U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

April 9, 2018

TO: Members, Subcommittee on Health

FROM: Committee Majority Staff

RE: Hearing entitled "Combatting the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care For Patients"

I. INTRODUCTION

The Subcommittee on Health will hold a hearing on Wednesday, April 11, 2018, at 2:15 p.m. in 2123 Rayburn House Office Building. The hearing will continue Thursday, April 12, 2018, at 10:15 a.m. in 2322 Rayburn House Office Building. The hearing is entitled, "Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care For Patients."

II. WITNESSES

The hearing will consist of two panels of witnesses. The first panel will be held on Wednesday, April 11, and the second panel will be held on Thursday, April 12.

Panel 1

- Kimberly Brandt, Principal Deputy Administrator for Operations, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services.

Panel 2

- Michael Botticelli, Executive Director, Grayken Center for Addiction, Boston Medical Center;
- Toby Douglas, Senior Vice President, Medicaid Solutions, Centene Corporation;
- David Guth, CEO, Centerstone;
- John Kravitz, CIO, Geisinger Health System; and,
- Sam Srivastava, CEO, Magellan Health.

III. BACKGROUND

Deaths due to overdoses of opioids and other drugs have ravaged American communities. According to the Centers for Disease Control and Prevention; 1,000 people are treated for opioid misuse in emergency departments per day, 115 Americans die per day, and opioid-related overdoses have increased steadily since 1999.[1]

While the impacts to Americans' health outcomes are staggering, the opioid crisis has negatively impacted society in numerous ways, such as causing a drop in life expectancy for the first time in 25 years.[2] The opioid crisis has also resulted in a contraction in the labor force by almost 1 million workers in the years between 1999 and 2015, which resulted in a loss of $702 billion in output.[3] In 2015, the total economic burden of the opioid epidemic was estimated to be $504 billion. While all states were negatively impacted, there is geographic variation in the burden. West Virginia had the greatest loss per person ($4,378) and Nebraska had the lowest loss per person ($394).[4] One recent analysis found that the annual cost for private sector employers for treating opioid addiction and overdoses has increased more than eight-fold since 2004, and more than one in five persons aged 55-64 had at least one opioid prescription in 2016.[5]

Patients served by Medicaid and Medicare are significantly impacted by the opioid crisis, given that the programs together will cover roughly one in three Americans this year.[6] As the two largest health care payers in America, both programs play key roles in identifying at-risk beneficiaries, providing treatment, and decreasing overdose deaths.

MEDICAID

Medicaid is the largest source of federal funding for behavioral health services—mental health and substance use disorder services—with nearly $71 billion in projected 2017 spending.[7] As the Medicaid and CHIP Payment and Access Commission (MACPAC) stated in 2017, "the opioid epidemic, which has reached most communities across the U.S., disproportionately affects Medicaid beneficiaries."[8] Of the two million non-elderly Americans with opioid addiction,

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[1] Centers for Disease Control and Prevention. "Drug Overdose Death Data." December 19, 2017. Available at https://www.cdc.gov/drugoverdose/data/statedeaths.html.
[2] Dowell, D., Arias E., Kochanek K. et al. "Contribution of Opioid-Involved Poisoning to the Change in Life Expectancy in the United States, 2000-2015." JAMA, September 2017. Available at https://jamanetwork.com/journals/jama/fullarticle/2654372
[3] American Action Forum. "The Labor Force and Output Consequences of the Opioid Crisis." March 27, 2018. Available at https://www.americanactionforum.org/research/labor-force-output-consequences-opioid-crisis/
[4] American Enterprise Institute. "The Geographic Variation in the Cost of the Opioid Crisis". Available at https://www.aei.org/wp-content/uploads/2018/03/Geographic_Variation_in_Cost_of_Opioid_Crisis.pdf
[5] Kaiser Family Foundation, "A Look at How the Opioid Crisis Has Affected People with Employer Coverage," April 2018. Available online at: https://www.kff.org/health-costs/press-release/analysis-cost-of-treating-opioid-addiction-rose-rapidly-for-large-employers-as-the-number-of-prescriptions-has-declined/
[6] Estimates made from enrollment estimates from the Congressional Budget Office and U.S. Census Bureau data.
[7] Government Accountability Office, "Medicaid: States Fund Services for Adults in Institutions for Mental Disease Using a Variety of Strategies," GAO-17-652, August 2017. Available at https://www.gao.gov/assets/690/686456.pdf
[8] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf

Medicaid provides health coverage for an estimated 38 percent of this population, which is the largest percentage of any insurer type.[9] Medicaid provides care to 4 in 10 adults with opioid use disorder and compared to other insurance types, provides a significantly higher percentage of inpatient and outpatient substance use disorder treatment.[10]

MACPAC found that "Medicaid beneficiaries are prescribed pain relievers at higher rates than those with other sources of insurance. They also have a higher risk of overdose and other negative outcomes, from both prescription opioids and illegal opioids such as heroin and illicitly manufactured fentanyl."[11] Not only are the number of Medicaid beneficiaries with opioid misuse disproportionately high, so too are the number of overdoses. Studies from North Carolina and Washington indicate high rates of opioid-related deaths for the Medicaid population (33 percent and 45 percent, respectively).

