

STATEMENT OF

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ON

EXAMINING HEROIN AND OPIATE ABUSE IN SOUTHWESTERN PENNSYLVANIA

**BEFORE THE
U.S. SENATE COMMITTEE ON FINANCE,
SUBCOMMITTEE ON HEALTH**

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on “Examining Heroin and Opiate Abuse in Southwestern Pennsylvania”
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Chairman Toomey 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 non-medical prescription drug use.

Opioid addiction is taking a real toll on communities, families and individuals both here in Pennsylvania and across the Nation. Deaths from drug overdose have risen steadily over the past two decades and have become the leading cause of injury death in the United States. Prescription drugs, especially opioid analgesics—a class of prescription drugs such as hydrocodone, oxycodone, and morphine used to treat both acute and chronic pain—have increasingly been implicated in drug overdose deaths over the last decade. From 1999 to 2013, the rate for drug poisoning deaths involving opioid analgesics nearly quadrupled. Deaths related to heroin also have increased sharply since 2010, with a 39-percent increase between 2012 and 2013.¹ It is estimated that 12 percent of all Medicaid beneficiaries ages 18-64 and 15 percent of uninsured individuals who could be eligible for Medicaid coverage have a substance use disorder. Given these alarming trends, it is time for a smart and sustainable response to prevent non-medical prescription opioid use and overdose and to treat people with opioid use disorder. The monetary costs and associated collateral impact to society due to Substance Use Disorder (SUD), including opioid use disorder, are high. In 2009, health insurance payers spent \$24 billion for treating SUDs, of which Medicaid accounted for 21 percent of spending.² 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.³

¹ National Center for Health Statistics/Centers for Disease Control and Prevention, *National Vital Statistics Report*, Final death data for each calendar year (Oct 2014).

² 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>

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>

Combating non-medical prescription opioid use, dependence, and overdose is a priority for Department of Health and Human Services (HHS) Secretary Burwell and the Administration at large. As part of that commitment, the Secretary 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 the use of medication-assisted treatment to treat opioid use disorder. As part of our role in these efforts across HHS, CMS released guidance⁴ to help states implement comprehensive, evidence-based service delivery approaches to substance use disorder treatment. CMS is establishing a new Medicaid demonstration opportunity for states seeking to undertake significant improvements in the delivery of care to individuals with substance use disorder.

Moving forward, CMS has a responsibility to protect the health of Medicare and Medicaid beneficiaries, here in Pennsylvania and across the Nation, by putting appropriate safeguards in place to help prevent non-medical use 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 Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes, and more beneficiary satisfaction with their Medicare coverage.⁵

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 from the initial focus of strengthening beneficiary access to prescribed drugs to also address prescription drug abuse and fraud. CMS is aware of potential fraud at the prescriber and pharmacy levels through "pill mill" schemes. This

⁴ State Medicaid Director Letter "New Service Delivery Opportunities for Individuals with a Substance Use Disorder" <http://www.medicaid.gov/federal-policy-guidance/downloads/SMD15003.pdf>

⁵ In 2013, more than one million distinct health care providers collectively prescribed \$103 billion in prescription drugs under the Part D program. In all, Part D spent \$3.9 billion on prescription opioids in the 2013. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html>

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. 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. We believe that broader reforms that result in better-coordinated care will help address several issues with the complex health care delivery system, including non-medical use of prescription drugs. CMS has, however, taken several steps to protect beneficiaries from the harm and damaging effects associated with non-medical prescription drug use and to prevent and detect fraud related to prescription drugs.

Initiatives to Strengthen Medicare Part D and Reduce Opioid Overutilization

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 which CMS encourages case management of Part D enrollees who have potential opioid overutilization that may present a serious threat to patient safety. To strengthen CMS' monitoring of Part D plan sponsors and to prevent overutilization of these medications, the Medicare Part D Overutilization Monitoring System (OMS) was implemented in 2013. The OMS requires Part D sponsors to implement effective safeguards to deter overutilization while maintaining a commitment to provide coverage for appropriate drug therapies that meet safety and efficacy standards. Through this system, CMS provides quarterly reports to sponsors on beneficiaries with potential opioid 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. To support additional monitoring by the new sponsor, the CMS

Medicare Advantage and Prescription Drug System (MARx) notifies a sponsor when a beneficiary targeted for an opioid point of sale edit changes plans.

We believe this Part D overutilization policy has played a key role in reducing opioid overutilization in the program. From 2011 through 2014, the number of potential opioid overutilizers, based on the CMS definition in the OMS,⁶ decreased by approximately 26 percent, or 7,500 beneficiaries.⁷

CMS has new tools to take action against problematic prescribers. 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. CMS is actively working to enroll over 400,000 prescribers of Part D drugs by January 2016, and will enforce the requirement that plans deny Part D claims that are written by prescribers who do not meet the necessary requirements by June 2016. These prescribers will be subject to the same risk-based screening requirements that have already contributed to the removal of nearly 575,000 provider and supplier enrollments from the Medicare program since the enactment of the Affordable Care Act. Requiring prescribers to enroll in Medicare will help CMS make sure that Part D drugs are prescribed by qualified individuals, and will prevent prescriptions from excluded or already 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 approach the implementation date, CMS and Part D sponsors will begin to target 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 stop filling and paying for prescriptions from unenrolled prescribers after the affected beneficiaries have received a three month provisional supply and written notice from their plans.

Additionally, CMS has established its authority to remove physicians or eligible professionals from Medicare when they demonstrate abusive prescribing patterns. A revocation for abusive

⁶ OMS defines overutilization as the use of opioids with cumulative daily morphine equivalent dose (MED) exceeding 120mg for at least 90 consecutive days with more than three prescribers and more than three pharmacies contributing to their opioid claims.

⁷ 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

prescribing would be based on criteria that demonstrates a pattern of improper prescribing and would address situations where the prescribing was not in compliance with Medicare requirements or where there were patient safety issues involved. CMS may 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. 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.

Proposals to Further Fight Opioid Overutilization in Medicare Part D

In addition to these initiatives, the FY 2016 President's Budget⁸ 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 high-risk Medicare beneficiaries to only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions, similar to requirements in 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.

In addition to CMS' existing authority, 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

⁸ Fiscal Year 2016 Budget in Brief, <http://www.hhs.gov/budget/fy2016-hhs-budget-in-brief/hhs-fy2016budget-in-brief-overview.html>

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.

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

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, one Part D plan sponsor terminated 51 pharmacies from its network as a result of the March 2015 Pharmacy Risk Assessment. Another Part D plan sponsor opened investigations on 16 pharmacies as a result of the September 2014 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, data analysis, impact calculations, clinical review of claims and medical records, and prescription drug invoice reconciliation reviews.

Data to Identify Outlier Prescribers

CMS used prescription drug event (PDE) data to identify 1,525 prescribers as outliers of Schedule II controlled substances in the 95th percentile for the number of prescriptions and the number of 30-day equivalent prescriptions. Using this information, CMS developed reports that clearly identified the differences in prescribing patterns for the identified outliers. Similar to CMS's comparative billing report initiatives, the goal is to: (1) proactively educate providers

about aberrant prescribing practices; (2) act as a deterrent by making providers aware of the Government's monitoring of their prescribing practices; and (3) reduce inappropriate prescribing. CMS then sent these reports to half of the providers, alerting them about their status as outliers. CMS also shared the list of outlier prescribers with Part D plan sponsors in an effort to augment their current utilization management program. We are further developing this and other approaches, using a similar analysis related to prescribing of atypical antipsychotics.

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.