STATEMENT OF

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ON

"RESPONDING TO AMERICA'S OVERDOSE CRISIS: AN EXAMINATION OF LEGISLATION TO BUILD UPON THE SUPPORT ACT"

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Chairs McMorris Rodgers and Guthrie, Ranking Members Pallone and Eshoo, and distinguished Members of the Subcommittee, thank you for the opportunity to provide an update on the Centers for Medicare & Medicaid Services' (CMS's) work to implement the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) and combat the opioid crisis.

Millions of Americans are directly impacted by opioid use disorder (OUD) and other substance use disorders (SUDs). The effects of the opioid crisis in particular are pronounced throughout the United States, with opioid-related overdoses and overdose deaths increasing since the early 2000s.[1] The Department of Health and Human Services (HHS) declared the opioid epidemic a public health emergency in 2017; the declaration was renewed most recently in March 2023, marking over five years.[2] In recent years, the COVID-19 pandemic exacerbated the existing SUD and mental health care crisis and disrupted health care delivery. This disruption was accompanied by the highest number of drug overdose deaths ever recorded in a 12-month period, driven primarily by synthetic opioids.[3]

[1] Report to Congress: Planning Grant Implementation Initial Report: https://www.medicaid.gov/medicaid/benefits/downloads/rtc-plan-grant-imp-rpt.pdf
[2] https://aspr.hhs.gov/legal/PHE/Pages/Opioid-31Mar2023.aspx
[3] CMS Data Highlight: https://www.cms.gov/files/document/data-highlight-jan-2022.pdf

The impact of SUD extends beyond the individual experiencing substance use disorder, as indicated by the prevalence of neonatal abstinence syndrome, fetal alcohol spectrum disorder, and increased spread of infectious diseases, including HIV and hepatitis C, in some areas of the United States. The most recent National Survey on Drug Use and Health found that in 2021, an estimated 5.6 million Americans aged 12 years or older had an OUD in the past year, and an estimated 46.3 million had a type of SUD.[4] CMS recognizes the severity of this widespread crisis and is committed to addressing it as comprehensively as possible.

Congress' leadership in enacting legislation including the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), the American Rescue Plan Act of 2021, the Bipartisan Safer Communities Act, and the Consolidated Appropriations Acts, of 2021 and 2023, have been instrumental in giving CMS the tools to increase access to equitable and high-quality behavioral health services treatment, bolster prevention efforts, enhance the data that informs our policies, and improve health outcomes. CMS works alongside ONDCP in support of the National Drug Control Strategy as we have implemented these programs.

CMS Behavioral Health Strategy

In 2022, President Biden announced a Strategy to Address Our National Mental Health Crisis which is designed to strengthen system capacity, connect more Americans to care, and create a continuum of support-transforming our health and social services infrastructure to address

[4] Report to Congress: Planning Grant Implementation Initial Report: https://www.medicaid.gov/medicaid/benefits/downloads/rtc-plan-grant-imp-rpt.pdf

mental health holistically and equitably. To bolster this work, CMS announced its Behavioral Health Strategy[5] (the CMS Strategy). With the release of the CMS Strategy, the Agency embarked on a multi-faceted approach to increase and enhance access to equitable and high-quality behavioral health services and improve outcomes for people covered by traditional Medicare, Medicare Advantage, Medicaid, the Children's Health Insurance Program (CHIP), and private health insurance. The CMS Strategy covers multiple elements including access to prevention and treatment services for substance use disorders, mental health services, crisis intervention, and pain care. The CMS Strategy further enables care that is well-coordinated and effectively integrated. The CMS Strategy also seeks to remove barriers to care and services, and to adopt a data-informed approach to evaluate our behavioral health programs and policies. Finally, the CMS Strategy strives to support a person's whole emotional and mental well-being and promote person-centered behavioral health care. As the largest health care payer in the United States, CMS is collaborating with our colleagues across HHS to align our efforts to increase access to equitable and high-quality behavioral health services treatment, bolster prevention efforts, enhance data, and improve health outcomes.

As described below, using the tools recently provided by Congress and existing authorities, CMS has taken significant action to improve behavioral health care and respond to the opioid crisis.

