Written Testimony

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before the Senate Committee on Finance

October 24, 2019

Introduction

Thank you, Chairman Grassley, Ranking Member Wyden, and distinguished Members of the Committee. As the U.S. Surgeon General, it is an honor and privilege to be before you today and have the opportunity to discuss the opioid crisis, the Department of Health and Human Services' (HHS or Department) 5-point strategy[1] to address this crisis, and my office's contributions to combating the epidemic. From the start of his Administration, President Trump has made addressing the opioid crisis a top priority. The Department and the Office of the Surgeon General share the President's commitment.

On October 26, 2017, at the request of President Trump and consistent with the requirements of the Public Health Service Act, the Acting Secretary of HHS declared a nationwide public health emergency regarding the opioid crisis, and on March 19, 2018 in New Hampshire, the President announced his "Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand." The Department has made addressing the crisis a top clinical priority and is committed to using our full expertise and resources to combat the epidemic. The SUPPORT Act, Pub. L. 115-271 (Oct. 24, 2018) and the Fiscal Year 2019 Consolidated Appropriation Act, which provide HHS new funding to address the opioid epidemic, will allow HHS agencies 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.

Over the past 15 years, communities across our Nation have been devastated by increasing prescription and illicit opioid misuse, addiction, and overdose. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health, in 2018, approximately 10.3 million Americans misused opioids; of that population, 9.9 million people misused prescription pain relievers, 808,000 people used heroin, and 2 million people had an opioid use disorder (OUD)[1] . While the number of individuals who misused opioids is down 3.7 percent from 2015, almost 400,000 Americans died of an opioid overdose over the past 20 years[2]. Most alarming is the rapid increase in overdose deaths involving illicitly made fentanyl and other highly potent synthetic opioids. According to provisional drug

[1] 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/.

[2] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018. Data are from the Multiple Cause of Death Files, 1999-2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

overdose death counts from the Centers for Disease Control and Prevention (CDC), predicted overdose deaths due to synthetic opioids rose approximately 10.4 percent between March 2018 and March 2019.[3] OUD and opioid-related overdose and death remain major issues that require a broader understanding of intersecting medical and public health factors.

Between 1999 and 2017, more than 399,000 people have died of overdose involving any opioid, including prescription and illicit opioids, such as heroin and illegally trafficked fentanyl. Overdoses involving opioids killed more than 47,000 people in 2017.[4]

Overall, opioid overdoses appear to plateau when comparing 2017 and 2018 data, which is notable given how aggressively the increases in all prior years over the past decade had been and suggests some success in reducing deaths from synthetic opioids and methadone; the preceding paragraph appropriately calls out illicit fentanyl, given deaths continue to accelerate for this category.

HHS' 5-Point Strategy to Combat the Opioid Crisis

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 help 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 collection and reporting 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.

To date, the Department has taken significant steps to advance the goals of our Opioid Strategy. This statement addresses my personal commitment to address the opioid epidemic, and the unique role that the Office of the Surgeon General serves in combatting this crisis. In order to

[3] Ahmad FB, Escobedo LA, Rossen LM, Spencer MR, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2019. Designed by LM Rossen, A Lipphardt, FB Ahmad, JM Keralis, and Y Chong: National Center for Health Statistics.
https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

[4] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018. Data are from the Multiple Cause of Death Files, 1999-2017, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.

provide a more comprehensive overview of the Department's coordinated strategy, it also highlights efforts within the Centers for Medicare & Medicaid Services (CMS) and across HHS.

My Work is Personal

In the case of substance use disorders (SUDs) and OUD, my office's work is quite personal as my family and I are among the millions of Americans affected by it. My younger brother, Philip, has struggled with this disease, which started with untreated depression and led to opioid misuse. Like many with co-occurring mental health and SUDs, my brother has cycled in and out of incarceration. Philip is currently serving a 10-year prison sentence for crimes committed to support his addiction. I share his story to illustrate that addiction can happen to anyone—even the brother of the U.S. Surgeon General.

Just as the opioid crisis has touched my life, it has also touched the lives of most Americans. This epidemic is blind to color, geography, or class and has affected every corner of our country. Quite simply, this crisis affects all of us.

Tackling Opioid Use Disorder and Other Substance Use Disorders

While the opioid epidemic continues to be our most pressing public health crisis, there is evidence that the Administration's commitment to the epidemic and HHS' five-point response strategy have had a substantial effect.

1. First, we have experienced a **nationwide decrease in opioid prescribing and use**. From January 2017 to June 2019, we've seen a **31 percent reduction in the total morphine milligram equivalents dispensed monthly** by retail and mail order pharmacies.[5] We've seen a **52.4 percent decrease in the number of first time heroin users** from 2016 to 2017.[6] And, between 2017 and 2018, approximately **1 million fewer Americans reported misusing opioids in the preceding year**.[7]

2. There is also evidence of **fewer drug overdose deaths**. As of March 2019, the 12-month rolling count of predicted overdose deaths **remained below 70,000** for fourth month in a row. This represents a **decrease of approximately 2 percent** from the corresponding 12-month period. During that period, **28 states reported a reduction in drug overdose deaths** and many experienced substantially larger decreases than the national average. For example, between February 2018 and February 2019, **there was a 14.7 percent reduction in Iowa, a 12.4 percent reduction in Ohio, a 11.5 percent**

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

[6] Substance Abuse and Mental Health Services Administration. (2018). Key substance use and mental health indicators in the United States: Results from the 2017 National Survey on Drug Use and Health (HHS Publication No. SMA 18-5068, NSDUH Series H-53). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/

[7] 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/.

reduction in Pennsylvania, an 8.2 percent reduction in Kentucky, and a 9.7 percent reduction in New Hampshire.[8]

3. Furthermore, we have seen progress in making both **medication-assisted treatment (MAT) and overdose-reversing medications more available**. From January 2017 to June 2019, the number of **patients receiving buprenorphine and naltrexone monthly increased by 28 percent and 55 percent, respectively**.[9] 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 378 percent increase in the number of prescriptions dispensed monthly by **retail and mail order pharmacies since 2017**.

4. **Consensus has now been achieved reached on how to best address pain**. In May 2019, the **Pain Management Best Practices Inter-Agency Task Force released its final report**, which provides a best practices roadmap for managing acute and chronic pain.

Of course, these indicators are only a fraction of the available statistics that illustrate our progress.

