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January 16, 2018

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-4182-P: Comments on Section II.A.1.a Medicare Part D Drug Management Programs

Dear Centers for Medicare and Medicaid Services (CMS) Staff:

The Pew Charitable Trusts is pleased to offer comments on the proposed regulations for Medicare Part D drug management programsⁱ as authorized by the Comprehensive Addiction and Recovery Act of 2016 (CARA). Pew is a nonpartisan research and policy organization dedicated to serving the public. Our work to address substance use disorders focuses on 1) reducing the inappropriate use of prescription opioids while ensuring that patients have access to effective pain management and 2) expanding access to effective treatment for substance use disorders, including through the increased use of medication-assisted treatment.

There is growing concern about potential overuse of opioids among Medicare Part D beneficiaries, which can result in overdose deaths and falls and fractures caused by adverse effects of these drugs on the central nervous system.ⁱⁱ This risk is highlighted by a recent analysis by the Office of the Inspector General that found almost 90,000 Medicare beneficiaries were at serious risk of opioid misuse or overdose from either receiving doses of opioids at or above 240 mg for 12 months or visiting multiple prescribers or pharmacies for the same or similar prescriptions.ⁱⁱⁱ

CARA Section 704 allows Medicare plan sponsors to establish drug management programs to proactively identify and intervene in instances when beneficiaries are at risk of harm from opioids and other drugs that are frequently misused, as determined by the Secretary of Health and Human Services. These programs, which are also known as patient review and restriction (PRR) programs, can increase care coordination by assigning at-risk patients to obtain these drugs from a designated prescriber, pharmacy, or both. PRR programs, which are widely used by Medicaid and private insurers, are valuable tools that allow plan sponsors to improve patient safety and reduce harm.^{iv}

The draft regulations incorporate strong beneficiary protections, including requiring that beneficiary preferences be used to select prescribers and pharmacies and using Medicare's existing appeals process that is familiar to beneficiaries. **However, the proposal does not give Medicare plan sponsors the ability to effectively protect Medicare beneficiaries from drug-related harms.** Further, we are concerned that the draft regulations do not draw upon insights on the effective implementation of these programs in Medicaid, where they have been used for more than three decades.

Shortcomings in the regulation, described in detail below, include 1) delayed identification and enrollment of at-risk beneficiaries in prescriber-based PRR programs, 2) criteria and thresholds that are likely to overlook potentially at-risk beneficiaries, 3) the omission of high-risk medications, and 4) an arbitrary end date for PRR program enrollment.

Background

To minimize the risk of opioid use, Part D plan sponsors have employed point-of-sale edits, which allow plans to deny opioid prescriptions or impose quantity limits at the point of dispensing when misuse is suspected. However, this strategy represents a retrospective intervention, which may be limited in its effectiveness. In addition, point-of-sale edits can delay or prevent access to medications for beneficiaries experiencing pain. In 2013, CMS introduced the Overutilization Monitoring System (OMS), which uses claims data to identify beneficiaries at highest risk of harms from opioids based on the dose and number of prescribers and pharmacies visited to obtain these prescriptions.^v Current OMS criteria for identifying potentially at-risk beneficiaries include patients who have 1) taken an average daily opioid dose equal to or greater than 90 morphine milligram equivalents—a standardized measure that can be used to assess dose-related risk of overdose—during the most recent six months, and 2) have obtained those prescriptions from three or more prescribers and three or more pharmacies. In addition, beneficiaries obtaining prescriptions at that dose threshold from five or more prescribers, regardless of the number of pharmacies used to obtain those prescriptions, are flagged for review by plans sponsors. Plans are expected to review these beneficiaries' use of opioids and implement case management and point-of-sale edits, if appropriate, to reduce the risk of harm.

This program has shown a degree of effectiveness. A CMS analysis comparing data from the fourth quarter of 2013 and the third quarter of 2014 found an overall 8 percent reduction in the number of beneficiaries who exceeded the established dose–prescriber–pharmacy threshold.^{vi} Although this reduction is commendable, the subset of beneficiaries with a repeat occurrence of exceeding the threshold increased by 26 percent during the same time period. Further, this decrease may reflect broader, national efforts to reduce opioid prescribing, which resulted in an 18 percent reduction in MME dispensed per capita between 2010 and 2015.^{vii} The limited effectiveness of existing strategies highlights the need for the PRR programs authorized by CARA.

