

STATEMENT OF

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ON

OPIOID USE AMONG SENIORS – ISSUES AND EMERGING TRENDS

BEFORE THE

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Statement of Sean Cavanaugh
on “Opioid Use Among Seniors – Issues and Emerging Trends”
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Chairman Collins, Ranking Member McCaskill, and members of the Committee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services’ (CMS’s) work to ensure that all Medicare beneficiaries are receiving the medicines they need while also reducing and preventing non-medical prescription drug use.

As you know, nonmedical opioid use is taking a real toll on communities, families, and individuals across the Nation. Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury or death in the United States. Prescription drugs, especially opioid analgesics—a class of prescription drugs that includes hydrocodone, oxycodone, and morphine used to treat both acute and chronic pain—have been increasingly implicated in drug overdose deaths over the last decade. From 2000 to 2014, the rate of overdose deaths involving opioids increased by 200 percent.¹ The monetary costs and associated collateral impact to society due to substance use disorder (SUD), including opioid use disorder, are substantial.

Combating non-medical prescription opioid use, dependence, and overdose continues to be a priority for Department of Health and Human Services (HHS) Secretary Burwell and the Administration as a whole. As part of that commitment, the Administration launched an evidence-based opioid initiative that focuses on three targeted areas: informing opioid prescribing practices, increasing the use of naloxone (a drug that reverses the deadly respiratory effects of opioid drug overdose), and expanding access to medication-assisted treatment to treat opioid use disorder. CMS’s actions under the Initiative reflect our responsibility to protect the health of Medicare beneficiaries by putting appropriate safeguards in place to help prevent non-

¹ Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report*, (Jan. 1, 2016) <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>

medical use 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 Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes, and more beneficiary satisfaction with their Medicare coverage.²

While many beneficiaries and prescribers utilize opioids in ways that are medically appropriate, Part D is not immune from opioid overutilization. In 2011, the Medicare Part D program spent \$2.7 billion on prescription opioids overall, of which \$1.9 billion (69 percent) was accounted for by prescription opioid users with spending in the top five percent; overall, almost 30 percent of Part D enrollees utilized prescription opioids in 2015.³ Based on input from the HHS Office of the Inspector General (OIG), the Government Accountability Office (GAO), and stakeholders, over the past several years, CMS has broadened from the initial focus of strengthening beneficiary access to prescribed drugs to also address prescription drug misuse, overuse, and fraud. CMS is aware of potential fraud at the prescriber and pharmacy levels through “pill mill” schemes. This is a term used by law enforcement to describe a physician, clinic, or pharmacy that is prescribing or dispensing prescription opioids for non-medical purposes, and where the prescription opioids are often diverted for sale on the illicit market. 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 has taken several steps to protect beneficiaries from the harm associated with non-medical prescription drug use, to prevent and detect fraud related to prescription drugs, and to reduce inappropriate use through better coordinated care. We

² In 2013, more than one million distinct health care providers collectively prescribed \$103 billion in prescription drugs under the Part D program. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html>

³ Suzuki, Shinobu. Potentially Inappropriate Opioid Use in Medicare 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>

believe, however, that broader reforms resulting in better-coordinated care will help address some of these issues related to the complexity and difficulty of communicating within the health care delivery system, including non-medical use of prescription drugs.

Initiatives to Strengthen Medicare Part D and Reduce Prescription Opioid Overutilization

A centerpiece of our strategy to reduce the inappropriate use of opioid analgesics in Part D is the adoption of an opioid overutilization policy in 2013. Under this policy, Medicare Part D plan sponsors implement enhanced drug utilization review of prescription opioids to deter overutilization while maintaining coverage for appropriate drug therapies that are deemed medically necessary and meet safety and efficacy standards. Specifically, under this policy, sponsors are expected to use various drug utilization management (DUM) tools if necessary to prevent continued overutilization of prescription opioids, including: improved formulary-level controls at the point of sale (such as safety edits and quantity limits), a retrospective review of beneficiaries' claim history and clinical activity to identify at-risk beneficiaries, case management outreach to at-risk beneficiaries' prescribers and pharmacies, and beneficiary-level point of sale claim edits (such as restricting the prescription opioids and quantities that a sponsor will cover for a specific beneficiary).