Office of the Surgeon General's Response to the Crisis

The Office of the Surgeon General has been fully engaged in the Department's response and has made important contributions to the achievements I have described. In 2018 alone, the office released a Spotlight on Opioids[2], a Digital Postcard[3] showing the five actions everyone can take to prevent opioid misuse, and a Surgeon General's Advisory on Naloxone and Opioid Overdose[4]. These publications convey effective strategies to prevent and treat OUD and support the successful recovery of those affected. I want to leave you with five key messages based on this scientific information:

1. First, **prevention, screening, and early intervention are critical.** Evidence-based prevention, screening, and intervention programs are effective and need to be initiated early in life. Traumatic experiences in childhood, sometimes referred to as adverse childhood experiences (ACEs), have been repeatedly linked to increased risk of substance misuse and SUD. So interventions must begin during childhood and continue throughout the lifespan to prevent or delay the initiation of substance use and stop the progression to SUD. To support these early interventions, the Administration for Children and Families (ACF) is working on implementation of the Family First Prevention Services Act, which provides Federal funding for services to help families remain safely together, preventing the need for foster care. As Surgeon General, I am committed to preventing opioid addiction before it starts by promoting: (1) safe

[8] Ahmad FB, Escobedo LA, Rossen LM, Spencer MR, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2019.
Designed by LM Rossen, A Lipphardt, FB Ahmad, JM Keralis, and Y Chong: National Center for Health Statistics. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

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

prescribing practices according to the CDC Guideline for Prescribing Opioids for Chronic Pain, (2) the benefits of opioid alternatives, and (3) safe storage and disposal.

2. Second, **treatment is effective but must be integrated into mainstream healthcare**. Addiction is a chronic disease of the brain, which must be treated with skill, compassion, and urgency. And as with other chronic diseases, we have evidence-based treatment that works, and we know that recovery is possible. Medications can successfully treat the chronic disease of addiction. MAT, the combination of FDA-approved medications for the treatment of OUD with psychosocial therapies and community-based recovery supports, is the gold standard for treating opioid addiction; yet, in the course of a year, only one in four people with OUD receives any treatment at all. For this reason, care models that integrate SUD services using medications and MAT into primary care hold tremendous promise and have the potential to greatly expand access to effective, evidence based OUD care.

3. Third, **knowing how to use naloxone and keeping it within reach can save a life and serve as a bridge to treatment and recovery**. As described in my advisory, increasing the awareness, availability, and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths. Since the advisory was published, more than 2.7 million 2-unit doses of naloxone have been distributed to states and local communities.[10] As the Surgeon General, I am focused on putting naloxone in the hands of first responders and community members.

4. Fourth, there are **many pathways to recovery**—a term that is expansive and goes beyond the remission of symptoms to include a positive change in the whole person. Recovery support services include mutual aid groups, housing, childcare, recovery coaches, and community services that provide continuing emotional and practical support.

   I saw the benefits of these services, first-hand, when I visited Belden Industries in Richmond, Indiana. Belden has developed a unique pilot project—called *Pathways to Employment*—in response to community needs and the labor market. Specifically, in collaboration with its local health department and community colleges, the technology company offers potential employees who fail drug tests opportunities to participate in drug counseling. Participants who stay in the recovery program are assured jobs. Belden is connecting those suffering from drug addiction to care with the goal of helping them become employment-ready.

   Recovery support services are also vital to Greyston Bakery's workforce development strategy. The bakery, which is located in Yonkers, New York, began its Open Hiring model in 1982. Under this model, Greyston provides employment opportunities without judging applicants or asking questions—no resume, work history, or background check are required—while providing a range of social support services including case management, life-skill building, and workforce training. This approach creates jobs for people who have traditionally been marginalized and considered "unemployable"— people with past felony convictions, persons who are homeless or have disabilities, and people with addiction. The bakery's motto is *"We don't hire*

[10] Data Provided by Emergent BioSolutions.

people to bake brownies; we bake brownies to hire people." At present, more than 60 percent of Greyston's bakers were formerly incarcerated.

I applaud these companies and others that are investing in their communities to improve health and create economic opportunities. While people will choose their own recovery pathway based on their cultural values, psychological and behavioral needs, and life circumstances, community-based recovery support services like those embraced by these innovative companies are instrumental in helping individuals resist relapse and rebuild their lives.

5. Fifth, when it comes to addiction, society is **moving from a primarily criminal justice-based model to a more balanced approach that better accounts for public health**. I believe that this shift cannot happen quickly enough. I'll return to my own family. Had my brother's addiction been treated like a disease rather than a moral failing, he might be significantly closer to recovery than he is today.
The stigma associated with SUDs keeps many sufferers from speaking about their troubles and seeking help. . Nowhere is stigma more prevalent than in the communities of color. The way we as a society view and address OUD and other SUDs must change; individual lives and the health of our nation depend on it.

CMS Role in Addressing the Opioid Crisis

As a payor, CMS plays an important part in HHS efforts by working to make sure clinicians are providing the right services to the right people at the right time. Medicare, Medicaid, and CHIP beneficiaries are CMS's top priority across all of its programs, and CMS works hard to protect their safety and put them in the driver's seat of their care. CMS is keenly focused on three areas—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.

<u>Preventing Overprescribing and Misuse of Opioids</u>

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. To ensure that balance is maintained, CMS will provide quality improvement technical assistance to those communities hit hardest by the opioid epidemic, particularly small, rural communities' physician practices and hospitals.

- *Improved Opioid Safety Reviews in Medicare Part D.* Due to the structure of the Medicare Part D program, Medicare Advantage Organizations (MAOs) and Medicare Part D sponsors have a primary role in detecting and preventing potential misuse of opioids. CMS's job is to oversee Medicare Part D plans to ensure that they are in compliance with requirements that protect beneficiaries, ensure access to opioids when needed, and can help prevent and address opioid overutilization. Medicare Part D plans are expected to use multiple tools, including better formulary management, case

management with beneficiaries' clinicians and pharmacists for coordinated care, and safety edits at the point of dispensing.

Medicare Part D sponsors are required to have concurrent drug utilization review (DUR) systems in place to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale (POS). Since 2013, CMS has incrementally adopted successful opioid policies in the Part D program to appropriately address opioid overutilization, while preventing interruption of medically necessary drug therapy. These policies incorporate prescriber involvement through pharmacist and payer efforts to give providers additional clinical information to better coordinate care.[11]

CMS recently finalized a series of additional changes in 2019 to further the goal of preventing OUD. Part D sponsors are now expected to implement improved opioid safety edits at the POS that alert a pharmacist of possible overutilization.[12] In real-time, the alerts can flag for a pharmacist that they should conduct additional review and/or consultation with the plan sponsor or prescriber to ensure that a prescription is appropriate.

Second, to reduce the potential for chronic opioid use or misuse, beginning in 2019, CMS expects all Part D sponsors to limit initial opioid prescription fills for the treatment of acute pain to no more than a seven days' supply.[13] This policy change is consistent with the CDC Guideline for Prescribing Opioids for Chronic Pain that states that opioids prescribed for acute pain in primary care settings and outside post-surgical pain should be limited to the minimal dose and amount necessary and, as a rule, three days or fewer unless otherwise clinically indicated.

Beginning in 2019, CMS also expects all sponsors to implement an opioid care coordination safety edit.[14] This new edit alerts pharmacists when a beneficiary's average daily opioid dose reaches high levels. When this occurs, plan sponsors are expected to direct pharmacists to consult with the prescriber to confirm their intent. If the pharmacy cannot fill the prescription as written, the pharmacist will give the beneficiary a notice explaining how the beneficiary or their prescriber can call or write to the Medicare drug plan to ask for a coverage decision, including an exception, about a drug they think should be covered. If their health condition requires, beneficiaries have the right to ask their plan for a fast decision or a decision even before they get the prescription filled at the pharmacy. . The prescriber only needs to attest to the Medicare drug plan that the cumulative level or days' supply is the intended and medically necessary amount for their patient.

