1015 of the SUPPORT Act, the data book details Medicaid beneficiaries' SUD diagnosis, enrollment type, and treatment service utilization with national and state level summaries to help researchers and

policymakers better understand where to focus their efforts. It pulls the data from CMS's new Transformed Medicaid Statistical Information System (T-MSIS), a robust and evolving collection of Medicaid and CHIP data files. The SUD data book includes an online interactive analytic tool. This tool's data and tables can be filtered, sorted, and downloaded in multiple formats using a graphical interface. This offers users the opportunity to customize their view of the data and better utilize it for analysis.

HHS also made important strides to ensure that our publicly available data and resources related to SUD, including OUD, is readily available and easy to navigate. As outlined in section 7021, HHS launched updates to our existing HHS.gov/Opioids website, adding the most currently available statistics and resources, including data that focuses on the opioid crisis along with key measures regarding our progress to date. We included a customized Grants.gov link on the homepage so that users can more easily locate currently available HHS funding opportunities related to substance use disorder. By utilizing this resource, stakeholders have easy access to available HHS funding opportunities that can help their communities address the evolving drug overdose epidemic.

We are also pleased by the recent launch of our interactive HHS Opioid Grants Dashboard; this resource helps our stakeholders visualize grants data and allows users to compare a variety of data at a glance. The data includes a listing of over 10,000 formula and competitive grants and cooperative agreements awarded under programs predominantly or entirely associated with addressing opioid use, abuse, and overdose death. The dashboard helps the public explore HHS opioid-related grants data by recipient type, geographic location, funding HHS agency, grant purpose, obligation rates, and more.

Lastly, section 7023 of the SUPPORT Act requires HHS to establish national-level metrics to help measure progress and success in curtailing the opioid crisis. Significant work has been underway within the Department, building on pre-existing efforts, to further implement this provision. HHS has identified and is regularly tracking several key national measures and related trends to help assess our progress and identify opportunities for improvement. Several of these measures are also being tracked as part of the federal government's Agency Priority Goal (APG) focused on Reducing Opioid Mortality and Morbidity. Goal action plans, targets, and updates on these measures are published quarterly and reflect our progress around addressing this crisis.[22]

HHS Five-Point Strategy – Advancing better pain management practices

As we combat the opioid crisis, and seek to reduce the unnecessary prescription of opioids, we cannot forget that pain is a significant problem. Current data indicate that at least 50 million Americans suffer from chronic pain; and of these, approximately 20 million suffer pain severe enough to substantially interfere with their daily activities. It is a false choice to say that we can either solve the opioid crisis **or** improve suffering from chronic pain; we can, and must, do both simultaneously.

Through the work of the Pain Management Best Practices Inter-Agency Task Force, we now have a best practices roadmap for managing acute and chronic pain. The report highlights that an individualized, multimodal, multidisciplinary approach to pain management is important when addressing pain.[23] It also emphasizes that the development of an effective patient-centered pain treatment plan should include meaningful outcomes that focus on improvements, including quality of life, improved functionality, and activities of daily living.

[22] https://www.performance.gov/hhs/2018-2019-apg/
[23] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

We have and continue to develop additional guidance to ensure the appropriateness of pain management and prescribing. Reducing the number of Americans who are addicted to opioids and reducing the rate of new addiction is one of the FDA's highest priorities. This may be achieved by ensuring that only patients with appropriate indications are prescribed opioids, and that the prescriptions are for durations and doses that properly match the clinical reason for which the drug is being prescribed in the first place. Working in synergy with CDC's initiatives, FDA's efforts to address the opioid crisis are focused on encouraging "right size" prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids.

Section 3002 of the SUPPORT Act requires FDA to advance the development of evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain for which gaps may exist. In FY 2018, FDA awarded a contract to the National Academies of Sciences, Engineering, and Medicine (NASEM), to help advance the development of evidence-based guidelines for appropriate opioid analgesic prescribing for acute pain resulting from specific conditions or procedures. In December 2019, NASEM published the consensus study report that examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps.[24] FDA will consider the report's recommendations as part of our efforts to advance development of evidence-based clinical practice guidelines.

Through cross-agency collaboration, CDC and CMS have also worked to develop guidance on pain management and OUD prevention for hospitals receiving payment (section 6092)[25] [26] [27]and provide periodic updates of opioid prescribing guidance for Medicare beneficiaries (section 6095)[28].

