STATEMENT OF

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ON

THE OPIOID CRISIS:

THE CURRENT LANDSCAPE AND CMS ACTIONS TO PREVENT OPIOID MISUSE

BEFORE THE

U.S. HOUSE COMMITTEE ON WAYS & MEANS

SUBCOMMITTEE ON OVERSIGHT

January 17, 2018

Statement of Kimberly Brandt
on
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Chairman Jenkins, Ranking Member Lewis, and members of the Subcommittee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services's (CMS's) work addressing the misuse of opioids by some providers and beneficiaries in the Medicare program. The Administration is aggressively fighting the opioid epidemic on all fronts. We understand the magnitude and impact the opioid misuse epidemic has had on our communities and are committed to a comprehensive and multi-pronged strategy to combat this public health emergency.

The number of Americans who are struggling with a substance use disorder, and specifically addiction to opioids, is staggering. In 2016 alone, nearly 64,000 Americans died from drug overdoses, the majority (over 42,000) of them from opioids. This amounts to nearly 116 Americans dying of an opioid-related overdose each day. Opioid addiction is deeply affecting communities, families, and individuals across the nation.

For this reason, combating the opioid epidemic is a top priority for the Department of Health and Human Services (HHS) and the Administration as a whole. In April 2017, HHS component agencies developed targeted initiatives to respond to this crisis with a multi-pronged approach identified to improve prevention, access to treatment and recovery services. HHS outlined its five-point Opioid Strategy, which provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. The comprehensive, evidence-based Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;

- Target the availability and distribution of overdose-reversing drugs to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;

- Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves;

- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and

- Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

At the request of President Trump and consistent with the requirements of the Public Health Service Act, the HHS Secretary declared a nationwide public health emergency regarding the opioid crisis. The President also directed that executive agencies use all appropriate emergency authorities and other relevant authorities to respond to America's deadly opioid crisis.

CMS's actions under HHS's Opioid Strategy reflect its responsibility to protect the health of Medicare beneficiaries by putting in place appropriate safeguards to help prevent non-medical use of opioids, while ensuring that beneficiaries can access needed medications and appropriate treatments. CMS is focused on critical steps to help reverse the trends in the opioid epidemic. CMS's efforts to address this emergency have evolved to reflect the increasing severity of the crisis. CMS is committed to working closely with clinicians, health plans, pharmacy benefit managers and other providers to make sure that we are best using all the tools at our disposal to combat this public health crisis. For example, CMS has conducted listening summits with states, clinicians, pharmacy benefit managers, other providers and Medicare Part D plan sponsors that focused on best practices and statutory and regulatory reforms that would allow stakeholders to more aggressively monitor and take action against opioid misuse. CMS is working with the recommendations received from stakeholders to develop a comprehensive strategy on addiction

and opioid abuse within CMS programs. Additionally, through the Center for Medicare and Medicaid Innovation, CMS sought public input and suggestions on innovative payment system models that will help promote effective substance abuse treatment programs, including models focused on opioids and substance use disorder.[1]

Preventing Overprescribing and Misuse 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, health outcomes, and beneficiary satisfaction with their Medicare coverage.[2] Approximately 70 percent of Medicare beneficiaries have Medicare prescription drug coverage either from a Part D plan or a Medicare Advantage Plan offering Medicare prescription drug coverage. In 2015, Medicare Part D spending was $137 billion; U.S. retail prescription spending was about $325 billion. While most beneficiaries utilize, and clinicians prescribe, opioids in ways that are medically appropriate, opioid overutilization is nonetheless a significant challenge for the Medicare Part D program. CMS is utilizing the feedback and recommendations from the HHS Office of Inspector General (OIG)[3], the Government Accountability Office (GAO)[4], and stakeholders to combat prescription opioid misuse, overuse, and fraud.

Due to the structure of the Medicare Part D program, Medicare Advantage Organizations (MAOs) and Medicare Part D sponsors also have a primary role in detecting and preventing potential fraud, waste and abuse, including the misuse of opioids. CMS requires plan sponsors to have effective compliance measures that include measures to detect, correct, and prevent fraud, waste, and abuse. CMS also helps plans identify individuals potentially at risk for opioid abuse.

MAOs and Medicare Part D sponsors, working with prescribing clinicians, are well positioned to identify and employ best practices and the most appropriate care management interventions for

[1] https://innovation.cms.gov/Files/x/newdirection-rfi.pdf
[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] For example: https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf, https://oig.hhs.gov/oei/reports/oei-03-15-00180.asp
[4] For example: https://www.gao.gov/products/GAO-18-15

enrollees using high dosages of opioids. Medicare Part D plans are expected to use multiple tools including safety edits at the point of dispensing, better formulary management, and case management with beneficiaries' clinicians aimed at coordinated care. We also expect all Medicare Part D sponsors to focus on improving the coordination of care among beneficiaries that use high dosages of opioids, and Medicare Advantage (MA) plans with prescription drug coverage in particular can expand the care management they provide enrollees. CMS encourages Medicare Part D sponsors and members of their Pharmacy and Therapeutics (P&T) committees to keep abreast of current research, guidelines, and training materials related to the appropriate use of opioids and best practices for care management.