[11] CY 2020 Final Call Letter, p. 225.
[12] CMS, Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Apr. 2, 2018), available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.
[13] Id. at p. 237.
[14] Id. at p. 235-236.

- *Non-Opioid Pain Relief Options in Medicaid*. Pursuant to section 1010 of the SUPPORT Act, CMS issued an Informational Bulletin in February of 2019 about Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management. The Bulletin expands on earlier guidance issued by CMS by providing information to states seeking to promote non-opioid options for chronic pain management. In addition to meeting the requirements of 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 the HHS 5-Point Strategy to Combat the Opioid Crisis.

- *Additional State Reporting.* Additionally, pursuant to section 1004 of the SUPPORT Act Section 1004, CMS issued an Informational Bulletin in August 2019 that states will be required to report on their policies related to reducing opioid-related misuse and abuse in Medicaid. Implementation of these provisions includes requirements regarding opioid prescription claim reviews at the POS and retrospective reviews; the monitoring and management of antipsychotic medication in children; identification of processes to detect fraud and abuse; and mandatory DUR report updates; as well as requirements for Medicaid MCOs. In order to comply with these new requirements, states must submit a State Plan Amendment by December 31, 2019.

- *Drug Management Programs for Medicare and Medicaid.* For years, states have been establishing and augmenting effective "lock-in" programs that require Medicaid enrollees who are "at-risk" for opioid misuse or addiction to use only one pharmacy and/or get prescriptions from only one medical office. The Comprehensive Addiction and Recovery Act of 2016 (CARA), Pub. L. 114-198, provided CMS with the authority to allow Medicare Part D plans to implement similar programs. For both Medicaid programs and Medicare Part D plans, these programs provide additional tools to promote better coordination between providers and for beneficiaries who meet the guidelines for lock-in.

  Under current law, states are able to implement lock-in requirements for enrollees who have utilized Medicaid services at a frequency or amount that is not medically necessary, according to guidelines established by the state. These limitations may be imposed for "a reasonable period of time." Almost all Medicaid agencies have a Lock-In or Patient Review and Restriction Program in which the state identifies potential fraud or misuse of controlled drugs by a beneficiary.

  In April 2018, as required by CARA, CMS finalized the framework under which Part D plan sponsors may adopt drug management programs (DMPs) beginning with plan year 2019.[15] DMPs allow Part D sponsors to limit certain beneficiaries to a specific opioid prescriber and/or dispensing pharmacy within their prescription drug benefit plan. The final rule incorporated input gathered from various stakeholders, including beneficiary advocates, clinicians, pharmacists, pharmacy benefit managers, and plan sponsors.[16] The

[15] CMS, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Fed. Reg. 16440, 16440 (Apr. 16, 2018).
[16] Id.

rule also incorporated and codified many aspects of the prior retrospective DUR Policy and the Overutilization Monitoring System (OMS), which identifies and reports beneficiaries who are potentially at risk of misusing or abusing opioids to Part D plan sponsors. These beneficiaries meet OMS criteria established under the final rule, which take into account the beneficiary's use of multiple opioid prescribers and dispensing pharmacies and their level of opioid use. Part D sponsors also have some leeway to identify additional potential at-risk beneficiaries in their plans.

Under DMPs, after case management with the beneficiary's prescribers and written notice to the beneficiary, Part D plan sponsors may determine that a beneficiary is an at-risk beneficiary and limit the beneficiary's access to coverage of opioids and/or benzodiazepines. To ensure care coordination, and depending on the specific coverage limitation the sponsor puts in place, at-risk beneficiaries receive their opioid medications from a specific prescriber and/or pharmacy that the beneficiaries may generally select. At-risk beneficiaries may also be subject to individualized POS claim edits that limit their coverage of opioids. Sponsors report to CMS the outcome of their case management review for each case, including whether the sponsor implemented a coverage limitation or not. It is important to note that most OMS cases are managed without a sponsor implementing a coverage limitation, which CMS views as the more desirable result for providers, their patients and Part D plans. Also important is that beneficiaries, and their prescribers on their behalf, also have the right to appeal these decisions.

Furthermore, provisions in the SUPPORT Act of 2018 provided CMS with the authority to implement additional policies in Medicare Part D to address the opioid epidemic. Section 2004 of the SUPPORT Act requires all Part D sponsors to have a drug management program for plan years beginning on or after January 1, 2022, although CMS notes that the majority of sponsors have already adopted DMPs in 2019. In addition, section 2006 requires that Part D enrollees with a history of opioid-related overdose, as defined by the Secretary, be included as potential at-risk beneficiaries under Part D drug management programs beginning on or after January 1, 2021.

The Medicare Part D opioid policies have been designed to promote improved communication between the pharmacy, doctor, and Medicare drug plan, and give providers additional tools to safely manage their patients' opioid use. The Medicare Part D opioid safety edits and DMPs generally do not apply to patients with cancer, patients receiving hospice, palliative, or end-of-life care, or patients who live in a long-term care facility. They also should not impact patient access to medication-assisted treatment (MAT) for OUD, such as buprenorphine.

- *Tools for State Medicaid Agencies.* While the Federal government establishes general guidelines for Medicaid, states design, implement and administer their own programs. CMS takes this partnership seriously and, because Medicaid is the single largest payer for behavioral health services, has been working under the current statutory framework to ensure that states have the tools they need and to share best practices to improve care for individuals with mental illnesses or SUD.

To reduce opioid misuse while ensuring access to treatment for acute and chronic pain, Medicaid programs can utilize medical management techniques such as step therapy, quantity limits, and morphine milligram equivalent (MME) limitations. Additionally, to increase oversight of certain prescription opioids, states have the option of amending their Preferred Drug Lists and Non-Preferred Drug Lists to require prior authorization for certain opioids.

States have long been required to develop a DUR program aimed, in part, at reducing inappropriate prescribing of outpatient prescription drugs covered under the State's Medicaid Program. Medicaid DUR is a structured, ongoing program that interprets patterns of drug use in Medicaid programs and includes prospective drug review, retrospective drug use review, data assessment of drug use against predetermined standards, and ongoing educational outreach activities conducted by Medicaid state agencies, managed health care systems, pharmacy benefit managers (PBMs), academic institutions and/or other applicable stakeholders. The Medicaid DUR Program promotes patient safety through state-administered utilization management tools and systems that interface with the claims processing systems. Additionally, CMS requires any MCO that includes covered outpatient drugs to operate a DUR program that is as comprehensive as the states fee-for-service (FFS) program.

Ensuring Access to Evidence-Based Treatment

A critical part of tackling this epidemic is making sure that beneficiaries with OUD have access to effective treatment options. Through its networks of health quality experts and clinicians, CMS advocates sharing best practices for pain management and substance use disorders, including OUD.