Delayed identification and enrollment of at-risk beneficiaries in prescriber-based PRR programs

The proposed regulations create a distinction between two common structures for PRR programs: programs that are pharmacy-only and those that include a prescriber. Prescriber-based PRR programs are described as a tool of last resort and their use is prohibited until at least six months after potentially harmful opioid use is identified by OMS reports. This approach overlooks the important role that prescribers play in these programs by managing the safe and effective use of pain management therapies. Further, it is unclear why CMS is establishing different standards for prescriber-based programs when the proposed rule already establishes a delayed enrollment process to protect beneficiaries from being enrolled in these programs unless it is necessary to ensure safe medication use. A majority of Medicaid fee-for-service PRR programs include prescribers in PRR programs, with 21 percent of programs requiring at-risk beneficiaries to receive controlled substance prescriptions from a designated prescriber and pharmacy and 45 percent of programs assigning a prescriber, pharmacy, and hospital.^{viii}

Further, rather than allowing plan sponsors to identify at-risk beneficiaries for prescriber-based PRR programs using their own claims data, the proposal requires plan sponsors to rely on CMS to identify beneficiaries via reports that are issued only quarterly. This approach will delay identification of beneficiaries at risk of harm. **CMS should revise the regulations to allow plan sponsors to use prescriber-based PRR programs along the same timeline proposed for pharmacy-based programs, which is consistent with the intent of the authorizing legislation.**

Criteria and thresholds likely to overlook potentially at-risk beneficiaries

According to the proposed regulations, potentially at-risk beneficiaries will be identified using the same criteria as OMS, but at different thresholds. The average daily opioid dose remains the same at 90 MME, but the thresholds for healthcare providers visited to obtain those prescriptions is increased to four or more prescribers and four or more pharmacies. The prescriber threshold for obtaining those prescriptions, regardless of the number of pharmacies used, is raised to six. Pew is concerned that the thresholds CMS proposes for the prescriber and pharmacy criteria for PRR programs are unnecessarily high and will prevent plan sponsors from identifying all beneficiaries potentially at-risk for opioid-related harm. **CMS should alter the proposed thresholds so that they are no higher than OMS to allow plans sponsors to adequately protect beneficiaries.**

In addition, the proposed rule does not allow plan sponsors to use other criteria that can be useful for identifying beneficiaries who may benefit from possible enrollment in a PRR program. Additional criteria can be used to identify those patients most at-risk for harm and avoid false positives (i.e., patients who are identified, but not appropriate for enrollment in PRR programs). This approach would also address CMS' concerns that using the OMS thresholds for prescribers and pharmacies would identify too many beneficiaries as being at-risk and place undue burden on plan sponsors. Nearly 75 percent of fee-for-service Medicaid PRR programs (28 of 38 programs) use at least five criteria and 13 percent (5 programs) use more than ten criteria to identify at-risk beneficiaries.^{ix} Other criteria used by Medicaid programs include visiting a certain number of emergency rooms or obtaining a certain number of controlled substances in the same therapeutic class over a specified time period. **Pew encourages CMS to allow plan sponsors to use additional criteria to improve the identification of potentially at-risk beneficiaries.**

Omission of high-risk medications

As proposed, plan sponsors may only apply PRR programs to opioids. This approach prevents plan sponsors from addressing the full spectrum of frequently misused drugs, including benzodiazepines and sedative hypnotics. Failure to include these medications places beneficiaries at risk of overdose and death. Their exclusion is of particular concern because it prohibits plan sponsors from doing what the agency previously instructed them to do. In 2016, CMS expressed concern about concurrent use of opioids and these drugs.^x Plan sponsors were encouraged to use claims data to identify affected beneficiaries and take steps to reduce potential harms. The need for this action is supported by CMS' own analysis that found over 3 million Medicare Part D beneficiaries had concurrent use of these therapies, with 1 million of those individuals considered to be high chronic users (defined as using the combination of drugs for more than four months).^{xi} Of note, 92 percent (35 of 38) of Medicaid fee-for-service PRR programs require patients to receive all controlled substances from designated providers.^{xii} Allowing Medicare plan sponsors to similarly address the misuse of all Drug Enforcement Administration (DEA) scheduled controlled substances will assist in efforts to reduce patient harm. **CMS should use the authority granted to the Secretary of Health and Human Services to include on the list of drugs subject to these programs all controlled substances in DEA Schedules II through V.**