To strengthen CMS's monitoring of Part D plan sponsors' compliance with the prescription opioid overutilization policy, the Medicare Part D Overutilization Monitoring System (OMS) was implemented in 2013. Through this system, CMS provides quarterly reports to sponsors on high-risk beneficiaries with potential prescription opioid overutilization identified through analyses of Prescription Drug Event (PDE) data and on beneficiaries referred by the CMS Center for Program Integrity (CPI). Sponsors provide CMS with the outcome of their review of each case. Sponsors that have concluded that a beneficiary-level point of sale edit is appropriate to reduce prescription opioid overutilization are expected to share this information with a new sponsor when the beneficiary moves to another plan, in accordance with applicable law. To support additional monitoring by the new sponsor, the CMS Medicare Advantage and Prescription Drug System (MARx) was enhanced to automate this process.

We believe this Part D overutilization policy has played a key role in reducing prescription opioid overutilization in the program. From 2011 through 2015, the number of potential

prescription opioid overutilizers identified within the OMS decreased by approximately 47 percent, or 13,753 beneficiaries.⁴

CMS also has a new tool to take action against problematic prescribers. CMS is requiring prescribers of Part D drugs to enroll in Medicare or have a valid opt-out affidavit on file and is establishing a new revocation authority for abusive prescribing patterns⁵. In 2015, CMS enrolled approximately 75,000 prescribers of Part D drugs. CMS is continuing to actively work to enroll the remaining prescribers and will enforce the requirement that plans deny Part D claims – for opioids or any other drugs – that are written by prescribers who do not meet the necessary requirements. These prescribers are subject to the same risk-based screening requirements that have already contributed to the removal of more than 700,000 provider and supplier enrollments from the Medicare program since the enactment of the Affordable Care Act. Requiring prescribers to enroll in Medicare helps CMS make sure that Part D drugs are prescribed by qualified individuals, and prevents prescriptions ordered by excluded or revoked prescribers from being filled. Currently CMS is monitoring Part D claims data to identify provider types with a disproportionate number of unenrolled prescribers, such as dentists, and focusing our outreach strategy to target them. As we move forward with implementation, CMS and Part D sponsors are conducting targeted outreach to individual high volume prescribers that remain unenrolled. Upon enforcement of the enrollment requirement, CMS will require Part D plans to use point of sale edits to deny payment for prescriptions from unenrolled prescribers after the affected beneficiaries receive a three month provisional supply and written notice from their plans.

Additionally, CMS has established its authority⁶ to remove physicians or eligible professionals from Medicare when they demonstrate abusive prescribing patterns or practices related to Part D drugs. A revocation for abusive prescribing is based on criteria that demonstrate a pattern or practice of improper prescribing, specifically whether the pattern or practice is abusive or represents a threat to patient safety and whether the pattern or practice of prescribing is not in compliance with Medicare requirements. CMS may also revoke a physician or eligible

⁴ There were 29,404 potential opioid overutilizers, (or 0.29% of all Part D opioid users) in 2011 and there were 15,651 potential opioid overutilizers, (0.13% of all Part D Opioid users) in 2015.

⁵ <https://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf>

⁶ <https://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf>

professional's Medicare billing privileges 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 suspends or revokes the physician or eligible professional's ability to prescribe drugs. These new revocation authorities provide CMS with the ability to remove problematic prescribers from the Medicare program and prevent them from treating people with Medicare.

CMS also released an interactive online mapping tool⁷ that shows geographic comparisons at the state, county, and ZIP code levels of de-identified Medicare Part D opioid prescription claims within the United States. This new mapping tool allows the user to see both the number and percentage of prescription opioid claims at the local level and better understand how this critical issue impacts communities nationwide. The data used in this mapping tool are from 2013 Medicare Part D prescription drug claims and do not contain beneficiary information. The data set, which is privacy-protected, contains information from over one million distinct providers who collectively prescribed approximately \$103 billion in prescription drugs and supplies paid under the Part D program. The data characterize the individual prescribing patterns of health providers that participate in Medicare Part D for over 3,000 distinct drug products. Of the 1.4 billion total Part D claims in 2013, there were approximately 80.7 million prescription opioid claims for 116 distinct prescription opioid products contributing to \$3.7 billion of the total Part D prescription drug costs.⁸ By openly sharing data in a secure, broad, and interactive way, CMS is supporting a better understanding of regional provider prescribing behavior variability and is adding insight to local health care delivery. We believe that this level of transparency will inform community awareness among providers and local public health officials.