Medicare Parts A and B cover substance use disorder services in multiple ways. Inpatient treatment in a hospital is covered if reasonable and necessary; treatment in a partial hospitalization program, such as an intensive outpatient psychiatric day treatment program, may also be covered when the services are furnished through hospital outpatient departments and Medicare-certified community mental health centers. Medicare currently pays for substance use disorder treatment services provided by physicians and other practitioners on a service-by-service basis under the Medicare Physician Fee Schedule (PFS), such as counseling services provided by a psychiatrist or other Medicare practitioners and an annual depression screening. Medicare Part B pays for medications used in physician offices or other outpatient settings that require a physician/practitioner to administer, including injections like extended-release formulations of naltrexone or buprenorphine or implants of drugs like buprenorphine used in medication-assisted treatment. CMS recently made changes to the Medicare PFS that help support the fight against the opioid epidemic, such as establishing separate coding and payment for the insertion and removal of buprenorphine implants, a key drug used in treatment for OUD, and improving payment for office-based behavioral health services. For 2020, CMS also proposed to create new coding and payment under the PFS for a bundled episode of care for management and counseling for OUD. The new proposed codes describe a monthly bundle of services for the treatment of OUD that includes overall management, care coordination, individual and group psychotherapy, and substance use counseling.

- *Medication-Assisted Treatment (MAT).* MAT is the use of FDA-approved medications, in combination with counseling and behavioral therapies, to treat SUDs, including OUD. MAT is a valuable intervention that has been proven to be the most effective treatment for OUD, particularly because it helps sustain long-term recovery and has been shown to reduce morbidity and mortality.[17]

  To increase access to MAT, CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT. In addition, CMS issued guidance on best practices in Medicaid for covering MAT in a joint informational bulletin with SAMHSA, the CDC, and the National Institute on Drug Abuse. CMS also released an informational bulletin with SAMHSA on coverage of treatment services for youth with SUD and guidance on the co-prescribing of opioids and benzodiazepines.

  While Medicaid programs vary greatly by state, all 50 states currently offer some form of MAT. Section 1006(b) of the SUPPORT Act requires state Medicaid programs to provide coverage for 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 Children's Health Insurance Program (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."

  Additionally, Section 2005 of the SUPPORT Act established a new Medicare Part B benefit for OUD treatment services, including MAT utilizing methadone, which can only be furnished by opioid treatment programs. CMS proposed to implement this new benefit for 2020 with flexibility to deliver the counseling and therapy services furnished as part of OUD treatment services via two-way interactive audio-video communication technology as clinically appropriate and zero beneficiary copayment for a time limited duration.

- *Increasing the Use of Naloxone to Reverse Opioid Overdose.* CMS is promoting improved access to the opioid overdose reversal drug naloxone by requiring that it appear on all Medicare Part D formularies. CMS is also encouraging sponsors to include at least one naloxone product on a generic or Select Care tier beginning in 2020.[18] The percentage of Part D plans that included at least one naloxone product on a non-branded tier for each of the past three plan years are: 42.4 percent for Calendar Years (CYs) 2018 and 2019 and 99.4 percent for CY 2020. Of all naloxone products on formulary, the

[17] Sordo, L., Barrio, G., Bravo, M. J., Indave, B. I., Degenhardt, L., Wiessing, L., ... Pastor-Barriuso, R. (2017). Mortality risk during and after opioid substitution treatment: Systematic review and meta-analysis of cohort studies. BMJ, 357. https://doi.org/10.1136/bmj.j1550.

[18] CMS, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Apr. 1, 2019), available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

percentage of products included on non-branded tiers are: 27.5 percent for CY 2018; 28.4 percent for CY 2019 and 63.3 percent for CY 2020. CMS recognizes that it is very important for Medicare beneficiaries and those who care for them to understand that these options are available to them under Medicare, so CMS is also working to educate clinicians, health plans, pharmacy benefit managers, and other providers and suppliers on services covered by Medicare to treat beneficiaries with OUD. In a number of cases, this includes education on naloxone products.

In addition, all Medicaid programs include forms of naloxone on their Medicaid Preferred Drug Lists. Many state Medicaid programs also have pharmacist protocols for dispensing naloxone through collaborative practice agreements, standing orders, or other predetermined guidelines. CMS has also issued guidance to states on improving access to naloxone.[19] States can offer training in overdose prevention and response for providers and members of the community, including family members and friends of opioid users.

- *SUD Treatment and Demonstrations in Medicaid.* Under section 1115 of the Social Security Act, the Secretary of HHS may approve experimental, pilot, or demonstration projects that, in the judgment of the Secretary, are likely to assist in promoting the objectives of certain programs under the Act, including Medicaid. In November 2017, CMS announced that it was using this authority to provide a streamlined process for states interested in increased access to treatment for individuals who are primarily receiving treatment or withdrawal management services for SUD. This opportunity allows coverage services to beneficiaries who are short-term residents in that meet the definition of an institution for mental diseases (IMD), provided that coverage is part of a state's comprehensive OUD/SUD strategy as long as the state is working to improve access to OUD and other SUD treatment in outpatient settings as well. In addition, states are expected to take certain steps to improve the quality of care for individuals with SUD, including OUD, particularly in residential treatment settings, including by requiring these settings to offer MAT as a treatment choice onsite or facilitating access offsite.

  This initiative offers a more flexible, streamlined approach to accelerate states' ability to respond to the national opioid crisis while enhancing states' monitoring and reporting of the impact of any changes implemented through these demonstrations. 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 in a timely and readily accessible manner on Medicaid.gov so that other states can learn from these programs; this cycle of evaluation and reporting will be critical to informing our evolving response to the national opioid crisis. To date, CMS has approved these section 1115 demonstrations in more than in 25 states.

[19] https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf and https://www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf

The Medicaid Innovation Accelerator Program (IAP), a project of the Center for Medicare and Medicaid Innovation, provides technical assistance to Medicaid agencies across a variety of topics, including SUD, aimed at moving forward Medicaid delivery and payment reforms. IAP works with states on designing, planning, and implementing strategies that improve their SUD delivery systems through technical assistance in areas such as: creating data dashboards; identifying individuals with an SUD; understanding which options are available to expand coverage for effective SUD treatment; and designing payment mechanisms for SUD services that incentivize better outcomes.

Another tool states have to improve access to treatment through their Medicaid programs is the implementation of a health home benefit focused on improving treatment for beneficiaries with opioid use disorder. Health homes are an optional Medicaid benefit through which states can improve care coordination and care management for individuals with chronic conditions, including substance use disorders. States can receive 90 percent federal matching funds for their expenditures on Medicaid health home services for the first 8 fiscal year quarters that the health home state plan amendment is in effect. Under the SUPPORT Act, States with a SUD-focused health home state plan amendment approved on or after October 1, 2018, may request that the Secretary extend the enhanced federal match period beyond the first 8 fiscal year quarters, for the subsequent two fiscal year quarters, for a total of 10 fiscal year quarters from the effective date of the state plan amendment.