Improving Access to SUD Prevention, Treatment, and Recovery Services

Medication-Assisted Treatment (MAT)

[5] CMS Behavioral Health Strategy: https://www.cms.gov/files/document/cms-behavioral-health-stategy.pdf

Ensuring that individuals can access the critical behavioral health treatment services they require is a top priority across CMS. Thanks to authorities in the SUPPORT Act, CMS implemented Medicare coverage of certain items and services provided by Opioid Treatment Programs (OTPs), which includes coverage of MAT, including MAT with methadone. By law, only certified OTPs can dispense methadone for the treatment of opioid use disorder and OTPs were not previously able to bill Medicare for MAT services. This meant that before the SUPPORT Act, individuals with Medicare receiving MAT at OTPs for their opioid use disorders had to pay out-of-pocket. Now, Medicare pays outpatient OTPs through bundled payments made for treatment, including necessary medications, counseling, and testing. There are now 1,426 OTPs enrolled in Medicare, which is 74% of the total OTPs certified by the Substance Abuse and Mental Health Services Administration (SAMHSA). In 2021, nearly half of beneficiaries with OUD who received MAT treatment did so under the OTP benefit. In the CY 2023 Physician Fee Schedule final rule, CMS finalized several changes to further expand access to treatment at OTPs for Medicare beneficiaries. Specifically, CMS finalized an increase to the bundled payments for Medicare services furnished at OTPs to take into account the severity of needs of the patient population receiving services in the OTP setting to recognize that longer therapy sessions are often required. CMS also clarified that OTPs can bill Medicare for medically reasonable and necessary services furnished via mobile units in accordance with SAMHSA and DEA guidance, which may help improve access to care in rural and underserved areas.

In April 2021, the CMS Innovation Center selected applicants for the Value in Opioid Use Disorder (OUD) Treatment Demonstration, a 4-year demonstration authorized by the SUPPORT Act that is testing whether a new care management fee and performance-based incentive for OUD treatment services can cut hospitalizations and improve health outcomes for individuals

with OUD. Specifically, Value in Treatment is testing whether the demonstration: reduces hospitalizations and emergency department visits; increases use of MAT for OUD; improves health outcomes for individuals with OUD, including reducing the incidence of infectious diseases such as Human Immunodeficiency Virus and hepatitis C; reduces deaths from opioid overdose; reduces utilization of inpatient residential treatment; and reduces Medicare program expenditures to the extent possible. CMS will have preliminary data to report on the above outcomes by the Fall of 2023. This data will be used to draft the first of two required Reports to Congress to be submitted no later than 3 years after the start of the demonstration or by March 31, 2024.

CMS has also worked to support state Medicaid agencies in their efforts to offer a broader range of MAT options for SUD by identifying and sharing best practices and providing technical assistance. Under section 1006(b) of the SUPPORT Act, states are required to cover MAT for many Medicaid beneficiaries from October 1, 2020 through September 30, 2025. In December 2020, CMS issued a letter to State Health Officials with guidance regarding this coverage requirement.[6] The agency has also required that state CHIP programs include coverage of mental health services necessary to prevent, diagnose, and treat a broad range of mental health symptoms, including SUD.[7] CMS is also conducting a demonstration project designed to increase the number of Medicaid providers delivering SUD treatment or recovery services.[8] Through this demonstration, in 2019, CMS awarded 15 states with 18-month planning grants.

[6] Section 1006(b) of the SUPPORT ACT; https://www.medicaid.gov/federal-policy-guidance/downloads/sho20005.pdf
[7] CMS SHO Letter: https://www.medicaid.gov/federal-policy-guidance/downloads/sho20001.pdf
[8] Section 1003 of SUPPORT Act

