DEPARTMENT OF HEALTH AND HUMAN SERVICES

Hearing titled, "Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs"

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Witnesses appearing before the
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Chairman Hatch, Ranking Member Wyden, and Members of the Committee, thank you for holding this important hearing. We appreciate the opportunity to communicate and share with the Committee the Department's ongoing activities, programs, and research directed toward responding to the opioid crisis in the United States.

From the start of his Administration, President Trump has made addressing the opioid epidemic a top priority, and at HHS we share the President's commitment to bringing an end to this crisis, which is exacting a heavy toll on individuals, families, and communities across the country. 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 19th in New Hampshire the President announced his "Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand." The Department has made the crisis a top clinical priority and is committed to using our full expertise and resources to combat the epidemic. The Fiscal Year 2018 Consolidated Appropriation Act, which provides 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 abuse, addiction, and overdose. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health (NSDUH), in 2016, over 11 million Americans misused prescription opioids, nearly 1 million used heroin, and 2.1 million had an opioid use disorder due to prescription opioids or heroin. While the number of individuals who misused opioids is down by one million from 2015, opioid overdoses and related deaths remain a major issue and one that requires a much broader understanding of a complicated problem. Over the past decade, the United States has experienced significant increases in rates of neonatal abstinence syndrome (NAS), hepatitis C infections, and opioid-related emergency department visits and hospitalizations. Most alarming are the continued increases in overdose deaths, especially the rapid increase since 2013 in deaths involving illicitly made fentanyl and other highly potent synthetic opioids. Since 2000, more than 300,000 Americans have died of an opioid overdose. Opioids were involved in 42,249 deaths in 2016, five times more than in 1999.

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

more rigorous research to better understand how existing programs or policies might be contributing to or mitigating the opioid epidemic.

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

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

To date, the Department has taken significant steps to advance the goals of our Opioid Strategy. This statement addresses the unique role that the Centers for Medicare & Medicaid Services (CMS) and the Administration for Children and Families (ACF) are taking to address this opioid crisis. In order to provide a more comprehensive overview of the Department's coordinated strategy, it also includes a summary of activities that may fall outside of the Committee's jurisdiction by highlighting efforts within the Office of the Assistant Secretary for Health (OASH), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Diseases Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA).

CMS Role in Addressing the Opioid Crisis

As a payor, CMS plays an important part in the HHS efforts by working to make sure providers are providing the right services to the right patients at the right time. Beneficiaries are CMS's top priority across all of our 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 OUDs by promoting CDC guidelines for opioid prescriptions and encouraging non-opioid pain treatments; 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 efforts.

Preventing Overprescribing and Misuse of Opioids

CMS is taking a number of steps to reduce overprescribing in order to help prevent the development of new OUDs that originate from opioid prescriptions while balancing the need for continued access to prescription opioids for certain medical conditions and pain management.

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. All Medicare Part D sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids given the public health crisis. CMS's job is to oversee Medicare Part D plans to ensure that they are in compliance with requirements that protect beneficiaries 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 aimed at coordinated care, and safety edits at the point of dispensing.

CMS recently finalized a series of additional changes for 2019 to further the goal of preventing OUD.[1] 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. This policy change is consistent with the Centers for CDC Guideline for Prescribing Opioids for Chronic Pain[2] that states that opioids prescribed for acute pain in most cases should be limited to three days or fewer, and that more than a seven-day supply is rarely necessary.

Safety edits alert a pharmacist of possible overutilization at the point of sale. In real-time they 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. In 2018, all plan sponsors are utilizing these safety edits. Beginning in 2019, we expect all sponsors to implement a new opioid care coordination safety-edit. This new edit would create an alert for pharmacists when a beneficiary's daily opioid usage reaches high levels. When this occurs, plan sponsors are expected to direct pharmacists to consult with the prescriber to confirm their intent. This new policy aims to strike a balance between addressing opioid overuse without a negative impact on the patient-doctor relationship, preserving access to medically necessary drug regimens, and reducing the potential for unintended consequences.

Lock-In Authority

For years, states have been establishing and augmenting effective "lock-in" programs that require Medicaid enrollees who are "at-risk" for misusing or abusing opioids to use only one pharmacy and/or get prescriptions from only one medical office. The Comprehensive Addiction and Recovery Act of 2016 (CARA) provides CMS with the authority to allow Medicare Part D plans to implement similar pharmacy and prescriber lock-in programs. For both Medicaid programs and Medicare Part D plans, lock-in programs are an additional tool to promote better coordination between providers and beneficiaries who meet the guidelines for lock-in.