- *Improving access to coordinated care for vulnerable populations.* CMS announced a funding opportunity for a five-year model that is designed to address fragmentation in the care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder. The primary goals of the Maternal Opioid Misuse (MOM) Model are to improve quality of care and reduce costs for pregnant and postpartum women with OUD and their infants; expand access, service-delivery capacity, and infrastructure; and create sustainable coverage and payment strategies that support ongoing coordination and integration of care. Up to $64.5 million will be provided to up to 12 state Medicaid agencies who will collaborate with local care-delivery partners, which could include health systems, hospital systems, or payers, such as a Medicaid managed care plans, to transform the care-delivery system for affected mothers and their infants. The MOM model will require awardees and their care-delivery partners to provide integrated physical and behavioral healthcare services, such as MAT, maternity care, relevant primary care services, and mental health services, as well as wraparound services like coordination, engagement and referrals to community and social supports. Primary care centers can be integrated into this care model in a number of ways including as an MAT prescribing site. States and care-delivery partners will have the flexibility to develop the care delivery structure that best fits their local context.

<u>Leveraging Data to Enhance Prevention and Treatment Efforts</u>

Data are a powerful tool and CMS is utilizing the vast amounts of data at our disposal to better

understand and address the opioid crisis. CMS is working with its partners to ensure that they have the data and information they need to make changes and improvements to help address the crisis.

- *Utilizing Medicare Data to Address Overutilization.* Through the OMS referred to above, CMS identifies and reports potential at-risk beneficiaries to Part D sponsors that have DMPs, and sponsors report to CMS the outcome of their case management review for each case. Starting this year, beneficiaries are identified as potentially at-risk and reported to plans if, in the most recent six months, their daily dose of opioids exceeds 90 MME; and if they have received opioids from three or more opioid prescribers and three or more opioid dispensing pharmacies, or from five or more than five prescribers, regardless of the number of opioid dispensing pharmacies.

  These criteria are called the minimum OMS criteria. Part D sponsors also have the flexibility to apply supplemental OMS criteria to identify potential at-risk beneficiaries with any level of opioids and received opioids from seven or more opioid prescribers and/or opioid dispensing pharmacies.

  In the 2019 Final Call Letter, CMS finalized additional enhancements to the OMS including revised metrics to track high opioid overuse and to provide additional information to sponsors about beneficiaries who take opioids and "potentiator" drugs, such as benzodiazepines, (which when taken with an opioid increase the risk of an adverse health event).[20] To help identify and prevent opioid users from taking duplicate or key "potentiator" drugs, in 2019 CMS also expects sponsors to implement additional safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

  CMS utilizes the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) to conduct data analysis that is shared with plan sponsors to help them identify outlier prescribers or pharmacies. For example, plans receive Quarterly Outlier Prescriber Schedule II Controlled Substances Reports, which provide a peer comparison of prescribers of Schedule II controlled substances. This report now provides a separate analysis of just Schedule II opioids. Plans also receive quarterly pharmacy risk assessment reports, which contain a list of pharmacies identified by CMS as high risk; plan sponsors can use this information to initiate new investigations, conduct audits, and potentially terminate pharmacies from their network, if appropriate. CMS has also sent letters to prescribers that include educational information and comparative prescribing data to, and held a webinar, for prescribers whose opioid prescribing patterns were different as compared with their peers on both a specialty and/or national level.

  In May, CMS sent letters to providers of opioid-naïve beneficiaries that received one or more selected procedures. Providers received the letters if 10 or more of their patients' average daily MME were in the 90th percentile or higher when compared to their peers, for a given procedure. CMS will monitor the prescribing patterns of those

[20] CMS, Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, at p. 235 (Apr. 2, 2018).

surgeons/prescribers who are in the subsequent 10 percentiles of prescribers as a comparison group. In addition, CMS intends to evaluate the prescribing of the two groups approximately 12 months after the issuance of the letters.

The SUPPORT Act includes further measures designed to address overprescribing and misuse of opioids. Section 6065 of the Act requires annual notification of outlier prescribers of opioids. Currently, CMS is deciding on the method for selecting outliers. CMS expects to mail the first set of letters in January 2020. Section 6063 of the Act requires the Secretary to establish a secure internet website portal to enable the sharing of data and referrals of "substantiated or suspicious activities" related to fraud, waste, and abuse between plan sponsors, CMS and CMS' program integrity contractors. It also requires plan sponsors to submit information on the corrective actions taken against those identified as over-prescribers. This would include information on investigations and any credible evidence of suspicious activities in plan sponsors' possession as well as information on other actions taken by plan sponsors related to inappropriate prescribing of opioids.

To assist clinicians in assessing their own opioid-prescribing practices while continuing to ensure patients have access to effective acute and chronic pain treatment, CMS released two interactive online mapping tools that display the Medicare Part D opioid prescribing rate and the Medicaid opioid prescribing rate for 2017. The Medicare Part D Opioid Prescription Mapping Tool[21] allows users to quickly compare Part D opioid prescribing rates in urban and rural areas at the state, county and ZIP code levels. The Medicaid Mapping Tool[22] allows users to review Medicaid opioid prescribing rates at the state level and compare prescribing rates in fee-for-service and managed care. The mapping tools also offer spatial analyses to identify "hot spots" or clusters in order to better understand how this critical issue impacts communities nationwide.

CMS is working with the National Quality Forum, the HHS Secretary's consensus-based entity, to review quality measures and measure concepts related to opioids and opioid use disorders. NQF's technical expert panel will review quality measures in this area, summarize and prioritize gaps in measurement, provide for revision of existing measures, address the need for development of new measures, and make recommendations for measure inclusion in certain health care quality-based programs. Measures of opioid use and disorder from state and federal surveys vary considerably and are often drawn from questions asked in clinical or diagnostic settings, raising concerns regarding the accuracy and comparability of the information and resulting estimates. As part of an ongoing effort to develop a standardized battery of opioid questions, NCHS has conducted cognitive testing and evaluation of opioid measures for use on national population health surveys and surveillance systems to inform measurement strategies for use in different settings and populations.

[21] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap_Medicare_PartD.html.
[22] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap_Medicaid_State.html.

In response to recommendations from the President's Commission on Combating Drug Addiction and the Opioid Crisis, and in compliance with the SUPPORT Act and to avoid any potential unintended consequences, CMS has updated the Hospital Consumer Assessment of Healthcare Providers and Systems patient experience of care survey by removing three pain communication questions, removing the quality measure based on these questions, and no longer publicly reporting on this measure on the Hospital Compare internet website.

- *Modernizing Medicaid Data Collection.* CMS has been working with states to implement changes to the way in which administrative data are collected by moving from the Medicaid Statistical Information System (MSIS) to the Transformed-MSIS (T-MSIS). More robust, timely, and accurate data via T-MSIS will strengthen program monitoring, policy implementation, and oversight of Medicaid and CHIP programs. CMS had transitioned all states to T-MSIS as of 2018. Together with our partners in all 50 states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands, CMS has made tremendous progress in preparing T-MSIS data for program oversight, evaluation, research, and program integrity. CMS continues to work with states to improve the quality of their data and to stay current with T-MSIS data submissions.