Through an emergency waiver under section 1135 of the Social Security Act, CMS subsequently extended the planning grants by 6 months to allow states additional time to complete planning grant activities as a result of the COVID-19 public health emergency. In 2021, CMS selected five states to implement successful strategies through a 36-month post-planning period during which they receive enhanced federal reimbursement for increases in Medicaid expenditures for substance use disorder treatment and recovery services. Since the start of this demonstration, CMS submitted a Report to Congress entitled "Planning Grant Implementation Initial Report," which provides details on (1) the states awarded planning grants under the SUPPORT Act section 1003 demonstration, (2) the criteria used to select these states, and (3) initial activities proposed or carried out under the planning grants. The planning grants allowed states to conduct Medicaid-specific needs assessments, improve data infrastructure, develop provider technical assistance and training, build statewide collaborations, initiate policy changes, and diversify funding and provider reimbursement. Furthermore, the planning grants allowed states to engage in strategic thinking that continues to sustain provider capacity efforts developed through the grant. The Agency for Healthcare Research and Quality also recently issued a Report to Congress that summarizes the experiences of states awarded planning grants and those selected for the post-planning period. CMS will also be issuing interim and final reports to Congress that will describe the activities carried out by post-planning states, the extent to which states have achieved the goals stated in their applications, states' plans for the sustainability of their SUPPORT Act projects, and an evaluation of the demonstration project.

In April 2023, HHS released new guidance to encourage states to apply for the new Medicaid Reentry Section 1115 Demonstration Opportunity that would allow states to implement an

innovative service delivery system to facilitate successful reentry transitions for Medicaid-eligible individuals leaving prisons and jails and returning to the community by offering a targeted set of pre-release benefits, including medication-assisted treatment for substance use disorders and case management services to address physical and behavioral health conditions. This demonstration, required by the SUPPORT Act, would help states increase care for individuals who are incarcerated in the period immediately prior to their release and aims to help them succeed and thrive during reentry.[9] California's section 1115 re-entry initiative was approved in January 2023, and CMS continues to review a number of pending requests before us. Demonstrations like these build on the priorities established by the SUPPORT Act and support the President's strategy to address the mental health crisis and the opioid epidemic.

The CMS Innovation Center has also launched the Maternal Opioid Misuse, or "MOM" Model, a patient-centered service delivery model that aims to improve the quality of care for pregnant and postpartum Medicaid beneficiaries with OUD and their infants. The MOM Model tests whether funding states to develop and implement interventions that deliver evidence-based, coordinated care and referrals to community or other support services will improve the outcomes of this population while reducing Medicaid expenditures. The MOM Model has seven state participants which include Colorado, Indiana, Maine, New Hampshire, Tennessee, Texas, and West Virginia. The MOM Model's five-year performance period began in January, 2020 and will end on December 31, 2024. As of March 31, 2023, there are 983 women participating in the Model, and awardees have highlighted that incorporating peer recovery support specialists has helped to engage beneficiaries and foster trust, and reduce experiences of inferior care and stigma.

[9] Section 5032 of the SUPPORT Act.

Additionally, the Center for Medicare and Medicaid Innovation is testing the Integrated Care for Kids, or "InCK" Model. Launched in January 2020, the InCK Model aims to meet physical and behavioral health needs of children including integrating behavioral health into pediatric practices and building in screenings for housing and food insecurity. There are seven InCK Award Recipients across six states, including a State Medicaid Agency, community mental health center, local health department and several hospitals. Each Award Recipient has received the necessary State Plan Amendment and/or waiver approval to begin implementation of their Alternative Payment Models, which represent some of the first Medicaid alternative payment models for pediatric populations across the country. Awardees have also established partnership councils comprised of local and state partners to establish their model priorities, referral processes, and data sharing agreements and begun screening and linking beneficiaries to necessary services, which include care coordination and case management services. Award Recipients are coordinating care, educating providers and communities, integrating data, improving ease of navigating service delivery, and designing individualized approaches based on their local community's needs. We hope this work can be the basis for larger scale system transformation in the broader pediatric population.

In June 2021, CMS submitted to Congress a report titled "Summary of Review and Recommendations for the Medicare and Medicaid Programs to Prevent Opioid Addictions and Enhance Access to Medication-Assisted Treatment," along with a "CMS Action Plan to Enhance Prevention and Treatment for Opioid Use Disorder," in collaboration with the Pain Management Best Practices Inter-Agency Task Force. These reports present key findings from the analysis of

coverage and payment policies and review of beneficiaries' access to care, and next steps. Additionally, these reports include an evaluation of price trends for drugs used to reverse opioid overdoses, and outlines recommendations to lower the prices of such drugs for consumers.