CMS is working to change its rules to improve prescription safety in the Medicaid program. SUPPORT Act section 1004 required CMS to revise its regulations on drug utilization reviews, a process that requires states to report on their practices to ensure opioids and other medications are dispensed safely. The new rules will require states to establish minimum standards that enhance their ability to identify or limit inappropriate prescribing of opioids. The changes will help ensure that opioid outpatient drug coverage is appropriate, medically necessary, and avoids adverse medical events. CMS issued guidance in August 2019 explaining new state requirements for minimum standards for safety edits and claims review processes. These standards will reduce excessive or otherwise dangerous fills of opioids and identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. CMS intends to issue a proposed rule to implement elements of the guidance later this year.

Pursuant to section 1010 of the SUPPORT Act, CMS issued an Informational Bulletin in February 2019 that provided state Medicaid agencies a set of approaches to promote non-opioid pain management and treatment. The guidance described examples of state strategies to manage prescription opioids and expand coverage options for non-opioid pain management. In addition to meeting the requirements of

[24] https://www.nap.edu/catalog/25555/framing-opioid-prescribing-guidelines-for-acute-pain-developing-the-evidence
[25] https://www.cdc.gov/drugoverdose/providers/index.html
[26] https://www.cdc.gov/drugoverdose/training/index.html
[27] https://www.cdc.gov/drugoverdose/patients/materials.html
[28] https://www.cms.gov/about-cms/story-page/opioid-misuse-resources#provider

the SUPPORT Act, this Bulletin supports the goal of reducing the use of opioids in pain management included in the President's Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand and is consistent with our Strategy. To provide additional options for non-opioid pain relief, in January 2020, CMS announced Medicare will begin to cover acupuncture for Medicare patients with chronic low back pain.

HHS Five-Point Strategy – Increasing naloxone availability and administration

Increasing the awareness, availability, and targeted distribution of naloxone is a critical component of our efforts to reduce drug overdose deaths. Availability of naloxone, an opioid antagonist that is used to temporarily reverse the effects of an opioid overdose, has increased dramatically, as evidenced by a 405 percent increase in the number of prescriptions dispensed monthly by retail and mail order pharmacies since 2017. With that, the Department is committed to ensuring that access to naloxone is not a barrier. We have continued to encourage and urge more Americans to carry the potentially lifesaving medication that can reverse the effects of an opioid overdose. Many first responders, such as emergency medical technicians and police officers, already carry naloxone. The Surgeon General recommended that more individuals, including family, friends and those who are personally at risk for an opioid overdose, also keep the drug on hand. The office of ADM. Giroir also released additional guidance detailing how naloxone can help save lives and should be prescribed to all patients at risk for opioid complications, including overdose.[29]

While we encourage the use and availability of naloxone, we are also working to ensure the initiation of comprehensive care for people who experience an overdose. Through SAMHSA's SOR grant program, and as outlined in section 7181, we are supporting the development of resources and protocols for care providers on discharging persons who present to their facilities with an opioid overdose. And to further our efforts to promote awareness on preventing drug overdoses, the Agency for Healthcare Research and Quality released two systematic reviews related to non-opioid treatments for chronic pain (as outlined in section 7161).[30] CMS is examining the issue as well. Last year, CMS solicited input from the public on the use of MAT initiation in the emergency department, including initiation of MAT, to help inform whether there should be separate payment for such services and will consider that input for future rulemaking.[31]

Expanding the use of the overdose-reversing drug naloxone is a key part of the public health response to the opioid crisis.

HHS Five-Point Strategy – Advancing Research

Innovative research on pain and addiction informs our clinical practices, reduces opioid prescribing, and gives us the tools and insights to combat the evolving substance use crisis. Research helps to ensure that policies are evidence-based and that patients are able to access the care they need. The National Institutes of Health (NIH) is the lead HHS agency providing support for cutting-edge research on addiction, mental health, OUD, overdose, and pain. Drug addiction and pain are complex neurological conditions, driven by many biological, environmental, social, and developmental factors. Continued

[29] https://www.hhs.gov/about/news/2018/12/19/hhs-recommends-prescribing-or-co-prescribing-naloxone-to-patients-at-high-risk-for-an-opioid-overdose.html
[30] https://effectivehealthcare.ahrq.gov/products/nonpharma-treatment-pain/research-2018
[31] Available at: https://www.govinfo.gov/content/pkg/FR-2019-11-15/pdf/2019-24086.pdf . November 15, 2019.

research is key to understanding the opioid crisis, informing future efforts, and developing more effective, safer, and less addictive pain treatments.

