STATEMENT OF

PATRICK CONWAY, M.D., MSc

ACTING PRINCIPAL DEPUTY ADMINISTRATOR,

DEPUTY ADMINISTRATOR FOR INNOVATION AND QUALITY, AND

CHIEF MEDICAL OFFICER,

CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

"WHAT IS THE FEDERAL GOVERNMENT DOING TO COMBAT THE OPIOID ABUSE EPIDEMIC?"

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Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS) work to ensure that all Medicare and Medicaid beneficiaries are receiving the medicines they need while also reducing and preventing prescription drug abuse.

Prescription drugs, especially opioid analgesics—a class of prescription drugs used to treat both acute and chronic pain such as hydrocodone, oxycodone, codeine, morphine, and methadone, have increasingly been implicated in drug overdose deaths over the last decade. Deaths related to heroin have also sharply increased since 2010, with a 39 percent increase between 2012 and 2013. Among drug overdose deaths in 2013, approximately 37 percent involved prescription opioids.[1] In 2013 drug overdose was the leading cause of injury death[2] and caused more deaths than motor vehicle crashes among individuals 25-64 years old.[3] The monetary costs and associated collateral impact to society due to Substance Use Disorder (SUD) are high. In 2009, health insurance payers spent $24 billion for treating SUDs, of which Medicaid accounted for 21 percent of spending.[4] The Medicare program, through Part D, spent $2.7 billion on opioids overall in 2011, of which $1.9 billion (69 percent) was accounted for by opioid users with spending in the top five percent.[5]

[1] Centers for Disease Control and Prevention. Drug Overdose in the United States: Fact Sheet, Home and Recreational Safety, accessed on October 28, 2013 from http://www.cdc.gov/drugoverdose/index.html
[2] Injury deaths are those caused by acute exposure to physical agents, e.g., mechanical force or energy, heat, electricity, chemicals, and ionizing radiation, in amounts or at rates that exceed the threshold of human tolerance, http://www.cdc.gov/nchs/data/nvsr/nvsr54/nvsr54_10.pdf
[3] Centers for Disease Control and Prevention. Drug Overdose in the United States: Fact Sheet, Home and Recreational Safety, accessed on October 28, 2013, http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html
[4] Centers for Disease Control and Prevention. Drug Overdose in the United States: Fact Sheet, Home and Recreational Safety, accessed on October 28, 2013 from http://www.cdc.gov/drugoverdose/index.html
[5] Suzuki, Shinobu. Potentially Inappropriate Opioid Use in Mediare Part D. MEDPAC. October 9, 2014. http://www.medpac.gov/documents/october-2014-meeting-presentation-potentially-inappropriate-opioid-use-in-medicare-part-d-.pdf?sfvrsn=0

CMS has a responsibility to protect the health of Medicare and Medicaid beneficiaries, by putting appropriate safeguards in place to help prevent overuse and abuse of opioids, while ensuring that beneficiaries can access needed medications and appropriate treatments for SUD.

Preventing Overprescribing and Abuse of Opioids in Medicare Part D

Since its inception in 2006, the Medicare Part D prescription drug benefit program has made medicines more available and affordable for over 55 million Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes, and more beneficiary satisfaction with their Medicare coverage.

Despite these successes, Part D is not immune from the nationwide epidemic of opioid abuse. Based on input from the Department of Health and Human Services' Office of the Inspector General (HHS OIG), the Government Accountability Office (GAO), and stakeholders, over the past several years, CMS has broadened its initial focus of strengthening beneficiary access to prescribed drugs to also address fraud and drug abuse by making sure Part D sponsors implement effective safeguards and provide coverage for drug therapies that meet safety and efficacy standards. The structure of the program, in which Part D plan sponsors do not have access to Part D prescriber and pharmacy data beyond the transactions they manage for their own enrollees, makes it more difficult to identify prescribers or pharmacies that are outliers in their prescribing or dispensing patterns relative to the entire Part D program. CMS is aware of potential fraud at the prescriber and pharmacy levels through "pill mill" schemes. This is a term used by local and state investigators to describe a physician, clinic, or pharmacy that is prescribing or dispensing opioids for non-medical and inappropriate purposes. We believe that broader reforms that result in better-coordinated care will help address several issues with the complex health care delivery system, including abuse of prescription drugs. CMS has, however, taken several steps to protect beneficiaries from the harm and damaging effects associated with prescription drug abuse and to prevent and detect fraud related to prescription drugs.