State Medicaid programs pay for roughly half of the births in the U.S. each year. As opioid misuse has increased in recent years, so has the number of pregnant women who use opioids. A study by the Government Accountability Office (GAO) noted that "almost 22 percent of pregnant Medicaid beneficiaries filled a prescription for an opioid during their pregnancy."[12] The use of opioids by pregnant women can produce a withdrawal condition in newborn infants known as neonatal abstinence syndrome. MACPAC cited research that "in 2012, 81 percent of the estimated $1.5 billion in hospital charges related to neonatal abstinence syndrome in infants born to women using opioids was billed to Medicaid."[13] GAO concluded that:

> The rising opioid crisis has caused a significant increase in the number of infants born and diagnosed with NAS, a condition that affects infants and their families, hospitals, and other health care providers who are treating them. The increase in infants born with NAS also increases medical and other treatment costs experienced by the federal government and states. [14]

[9] Kaiser Family Foundation. "Medicaid's Role in Addressing the Opioid Epidemic." Available at https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/
[10] Kaiser Family Foundation. "Medicaid's Role in Addressing the Opioid Epidemic." Available at https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/
[11] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf
[12] Government Accountability Office, "Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome," October 2017, GAO-18-32. Available at: https://www.gao.gov/assets/690/687580.pdf
[13] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf
[14] Government Accountability Office, "Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome," October 2017, GAO-18-32. Available at: https://www.gao.gov/assets/690/687580.pdf

Providing Treatment for Patients with Substance Use Disorder

For treatment, Medicaid has several pharmacy and medical benefits for treating opioid use disorder that vary by state. A primary pharmaceutical treatment offered to patients with opioid abuse and/or substance use disorder is medication-assisted treatment (MAT). The Substance Abuse and Mental Health Services Administration (SAMHSA) describes MAT as "the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders."[15] Of the three types of pharmaceutical drugs commonly used to treat opioid addiction, all states cover at least two types and 48 states cover all three types.[16] MACPAC noted that "there is considerable variation in available services across states, since many are optional under the Medicaid statute."[17] State MAT coverage depends on several factors, including financial impact, supply of providers, demand for medication type, and benefit/risk considerations.

In working to combat the opioid crisis, it is important that state Medicaid programs carefully evaluate the clinical criteria for MAT and impacted patient populations. For example, the findings from a 2016 Centers for Medicaid and Medicaid Services (CMS) informational bulletin on best practices for addressing prescription opioid overdoses, misuse, and addiction in Medicaid noted that methadone can be an important tool in helping Medicaid beneficiaries who struggle with substance use disorder, but cautioned that "methadone in particular accounts for a disproportionate share of opioid-related overdoes and death." The bulletin also found that "the increased risk of morbidity and mortality associated with methadone is evident in the Medicaid population."[18]

A 2018 study found that states have been reducing the use of methadone in part because of an increase in the number of methadone-related deaths between 2007 and 2014.[19] States have also reported they face challenges with setting up contracts between methadone clinics and managed care organizations. As one example, in the early 2000s, Tennessee managed care organizations were frequently unable to establish contracts with methadone clinics due to the inability to agree on payment mechanisms and quality of care requirements.[20]

Non-pharmaceutical treatment of opioid use disorder in Medicaid occurs in inpatient, outpatient, residential, and community-based settings. MACPAC's 2017 analysis found that

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[15] See SAMHSA website. Available at: https://www.samhsa.gov/medication-assisted-treatment
[16] Advocates for Human Potential, Inc. "Residential Substance Abuse Treatment: A Comprehensive Listing of What States Cover for Substance Use Disorder, Including Medications." February 13, 2018. Drugs include methadone, naltrexone, and buprenorphine. For more information, see SAMHSA website. Available at: https://www.samhsa.gov/medication-assisted-treatment
[17] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf
[18] Centers for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, "Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction," January 28, 2016. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf
[19] The Pew Charitable Trusts. "The Use of Methadone for Pain by Medicaid Patients." Available at http://www.pewtrusts.org/en/research-and-analysis/reports/2018/03/the-use-of-methadone-for-pain-by-medicaid-patients
[20] Aaron Butler, Email Communication, April 4, 2018.

"Medicaid is responding to the opioid crisis by covering treatment, innovating in the delivery of care, and working with other state agencies to reduce misuse of prescription opioids."[21] State Medicaid programs adopt strategies and design their programs to meet the needs of their Medicaid beneficiaries resulting in variations in covered treatment services and settings. However, as MACPAC noted, "there are gaps in the continuum of care, and states vary in the extent to which they cover needed treatment."[22]

While it is important that states provide a continuum of care to serve the needs of Medicaid beneficiaries, one of the barriers to appropriate treatment consistently identified by Medicaid directors and health policy experts is a prohibition on federal Medicaid matching funds for paying for care for certain Medicaid beneficiaries in Institutions for Mental Diseases (IMD). This payment exclusion is known as the "IMD exclusion" and is long-standing policy under Medicaid. Under the Medicaid statute, federal funding cannot be used to finance care for Medicaid beneficiaries aged 21 to 64 receiving mental or substance use disorder care in a residential facility that has more than 16 beds.[23] When a Medicaid-eligible individual is a patient in an IMD, he or she cannot receive Medicaid coverage for services provided inside or outside the IMD.