CMS has also significantly expanded its oversight of Medicare Part D plans to ensure that they are in compliance with requirements that protect beneficiaries and can help prevent and address opioid overutilization. CMS has a robust Medicare Part D opioid overutilization policy to provide specific guidance to plans on how to employ more effective drug utilization review programs to reduce overutilization of opioids and maintain access to needed medications among beneficiaries. CMS plans to require all Medicare Part D sponsors to submit a written strategy for addressing overutilization of prescription opioids, given the public health emergency, to CMS in Spring 2018.[5] This information will help CMS better understand the approaches sponsors are taking, from both their Medicare and commercial lines, and CMS intends to disseminate best practices. CMS has implemented multiple initiatives that work together to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion in the Medicare program. These strategies include a medication safety approach to improve care coordination for high risk beneficiaries using opioids, quality metrics for plan sponsors, and data analysis of prescribing patterns to target potential fraud, waste, and abuse.

Overutilization Monitoring System (OMS)

In addition, CMS uses the Overutilization Monitoring System (OMS) to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications, including opioid pain

[5] https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html

medications. CMS provides quarterly reports of high risk beneficiaries to Medicare Part D plans through the OMS to assist plans in their efforts, and plans update CMS on their actions taken to reduce the risk of overutilization. If the plan sponsor of a particular beneficiary's plan has concluded that a beneficiary-level point-of-sale edit is appropriate to reduce prescription opioid overutilization, the sponsor may do so with the agreement of the beneficiary's prescribers or without such agreement if the prescribers did not respond to the sponsor's efforts to engage in case management with the prescribers. Also, if the beneficiary later changes plans, that sponsor is expected to use CMS's systems to share such a finding with the new sponsor. There has been a 61 percent decline in the number of beneficiaries meeting the OMS criteria from calendar years 2011-2016 even though enrollment in Part D is increasing.[6] It is an encouraging sign that there has been a reduction in enrollees who are at the highest risk of harm for opioid overuse. CMS has continued to refine and improve the criteria used in OMS. Beginning this year, beneficiaries will be identified and reported to plans if in the most recent six months their use of opioids exceeds an average daily morphine equivalent dose (MED) of 90mg for any duration; and if they have received opioids from more than three prescribers and more than three pharmacies, or from more than five prescribers regardless of the number of opioid dispensing pharmacies.[7] CMS appreciates the work and recommendations of the HHS OIG that have helped us to make this work more effectively.

More recently, CMS has focused on the concurrent use of opioids and benzodiazepines, and wants to raise public awareness of this important issue. The combination of opioids and benzodiazepines can exacerbate respiratory depression, which is the primary factor in fatal opioid overdose. The risk of opioid-related morbidity and mortality is increased in all patients receiving opioids, even those who do not show signs of aberrant drug behavior. In a 2015 study, investigators found that 49 percent of the study's population who died from a drug overdose while taking opioid analgesics were concurrently prescribed benzodiazepines.[8] The Centers for Disease Control and Prevention advises clinicians to avoid prescribing opioids and benzodiazepines concurrently whenever possible to avoid putting patients at greater risk for

[6] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf
[7] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf
[8] Park TW, Saitz R, Ganoczy D, et al. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. BMJ 2015;350:h2698

potentially fatal overdose.[9] For these reasons, beginning in October 2016, CMS added a concurrent benzodiazepine use flag to OMS reports to alert sponsors that high risk beneficiaries have concurrent use of these medications.[10]

Although Medicare Part D sponsors' retrospective case management and CMS oversight through the OMS reduced very high risk overutilization of opioids in the Medicare Part D program, given the continuing national opioid epidemic, CMS believes that there may be opportunity for Medicare Part D sponsors to reduce such risk through safety alerts at the time of dispensing. Medicare Part D sponsors commonly implement safety edits to prevent the unsafe dosing of drugs at the time of dispensing as part of their concurrent drug utilization review requirements for all Medicare Part D drugs, such as drug-drug interactions, therapeutic duplication, or an incorrect drug dosage (e.g., doses above the FDA-approved maximum dosing). Plan sponsors can implement either soft or hard formulary-level safety edits. Soft edits are those that alert a pharmacist of possible overutilization at the point of sale and can be overridden by the pharmacist, while hard edits are alerts at the point of sale that require prescriber authorization and sponsor action to resolve the edit. For calendar year 2017, Medicare Part D sponsors were expected to implement additional soft or hard formulary-level safety edits for opioids based on a cumulative dose, using reasonable controls to limit false positives. As in 2017, we continue to expect sponsors to implement formulary-level soft and/or hard opioid safety edits for 2018, but hard edits are not required.