Under current law[3], 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

[1] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02-2.html

[2] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html

[3] 42 CFR 431.54(e)

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.

CMS recently implemented the new CARA lock-in requirements in Part D to provide an important additional tool to combat the growing opioid epidemic that is devastating families and communities across the nation.[4] CARA requires CMS to establish through regulation a framework that allows Part D sponsors to implement drug management programs. The policy incorporated input gathered from various stakeholders, including beneficiary advocates, clinicians, pharmacists, pharmacy benefit managers, and plan sponsors. With a focus on addressing opioid misuse, the proposal would integrate our new "lock-in" authority with current CMS programs aimed at curbing the opioid epidemic. For example, Part D plan sponsors implementing a drug management program could limit an at-risk beneficiary's access to coverage of frequently abused drugs beginning in 2019 through a beneficiary-specific Point of Sale (POS) claim edit and/or by requiring the beneficiary to obtain frequently abused drugs from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. In addition, the President's FY 2019 Budget[5] includes a proposal that would provide the HHS Secretary with the authority to require plan participation in a prescriber and/or pharmacy lock-in program to prevent prescription drug abuse in Medicare Part D; this proposal would save an estimated $100 million over ten years.

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, and 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 substance use disorders (SUD).

To reduce opioid misuse without restricting access to legitimate services, Medicaid programs can utilize medical management techniques such as step therapy, prior authorization, and quantity limits. For example, Vermont implemented prior authorization criteria which involves step therapy for methadone as a treatment of pain, requiring that patients must have documented side effects, allergies, or treatment failure to a preferred, long-acting opioid before being prescribed methadone for pain. Virginia implemented prior authorization criteria which involves additional documentation by both providers and beneficiaries before long-acting opioids can be approved for managing chronic, nonmalignant pain. As of FY 2016, thirty-seven states have edits in place to limit the quantity of short-acting opioids that will be covered for a beneficiary and thirty-nine states have similar edits in place to limit the quantity of long-acting opioids. 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.

[4] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2019-Medicare-Advantage-Part-D-Final-Rule.pdf

[5] https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf

States are required to report on their providers' prescribing patterns, including prescription opioids, as part of the Medicaid Drug Utilization Review (DUR) program. This is a two-phase process that is conducted by the state Medicaid agencies. During the first phase, (prospective DUR), the state agency's electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, contraindications, incorrect dosage, and clinical misuse or abuse. The second phase (retrospective DUR) involves ongoing and periodic examination of claims to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care.

The President's FY 2019 Budget includes a proposal that would establish minimum standards for Medicaid Drug Utilization Review programs. Currently, CMS does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Establishing minimum standards would not only help increase oversight of opioid prescriptions and dispensing in Medicaid, but would save the program an estimated $245 million over 10 years.

Ensuring Access to Evidence-Based Treatment

A critical part of tackling this epidemic is making sure that beneficiaries grappling with OUD have access to the most effective treatment options. Through its networks of health quality experts and clinicians, CMS advocates the sharing of best practices for OUD screening and treatment.

Medicare Parts A and B cover and pay for substance abuse 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, is also covered when the services are furnished through hospital outpatient departments and Medicare-certified community mental health centers. Medicare pays for substance abuse treatment services provided by physicians and other practitioners on a service-by-service basis under the Medicare Physician Fee Schedule, such as counseling services provided by a psychiatrist. Medicare Part B pays for medications used in physician offices or other outpatient settings that require a physician/practitioner to administer, including injections like naltrexone or implants of drugs like buprenorphine used in medication-assisted treatment. In addition, CMS recently made changes to the Medicare Physician Fee Schedule 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 medication-assisted treatment for opioid addiction, and improving payment for office-based behavioral health services.

Medication-Assisted Treatment (MAT)

Medication-Assisted Treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to treat SUDs, including OUDs. MAT is a valuable intervention that has been proven to be the most effective treatment for OUD, particularly because it sustains long-term recovery and has been shown to reduce opioid-related morbidity and mortality.[6] To increase access to MAT, CMS requires that Medicare Part D formularies

[6] https://www.ncbi.nlm.nih.gov/pubmed/24500948

include covered Medicare Part D drugs used for MAT and mandates Medicare Part C coverage of the behavioral health element of MAT services. 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.[7] CMS also released an informational bulletin with SAMHSA on coverage of treatment services for youth with SUD.[8]

While Medicaid programs vary greatly by state, all 50 states currently offer some form of MAT. In addition, the President's FY 2019 Budget includes a proposal that would require state Medicaid programs to cover all FDA-approved MAT for OUD, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from OUD; this provision would result in an estimated $865 million is savings over ten years.