Strengthening State-Based Solutions Through Substance Use Disorder Waivers

To address gaps in care and provide needed treatment, state Medicaid programs have several options to expand substance use disorder Medicaid services through state plan options and waivers. In 2015, CMS invited states to apply for section 1115 demonstration waivers to test

[21] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf

[22] Medicaid and CHIP Payment and Access Commission, "Medicaid and the Opioid Epidemic," Chapter 2 in June *2017 Report to Congress on Medicaid and CHIP*. Available at: https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf

[23] See Social Security Act 1905(a)(B). According to SSA §1905(i), the term 'institution for mental diseases' means a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. Determination of whether a facility is an IMD depends on whether its overall character is that of a facility established and maintained primarily to care for and treat individuals with mental diseases. Examples include a facility that is licensed or accredited as a psychiatric facility or one in which mental disease is the current reason for institutionalization for more than 50% of the patients. However, even with the IMD exclusion, states can receive federal Medicaid matching funding for inpatient mental health services for individuals aged 21 through 64 outside of an IMD. States can provide Medicaid coverage for services rendered in facilities that do not meet the definition of an IMD, such as facilities with 16 or fewer beds and facilities that are not primarily engaged in providing care to individuals with mental diseases. Under Medicaid managed care coverage, states may make monthly payments to managed care organizations for enrollees aged 21 through 64 who are patients in an IMD, as long as the length of stay in the IMD is no more than 15 days during the month of the payment. For the definition of IMDs, the term *mental disease* includes diseases listed as mental disorders in the International Classification of Diseases, with a few exceptions (e.g., mental retardation). (See Centers for Medicare & Medicaid Services, *State Medicaid Manual*, Part 4, §4390.) Under this definition, substance use disorders are included as mental diseases. If the substance abuse treatment follows a psychiatric model and is performed by medical personnel, it is considered medical treatment of a mental disease. Some states have benefitted from modest flexibility under Medicaid managed care regulations. For example, under current Medicaid managed care regulations, Medicaid beneficiaries in some states may receive treatment in an IMD "in lieu of" other services for up to 15 days.

innovative policy approaches for substance use disorder.[24] Most of the 10 approved states[25] have used this waiver authority to waive the IMD payment exclusion. Other covered waiver services include peer supports, support for housing and employment, and community-based treatment.[26] Also, four states have used supplemental Disproportionate Share Hospital payments to reimburse IMDs.[27]

In November 2017, the CMS released updated guidance explain how the agency seeks to work with states on section 1115 demonstrations to improve care for Medicaid beneficiaries with substance use disorder.[28] CMS noted at the time that "the Medicaid Innovation Accelerator Program (IAP) will continue to be available to states that would benefit from strategic design support related to improving their treatment delivery systems."[29]

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 demonstration waiver proposals. Some specific examples of IAP's assistance to states include individualized rapid response technical support that helps state Medicaid programs identify strong examples of state Medicaid Substance Use Disorder (SUD) activities and direct technical support to states interested in designing comprehensive MAT service delivery models and corresponding payment approaches.[30]

A few Medicaid programs also have used an optional Medicaid State Plan benefit that allows them to establish health homes to coordinate care for Medicaid beneficiaries who have chronic conditions, including substance use disorder.[31] Several state Medicaid programs have seen very positive outcomes from using a health home for individuals with substance use disorder.

MEDICARE

Medicare serves a unique population in the context of the opioids conversation. The Medicare program serves as the healthcare coverage provider to over 58 million

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[24] CMS, "New Service Delivery Opportunities for Individuals with Substance Use Disorder". July 27, 2015, Available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd15003.pdf
[25] The 10 States are: CA, IN, KY, LA, MA, MD, NJ, UT, VA, and WV
[26] Kaiser Family Foundation. "Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers." Available at https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-demonstration-waivers-the-current-landscape-of-approved-and-pending-waivers/
[27] MACPAC, "Report to Congress on Medicaid and CHIP." March 2018.
[28] Centers for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. State Medicaid Director letter #17-003, "Strategies to Address the Opioid Epidemic." Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf
[29] Centers for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. State Medicaid Director letter #17-003, "Strategies to Address the Opioid Epidemic." Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf
[30] See CMS's website for more information. Available at: https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/program-areas/reducing-substance-use-disorders/individualized-technical-support-opportunities/index.html
[31] See CMS website on Medicaid Health Homes under Section 1945 of the Social Security Act. Available at https://www.medicaid.gov/medicaid/ltss/health-homes/index.html

beneficiaries. This number is projected to rise to over 80 million by 2030. In serving the over age 65 population, Medicare accounts for a large share of total opioid prescriptions. In 2016, one out of every three beneficiaries was prescribed an opioid through Medicare Part D. In total, this equates to almost 80 million prescriptions and $4 billion in Medicare Part D spending. While many Medicare beneficiaries with serious pain-related conditions are being properly prescribed opioids, there is mounting evidence of opioid misuse in the Medicare system. As more seniors and individuals with disabilities come into the program, the challenges of fraud, misuse, and abuse will only increase. The committee will look at legislation that seeks to address these challenges on multiple levels in the Medicare program, through engaging providers, educating beneficiaries, and ensuring CMS has the tools to succeed.