A centerpiece of our strategy to reduce the inappropriate use of opioid analgesics in Part D is the adoption of a policy and guidance by CMS by which Part D sponsors identify Part D enrollees who have potential opioid or acetaminophen overutilization that may present a serious threat to patient safety. Acetaminophen is included in this strategy because it is manufactured in

combination with many opioids, and unlike opioids has an FDA-approved maximum daily dose. Overutilization of opioids or acetaminophen products can result in serious adverse events including death. To strengthen CMS's monitoring of Part D plan sponsors' drug utilization management programs to prevent overutilization of these medications, the Medicare Part D Overutilization Monitoring System (OMS) was implemented in 2013. Through this system, CMS provides quarterly reports to sponsors on beneficiaries with potential opioid or acetaminophen overutilization identified through analyses of Prescription Drug Event (PDE) data and through beneficiaries referred by the CMS Center for Program Integrity (CPI). Sponsors are expected to utilize various drug utilization monitoring (DUM) tools, including: formulary-level controls at point of sale (such as safety edits and quantity limits); a review of previous claim and clinical activity to identify at-risk beneficiaries, case management outreach to beneficiaries' prescribers and pharmacies, and beneficiary-level point of sale claim edits, if necessary to prevent continued overutilization of opioids. Lastly, sponsors that have concluded such point of sale edits are appropriate are expected to share information with a new sponsor when the beneficiary moves to another plan in accordance with applicable law.

We believe this Part D overutilization policy has played a key role in reducing opioid and acetaminophen overutilization in the program. A comparison of overutilization shows a significant reduction of opioid and acetaminophen overutilization in Part D since the overutilization policy went into effect. From 2011 through 2014, the number of potential opioid overutilizers, based on the CMS definition in the OMS, decreased by approximately by approximately 26 percent, or 7,500 beneficiaries[6]. In addition, from 2011 through 2014, the number of beneficiaries identified as potential acetaminophen overutilizers, based on the CMS definition in the OMS, decreased by more than 91 percent, or 70,000 beneficiaries.[7]

CMS also contracts with the Medicare Drug Integrity Contractor (MEDIC), which is charged with identifying and investigating potential fraud and abuse, and developing cases for referral to law enforcement agencies. In September 2013, CMS directed the MEDIC to increase its focus on proactive data analysis in Part D. As a result, the MEDIC identified vulnerabilities and then

[6] There were 29,404 potential opioid overutilizers, (or 0.29% of all Part D opioid users) in 2011 and there were 21,838 potential opioid overutilizers, (0.18% of all Part D Opioid users) in 2014

[7] There were 76,581 potential acetaminophen overutilizers, (or 0.81% of all Part D acetaminophen users), in 2011 and in 2014 there were 6,286 (0.06% of all Part D acetaminophen users) in 2014

performed analyses that resulted in notification to plan sponsors to remove records associated with inaccurate data leading to improper payments made in FYs 2011 and 2012. This increased focus on proactive analysis resulted in savings of $4.8 million from decreased provider payments, $21 million for unallowable charges for medications during a hospice stay, and $80 million for Transmucosal Immediate Release Fentanyl drugs without a medically-acceptable indication.

CMS has new tools to take action against problematic prescribers and pharmacies. CMS issued a Final Rule on May 23, 2014, that both requires prescribers of Part D drugs to enroll in Medicare or have a valid opt-out affidavit on file and establishes a new revocation authority for abusive prescribing patterns. Additionally, CMS may now also revoke a prescriber's Medicare enrollment if his or her Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked, or the applicable licensing or administrative body for any State in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs.

Last year, CMS finalized a rule[8] that includes a provision to give CMS, its antifraud contractors, and the Government Accountability Office (GAO) the ability to request and collect information directly from pharmacy benefit managers, pharmacies and other entities that contract or subcontract with Part D Sponsors to administer the Medicare prescription drug benefit. The provision streamlines CMS' and its anti-fraud contractors' investigative processes. Previously, it took a long time for CMS' contractors who were often assisting law enforcement to obtain important documents like invoices and prescriptions directly from pharmacies, because they worked through the Part D plan sponsor to obtain this information. This provision provides more timely access to records, including for investigations of Part D fraud and abuse, and responds to recommendations from the Department of Health and Human Services (HHS) Office of Inspector General.