Proposals to Further Fight Prescription Opioid Overutilization in Medicare Part D

In addition to these initiatives, the FY 2017 President's Budget⁹ includes several proposals that would provide CMS with additional tools to curb inappropriate use of prescription opioids. One proposal to prevent prescription drug abuse in Medicare Part D would give the HHS Secretary

⁷ CMS, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html>

⁸ CMS, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-11-03.html>

⁹ Fiscal Year 2017 Budget in Brief, <http://www.hhs.gov/about/budget/fy2017/budget-in-brief/index.html>

authority to establish a program in Medicare Part D that would require that high-risk Medicare beneficiaries only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions, similar to requirements many states have implemented in Medicaid. The Medicare program would be required to ensure that Medicare beneficiaries retain reasonable access to Medicare services of adequate quality, and, in addition, the restricted period for a given beneficiary could only last for “a reasonable period of time.” This proposal is part of a coordinated set of Administration proposals to address prescription drug abuse. While our current efforts can identify overutilization that results from inappropriate or even illegal activity by an enrollee, prescriber, or pharmacy, CMS’s statutory authorities are limited.

In addition to CMS’s existing authority, the FY 2017 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. Although 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 prescription 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 irresponsible prescribing or harmful medical care, coverage and payment of this questionable prescribing could be avoided in Medicare, saving resources while protecting beneficiaries from harm.

Data Analysis Conducted by the Medicare Drug Integrity Contractor (MEDIC)

CMS also contracts with the National Benefit Integrity (NBI) MEDIC, which is charged with identifying and investigating potential fraud, waste, and abuse in the Part C and Part D programs on a national level, 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,

including producing, at a minimum, quarterly reports to plan sponsors on specific data projects, such as high risk pharmacy assessments.¹⁰

These assessments contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with information to initiate new investigations, conduct audits, and ultimately terminate pharmacies from their network. For example, Part D plan sponsors have taken actions such as terminations and audits on pharmacies as a result of the December 2015 Pharmacy Risk Assessment. The NBI MEDIC also conducts data analysis and other work to support ongoing law enforcement activities. Examples of the assistance that the NBI MEDIC provides includes: data analysis, impact calculations, clinical review of claims and medical records, and prescription drug invoice reconciliation reviews.

Access to Treatment

Despite efforts such as those outlined above, opioid addiction continues to be a significant public health concern. In October 2015, the President issued a Memorandum directing Federal Departments and Agencies to identify barriers to medication-assisted treatment (MAT) for opioid use disorders and develop action plans to address these barriers. In response, CMS will use available vehicles to inform physicians, Medicare Advantage (MA) organizations, and Part D sponsors about MAT coverage, including clarifying that MA plans have the same obligation to cover addiction treatment as is available under Original Medicare and that Part D plans must ensure access to MAT that are covered under Medicare Part D.

It is critical that Medicare beneficiaries who are in need of these therapies have appropriate access to these drugs in Part D. CMS has informed Part D sponsors that Part D formulary and plan benefit designs that hinder access to MAT, either through overly restrictive utilization management strategies or high cost-sharing, will not be approved.

Conclusion

¹⁰ CMS uses multiple indicators in our high risk pharmacy assessment, including factors such as average number of prescriptions per beneficiary, average number of prescriptions per prescriber ID, percentage of prescriptions that were for Schedule II drugs, and average amount paid per prescriber ID.

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 implement effective safeguards and provide coverage for medically necessary drug therapies that meet standards for safety and efficacy and to continue to ensure that beneficiaries have access to needed treatment. Although there is still work that needs to be done, CMS is confident that our initiatives will maintain beneficiary access to appropriate medications for pain control while decreasing inappropriate opioid prescribing patterns and reducing the rate of opioid use disorders, overdoses.