Crisis Services

The Consolidated Appropriations Act, 2023 further increased access to crisis services in Medicare after January 1, 2024 by increasing payment for services including psychotherapy, mobilization of resources to defuse the crisis and restore safety, and implementation of psychotherapeutic interventions to minimize the potential for psychological trauma. Medicare will pay an enhanced payment amount when these services are furnished in certain settings such as a home or mobile unit. CMS is on track to implement this provision and will conduct outreach and education on psychotherapy for crisis services that are furnished in settings eligible for the enhanced payment amount and the use of auxiliary personnel (including peer support specialists) in the furnishing of psychotherapy for crisis and behavioral health integration services.

For individuals with Medicaid, CMS has been working with states to implement the American Rescue Plan Act's five-year Medicaid option for enhanced federal matching funds, and exemptions from otherwise applicable requirements, for states to provide community-based mobile crisis intervention services that meet certain criteria established in statute, helping states integrate these services into their Medicaid programs, which is a critical component in establishing a sustainable and public health-focused support network.[10] In September 2021, CMS awarded $15 million in planning grants to 20 states to support development of these mobile crisis

[10] ARP Mobile Crisis SHO: https://www.medicaid.gov/federal-policy-guidance/downloads/sho21008.pdf

intervention services, and provided one-year extensions for those grants through September 2023 for most of the participating states. CMS has also worked with states and local education agencies to make it easier for school-based mental health professionals to seek reimbursement from Medicaid, releasing significant guidance on the subject in August 2022 and May 2023.[11]

Telehealth

The SUPPORT Act significantly changed Medicare payment for telehealth by removing the geographic and site of service limitations for telehealth services furnished to individuals diagnosed with a substance use disorder for the purpose of treating the substance use disorder or a co-occurring mental health disorder. This change allowed Medicare telehealth services to be furnished in patient's homes and outside of rural areas. The Consolidated Appropriations Act, 2021 further expanded these changes to all Medicare mental health telehealth services furnished by physicians and practitioners, and CMS built upon this expansion by finalizing policies that allow hospital staff, rural health clinics, and federally qualified health centers to furnish remote mental health services to Medicare patients in their homes. Use of audio-only technology for these services is also permissible if the patient is not capable of or does not consent to use video technology.

In March 2023, a collaborative study by CMS, CDC and NIH demonstrated that the expanded availability of OUD-related telehealth services and medications during the COVID-19 pandemic was associated with a lowered likelihood of fatal drug overdose among Medicare beneficiaries.

[11] Referenced CIBs: School-Based Services in Medicaid: Funding, Documentation, and Expanding Services And Delivering Services in School-Based Settings: A Comprehensive Guide to Medicaid Services and Administrative Claiming

These findings underscore the need for continued expansion of these potentially life-saving interventions across clinical settings. [12] A January 2022 CMS data highlight which assessed changes in medication treatment among beneficiaries with OUD amid COVID-19 telehealth expansion found that beneficiaries who have accessed medication treatment for OUD had lower use of inpatient and/or emergency department visits. This suggests that more effective management of OUD generally may help reduce instances of more acute and costly care.

Recognizing the importance of expanded access to telehealth services for people with substance use disorder, the SUPPORT Act also authorized CMS to identify opportunities for the utilization of telehealth delivery methods to increase access to Medicaid services in rural areas.[13] CMS provided guidance to states regarding federal reimbursement for furnishing services and treatment for substance use disorders under Medicaid using services delivered via telehealth, including in School-Based Health Centers.[14]

Non-Opioid Alternatives

The SUPPORT Act recognized the need to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives to reduce the risk of OUD. The Act required CMS to review certain Medicare payments for hospital outpatient and ambulatory surgical centers for opioids in comparison to evidence-based non-opioid alternatives for pain management.[15] Under this authority, CMS is making separate payments for certain non-opioid pain management drugs

[12] CMS Press Release: https://www.cms.gov/newsroom/press-releases/increased-use-telehealth-services-and-medications-opioid-use-disorder-during-covid-19-pandemic
[13] Section 1009 (b) of the SUPPORT Act
[14] CIB: Rural Health Care and Medicaid Telehealth Flexibilities, and Guidance Regarding Section 1009 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271), entitled Medicaid Substance Use Disorder Treatment via Telehealth
[15] Section 6082 of the SUPPORT Act

and biologicals that function as surgical supplies that meet established criteria when furnished in the ambulatory surgical setting.[16]