IV. LEGISLATION

The Subcommittee will consider a package of legislation to address the opioid crisis, which include amendments to the Medicaid, Medicare Part B, and Medicare Part D programs. The package includes the following bills:

MEDICAID:

1. **H.R. ____, Limited repeal of the IMD Exclusion for adult Medicaid beneficiaries with substance use disorder.** The National Association of Medicaid Directors (NAMD) notes that "states have long identified the IMD payment exclusion as a policy barrier that has impeded access to medically necessary inpatient services for vulnerable populations with mental health and substance use disorders." This barrier "prevents Medicaid programs from achieving parity in coverage for behavioral health services" and "also unnecessarily complicates the care experience for such individuals."[32] In one context, NAMD has encouraged the development of "distinct stay-limits appropriate for individuals with mental health and substance use disorder diagnoses."[33]

   The discussion draft allows state Medicaid programs from FY2019 through FY2023 to remove the IMD exclusion for Medicaid beneficiaries aged 21-64 with a substance use disorder. Medicaid would pay for up to 90 total days of care in an IMD during the calendar year. Beneficiaries would need to be assessed after the first 30 days to determine if continued care (for the approval of up to 60 additional days) is medically necessary. The bill also requires states to maintain the level of funding and number of beds in IMDs in a state before a state adopts this option.

2. **H.R.____, Medicaid Pharmacy Home Act.** As noted previously, given the scope of the Medicaid program, some Medicaid beneficiaries struggle with substance use disorder or drug diversion. CMS noted in 2012 that "the impact of drug diversion on the Medicaid

[32] National Association of Medicaid Directors memo to Congressional staff, "Medicaid IMD Exclusion – Background and Available Pathways for States," September 12, 2016. Available at: http://medicaiddirectors.org/publications/namd-memo-on-the-medicaid-imd-exclusion/
[33] National Association of Medicaid Directors December 14, 2016 letter to CMS leadership. Available at: http://medicaiddirectors.org/wp-content/uploads/2016/12/NAMD-Managed-Care-IMD-Recommendations-to-CMS.pdf

program goes beyond just the cost of the prescription drugs. There are also the costs associated with doctor's visits, emergency department treatment, rehabilitation centers, and other health care needs, not to mention the human toll."[34] State Medicaid programs have several tools that can be used to decrease the supply of unnecessary opioids for beneficiaries that are at-risk for, or have, substance use disorder or drug diversion. CMS has identified establishing or augmenting effective recipient "lock-in" programs for recipients who over utilize prescription drugs as an element of a robust state Medicaid controlled prescription drug program.[35] CMS notes that "in an attempt to end pharmacy-hopping, some state Medicaid programs are requiring high users of certain drugs, including OxyContin, Xanax and Valium, to use only one pharmacy and get prescriptions for controlled substances from only one medical office."[36]

In October 2017, CMS stated that "almost all Medicaid agencies, except Florida, 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."[37] Many state Medicaid programs have informed the Committee that provider and pharmacist assignment programs are an important tool to restrict at-risk beneficiaries to specific providers in order to monitor services being utilized and reduce inappropriate utilization and improve care.

The discussion draft requires all state Medicaid programs to have a provider and pharmacist assignment program that identifies Medicaid beneficiaries at-risk for substance use disorder and assigns them to a pharmacy home program. The pharmacy home program must set reasonable limits on the number of prescribers and dispensers that beneficiaries may utilize, whether under a fee-for-service or managed care arrangement. The bill also codifies a requirement (currently, a regulation) that requires Medicaid managed care plans have a similar program.

3. **H.R.____, Medicaid DRUG Improvement Act.** Drug utilization review (DUR) is an important tool state Medicaid programs use to manage pharmaceutical utilization and expenditures. DUR can be used to manage dosage, quantity, and cumulative number of prescriptions.

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[34] See CMS bulletin, "Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid," January 2012. Available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/downloads/drugdiversion.pdf

[35] See CMS bulletin, "Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid," January 2012. Available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/downloads/drugdiversion.pdf

[36] See CMS bulletin, "Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid," January 2012. Available at: https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/downloads/drugdiversion.pdf

[37] The fee-for-service data from the FFY 2016 DUR reports have been compiled and are CMS's website. Available at: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2016-dur-summary-report.pdf Florida allows managed care organizations serving Medicaid beneficiaries to have a provider or pharmacist assignment program, but it is not required.

Under current law, state Medicaid programs are required to report their DUR activities each year to the CMS.[38] Specifically, states are required to report their state's prescribing habits, cost savings generated from their DUR programs and their program's operations, including adoption of new innovative DUR practices via the *Medicaid Drug Utilization Review Annual Report*.[39] As CMS explains, the Medicaid DUR program "promotes patient safety through state-administered utilization management tools and systems that interface with CMS' Medicaid Management Information Systems."[40]

Under the DUR program, the state Medicaid agency's electronic monitoring system screens prescription drug claims to identify problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy, and clinical misuse or abuse. A second retrospective DUR involves ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary care and implements corrective action when needed. DUR activities can be effective in managing the number of opioid prescriptions and mitigating dangerous drug-drug interactions.

A review of the most recent DUR report published by CMS demonstrates variability across state Medicaid programs in DUR activities. For example, some states set limits on the number of refills of opioids and the total milligrams of opioids that can be prescribed in a day, while others do not have any limits.