Under an additional proposal in the President's FY 2019 Budget, CMS would conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. This demonstration could be expanded nation-wide if successful in key metrics, such as reducing opioid-related deaths among beneficiaries, reducing hospitalization for opioid poisoning, and reducing emergency room utilization for opioid-related issues. Through this proposal, Medicare would provide bundled reimbursement on a per-week-per-patient basis to providers for methadone treatment or similar MAT and would recognize opioid treatment programs and substance abuse treatment facilities as independent provider types; outpatient counseling would be billed separately as clinically necessary. The model would be allowed to target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive substance abuse treatment, including MAT and SUD counseling.

Increasing the Use of Naloxone to Reverse Opioid Overdose

CMS is also promoting improved access to the opioid overdose reversal drug naloxone by requiring that it appear on all Medicare Part D formularies.[9] 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.[10]

In addition, Medicaid programs in a number of states include forms of naloxone on their Medicaid Preferred Drug Lists. CMS has also issued guidance to states on improving access to naloxone.[11] States can offer training in overdose prevention and response for providers and members of the community, including family members and friends of opioid users.

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[7] https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf

[8] https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf

[9] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf

[10] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1604.pdf

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

Substance Use Disorder (SUD) Treatment and Demonstrations in Medicaid
Under the demonstration authority granted by section 1115 of the Social Security Act, CMS can waive certain federal requirements so that states can test new or existing ways to deliver and pay for health care services in Medicaid. Last November, CMS announced that it was using this authority to provide for a streamlined process for states interested in designing demonstration projects that increase access to treatment for OUDs and other SUDs by permitting services to be covered in an institution for mental diseases (IMD) as part of a state's comprehensive OUD/SUD strategy. Current law prohibits Medicaid from making payments to IMDs for services rendered to Medicaid beneficiaries ages 21 to 64. Previously, states seeking to cover services otherwise subject to the exclusion of coverage for IMD patients had been required to meet rigid CMS standards concerning operational details for implementation before Medicaid demonstration approvals could be granted. The new policy will allow states to begin to provide better treatment options more quickly while improving the continuum of care over time.

CMS is encouraging states to apply for approval of a five-year demonstration allowing them to receive federal financial participation for services to treat addiction to opioids or other substances, including services provided to Medicaid beneficiaries residing in IMDs, as these states work to improve access to treatment in outpatient settings as well. In addition, CMS is working with states that operate these demonstrations to establish strong quality of care standards, particularly for residential treatment settings.

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. States must also make available on Medicaid.gov information on the progress and outcomes of these demonstrations and evaluations 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 have approved these waivers for five states – Louisiana, New Jersey, Utah, Indiana, and Kentucky.

To further support this initiative, throughout 2018, the Medicaid Innovation Accelerator Program (IAP) will be available to states that would benefit from strategic design support related to improving their treatment delivery systems. The IAP provides states with access to national learning opportunities and technical expert resources, including strategic design support to states planning targeted addiction treatment delivery system reforms and developing 1115 proposals. In addition, CMS is available to provide technical assistance to states on how to meet federal transparency requirements as well as to preview states' draft 1115 proposals and public notice documentation to help ensure states successfully meet federal requirements.

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 benefit for which states can receive 90 percent

federal match for the first two years to improve care coordination and care management for individuals with chronic conditions including substance use disorders.[12]

Leveraging Data to Enhance Prevention and Treatment Efforts

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

CMS uses the Overutilization Monitoring System (OMS) to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications, including opioid pain medications. CMS has continued to refine and improve the criteria used in OMS. OMS identifies and reports on beneficiaries with a high risk of misusing opioids and plan sponsors can then use these reports generated by OMS to conduct case management and beneficiary-specific edits. Starting this year, beneficiaries are now identified as at-risk and reported to plans if, in the most recent six months, their daily dose of opioids exceeds 90 morphine milligram equivalent (MME); and if they have received opioids from more than three prescribers and more than three pharmacies, or from more than five prescribers, regardless of the number of opioid dispensing pharmacies.[13]

In the 2019 Final Call Letter[14], CMS finalized additional enhancements to the OMS including revised metrics to track high opioid overuse and to provide additional information to sponsors about high risk beneficiaries who take opioids and "potentiator" drugs, such as benzodiazepines, (which when taken with an opioid increase the risk of an adverse event). 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 opioids. Plans also receive quarterly pharmacy risk assessment reports, which contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with 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 billing

[12] Four states currently focus health home benefits on improving treatment for opioid use disorders: VT, MD, RI, and ME.

