**STATEMENT OF**

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**ON**

# COMBATTING THE OPIOID CRISIS: IMPROVING THE ABILITY OF MEDICARE AND MEDICAID TO PROVIDE CARE FOR PATIENTS

**BEFORE THE**

**U.S. HOUSE COMMITTEE ON ENERGY & COMMERCE**

**SUBCOMMITTEE ON HEALTH**

**April 11, 2018**

**"Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients"**
**U.S. House Committee on Energy & Commerce**
**Subcommittee on Health**
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Chairman Burgess, Ranking Member Green, and members of the Subcommittee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services's (CMS's) work addressing the misuse of opioids by some providers and beneficiaries in our programs. The Administration is aggressively fighting the opioid epidemic on all fronts. We understand the magnitude and impact the opioid misuse epidemic has had on our communities and are committed to a comprehensive and multi-pronged strategy to combat this public health emergency.

The number of Americans who are struggling with an opioid use disorder (OUD), is staggering. In 2016 alone, nearly 64,000 Americans died from drug overdoses, the majority (over 42,000) of them involved opioids. On average, 116 Americans die every day from an overdose involving opioids.[1] Opioid addiction is deeply affecting communities, families, and individuals across the nation. The estimated cost of the lost lives and worsened health of Americans due to the opioid crisis exceeded $500 billion in 2015.[2]

At the request of President Trump and consistent with the requirements of the Public Health Service Act, the Secretary of the Department of Health and Human Services (HHS) declared a nationwide public health emergency regarding the opioid crisis. The President also directed that executive agencies use all appropriate emergency authorities and other relevant authorities to respond to America's deadly opioid crisis. Last month, President Trump further highlighted the Administration's commitment to tackling the opioid crisis by announcing a goal of cutting the number of legal opioid prescriptions by one-third within three years.

For this reason, combating the opioid epidemic is a top priority for the Department of Health and Human Services (HHS) and the Administration as a whole. The President's Fiscal Year (FY) 2019 Budget proposes a number of legislative and administrative policy changes within

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[2] https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf

Medicare and Medicaid to combat the opioid epidemic and address serious mental illness and provides a historic level of new resources across HHS – $10 billion – to build upon the work started under the 21st Century Cures Act. The Budget's targeted investments advance HHS's five part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication assisted therapies;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

As a payor, CMS plays an important part in this plan by working to make sure providers are providing the right services to the right patients at the right time. Beneficiaries are our top priority across all of our programs, and we work 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 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. Our job at CMS 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.[3] 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 Disease Control and Prevention's (CDC) Guideline for Prescribing Opioids for Chronic Pain[4] 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

[3] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02-2.html
[4] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html

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[5], 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.

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.[6] CARA requires CMS to establish through regulation a framework that allows Part D sponsors to implement drug management programs. Our 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 our current 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[7] 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

[5] 42 CFR 431.54(e)

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

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

because Medicaid is the single largest payer for behavioral health services, we have been working under our 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.

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.[8] To increase access to MAT, CMS requires that Medicare Part D formularies 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 the Substance Abuse and Mental Health Services Administration (SAMHSA), the CDC, and the National Institute on Drug Abuse.[9] CMS also released an informational bulletin with SAMHSA on coverage of treatment services for youth with SUD.[10]

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.

[8] https://www.ncbi.nlm.nih.gov/pubmed/24500948
[9] https://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-07-11-2014.pdf
[10] https://www.medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf

*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.[11] We recognize 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.[12]

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.[13] States can offer training in overdose prevention and response for providers and members of the community, including family members and friends of opioid users.

*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, we announced that we were 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.

We are encouraging states to apply for CMS approval of a five-year demonstration allowing them to receive federal financial participation for services to treat addiction to opioids or other

[11] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf
[12] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1604.pdf
[13] https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf and https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf

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, we are 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, we 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.[14]

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

**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. We are also working with our 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.[15]

In the 2019 Final Call Letter[16], 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 we also expect 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

[15] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf
[16] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf

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 data to, and held webinars[17] 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.[18]

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[19] 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

[17] https://www.cbrinfo.net/cbr201801-webinar
[18] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html
[19] http://qioprogram.org/about/why-cms-has-qios

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. [20]

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 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.

**Conclusion**

CMS is actively engaged in addressing the opioid epidemic and is committed to implementing effective tools across our programs. CMS will continue to work with beneficiary and advocacy groups, health plans, states, our federal and state partners, and other interested stakeholders to address this devastating epidemic. This epidemic is devastating families and communities, and CMS is committed to using all the tools at its disposal to take meaningful action to stem this tide. We look forward to working with this Committee and the Congress on these efforts.

[20] https://www.medicaid.gov/medicaid/data-and-systems/macbis/tmsis/index.html