Arbitrary end date for PRR program enrollment

The regulations propose that the beneficiaries be automatically discharged from a PRR program one year after the date of enrollment. CMS states that this time period was selected because it was the timeframe most commonly recommended in responses to the agency's December 2016 request for input on the development of these regulations. The agency also reported that a 12-month period was most common for Medicaid PRR programs based on a survey of those programs.^{xiii} However, a review of the

cited report finds wide variation in the duration of these programs. Thirteen states reported a 12-month duration for their programs, but 34 states were categorized as “other.” Timeframes for states in the other category ranged from 9 months to 5 years, with 24 months being the most commonly reported duration. Pew’s analysis of Medicaid fee-for-service programs found that 41 percent (16 programs) of the PRR programs enroll beneficiaries for 24 months, while 31 percent (12 programs) enroll at-risk patients for 12 months.^{xiv} Importantly, at the end of these time periods, an assessment is conducted to determine if a patient’s controlled substance use still requires PRR program enrollment to prevent inappropriate use. **Pew strongly encourages CMS to revise the regulations to include a risk assessment as part of the determination as to whether a PRR program is still needed to prevent drug-related harms.**

Thank you for the opportunity to comment on draft regulations for the use of drug management programs to address potentially inappropriate or harmful drug use in Medicare. Should you have any questions or if we can be of further assistance with your work, please contact me by phone at 202-540-6916 or via email at creilly@pewtrusts.org.

Sincerely,



Cynthia Reilly, MS, BS Pharm
Project Director, Substance Use Prevention and Treatment Initiative

ⁱ As Proposed in CMS–4182–P Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

ⁱⁱ The Pew Charitable Trusts. Risks of opioid use in the elderly and Medicare populations. Available at <http://www.pewtrusts.org/en/multimedia/data-visualizations/2015/risks-of-opioid-use-in-the-elderly-and-medicare-populations>

ⁱⁱⁱ U.S. Department of Health & Human Services’ Office of Inspector General. Opioids in Medicare Part D: Concerns about extreme use and questionable prescribing. Available at <https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf>

^{iv} Centers for Disease Control and Prevention (CDC). Patient review & restriction programs. Lessons learned from state Medicaid programs. https://www.cdc.gov/drugoverdose/pdf/pdo_patient_review_meeting-a.pdf

^v Centers for Medicare and Medicaid Services (CMS). Announcement of calendar year (CY) 2018 Medicare Advantage capitation rates and Medicare Advantage and part D payment policies and final call letter and request for information. Available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>

^{vi} CMS. Announcement of calendar year (CY) 2017 Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies and final call letter, April 4, 2016. <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf>

^{vii} CDC. Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015. Available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm?s_cid=mm6626a4_w

^{viii} The Pew Charitable Trusts. Curbing prescription drug abuse with patient review and restriction programs: Learning from Medicaid agencies. Available at <http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2016/03/curbing-prescription-drug-abuse-with-patient-review-and-restriction-programs>

^{ix} The Pew Charitable Trusts. Curbing prescription drug abuse with patient review and restriction programs: Learning from Medicaid agencies.

^x CMS. Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 4, 2016. <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf>

^{xi} CMS. Concurrent use of opioids and benzodiazepines in a Medicare Part D population, accessed January 6, 2018.

<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Concurrent-Use-of-Opioids-and-Benzodiazepines-in-a-Medicare-Part-D-Population-CY-2015.pdf>

^{xii} The Pew Charitable Trusts. Curbing prescription drug abuse with patient review and restriction programs: Learning from Medicaid agencies.

^{xiii} CMS. Center for Medicaid and CHIP Services. Medicaid drug utilization review state comparison/summary report FFY. 2015 Annual Report Prescription Drug Fee-For-Service Programs, December 2016. <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/2015-dur-summary-report.pdf>

^{xiv} The Pew Charitable Trusts. Curbing prescription drug abuse with patient review and restriction programs: Learning from Medicaid agencies.