Medicare Part D "Lock In"

The Comprehensive Addiction and Recovery Act of 2016 (CARA) permits CMS to take important steps to help combat this epidemic. The law provides CMS with the authority to allow Medicare Part D plans to implement pharmacy and prescriber lock-in for their Medicare Part D beneficiaries that are determined to be "at-risk" of opioid misuse or abuse, subject to appropriate protections. Pharmacy and prescriber lock-in will provide plans with an additional tool to better coordinate care with their providers for the beneficiaries who meet the guidelines for lock-in. CMS held a listening session seeking input on key aspects of lock-in implementation, and

[9] http://www.cdc.gov/drugoverdose/prescribing/guideline.html.
[10] https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html

received feedback from various stakeholders including beneficiary advocates, clinicians, pharmacists, pharmacy benefit managers and plan sponsors. They highlighted ways to successfully implement a lock-in provision, but also raised concerns with how to align lock-in with existing tools used in Medicare Part D to promote the safe use of opioids, as well as how to protect medically necessary access to opioids.

With stakeholder input in mind, CMS has proposed through rulemaking a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or "at-risk beneficiaries."[11] Specifically, CMS has proposed to focus its lock-in efforts to address opioid misuse in Medicare Part D. The proposal would integrate the Medicare Part D lock-in with the current Part D Opioid Drug Utilization Review (DUR) Policy and OMS. As described above, this current policy involves Part D prescription drug benefit plans engaging in case management with prescribers when an enrollee is found to be taking a very high dose of opioids and obtaining them from multiple prescribers and multiple pharmacies who may not know about each other. Thus, this proposal expands upon an existing, innovative, successful approach to reduce opioid overutilization in the Part D program by improving quality of care through coordination while maintaining access to necessary pain medications when clinically indicated. As with any proposed rule, CMS is seeking public input from all stakeholders and accepted public comment until January 16, 2018.

Preventing Inappropriate Prescribing of Opioids through Provider and Prescriber Data Initiatives

CMS has a number of authorities to help curtail prescribing practices that place patients at risk of harm. These authorities are employed judiciously to prevent bad actors who fail to meet Medicare requirements from harming beneficiaries. These efforts have helped CMS protect the most vulnerable beneficiaries from the harms associated with opioid overuse. CMS will continue to coordinate efforts to ensure that future prescribers identified as having questionable opioid prescribing patterns are referred for appropriate administrative action.

[11] https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare

Detecting and Preventing Potential Fraud, Waste, and Abuse through the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC)

CMS utilizes the NBI MEDIC to identify and investigate potential fraud, waste and abuse in Medicare Part C and Part D, and to refer cases to law enforcement agencies when necessary. In particular, the NBI MEDIC identifies prescribers of drug combinations known to increase the effects of opioids, those with prescribing behavior that indicates they may be operating a pill mill, and those who prescribe Transmucosal Immediate-Release Fentanyl products to non-cancer patients. CMS shares this information with plans to assist in their investigation of fraud, waste and abuse.

The NBI MEDIC also conducts data analysis and other work to support ongoing law enforcement activities. Examples include impact calculations, medical review of claims and medical records, and prescription drug invoice reconciliation reviews. As a result of its work, the NBI MEDIC makes recommendations for administrative action to both CMS and the OIG, including revocations of Medicare billing privileges and exclusions from Federally funded health care programs.

Additionally, plan sponsors report potential fraud to the NBI MEDIC. The NBI MEDIC uses the Predictive Learning Analytics Tracking Outcome (PLATO) system, which is a voluntary, web-based system that allows CMS, the NBI MEDIC, and plan sponsors to more easily share information and help combat potential fraud, waste and abuse in the Medicare Advantage and Medicare Part D programs. CMS's federal law enforcement partners can also access PLATO data.

CMS has directed the NBI 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. 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 potentially terminate pharmacies from their network, if appropriate. In addition to the Quarterly Pharmacy Risk Assessment, the NBI MEDIC produces a Quarterly Outlier Prescriber Schedule II Controlled Substances Report, which provides a peer comparison of Schedule II controlled substances.

Using CMS Data to Understand Prescribing Patterns

To assist clinicians, nurses, and other health care providers to assess opioid-prescribing habits while continuing to ensure patients have access to the most effective pain treatment, CMS released an interactive online mapping tool. The mapping tool allows the user to see both the number and percentage of opioid claims at the local level and offers spatial analyses to identify "hot spots" or clusters in order to better understand how this critical issue impacts communities nationwide.[12] The data reflect Medicare Part D prescription drug claims prescribed by health care providers. The data used in the mapping tool are de-identified to protect beneficiary privacy, contain information from over one million distinct providers, and characterize the individual prescribing patterns of those providers that participate in Medicare Part D. 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.