  CMS is now using TMSIS data for program integrity and other purposes and used T-MSIS data to prepare a Substance Use Disorder data book, as required by the SUPPORT Act. The data book will be published this fall and will present nationwide T-MSIS data for the first time. CMS has begun to develop tools for T-MSIS users, as well as work with states to improve the quality of data submitted. For example, CMS is developing data quality information, which aggregates data quality findings in topical areas as well as by state. This information will help users of the T-MSIS data, which CMS plans to use for program oversight efforts. T-MSIS includes data on prescription opioids, and CMS looks forward to working with states to fully utilize this data in innovative ways that will augment efforts to combat opioid misuse.

The Role of ACF, SAMHSA, CDC, NIH, FDA and HRSA in Addressing the Opioid Crisis

ACF

The Regional Partnership Grant Program:

Since 2007, the Regional Partnership Grant (RPG) Program has been a cornerstone to the ACF Children's Bureau's efforts to improve outcomes for children and families affected by parental substance use. The intent of the RPG program, authorized under Sections 436 and 437 of the Social Security Act as part of the Promoting Safe and Stable Families program, is to increase the well-being, improve permanency outcomes, and enhance the safety of children and families in the child welfare system who are affected by parental substance use. The grants are funded to build system-level capacity to support families through collaborative partnerships among child welfare, substance use disorder treatment, court systems, and other family support systems and

organizations to implement evidence-based, evidence-informed and promising programs and strategies with children and families. To date, there have been five rounds of RPG projects, consisting of 101 grants, in 36 states. The RPG Program was reauthorized in February 2018. Under this reauthorization, ACF anticipates awarding RPG Round 6, consisting of eight grants in eight states, awarded in September 2019.

Regional Partnership Grants Round 2 (2012-2017) Interim Findings

The RPG national cross-site evaluation has resulted in several significant, interim findings from RPG Round 2 that will be formally shared in a forthcoming Report to Congress. These interim findings represent the work of RPG Round 2 projects that operated from September 2012 to September 2017. Findings from RPG Round 3 projects, will be identified and disseminated following the conclusion of their grants this September, and the completion of data analysis by the national cross-site evaluator. In June 2019, the national cross-site evaluation for RPG projects in Round 4 and 5 was officially launched and findings from this evaluation will be shared at appropriate intervals in the future.

From October 2012 to April 2017, the 17 RPG Round 2 grantees enrolled 11,416 adults and children —55 percent of whom were children, the majority under five years old. The strategies and services provided by the RPGs included: expanded and timely access to comprehensive family-centered treatment; creation or expansion of family treatment drug courts; in-home services; case management and case conferencing; and use of evidence-based and evidence-informed practice approaches, such as recovery coaches, mental health, and trauma-informed services; parent-child interventions; and strengthening of cross-system collaboration. Most RPG Round 2 families received at least one evidence-based program.

Interim findings demonstrate many adult and child outcomes improved significantly following entry into RPG. These findings include a significant decrease in adult drug and alcohol use between program entry and exit, and adult mental health and parenting attitudes improved significantly with fewer attitudes about parenting that placed their children at risk of maltreatment. Additionally, there was a significant reduction in rates of substantiated maltreatment. Thirty-six percent of children in RPG had an instance of substantiated maltreatment in the year before RPG, and this decreased to just seven percent of children in the year after RPG enrollment. Removals of children from the home were also less common: 29 percent of children experienced a removal in the year before RPG enrollment, and only 6 percent of children were removed from the home after entering RPG. Reunifications with the family of origin or other permanent placements were also more common in the year after RPG entry than in the year before. The cross-site evaluation also completed analysis of the adults in RPG Round 2 that indicated at program entry they were opioid users. As a result of participation in RPG program, opioid use in particular appears to be an area of significant improvement. Approximately 16 percent of adults were recent prescription opioid users at program entry, and only four percent of adults indicated at program exit that they were recent prescription opiate users.

National Center on Substance Abuse and Child Welfare's (NCSACW) Work to Address the Impact on the Opioid Crisis on the Child Welfare System

The National Center on Substance Abuse and Child Welfare (NCSACW) is a HHS initiative jointly funded by SAMHSA's Center for Substance Abuse Treatment and the Administration for Children and Families' Children's Bureau and administered by SAMHSA. The mission of the NCSACW is to improve family recovery, safety, and stability by advancing practices and collaboration among agencies, organizations and courts working with families affected by substance use and co-occurring mental health disorders and child abuse or neglect. The NCSACW provides training and technical assistance (TA) to families affected by substance use disorders, including opioid use disorders, and involved with the child welfare system. The NCSACW saw a dramatic and sizable increase in TA responses related to opioids from 2009 to 2018. Since that time, the most common technical assistance topics continue to be related to the opioid epidemic, and more specifically have been on the Child Abuse Prevention and Treatment Act (CAPTA) Plans of Safe Care, working with pregnant and parenting women, and infants with prenatal substance exposure. TA responses included sharing of information on related topics such as best practices in the treatment of opioid use disorders during pregnancy and collaboration to support infants with prenatal substance exposure and their families. The NCSACW also creates written materials that support communities in addressing the opioid epidemic. In 2016, the NCSACW released A Collaborative Approach to the Treatment of Pregnant Women with Opioid Use Disorders. This publication continues to be one of the most-downloaded resource from the NCSACW website. Web-based tutorials are also provided to train substance use disorder treatment, child welfare, and court professionals. The content of these tutorials includes information on opioid use disorders, CAPTA, and Plans of Safe Care. The website receives approximately 60,000 visitors per year. Additionally, in September 2019, the NCSACW released their updated Child Welfare Training Toolkit, which includes specific training modules on considerations for families in the child welfare system affected by opioids, methamphetamines, and understanding prenatal substance exposure and child welfare implications.

NCSACW also provides a limited amount of in-depth TA to state, tribal, and local agencies to assist in developing cross-system partnerships and the implementation of best practices to address the needs of this population. The NCSCAW's Infants with Prenatal Substance-Exposure In-Depth Technical Assistance (IPSE-IDTA) program continues working to advance the capacity of agencies to improve the safety, health, permanency, and well-being of infants with prenatal substance exposure and the recovery of pregnant and parenting women and their families.

SAMHSA

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.

SAMHSA administers the State Opioid Response (SOR) grants to provide flexible funding to state governments to increase access to medication-assisted treatment using medications approved by the Food and Drug Administration (FDA), reduce unmet treatment needs, and reduce opioid overdose related deaths through the provision of prevention, treatment and recovery activities for Opioid Use Disorder in the ways that meet the needs of their state.

In FY 2018, a total of $930,000,000 (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 $1.4 billion in supplemental and continuation funds. Other funding, including $50 million for tribal communities under the Tribal Opioid Response (TOR) grant program, has been awarded separately.

Previously, SAMHSA awarded $485 million to states and U.S. territories in FY 2017 and an additional $485 million in FY 2018 through the Opioid State Targeted Response (STR) grants, a two-year program authorized by the 21st Century Cures Act (P.L. 114-255). 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. SAMHSA also has several initiatives aimed specifically at advancing the utilization of medication-assisted treatment (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.

SAMHSA is also implementing section 3201 of the SUPPORT Act. , which broadened the eligibility requirements needed to prescribe buprenorphine, and thus should result in greater access to treatment for individuals with opioid use disorder.