To increase access to opioid alternatives for Medicaid enrollees, in February 2019 CMS issued an informational bulletin[17] with information for states seeking to promote non-opioid options for chronic pain management. Specifically, the guidance describes Medicaid authorities that states may use for coverage of non-opioid pharmacologic and non-pharmacologic pain management therapies, highlights some preliminary strategies used by several states, and includes useful resources to help states consider appropriate pain relief approaches within the context of the national opioid crisis.

Monitoring Overutilization

CMS has also been monitoring overutilization of prescription drugs in the Medicare Part D program through prescriptions drug event data and other data since Part D's inception in 2006. CMS requires Part D plan sponsors to operate drug utilization review, quality assurance, and medication therapy management programs. In recent years, CMS has introduced enhanced Medicare Part D opioid overutilization policies with the aim of promoting appropriate stewardship of prescription opioid utilization while still preserving medically necessary access to pain treatment. These policies also incentivize collaboration and care coordination among Medicare drug plans, pharmacies, providers, and patients in order to prevent opioid misuse and promote safer prescribing practices. The SUPPORT Act built upon CMS' Part D efforts,

[16] CY 2023 OPPS/ASC final rule with comment period (87 FR 72083 through 72090).
[17] Required by Section 1010 of the SUPPORT Act; CMCS Informational Bulletin: https://www.medicaid.gov/federal-policy-guidance/downloads/cib022219.pdf

requiring all Part D sponsors to have a drug management program in place and beneficiaries with histories of opioid-related overdose must be included in those drug management programs.[18].

Additionally, section 1004 of the SUPPORT Act requires an annual Report to Congress to address specified drug utilization (DUR) elements for certain prescription drugs in state Medicaid programs. The first report to congress was published on November 7, 2022[19]. There are several DUR provisions in section 1004 of the SUPPORT Act with respect to Medicaid Fee-for-Service (FFS) and Managed Care Entity (MCE) pharmacy programs, which cover the policy goals of protecting patients from, and educating providers about, opioid overutilization, as well addressing the clinical appropriateness of use of antipsychotic medications in children. These provisions and their implementing regulations establish drug utilization review standards to supplement existing requirements under section 1927(g) of the Act, in an effort to reduce opioid-related fraud, misuse and abuse. This Report to Congress specifically addresses the States' implementation status for these provisions, including requirements regarding opioid prescription claim reviews at the point of sale (POS) and retrospective reviews.

The SUPPORT Act also requires states to establish a qualified prescription drug monitoring program (PDMP) and authorized CMS to match state expenditures for activities to design, develop, or implement their PDMPs at 100 percent, for quarters during fiscal years 2019 and 2020.[20] In its June 2021 Report to Congress, CMS described best practices on the use of PDMPs

[18] Sections 2004 and 2006 of the SUPPORT Act
[19] https://www.medicaid.gov/medicaid/downloads/sud-prev-medicaid-drug-rev-util.pdf
[20] Section 5042(a) of the SUPPORT Act

and on protecting the privacy of Medicaid beneficiary information maintained in and accessed through PDMPs.[21]

CMS has also developed a methodology for determining outlier Part D prescribers when concurrently prescribing benzodiazepines and opioid medications, consistent with section 6065 of the SUPPORT Act.[22] Individuals who take benzodiazepines and opioids together are at higher risk for adverse events and overdose. Based on this analysis, CMS sends annual letters to notify identified Part D prescribers that they are in the highest 10th percentile of Part D prescribers in their specialty and state. As a collaborative partner, CMS strives to provide meaningful and informative data and believes that sharing this data, along with current prescribing guidelines, will help Part D prescribers provide the best possible care to prevent and relieve pain and maximize function for patients with pain. As required by section 6065 of the SUPPORT Act, CMS makes this aggregate Part D outlier prescriber information available on the CMS website.[23]