Similarly, some states have programs focused on the oversight of prescribing antipsychotic medications for children, while others do not. A 2018 study of children in Medicaid and CHIP suggests that psychotherapeutic drug claims account for between 30 and 40 percent of all prescriptions for children. The study's authors highlight concern for overprescribing and prescribing by providers with limited expertise.[41]

The discussion draft requires all state Medicaid programs to use common sense DUR activities to help combat the opioid crisis. State Medicaid programs will be required to put limitations in place for opioid refills, monitor concurrent prescribing of opioids and other drugs (such as benzodiazepines and antipsychotics), monitor antipsychotic prescribing for children, and have at least one buprenorphine/naloxone combination drug on the Medicaid drug formulary.

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[38] See Section 1927(g)(3) of the Social Security Act. 42 CFR Subpart K – Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims, Section 456.700-456.725, provides the requirements for the DUR program.

[39] The fee-for-service data from the FFY 2016 DUR reports have been compiled and are CMS's website. Available at: https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2016-dur-summary-report.pdf

[40] See CMS's website for the Medicaid Drug Utilization Review program. Available at https://www.medicaid.gov/medicaid/prescription-drugs/drug-utilization-review/index.html

[41] Zhao L, Cross-Barnet C, and McClair V. "Prescription Drug Use and Cost Trends Among Medicaid-Enrolled Children with Disruptive Behavioral Disorders." *Journal of Behavioral Health Services and Research*. 23 March 2018.

4. **H.R.____, Medicaid PARTNERSHIP Act.** Prescription Drug Monitoring Programs (PDMPs) are statewide electronic databases that collect prescribing and dispensing data on controlled substances. In general, providers and pharmacists have access to these databases to identify patients that are engaging in potential fraud or misuse of controlled substances. Many health care providers, pharmacists, and other clinical and substance use disorder experts have identified wider use of PDMPs as an important tool in combatting the opioid crisis.

   PDMPs also reduce substance use disorder by preventing doctor or pharmacy shopping and identifying patients at-risk of drug of substance use disorder. Evidence from New York suggests that PDMPs are associated with a 75 percent decrease in the number of beneficiaries who have more than one prescriber and dispenser.[42] Implementation of Florida's PDMP was associated with a 25 percent decrease in mortality related to oxycodone.[43] A 2016 information bulletin from CMCS highlighted that "other states showed a decrease in controlled substance prescriptions and patients visiting multiple practitioners seeking opioid pain medications. In addition, states were able to identify patients in need of addiction or pain management support." [44]

   The discussion draft would require the Medicaid program in each state program to integrate PDMP usage into a Medicaid provider's (including pharmacists) clinical workflow. Providers should check the PDMP of each patient before prescribing or dispensing a controlled substance. The bill also establishes basic standard criteria that a PDMP must meet to be counted as a qualified PDMP. The bill would require state Medicaid programs to report to CMS on how their PDMPs are working and the number of covered providers who are using the PDMPs, as well statewide trends in controlled substance utilization. The bill will allow CMS to work with states on promoting PDMP use and issue a report that will both aggregate state PDMP data as well as offer guidance to states on how they can both improve and use their PDMPs to reduce the abuse of controlled substances.

5. **H.R. ____, Incentives to Create Medicaid Health Homes to Treat Substance Use Disorder.** Health homes provide wrap-around services, such as care coordination, to individuals with chronic conditions.[45] State Medicaid programs can used an optional Medicaid State Plan benefit under current law to establish health homes that coordinate care for people with Medicaid who have chronic conditions, including substance use and serious mental illness.[46] Health homes allow states to pay for team-based care including

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[42] PDMP Center of Excellence at Brandeis University. "Mandating PDMP participation by medical providers: Current Status and Experience in Selected States.", 2014. Available at http://www.pdmpexcellence.org/content/mandating-medical-providerparticipation-pdmps.
[43] Delcher C, Wagenaar AC, Goldberger BA, Cook RL, Maldonado-Molina MM. "Abrupt decline in oxycodone caused mortality after implementation of Florida's Prescription Drug Monitoring Program." *Drug Alcohol Depend*. 2015, available at https://www.ncbi.nlm.nih.gov/pubmed/25746236
[44] Centers for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, "Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction," January 28, 2016. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf
[45] Social Security Act, Section 2703
[46] Social Security Act, Section 1945

wrap-around services such as comprehensive care management, care coordination, and support services. The option for state Medicaid programs to adopt a health home with enhanced funding provides an incentive for states to develop hubs where beneficiaries with substance use disorder can have access to these valuable wrap-around services as well.

To date, four states have approved health homes that have specifically targeted beneficiaries with substance use disorder and have experienced positive results.[47] For example, South Dakota's Health Home for patients with substance use disorder has served 5,922 patients, improved clinical outcomes such as screening for depression and substance use disorder, and avoided $7.7 million in costs.[48] Another state with a health home for patients with substance use disorder has informed the Committee that compared to a control group, the state is saving money through continuing the health home. Beyond just the health homes for patients with substance use disorder, CMS report notes that:

> States report that they plan to continue the programs after the eight-quarter enhanced (90 percent) federal match ends; they believe that the cost savings resulting from improved health status and reduced utilization are expected to, at a minimum, cover the costs of the health home program and anticipate savings in excess of health home costs.[49]

This suggests that investing in health homes is likely to yield positive benefits for patients that persist in Medicaid programs well beyond the period of enhanced funding.