Using CMS Quality Measures to Assess Program Effectiveness

CMS also uses quality measures developed by the Pharmacy Quality Alliance to assess reductions in opioid overuse across the Medicare Part D program. CMS tracks overall statistics and progress, as well as plan performance, related to the proportion of Medicare Part D beneficiaries using high doses of opioids, those receiving opioids from multiple providers or pharmacies, and those who meet both measures' criteria. CMS communicates with plans about their performance on each of these measures, including sharing information about specific beneficiaries identified, and plan sponsors with the lowest rating on each measure are required to report actions they will take to improve performance.

Proposed Preclusion List

CMS has a responsibility to protect Medicare Part D beneficiaries and the integrity of the program, while minimizing disruption to beneficiaries' access to needed Medicare Part D

[12] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html

medications and the administrative burden on the provider community. To strike this balance, CMS has recently proposed[13] that a Part D plan sponsor must reject, or must require its pharmacy benefit manager to reject, a pharmacy claim for a Medicare Part D drug if the individual who prescribed the drug is included on a "preclusion list." The preclusion list would consist of certain prescribers that fall within either of two categories. The first category would be individuals and entities who are currently revoked from Medicare, are under an active reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. The second category would be individuals and entities whose billing privileges have engaged in behavior for which CMS could have revoked the prescriber's billing privileges to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

The Healthcare Fraud Prevention System (HFPP)

The Healthcare Fraud Prevention Partnership (HFPP) is a voluntary, public-private partnership consisting of the Federal Government, state agencies, law enforcement, private health insurance plans, and healthcare anti-fraud associations. Established in July 2012 by the Secretary of HHS and the U.S. Attorney General, the HFPP provides visibility into the larger universe of healthcare claims and claimants beyond those encountered by any single partner. The ultimate goal of the HFPP is to exchange facts and information to identify trends and patterns that will uncover potential fraud, waste, and abuse that may not otherwise be identified.

The HFPP provides a unique opportunity for payers to combat the opioid crisis by identifying and sharing strategies to prevent prescription opioid misuse and opioid use disorder. By sharing information among payers, the HFPP aims to identify and intervene on behalf of patients at risk of opioid-related harm, as well as to target fraud, waste, and abuse in opioid prescribing. In January 2017, the HFPP released a White Paper that describes the best practices for serious consideration by all healthcare payers and other relevant stakeholders to effectively address and

[13] https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare

minimize the harms of opioids while ensuring access to medically necessary therapies and reducing fraud, waste, and abuse.

Ensuring Access to Needed Treatments

A critical part of tackling this epidemic is making sure that Medicare beneficiaries grappling with Opioid Use Disorder (OUD) have access to the most effective treatment options. While there is no distinct Medicare benefit category for substance abuse treatment, such services are covered by Medicare when reasonable and necessary. Medicare covers a full range of services, including those provided for substance use disorders. Through its networks of health quality experts and clinicians, CMS advocates the sharing of best practices for OUD screening and treatment.

CMS is also working to encourage clinical screenings to identify individuals suffering from OUD and increasing access to behavioral and medication-assisted treatment (MAT), the most effective treatment for OUD. MAT is the use of medications, in combination with counseling and behavioral therapies, to treat substance use disorders, including opioid use disorders. MAT is a valuable intervention that has been proven to be the most effective treatment for opioid use disorder, particularly because it sustains long term recovery and has been shown to reduce opioid-related morbidity and mortality.[14] CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT and mandates Medicare Part C coverage of the behavioral health element of MAT services. In addition, CMS is promoting improved access to the opioid overdose reversal drug naloxone by requiring that the antidote appear on all Medicare Part D formularies. We recognize that it is very important for Medicare beneficiaries and those who care for them to understand that these options are available to them under Medicare, so CMS is also working to educate clinicians, health plans, pharmacy benefit managers, and other providers and suppliers on services covered by Medicare to treat beneficiaries with OUD.[15]

[14] https://www.ncbi.nlm.nih.gov/pubmed/24500948
[15] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1604.pdf

Conclusion

CMS is actively engaged in addressing the opioid epidemic and is committed to implementing effective tools in the Medicare program. CMS will continue to work with beneficiary and advocacy groups, health plans, our federal partners, and other interested stakeholders to address this devastating epidemic. CMS is committed to working with Medicare Part D sponsors to assure they are in compliance with requirements that protect beneficiaries and can prevent and address opioid overutilization. This epidemic is devastating families and communities, and CMS is committed to using all the tools at its disposal to take meaningful action to stem this tide. We look forward to working with this Committee and the Congress on these efforts.