[13] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf

[14] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf

data to, and held webinars[15] for prescribers whose opioid prescribing patterns were different as compared with their peers on both a specialty and/or national level.

To assist clinicians, nurses, and other health care providers to assess opioid-prescribing habits while continuing to ensure patients have access to the most effective pain treatment, CMS released an interactive online mapping tool. The mapping tool allows the user to see both the number and percentage of opioid claims at the local level and offers spatial analyses to identify "hot spots" or clusters in order to better understand how this critical issue impacts communities nationwide.[16]

The CMS' Quality Innovation Network Quality Improvement organization (QIN-QIOs) program, consisting of 14 quality contractors, works to improve healthcare quality and safety for Medicare beneficiaries. The QIN-QIO program[17] has established a methodology using CMS claims data to identify adverse events, hospital admissions, readmissions, emergency visits, and observation stays for high-risk Medicare beneficiaries who have taken an opioid medication in the outpatient setting. QIN-QIOs collaborate with providers and other community coalitions, using their reports to support local and national efforts to address the opioid epidemic and increase surveillance of adverse events.

Modernizing Medicaid Data Collection

CMS has been working with states to implement changes to the way in which administrative data is 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 is working to transition all states to T-MSIS and has made significant progress. As of March 8, 2018, 49 states plus the District of Columbia and Puerto Rico have begun submitting T-MSIS data. These entities represent 98 percent of the Medicaid and CHIP population. CMS continues to work with the remaining states to help them submit data and expects all states to report T-MSIS data. [18]

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 a data quality assessment for users, which aggregates data quality findings in a user-friendly tool. These efforts will help states report complete and comparable 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 President's FY 2019 Budget also includes a proposal to require states to monitor high-risk billing activity to identify and remediate prescribing and utilization patterns that may indicate

[15] https://www.cbrinfo.net/cbr201801-webinar
[16] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html
[17] http://qioprogram.org/about/why-cms-has-qios
[18] https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/index.html

abuse or excessive utilization of certain prescription drugs in the Medicaid program. States are currently authorized to implement prescription drug monitoring activities, but not all states have adopted such activities. States would have flexibility to choose one or more drug classes and must develop or review and update their care plans to reduce utilization and remediate any preventable episodes to improve Medicaid integrity and beneficiary quality of care.

ACF Role in the Opioid Crisis

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 support 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 four rounds of Regional Partnership Grants, with Round 4, consisting of 17 grants in 17 states, awarded in September 2017.

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

The cross-site evaluation has resulted in several significant, interim findings that will be formally shared in a forthcoming Report to Congress. 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 7 percent of children in the year after RPG enrollment. Removals of children from the home were also less common. Twenty-nine percent of children experienced a removal in the year before RPG enrollment, and only six 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 2017. 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 the most-downloaded resource from the NCSACW website with 2,148 downloads to date. 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, Child Abuse Prevention and Treatment Act (CAPTA), and Plans of Safe Care.

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 Substance-Exposed Infants In-Depth Technical Assistance (SEI-IDTA) program is 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. Currently, Delaware, New York, Florida, Maryland, North Carolina, and West Virginia are receiving time-limited SEI-IDTA to develop policy and protocols on the prenatal substance exposure provisions CAPTA.

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

OASH coordinates multiple efforts across HHS and other federal agencies that address cross-cutting issues related to opioids and pain.

- Pain Management Best Practices Inter-Agency Task Force (Task Force)—The Task Force was established by the Comprehensive Addiction and Recovery Act of 2016 to: 1) Identify gaps or inconsistencies in pain management best practices, 2) Propose recommendations on addressing identified gaps or inconsistencies, and 3) Develop a strategy for disseminating information about the Task Force recommendations. The Task Force will include a broad spectrum of stakeholders Task Force representatives will include a variety of federal and non-federal stakeholders including patients, veteran services, first responders, health care providers, and experts in pain, addiction, mental health, and other areas of expertise.
- National Pain Strategy (NPS)—OASH and NIH are implementing the NPS, which is a coordinated plan to reduce the burden of chronic pain in the United States; and to achieve a system of care in which all people receive high quality, evidence-based pain care. Areas of focus include population research, disparities, and education and training, among others.