To incentivize state Medicaid programs to use health home waivers for Medicaid beneficiaries with substance use disorder, the discussion draft extends the enhanced match from eight quarters to 12 quarters if states meet quality, cost, and access targets set by CMS.

6. **H.R. ____, Medicaid IMD ADDITIONAL INFO Act.** Under the Medicaid statute, federal funding cannot be used to finance care for Medicaid beneficiaries aged 21 to 64 receiving mental or substance use disorder care in a residential facility that has more than 16 beds.[50] This IMD exclusion includes an exception for inpatient psychiatric care. There are four broad criteria for a facility to qualify as an IMD and receive Medicaid reimbursement:
(1) it must be licensed as a psychiatric facility,

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[47] CMS, "State-by-State Health Home State Plan Amendment Matrix," updated December 2017. Available at: https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-home-information-resource-center/downloads/state-hh-spa-at-a-glance-matrix.pdf See also "Medicaid Health Homes: An Overview," December 2017. Available at https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-home-information-resource-center/downloads/hh-overview-fact-sheet.pdf
[48] South Dakota Department of Social Services, "Health Home Data Dashboard.", Available at http://dss.sd.gov/healthhome/dashboard.aspx
[49] CMS "Interim Report to Congress on the Medicaid Health Home State Plan Option." Available at: https://www.medicaid.gov/medicaid/ltss/downloads/health-homes/medicaid-health-home-state-plan-option.pdf
[50] Social Security Act 1905(a)(B)

(2) it falls under the State Mental Health authority jurisdiction,
(3) more than 50 percent of patients must have been admitted with a need for institutionalization, and
(4) it must specialize in providing psychiatric and psychological care.
Beyond these four criteria, there is limited published data or information on IMDs.[51]

The discussion draft directs the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on IMDs. The study shall report on the requirements, standards, and oversight that State Medicaid programs have for IMDs. MACPAC, considering input from stakeholders, shall summarize the findings and make recommendations on improvements and best practices. The report is due no later than January 2020.

7. **H.R. ____, Improving Medicaid Data Timeliness Act.** Congress, researchers, advocates, and Medicaid stakeholders have often noted the significant lag in Medicaid expenditure data. The lag in such data makes it more challenging for policymakers to have timely, complete information for understanding the evolving role of the Medicaid program. Such an understand is particularly important when state Medicaid programs face a challenge on the scope and scale of the opioid crisis. In general, having more accurate and timely Medicaid data is an important tool for policymakers interested in developing effective, targeted solutions.

   Section 1132 of the Social Security Act requires that Medicaid claims to be filed within a two-year period.[52] This requirement was put in place in 1980. Since then, the provision of law regarding the timeframe for claim submission has not changed, even though payment systems have continually been upgraded and claims have moved from paper to electronic submission.

   Currently, CMS still allows a two-year filing window to claim Federal Financial Participation for State medical assistance payments. This two-year window creates a consistent lag in Medicaid data, such that in any given year, the most complete Medicaid data is old and outdated. While the requirement in law remains unchanged, according to a review of state claims, 98 percent or more of claims are filed within one year of the date of service. This suggests that updating the allowable timeframe in statute would not be disruptive, but could improve the timeliness of Medicaid expenditure data so policymakers have a more accurate and nuanced understanding of trends in the Medicaid program.

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[51] Some of the most comprehensive information currently available comes from the Substance Abuse and Mental Health Services Administration at the U.S. Department of Health and Human Services. See the "National Survey of Substance Abuse Treatment Services, 2015" and also the "National Directory of Mental Health Treatment Facilities, 2017." The first document is available at https://www.dasis.samhsa.gov/dasis2/nssats/2015_nssats_rpt.pdf and the second document is available at https://www.samhsa.gov/data/sites/default/files/2017%20MH%20Directory.pdf See also Government Accountability Office, "Medicaid: States Fund Services for Adults in Institutions for Mental Disease Using a Variety of Strategies," GAO-17-652, August 2017. Available at https://www.gao.gov/assets/690/686456.pdf

[52] Public Law 96-272

The discussion draft reduces the filing window from two years to one year.

8. **H.R. ____, Medicaid Graduate Medical Education Transparency Act.** One important way to help combat the opioid crisis and help provide care for patients with substance use disorder is to ensure federal spending on the health care workforce is adequately helping providers identify, treat, manage, and refer patients with substance use disorder. Thus, federally funded graduate medical education (GME) can play a role in combating the opioid crisis—especially by helping fund the training of the next generation of physicians and professionals caring for patients.

   The federal government contributes to the direct and indirect cost of GME through Medicaid, Medicare, Veterans Administration, and Department of Defense. State Medicaid programs are not required to finance GME, but all states currently do use Medicaid funds to support GME. Federal agencies and state Medicaid agencies spent over $16.3 billion on GME training in 2015 to support direct and indirect costs of training.[53] Medicaid is the second largest federal payer of GME. In 2015, Medicaid spending accounted for 16 percent of total federal spending on GME training, or $2.4 billion. [54]

   While the U.S. Department of Health and Human Services (HHS) collects Medicaid GME expenditure information from states, the information is not granular enough to understand how the program is helping to meet physician workforce needs.[55] Congress also lacks insight into how state Medicaid programs may leverage GME funds to adequately equip physicians to combat substance use disorder.