CDC

As the nation's public health and prevention agency, 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 death. CDC continues to be committed to the comprehensive priorities outlined in the HHS strategy and to saving the lives of those touched by this epidemic. CDC's work falls into five key strategies to address opioid overdose and other opioid-related harms: (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.

CDC tracks and analyzes data to improve our understanding of this epidemic. According to the most recent provisional data, there were 69,096 drug overdose deaths predicted in the 12-month period ending March 2019. This is a slight decrease from 70,924 drug overdose deaths when compared to the 12 month period ending in March 2018.[23] CDC's data indicate that the epidemic continues to be driven by synthetic opioids, including illicitly manufactured fentanyl. Additionally, in March 2019, there were approximately 145,000 predicted drug overdose deaths

[23] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

involving cocaine, representing an increase from March 2018, and nearly 14,000 drug overdose deaths involving psychostimulants, a 24 percent increase from March 2018.[24] Given the evolving nature of this epidemic, it is essential that we continue to track and analyze data to target prevention efforts.

Data are crucial in driving public health action. Timely, high-quality data can help public health, public safety, and mental health experts better understand the problem, focus resources where they are needed most, and evaluate the success of prevention and response efforts. 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. CDC's Overdose Data to Action (OD2A) is a 3 year cooperative agreement that began in September 2019 and focuses on the complex and changing nature of the drug overdose epidemic and highlights the need for an interdisciplinary, comprehensive, and cohesive public health approach. CDC has awarded $301 million in new funding for the first year of a 3-year cooperative agreement $, Washington, D.C., 16 localities, and two territories to advance the understanding of the opioid overdose epidemic and to scale-up prevention and response activities. These funds will support state, territorial, county, and city health departments in obtaining high quality, more comprehensive, and timelier data on overdose morbidity and mortality and using those data to inform prevention and response efforts. This cooperative agreement builds upon CDC's OPIS Initiative and the OPIS Surge Support emergency funding.

Over three years, recipients will gather and rapidly report data that includes the substances, circumstances, and locations leading to overdoses and deaths. In addition, recipients will work to strengthen prescription drug monitoring programs, improve state-local integration, establish links to care, and improve provider and health system support.

CDC is also collaborating with SAMSHA on an evaluation of MAT to improve the evidence base, with the intent of scaling up MAT to achieve population-level impact. The purpose of this effort is to assess the type of MAT and the contextual, provider, and individual factors that influence implementation and improved patient well-being. CDC will be following 3,500 patients over the next two years. This evaluation will address the gaps that currently exist about MAT treatment, including:

- What are the features of programs that make MAT work?
- Who does it work for and which MAT works best for whom?
- What are the long-term risks and benefits associated with the different types of MAT medications?

Finally, CDC developed the CDC Training Series Applying CDC's Guideline for Prescribing Opioids, a web-based training to help providers gain a deeper understanding of the CDC Guideline for Prescribing Opioids for Chronic Pain and implement it into primary care practice. One of the trainings, "Assessing and Addressing Opioid Use Disorder" provides education to providers on methods for assessing and addressing an opioid use disorder when it is suspected.

[24] https://www.cdc.gov/mmwr/volumes/68/wr/mm6817a3.htm?s_cid=mm6817a3_e

Following the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain in 2016, the medical and health policy communities have largely embraced its recommendations.[25]

CDC is also taking the lead in preventing opioid-related harms such as the spread of infectious disease and the impact of opioids on mothers and babies. The number of new hepatitis C infections has more than tripled since 2010, with an estimated 44,000 people newly infected and 17,253 associated deaths in 2017. One of the greatest successes in HIV prevention has been among people who injection drugs, with an 80 percent decrease in injection drug use-associated infections over time. Since 2011, our progress preventing new infections has stalled, and we are at risk of reversing our success, as seen by multiple outbreaks of injection drug use-associated with HIV throughout the country just in the last year. In 2015, the rate of hepatitis C among U.S. women giving birth was more than five times higher than it was fifteen years prior (in 2000).[26] Further, both new infections and deaths associated with hepatitis C and hepatitis B are largely underreported. Infectious disease surveillance is essential in order to understand epidemics and facilitate more effective state and local responses. Moreover, evidence-based, prevention programs such as syringe services programs – sometimes referred to as needle exchanges – are proven effective in preventing infectious disease among people who use drugs. People who access syringe service programs are three times more likely to stop injecting drugs. In addition to access to and disposal of sterile syringes and injection equipment, syringe service programs can provide a range of services or referrals to services such as substance use disorder treatment, including medication assisted therapy; testing, and linkage to care for infectious diseases; Naloxone distribution to prevent overdose; and vaccination for hepatitis A and B.

National Institutes of Health (NIH)

NIH is the lead HHS agency providing support for cutting-edge research on addiction, mental health, pain and opioid misuse, opioid use disorder, and overdose. Drug addiction and pain are complex neurological conditions, driven by many biological, environmental, social, and developmental factors. Continued research will be key to understanding the opioid crisis, informing future efforts, and developing more effective, safer, and less addictive pain treatments.

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. The result of these discussions is the awarding of 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 Helping to End Addiction Long-term (HEAL) Initiative. The 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

[25] https://www.nejm.org/doi/full/10.1056/NEJMp1904190. Tamara M. Haegerich, Christopher M. Jones, Pierre-Olivier Cote, Amber Robinson, Lindsey Ross. (2019) Evidence for state, community and systems-level prevention strategies to address the opioid crisis. *Drug and Alcohol Dependence* **204**, 107563.
[26] https://www.cdc.gov/mmwr/volumes/68/wr/mm6839a1.htm?s_cid=mm6839a1_e&deliveryName=USCDC_921-DM10135

research to practice for the treatment of opioid addiction, (2) new strategies to prevent and treat opioid addiction, (3) novel medication for opioid use disorder, (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 prevent addiction 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 a clinical trials network for pain therapeutics development will be developed. Best practices for pain management will be further explored, including nondrug and integrated therapies. Finally, innovative neurotechnologies 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 opioid use disorder; and the use of nondrug and mind/body techniques 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 are partnering with research sites in four states to measure the impact of these efforts.

Finally, NIH is engaged in efforts to advance the HHS Opioid Strategy pillar of advancing the practice of pain management. NIH worked with HHS and agencies across government to develop the National Pain Strategy, the government's first broad-ranging effort to improve how pain is perceived, assessed, and treated, and is now working with other Departments and Agencies and external stakeholders to implement this Strategy. NIH is also involved in implementing the Federal Pain Research Strategy, a long-term strategic plan developed by the Interagency Pain Research Coordinating Committee (IPRCC) and the National Institutes of Health to advance the federal pain research agenda.