- Behavioral Health Coordinating Council (BHCC)—The Assistant Secretary for Health and the Assistant Secretary for Mental Health and Substance Use co-lead the BHCC, which is a convening body that provides guidance and recommendations on the HHS behavioral health agenda. Areas of focus include prescription drug and opioid abuse, behavioral health and primary care integration, and serious mental illness, among others.

- The Surgeon General is also within OASH. U.S. Surgeon General Jerome M. Adams, M.D., recently released a public health advisory to urge more Americans to carry a potentially lifesaving medication that can reverse the effects of an opioid overdose. The medication, naloxone, is already carried by many first responders, such as EMTs and police officers. The Surgeon General is now recommending that more individuals, including family, friends and those who are personally at risk for an opioid overdose, also keep the drug on hand. Expanding the use of the overdose-reversing drug naloxone is a key part of the public health response to the opioid crisis, and is one of the five components of the HHS Opioid Strategy.

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 Opioid State Targeted Response (STR) grants, a two-year program authorized by the 21st Century Cures Act (P.L. 114-255). By providing $485 million to states and U.S. territories in fiscal year (FY) 2017, this program allows states to focus on areas of greatest need, including increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of the full range of prevention, treatment and recovery services for opioid use disorder.

In November 2017, SAMHSA announced that it was accepting applications for $1 million in grants for Opioid State Targeted Response (STR) Supplements. The purpose of this program is to expand and enhance prevention, treatment, and recovery support efforts in the states hardest hit by the nation's opioid epidemic. The purpose of the supplemental funding is to bolster efforts already being made through the STR grant program. On March 19, 2018, SAMHSA awarded grants to three states that are among those with the highest overdose death rates and greatest

increases in death rates. This funding follows the STR grants which SAMHSA distributed to states and territories based on number of overdose deaths and the number of people needing treatment.

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.

As the nation's public health and prevention agency, CDC is applying scientific expertise to understand the epidemic and use that information to create interventions to prevent further harms, including the spread of infectious disease and the impact of opioids on mothers and babies. 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. Since 1999, more than 632,000 Americans have died from drug overdoses. In 2016, the death toll continued to rise. Over 63,600 deaths resulted from drug overdoses.[19] More than 42,000 of those deaths involved opioids.[20] According to the most recent provisional data, there were 67,344 drug overdose deaths in the 12-month period ending August 2017. This is an increase of nearly 8,000 deaths attributed to drug overdose compared to the 12-month period ending August 2016. CDC's data indicate that these increases were primarily driven by synthetic opioids, including illicitly manufactured fentanyl. 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. During the past few years, CDC has invested in strengthening the capacity of states to monitor the opioid overdose epidemic and target their prevention activities. CDC currently provides funding and scientific support to 45 states and Washington, D.C. to equip states with the tools and technical expertise they need to implement a comprehensive prevention program within their communities. States utilize their funding to enhance Prescription Drug Monitoring Programs (PDMPs) and leverage them as public health tools, improve health system and insurer practices for safer opioid prescribing, support community-level response and prevention activities, and evaluate policies

[19] https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm
[20] https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm

that may impact the opioid epidemic (e.g., naloxone distribution and Good Samaritan laws). In addition, CDC funds 32 states and Washington, D.C. to improve the timeliness and comprehensiveness of fatal and non-fatal opioid-involved overdose reporting and to disseminate data to stakeholders.

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 recent threefold increase in hepatitis C and the 2015 HIV outbreak in Indiana underscore the urgency of the issue. New hepatitis C infections have increased more than 167 percent in recent years and states like Kentucky, Tennessee, Virginia, and West Virginia reported a 364 percent increase in new hepatitis C infections from 2006 to 2012 in persons under 30. Surveillance for viral hepatitis is limited. Infectious disease surveillance is essential to know the true scale of the epidemic and facilitate more effective state and local responses.

NIH is the lead HHS agency providing support for cutting-edge research on 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 recently launched NIH Helping to End Addiction Long-term (HEAL) Initiative. This new Initiative will (1) advance our understanding of the genetic, social, and other factors that put patients at increased risk for opioid misuse and addiction, (2) expand the therapeutic options available for treating opioid use disorder and overdose, (3) explore the effectiveness of medication-assisted treatment in conjunction with nondrug treatment approaches such as cognitive therapy and meditation, (4) develop new treatments for OUD, including immunotherapies that can block the effects of opioids on the brain, and (5) evaluate treatment options for neonatal abstinence syndrome. The HEAL Initiative also will also include a demonstration study to test the integration of multiple addiction prevention and treatment approaches into healthcare and criminal justice settings in states with the highest rates of opioid misuse and overdose.