[8] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, https://www.federalregister.gov/articles/2014/05/23/2014-11734/medicare-program-contract-year-2015-policy-and-technical-changes-to-the-medicare-advantage-and-the

In addition to these initiatives, the FY 2016 President's Budget[9] includes several proposals that would provide CMS with additional tools to prevent inappropriate use of opioids. One proposal to prevent prescription drug abuse in Medicare Part D would give the Secretary of Health and Human Services (HHS) the authority to establish a program that would require that high-risk Medicare beneficiaries only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions, similar to many State Medicaid programs. The Medicare program would be required to ensure that beneficiaries retain reasonable access to services of adequate quality. Currently, CMS requires Part D sponsors to conduct drug utilization reviews, which assess the prescriptions filled by a particular enrollee. These efforts can identify overutilization that results from inappropriate or even illegal activity by an enrollee, prescriber, or pharmacy. However, CMS' statutory authority to take preventive measures in response to this information is limited.

The FY 2016 President's Budget also proposes to provide the Secretary with new authorities to: (1) suspend coverage and payment for drugs prescribed by providers who have been engaged in misprescribing or overprescribing drugs with abuse potential; (2) suspend coverage and payment for Part D drugs when those prescriptions present an imminent risk to patients; and (3) require additional information on certain Part D prescriptions, such as diagnosis and incident codes, as a condition of coverage. While Part D sponsors have the authority to deny coverage for a prescription drug on the basis of lack of medical necessity, there are currently no objective criteria to inform the medical necessity determination, such as maximum daily dosages, for some controlled substances, especially opioids. Therefore, the only basis for establishing medical necessity in these cases is prescriber attestation. If the integrity of the prescriber is compromised, the finding of medical necessity is compromised as well. If the Secretary had clear authority to intervene in these patterns suggestive of abusive prescribing or harmful medical care, the incidence of coverage and payment of such questionable prescribing could be reduced in Medicare.

Preventing Overprescribing and Abuse of Opioids in Medicaid

[9] Fiscal Year 2016 Budget in Brief, http://www.hhs.gov/budget/fy2016-hhs-budget-in-brief/hhs-fy2016budget-in-brief-overview.html

Many State Medicaid Agencies have started using a variety of approaches to prevent prescription drug abuse. These efforts include expanding the Medicaid benefit to include behavioral health services for those with an addiction to prescription drugs, and provider enrollment and monitoring to ensure providers are appropriately evaluated upon initial enrollment and reevaluated in years following. States are also using pharmacy management review and restriction programs which confine patients with high-utilization of prescription pain medication to a single provider and pharmacy.

The FY 2016 President's Budget proposes requiring states to track high prescribers and utilizers of prescription drugs in Medicaid. States are currently authorized to implement prescription drug monitoring activities, but not all states have adopted such activities. Under this proposal, states would be required 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 could choose one or more drug classes and would need to develop or review and update their care plan to reduce utilization and remediate preventable episodes to improve Medicaid integrity and beneficiary quality of care.

Partnering with States to Improve Access to Care

In addition to efforts to prevent opioid abuse, CMS is committed to meeting the needs for Medicare and Medicaid beneficiaries seeking treatment for addiction. Although CMS does not determine what services are provided in each State Medicaid program to prevent and treat opioid abuse, CMS is encouraged by the increased efforts by States to develop effective strategies for designing benefits for this population. Many States have included behavioral health services for individuals with substance use disorders (SUDs) in their State Plans and various Medicaid managed-care organizations (MCOs) or in Waiver programs. CMS recently released a Notice of Proposed Rule Making regarding the application of the Mental Health Parity and Addiction Equity Act to the Medicaid and Children's Health Insurance Program.[10] The NPRM seeks to

[10] Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans, https://www.federalregister.gov/articles/2015/04/10/2015-08135/medicaid-and-childrens-health-insurance-programs-mental-health-parity-and-addiction-equity-act-of

make sure that MCOs' and states' benefit limitations on mental health and substance use disorder benefits are no more restrictive than those on medical/surgical benefits.

CMS also launched the Medicaid Innovation Accelerator Program (IAP) in July 2014 with the goal of improving health and health care for Medicaid beneficiaries by supporting states' efforts to accelerate new payment and service delivery reforms. The IAP will enhance CMS's wide ranging efforts to improve care by supporting system-wide payment and delivery system reform innovation. Through the IAP, states receive technical assistance and other types of technical support designed to accelerate the development and testing of Substance Use Disorder (SUD) service delivery innovations including efforts to curb prescription drug abuse. Strategies being pursued include:

- Payment and health care delivery models: Identify successful service delivery models, benefit strategies, and payment methodologies to promote improved care and better coordination between individuals with SUDs and health care systems;
- Data analytics: Support states in using data to better understand the needs of the Medicaid populations that have a SUD or that are at-risk of developing a SUD;
- Quality measurement: Collect and test metrics that support states in more accurately measuring improvements in health outcomes for individuals with SUDs;
- Rapid-cycle learning: Assist states in understanding how to integrate elements of rapid-cycle learning as part of their SUD-related projects; and
- State to state learning: Lesson sharing interventions used by other states.