CMS is harnessing key data and analytic tools in order to understand and address the opioid crisis, which include: the Part D Prescriber Public Use File, which provides information on all prescription drugs covered by Part D plans; Medicare Part D and Medicaid Opioid Prescribing Mapping Tools, which are interactive tools that show geographic comparisons of de-identified Medicare Part D and Medicaid opioid prescriptions filled within the United States; the Overutilization Monitoring System, which monitors opioid overutilization by identifying

[21] Report to Congress, "State Challenges and Best Practices Implementing PDMP Requirements Under Section 5042 of the SUPPORT Act": https://www.medicaid.gov/medicaid/data-and-systems/downloads/rtc-5042-state-challenges.pdf
[22] https://www.cms.gov/files/document/methodology-comparison.pdf
[23] https://www.cms.gov/files/document/opioid-and-benzodiazepine-prescribing-patterns.pdf

potential at-risk beneficiaries for Medicare Part D drug management programs (DMPs) using CMS data; and reviewing quality measures in order to better identify gaps in measurement and quality improvement efforts with respect to combating the opioid crisis.

In August 2022, CMS released a proposed rule to promote consistent use of nationally standardized quality measures in Medicaid and CHIP. This will help identify gaps and health disparities among the millions of people enrolled in these programs. In November 2022, CMS released information on updates to the 2023 and 2024 Core Set of health care quality measures for adults enrolled in Medicaid, in order to support states' efforts to meet the upcoming 2024 mandatory reporting requirements.[24] The SUPPORT Act established one such new requirement; mandatory state reporting of the behavioral health measures included in the core set of adult health quality measures beginning with the annual state report in fiscal year (FY) 2024.[25]

Following the implementation of these changes, the behavioral health measures will be mandatory in FY 2024, but all other measures for the adult health quality measure core set are still voluntary. In addition, the SUPPORT ACT did not include appropriated funds to support CMS implementation of this requirement, which substantially limits CMS capacity to both collect and analyze all measures and creates a lack of parity with the child core set measures, which are all mandatory and funded annually.[26]

[24] https://www.medicaid.gov/federal-policy-guidance/downloads/cib111522.pdf
[25] Section 5001 of the SUPPORT Act
[26] Section 5001 of the SUPPORT Act

As required by the SUPPORT Act, CMS has released annually the Transformed Medicaid Statistical Information System (T-MSIS) SUD Data Book, which includes data on Medicaid beneficiaries treated for any SUD, and the services they received, along with an interactive T-MSIS SUD Data Book data analytics tool.[27] The fourth annual Data Book was released in November 2022.[28]

Fiscal Year 2024 Budget Proposals

The President's FY 2024 budget[29] includes numerous proposals across HHS that would further the Administration's commitment to ensure that every American gets the behavioral health care they deserve. Within CMS, the budget includes proposals that would strengthen mental health parity protections, reduce financial barriers to access to certain behavioral health services in Medicare and private insurance plans, and convert the Medicaid Certified Community Behavioral Health Clinics demonstration into a permanent program. CMS looks forward to working with our colleagues throughout the federal government to better align and improve our efforts.

Conclusion

Using the tools provided by Congress, including the SUPPORT Act, CMS has taken steps to expand access to substance use treatment and prevention services, and is committed to building on these efforts at every opportunity. The substance use crisis has impacted millions of American

[27] Section 1015 of SUPPORT Act
[28] T-MSIS Analytic Files: https://www.medicaid.gov/medicaid/data-systems/macbis/medicaid-chip-research-files/transformed-medicaid-statistical-information-system-t-msis-analytic-files-taf/index.html
[29] Budget of the U.S. Government Fiscal Year 2024: https://www.whitehouse.gov/wp-content/uploads/2023/03/budget_fy2024.pdf

families, and while there remains much additional work to do, our collective efforts to address the mental health and substance use crisis have improved access to treatment and prevention services. By executing the comprehensive CMS Strategy, bolstered by the authorities provided by Congress in the SUPPORT Act, CMS will continue to work to expand access to critical SUD treatment services and remove barriers to care and services and improve outcomes for people covered by traditional Medicare, Medicare Advantage, Medicaid, the Children's Health Insurance Program (CHIP), and private health insurance. Thank you for the opportunity to testify on this important issue.