   The discussion draft improves transparency in the GME program by requiring state Medicaid programs to report periodically to the CMS data and information on how GME funds are being used to support physician training. The bill also requires state Medicaid programs to report specific information on how physicians are trained in specialties that are essential in the opioid crisis (i.e., psychiatry, addiction medicine, etc.) and how GME recipients are using Medicaid funds to train physicians on substance use disorder.

9. **H.R. ____, Protecting NAS Babies Act.** Pregnant women who use or misuse opioids may give birth to infants who experience withdrawal conditions. Commonly referred to as Neonatal Abstinence Syndrome (NAS), the infant's symptoms range from crying to difficulties in breathing. NAS requires specific treatment that primarily occurs in the inpatient setting. However, there are not agreed upon guidelines for NAS treatment, and treatment in outpatient settings has been limited to a small number of facilities. In order

[53] Government Accountability Office, "Physician Workforce: HHS Needs Better Information to Comprehensively Evaluate Graduate Medical Education Funding," March 2018. Available at: https://www.gao.gov/assets/700/690581.pdf
[54] Government Accountability Office, "Physician Workforce: HHS Needs Better Information to Comprehensively Evaluate Graduate Medical Education Funding," March 2018. Available at: https://www.gao.gov/assets/700/690581.pdf
[55] GME transparency was a recommendation in the 2014 National Academies of Science, Engineering, and Medicine Report.

to expand access to NAS treatment, state Medicaid programs could benefit from guidance and recommendations from HHS for delivery of care.

The discussion draft requires HHS to establish a strategy to implement recommendations from the report, "Protecting Our Infants Act: Final Strategy."[56] Recommendations aim to enhance the treatment and care of newborns suffering from Neonatal Abstinence Syndrome. The strategy must include a timeline for implementation, explanation on how the Department plans to disseminate best practices to state health agencies, and any additional statutory authorities the Department needs to meet the requirements of this bill.

10. **H.R. ____, HUMAN CAPITAL in Medicaid Act.** As noted previously in this memo, the Medicaid program has a important part to play in combatting the opioid crisis and providing care for patients with substance use disorder. Medicaid plays a critical role in the opioid crisis, both as a payor providing treatment and interventions as well as a large decentralized government program. Yet, in efforts designed to build capacity in the health care workforce, too often the key role of Medicaid program leadership is overlooked.

    While the opioid crisis presents Medicaid directors with a challenge that is large in scope, it is just one of the challenges Medicaid leaders face, and states need to be equipped with the best Medicaid leaders possible. Yet, states struggle to hire and retain high-caliber Medicaid leaders. A December 2016 report from the National Association of Medicaid Directors (NAMD) noted that "Medicaid Director compensation falls far behind what their peer equivalents in the private sector make."[57] The tenure for a Medicaid Director is a merely 19 months, and roughly two-thirds of Directors have been in their position for less than two years.[58] In their survey, the association also found:

    > 31 states cited budgetary constraints at the administrative, agency, or state level as a major impediment to reform. Even more states (38) indicated that they experienced staffing challenges in the past year, with 12 states citing insufficient compensation, 12 states citing poor recruitment, and seven states citing limited professional development as reasons why it is hard to attract and keep employees.[59]

    Given the growing role of Medicaid in the health care delivery system and the importance Medicaid plays in combatting the opioid crisis, The discussion draft provides enhanced federal medical assistance percentage to use toward recruit and retain talented leaders with specific expertise and capabilities.

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[56] Johnson K., "Protecting our Infants Act: Final Strategy Now Available." Substance Abuse and Mental Health Services Administration. Available at https://blog.samhsa.gov/2017/06/28/protecting-our-infants-act-final-strategy-now-available/#.WsUDw7pFyUk

[57] National Association of Medicaid Directors. "State Medicaid Operations Survey." December 2016. Available at http://medicaiddirectors.org/wp-content/uploads/2016/12/NAMD_OpsSurveyReport_FINAL.pdf

[58] National Association of Medicaid Directors. "State Medicaid Operations Survey." December 2016. Available at http://medicaiddirectors.org/wp-content/uploads/2016/12/NAMD_OpsSurveyReport_FINAL.pdf

[59] National Association of Medicaid Directors. "State Medicaid Operations Survey." December 2016. Available at http://medicaiddirectors.org/wp-content/uploads/2016/12/NAMD_OpsSurveyReport_FINAL.pdf

11. **H.R. 3192, CHIP Mental Health Parity Act.** This bill was introduced by Rep. Joseph Kennedy, III (D-MA). The Children's Health Insurance Program (CHIP) provides health coverage to eligible children, through both Medicaid and separate CHIP programs. H.R. 3192 will require all CHIP plans to cover treatment of mental illness and substance use disorders.

12. **H.R. 4998, Health Insurance for Former Foster Youth Act.** This bill was introduced by Rep. Karen Bass (D-CA). Under current law, foster youth with Medicaid coverage before they turn 18 may stay in Medicaid until the age of 26. However, such foster youth lose Medicaid coverage if they move out of their state. This bill will amend current law to allow such foster youth to continue to receive Medicaid benefits even if they move to another state.

13. **H.R.____, To amend title XIX of the Social Security Act to provide for a demonstration project to increase substance use provider capacity under the Medicaid program.** This bill would create a demonstration project for five years for up to ten states that have committed to Medicaid delivery system advancements for substance use disorders. This measure would allow certain states to receive an enhanced match for training and technical assistance and other incentive activities to enroll new providers treating substance use disorder in Medicaid or expand existing substance use disorder provider capacity.