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.

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.

The issue of opioid misuse and abuse remains one of FDA's highest priorities and the agency has a critical and unique role to play in addressing this national crisis. FDA's regulatory oversight of lawfully prescribed drugs gives the agency important opportunities to impact prescribing in ways that can reduce the rate of new addiction while making sure patients with medical needs have access to appropriate therapy. FDA also plays an important role in interdiction of unlawful drugs, in particular, illegal drugs that are shipped through International Mail Facilities.

Some percentage of patients who are prescribed opioids will develop an addiction to these drugs. Addiction is characterized by a pronounced craving for the drug, obsessive thinking about the drug, erosion of inhibitory control over efforts to refrain from drug use, and compulsive drug taking. This is very different than physical dependence on opioids. The repeated administration of any opioid almost inevitably results in the development of tolerance and physical dependence. These short-term results of physical dependence from repeated opioid administration require dose tapering. FDA has taken steps to address both the risk of addiction and physical dependence. FDA recently announced its plans to expand the risk management plans, known as Risk Evaluation and Mitigation Strategies or REMS, to incorporate, for the first time, all opioid analgesics that are intended for use in the outpatient setting, including the immediate-release formulations. FDA has revised the associated Blueprint[21] for how providers should be educated about pain management in general, and prescribing opioid analgesics specifically. And we are requiring that this training be extended to all providers likely to come into contact with patients who are prescribed these medicines, including nurses and pharmacists.

[21] *https://www.regulations.gov/contentStreamer?documentId=FDA-2017-D-2497-0683&attachmentNumber=1&contentType=pdf*.

FDA also is taking immediate action when needed, as it did with FDA's first-of-its-kind request to remove a marketed opioid pain drug from sale due to the public health consequences associated with the product's abuse. The agency is also looking closely at certain opioids that may have a higher abuse potential. This includes oxymorphone, an active ingredient in certain opioid drugs. If it is determined, through a scientific process, that a particular opioid drug was more prone to abuse, and addiction, FDA would consider taking additional regulatory steps.

One key to reducing the rate of new addiction is to rationalize prescribing to help make sure that patients are prescribed opioids only when medically indicated. When a prescription is written, it should be for a dose and duration of use that comports closely with the clinical purpose. FDA is considering several potential strategies to promote proper opioid prescribing and dispensing that involve new measures with respect to how opioid products are packaged and labeled, and how providers are educated about their proper prescribing.

On the issue of illegal narcotics, such as illicit fentanyl, that are coming into the United States via international mail, FDA has taken action to enhance our operations at international mail facilities (IMFs). FDA plays an important role related to the interdiction work that takes place in the IMFs. When an illegal controlled substance is identified in the IMFs, our partners at Customs and Border Protection (CBP) will immediately seize it, such that products readily and initially identified as controlled substances will not come to the FDA investigators in these facilities. Instead, what FDA is tasked with opening, inspecting, and sometimes testing include products that are perceived to be illegally-imported FDA-regulated drug products; for example, if they are products such as kratom and believed to be counterfeit drugs or unapproved drug products. But as part of our work to examine what initially are believed to be non-opioid drug products, we still identify a large amount of controlled substances, in some cases because they might be disguised as other kinds of drug products. To give you some statistics on the scope of the risk: From the end of September 2017 through January 2018, of about 5,800 suspicious packages that FDA was tasked with inspecting because they were suspected of containing illegal prescription or counterfeit drugs or dietary supplements, 376 were controlled substances, including opioids, and were referred back to CBP for seizure. In some measure, the FDA investigators are a last line of defense in the IMFs, working closely with CBP. As the sophistication of those trying to penetrate our mail facilities continues to increase, this represents a growing vulnerability.

To address these risks, last year, FDA tripled the number of import investigators we have in the IMFs, allowing us to nearly quadruple the number of suspicious packages that we're able to open and inspect. This has taken our footprint from 8 to 22 full time employees (FTEs), the maximum capacity that our space in these facilities allows.

Conclusion

HHS is actively engaged in addressing the opioid epidemic and is committed to implementing effective tools across our programs. We look forward to continuing to work with this Committee and the Congress on these efforts.