FDA

Reducing the number of Americans who are addicted to opioids and cutting the rate of new addiction is one of the FDA's highest priorities. This may be achieved by ensuring that only

appropriately indicated patients 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. 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. The SUPPORT Act, enacted by Congress in 2018, allows FDA to require special packaging for opioids and other drugs that pose a risk of abuse or overdose. Earlier this year, FDA opened a public docket to solicit feedback on potential use of this new authority to require that certain immediate-release opioid analgesics be made available in fixed-quantity, unit-of-use blister packaging. The availability of these new packaging configurations could help prescribers to more carefully consider the amount of opioid pain medication they prescribe. Reducing the amount of unnecessary opioid pain medication prescribed will lead to fewer pills left in medicine cabinets that could be inappropriately accessed by family members or visitors, including children, and could potentially lower the rate of new opioid addiction.

Opioid analgesics present unique challenges: they have benefits when used as prescribed yet have very serious risks and can cause enormous harm when misused and abused. Our goal has been to ensure product approval and withdrawal decisions are science-based and that the agency's benefit-risk framework considers not only the outcomes of prescription opioids when used as prescribed but also the public health effects of inappropriate use. The agency recently issued a new draft guidance which describes the application of the benefit-risk assessment framework that the agency uses in evaluating applications for opioid analgesic drugs and summarizes the information that can be supplied by opioid analgesic drug applicants to assist the agency with its benefit-risk assessment, including considerations about the broader public health effects of these products in the context of this crisis. In addition, FDA held a public meeting to further discuss the agency's benefit-risk assessment of opioid analgesics, including the manner in which risks of misuse and abuse of these products factor into the benefit-risk assessment and whether an applicant for a new opioid analgesic should be required to demonstrate that its product has an advantage over existing drugs in order to be approved.

Given the scale of the opioid crisis, with millions of Americans already affected, prevention is not enough. We must do everything possible to address the human toll caused by opioid use disorder and help those suffering from addiction by expanding access to lifesaving treatment. FDA is supporting the treatment of those with opioid use disorder and promoting the development of improved, as well as lower cost, forms of medication-assisted treatment. FDA is also working to increase availability of all forms of naloxone, an emergency opioid overdose reversal treatment. Among other actions, FDA has approved the first generic naloxone hydrochloride nasal spray, granted priority review to all generic applications for products that can be used as emergency treatment of known or suspected opioid overdose, and for the first time proactively developed and tested a Drug Facts label to support development of over-the-counter naloxone products.

FDA plays an important enforcement role when it comes to the illicit market for diverted opioids and illegal drugs. One of those roles is collaborating with U.S. Customs and Border Protection (CBP) on interdiction work on drugs being shipped through the mail. Earlier this year, FDA

implemented new authority granted by Congress to treat imported articles as drugs when they meet certain requirements, even in the absence of certain evidence of intended use. This allows FDA to more efficiently apply its existing authorities to appropriately detain, refuse, and/or administratively destroy these articles if they present significant public health concern. FDA also signed a Letter of Intent with CBP that addresses information sharing, operational coordination for better targeting of higher risk parcels, and collaborative strategies more specific to each agency's respective regulatory enforcement requirements. In addition, FDA continues to target illegal sales of opioids online and work with internet stakeholders to advance a proactive approach to cracking down on internet traffic in illicit drugs to address this public health emergency.

Health Resources and Services Administration (HRSA)

HRSA investments in community health centers, rural communities, and workforce programs establish and expand access to opioid and other substance use disorder (OUD/SUD) services. These programs work toward integrating behavioral health services into primary care to better meet the needs of communities across the country.

In FY 2019, through the Integrated Behavioral Health Services (IBHS) Program, HRSA awarded more than $200 million to 1,208 health centers across the nation to increase access to high quality, integrated behavioral health services, including the prevention and treatment of OUD/SUD. Health centers are using this funding to hire behavioral health providers, train health center staff to support the delivery of OUD/SUD and mental health services in primary care settings, deliver OUD/SUD and mental health services via telehealth, and improve awareness of and facilitate access to services through outreach, partnerships, and community integration efforts.

This new funding builds on the success of HRSA health center program investments in recent years. In FY 2017 and FY 2018, HRSA awarded more than $550 million to expand behavioral health services and increase access to critical OUD/SUD treatment. The impact of these programs is evident in the expansion of MAT in primary health care settings. Overall, the number of health center providers eligible to provide MAT increased nearly 190 percent (from 1,700 in 2016 to 4,897 in 2018) and the number of patients receiving MAT increased 142 percent (from 39,075 in 2016 to 94,528 in 2018).

In FY 2018, HRSA launched the multi-year Rural Communities Opioid Response Program (RCORP) to support OUD/SUD prevention, treatment, and recovery services in high-risk rural communities. Through RCORP, in FY 2018 and FY 2019, HRSA awarded $43 million to 215 rural grantees to establish partnerships with stakeholders and develop plans for addressing the treatment and recovery needs in their communities. In August 2019, HRSA awarded $111 million to 96 rural organizations across 37 states to implement comprehensive OUD/SUD programs, and expand access to MAT in eligible hospitals, health clinics, or tribal organizations in high-risk rural communities. HRSA also established three Centers of Excellence on Substance Use Disorders to identify and disseminate evidence-based best practices.

HRSA workforce programs expand and enhance the OUD/SUD 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 academic and community partnerships, enabling clinicians to provide integrated behavioral health care and treatment services in underserved communities.

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. This new initiative broadened the NHSC to include SUD counselors, pharmacists, and registered nurses, and approximately 1,100 awards were made. 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. In addition to these new programs, the NHSC now offers $5,000 incentive awards to practitioners who obtain DATA 2000 Waivers and demonstrate that they provide MAT at NHSC- approved clinical sites. Nearly 200 providers received these incentive awards when they continued their service in 2019.

Future Directions and Conclusion

As my testimony has highlighted, there is cause for optimism in addressing OUD. Under this Administration, an historic investment has been made in combating the crisis. For example, as mentioned previously, the NIH recently awarded nearly $1 billion across 375 projects in 41 states as part of its HEAL Initiative, to support research in key areas where we need better tools to treat or prevent opioid addiction. In fact, between FYs 2016- 2019, HHS has awarded over $9 billion in grants to states, tribes, and local communities to address this public health issue.

We have amassed a wealth of evidence on effective prevention, early intervention, treatment, and recovery strategies. Implementation of HHS' five-point strategy, along with the efforts of other Federal Government agencies, has resulted in reductions in opioid use and drug overdose deaths , increased access to medication assisted treatment, and increased the availability and distribution of overdose-reversing medications.

Even so, challenges remain. To that end, HHS' immediate priorities include addressing the surge of methamphetamine use and overdose, the introduction of new and highly lethal fentanyl analogues and other synthetic opioid analogues, and improving, demonstrating, and expanding the integration of Federal, state, local, and non-governmental efforts at the community-level. Among these initiatives are comprehensive syringe services programs, Emergency Department MAT programs with warm hand-offs following overdose, and efforts to expand the behavioral

health workforce. Ultimately, we need to pay attention not just to addiction, but also to mental health, ACEs, and the social determinants that exist in ***all*** communities.

Although we are making tremendous progress in our fight against the opioid epidemic, no one is declaring victory at this time. Indeed, we have only begun the public health fight against SUDs in our country. The Department will continue to devote its resources to solving this critical public health issue. And, as U.S. Surgeon General, I echo that pledge.

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

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