14. **H.R.____, Require State Medicaid Programs to Report on All Core Behavioral Health Measures.** This bill would require state Medicaid programs to report on the 11 behavioral health measures that are included in CMS's 2018 Core Set of Adult Health Care Quality Measures for Medicaid.[60] A more complete view of behavioral health quality of care will inform Congress, CMS, and stakeholders on how to target improvement moving forward.

15. **H.R. 4005, Medicaid Reentry Act.** This bill was introduced by Rep. Paul Tonko (D-NY) and will amend title XIX (Medicaid) of the Social Security Act to allow state Medicaid programs to receive federal matching dollars for medical services furnished to an incarcerated individual during the 30-day period preceding the individual's release.

16. **H.R. ____, To amend title XIX of the Social Security Act to provide for Medicaid coverage protections for pregnant and postpartum women while receiving inpatient treatment for a substance use disorder.**

17. **H.R.1925, At-Risk Youth Medicaid Protection Act.** This bill was introduced by Rep. Tony Cardenas (D-CA) and will prohibit state Medicaid programs from terminating a juvenile's medical assistance eligibility because the juvenile is incarcerated. A state may suspend coverage while the juvenile is an inmate, but must restore coverage upon release

[60] Available at: https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2018-adult-core-set.pdf

without requiring a new application unless the individual no longer meets the eligibility requirements for medical assistance. A state must process an application submitted by, or on behalf of, an incarcerated juvenile, notwithstanding that the juvenile is an inmate.

MEDICARE PART B:

18. **H.R. 3331, to amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology.** The bill was introduced by Rep. Lynn Jenkins (R-KS).

19. **H.R. ____, Incentivizing Non-Opioid Drugs.** This discussion draft will create a temporary pass through payment to encourage the development of non-opioid drugs for post-surgical pain management in Medicare.

20. **H.R. ____, CMS Action Plan.** This discussion draft will establish an Action Plan, including studies, reports to Congress, and meetings with stakeholders, for the purpose of addressing the opioid crisis.

21. **H.R. ____, Use of Telehealth to Treat Opioid Use Disorder.** This discussion draft will instruct CMS to evaluate the utilization of telehealth services in treating opioid use disorder.

22. **H.R. ____, Alternative Payment Model for Treating Substance Use Disorder.** This discussion draft will create a demonstration project for an Alternative Payment Model for treating substance use disorder. This model includes the development of measures to evaluate the quality and outcomes of treatment.

23. **H.R. ____, Initial Pain Assessment.** This discussion draft will add a pain assessment as part of the Welcome to Medicare initial examination, and provide intervention about non-opioid alternatives, as appropriate.

24. **H.R. ____, Adding Resources on Non-Opioid Alternatives to the Medicare Handbook.** This discussion draft will direct CMS to compile education resources for beneficiaries regarding opioid use, pain management, and alternative pain management treatments, and include these resources in the "Medicare and You" handbook.

25. **H.R. ____, Post-Surgical Injections as an Opioid Alternative.** This discussion draft will seek to incentivize post-surgical injections as a pain treatment alternative to opioids by reversing a reimbursement cut for these treatments.

MEDICARE PART D:

26. **H.R. 3528, Every Prescription Conveyed Securely Act,** by Reps. Katherine Clark (D-MA) and Markwayne Mullin (R-OK). The bill will require e-prescribing, with

exceptions, for coverage of prescribed controlled substances under the Medicare Part D program.

27. **H.R. ____, Mandatory Lock-In.** This discussion draft will build off of work done in the Comprehensive Addiction Recovery Act (CARA), and will require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries.

28. **H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act.** The bill was introduced by Rep. David Schweikert (R-AZ) and seeks to standardize electronic prior authorization for prescription drugs under Medicare Part D.

29. **H.R. ____, Beneficiary Education.** This discussion draft will require prescription drug plans under Medicare Part D to include information on the adverse effects of opioid overutilization and coverage of non-pharmacological therapies and non-opioid medications or devices used to treat pain.

30. **H.R. ____, Evaluating Abuse Deterrent Formulations.** This discussion draft will direct CMS to evaluate the use of abuse-deterrent opioids in Medicare plans.

31. **H.R. ____, Prescriber Notification.** This discussion draft will require CMS to establish a prescriber threshold based on specialty and geographic area, which could designate a prescriber as an outlier opioid prescriber. CMS would then be responsible for notifying prescribers identified as outliers of their status.

32. **H.R. ____, Prescriber Education.** This discussion draft will direct CMS to work with Quality Improvement Organizations to engage in outreach with prescribers identified as clinical outliers to share best practices.

33. **H.R. ____, Medication Therapy Management (MTM) Expansion.** This discussion draft will add beneficiaries at-risk for prescription drug abuse to the list of targeted beneficiaries to be eligible for MTM under Part D.

34. **H.R. ____, CMS/Plan Sharing.** This discussion draft will help facilitate communication between MA organizations, Part D plan sponsors, and CMS relating to substantiated fraud, waste, and abuse investigations.

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Paul Edattel, Josh Trent, James Paluskiewicz, Caleb Graff, Jay Gulshen, or Caprice Knapp of the Committee staff at (202) 225-2927.