States can get involved in the IAP SUD work in three different ways:

- The High-Intensity Learning Collaborative (HILC) is a year-long technical assistance initiative designed to support a small number of States in developing the necessary policy and infrastructure changes to improve care and outcomes for individuals with SUDs.
- Targeted Learning Opportunities (TLO) is a web-based learning series designed to support States in developing strategies for improving their SUD systems.
- National Dissemination provides access to materials including webinars, lessons learned, and other resources developed for the HILC and TLO that have been adapted for distribution.

To date, over 35 states have participated in Targeted Learning Opportunities (TLO) learning sessions. Seven states comprise the year-long High Intensity Learning Collaborative (HILC)[11]. HILC states are actively working with CMS and experts to conduct data analytics, track quality measures, improve SUD benefits and service delivery, and explore value-based payment models as part of an overall effort to improve care and outcomes for individuals with SUDs. Several of these states, including Kentucky, Pennsylvania, Louisiana, and Michigan, are especially focused on reducing opioid dependence through their work in IAP.

As part of this initiative, CMS, in coordination with CDC, SAMSHA, and NIH, issued an informational bulletin on Medication Assisted Treatment (MAT) for Substance Use Disorders in the Medicaid program.[12] This informational bulletin provides background information about MAT, examples of state-based initiatives, and useful resources for states to help ensure proper delivery of these services.

To improve outcomes, the three medications that have received FDA-approval for treating opioid use disorders, Methadone, Buprenorphine, and Naltrexone, are recommended to be combined with behavioral therapies. Research shows that when treating SUDs, a combination of medication and behavioral therapies is the most effective combination of treatment. Behavioral therapies help patients engage in the treatment process, modify their attitudes and behaviors related to drug and alcohol abuse, and increase healthy life skills. These treatments can also enhance the effectiveness of medications and help people stay in treatment longer. While State Medicaid programs are not required to include all drugs on their preferred drug lists, we encourage states to understand the value of MAT and improving access to substance use disorder treatment medicines.

State Medicaid programs have used a variety of innovative approaches to treat beneficiaries with SUD. For example, last year, Vermont received approval to implement a Medicaid health home program that provides specialized treatment and recovery services to beneficiaries with SUDs. States may also utilize processes to help manage the prescribing of addiction medications and delivery of evidence-based behavioral therapies, including prior authorization, documentation of

[11] States participating in HILC are Kentucky, Louisiana, Michigan, Minnesota, Pennsylvania, Texas and Washington.
[12] CMCS Informational Bulletin, "Medication Assisted Treatment for Substance Use Disorders", July 11, 2015, http://medicaid.gov/federal-policy-guidance/downloads/cib-07-11-2014.pdf

behavioral therapy, and quality or duration limits. States should ensure that these strategies are consistent with the Mental Health Parity and Addiction Equity Act, when appropriate.

In January, CMS released an additional informational bulletin[13] on behavioral health services available to youth with SUDs, including opioid use disorders. This bulletin is intended to assist States to design a benefit that will meet the needs of youth with SUDs and their families and helps States comply with Medicaid requirements. These services include: screenings and assessments to identify, address and create care plans as early as possible; outpatient treatments such as individual and group counseling to assist a beneficiary in achieving specific objectives of treatment or care; medication-assisted treatment to prevent, stabilize or ameliorate symptoms arising from treatment; recovery services and supports, such as peer-to-peer mentoring, to educate and support a patient to successfully make behavioral changes necessary to recover; and residential treatment programs that offer a planned and structured regimen of care in a residential setting.[14]

Conclusion

CMS is dedicated to providing the best possible care to beneficiaries while also ensuring taxpayer dollars are spent on medically appropriate care. CMS has broadened its focus from ensuring beneficiaries have access to prescribed drugs to ensuring that Part D sponsors and State Medicaid programs implement effective safeguards and provide coverage for drug therapies that meet standards for safety and efficacy. Although there is still work that needs to be done, CMS is confident that our initiatives will help to reduce the rate of opioid addiction and overdoses in both Medicare and Medicaid.

[13] CMCS Informational Bulletin, "Coverage of Behavioral Health Services for Youth with Substance Abuse", January 26, 2015, http://medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf
[14] CMCS Informational Bulletin, "Coverage of Behavioral Health Services for Youth with Substance Abuse", January 26, 2015, http://medicaid.gov/federal-policy-guidance/downloads/cib-01-26-2015.pdf