Section 7041 provided NIH additional authorities to conduct high-impact, cutting edge research. Over the last year, NIH has continued its work with stakeholders and experts across scientific disciplines and sectors to identify areas of opportunity for research to combat the opioid crisis. These discussions have centered on ways to reduce the over prescription of opioids, accelerate development of effective non-opioid therapies for pain, and provide more flexible options for treating opioid addiction.

As a result of discussions to further research efforts, NIH awarded over 375 grants, contracts, and cooperative agreements across 41 states for a total of $945 million in FY 2019 funding, for the second year of the NIH HEAL (Helping to End Addiction Long-term[SM]) Initiative. This Trans-NIH research initiative aims to improve treatments of opioid misuse and addiction and to enhance pain management. The six specific areas of focus this year are (1) translation of research to practice for the treatment of opioid addiction, (2) new strategies to prevent and treat opioid addiction, (3) novel medication for OUD, (4) enhanced outcomes for infants and children exposed to opioids, (5) clinical research in pain management, and (6) preclinical and translational research in pain management.

The HEAL Initiative will also reduce reliance on opioids through enhanced pain management. A longitudinal study will explore the transition from acute to chronic pain, non-addictive pain medications development efforts will be enhanced by data sharing, and two clinical trial networks to determine the optimal treatments for many pain conditions. Best practices for pain management will be further explored, including nondrug and integrated therapies. Finally, innovative neuro-technologies will be used to identify potential new targets for the treatment of chronic pain, and biomarkers that can be used to predict individual treatment response will be explored and validated.

The NIH HEAL Initiative will build on extensive, well-established NIH research that has led to successes such as the development of the nasal form of naloxone, the most commonly used nasal spray for reversing an opioid overdose; the development of buprenorphine for the treatment of OUD; and the use of behavioral interventions, such as cognitive behavioral therapy, and mind/body approaches to help patients control and manage pain, such as yoga, tai chi, acupuncture, and mindfulness meditation.

Advances that NIH is working to promote may occur rapidly, such as improved formulations of existing medications, longer-acting overdose-reversing drugs, and repurposing of medications approved for other conditions to treat pain and addiction. Others may take longer, such as novel overdose-reversal medications, identifying biomarkers to measure pain in patients, and new non-addictive pain medications.

A large component of the HEAL Initiative with the potential for rapid impact is the HEALing Communities Study, a multisite implementation study, testing an integrated set of evidence-based practices across health care, behavioral health, justice, and other community-based settings. The goal of the study is to reduce opioid-related overdose deaths by 40 percent over the course of three years, in communities highly affected by the opioid crisis. Sixty-seven such communities have partnered with research sites in four states to measure the impact of these efforts.

Lastly, around pain research, section 7042 amended the duties of the Interagency Pain Research Coordinating Committee (IPRCC) and NIH is working to incorporate those outlined requirements in the committee's activities in the following ways:

- The IPRCC selected most important advances in pain research, including those relevant to best practices, from resources such as peer-reviewed publications. The science advances are updated annually and the current set is posted at IPRCC.NIH.GOV.
- A table with systematic reviews on non-pharmacological treatments for pain was developed and is posted on the IPRCC website.
- The IPRCC periodically updates on critical gaps in basic and clinical research on the symptoms and causes of pain. The IPRCC will now also report gaps in research on the risk factors for, and early warning signs of, substance use disorders in populations with acute and chronic pain.

Priorities Moving Forward

As our testimony has highlighted, we have made measurable progress in addressing OUD; over $9 billion dollars has been awarded since FY 2016. We have seen a decline in drug overdose deaths, and more people are now on medication-assisted treatment. The SUPPORT Act has been instrumental in supporting the work that we do, strengthening the work around our Five-Point Strategy to address the opioid crisis. We are committed to continuing our work to successfully implement our SUPPORT Act provisions.

Thank you for the opportunity to testify on this important issue.