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March 6, 2015

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: 2016 Advance Notice and Draft Call Letter: Proposed Expansion of the Overutilization Monitoring System and Alternative Mechanisms to Address Potential Overuse of Prescription Opioids by Part D Beneficiaries

To Whom It May Concern:

The Pew Charitable Trusts is pleased to offer comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed expansion of the Overutilization Monitoring System (OMS) to address potential overuse of prescription opioids by Part D beneficiaries, as described in the 2016 Advance Notice and Draft Call Letter. Pew is an independent, nonpartisan research and policy organization dedicated to serving the public. Our prescription drug abuse project works to develop and support policies that will help reduce the inappropriate use of prescription drugs while ensuring that patients with legitimate medical needs have access to effective pain management.

Pew supports the intent of CMS to address prescription drug abuse in the Medicare Part D population through the proposed expansion of the OMS, but we recommend that CMS pursue implementation of patient review and restriction (PRR) programs as a proactive strategy to address opioid abuse. Major insurers and state Medicaid programs have implemented PRRs in their employer-based and managed care and fee-for-service Medicaid plans. These programs are designed to identify and allow plan sponsors to intervene in instances when patients over-utilize prescription opioids and other prescription drugs that are subject to abuse. PRRs increase care coordination by requiring that individuals use a designated pharmacy or physician to obtain prescriptions for controlled substances. To ensure that these programs do not restrict patients for whom high-dose opioid therapy is clinically appropriate, plan sponsors provide an appeals process and conduct a clinical review to exclude patients who are receiving hospice or cancer treatment. Beneficiaries can also provide input on the selection of prescribers and pharmacies to ensure reasonable access, including consideration of geographic location, travel time, and part-time or out-of-state residencies.

State Medicaid programs that have adopted PRRs have generated cost savings, decreased the use of prescription opioids, and reduced patient visits to multiple doctors and emergency rooms to obtain these drugs, as described in proceedings from a Centers for Disease Control and Prevention expert panel meeting.[i] Current law does not clearly permit use of these programs in Medicare, despite the fact that officials from CMS and other government agencies have indicated a willingness to explore use of these programs.[ii,iii] By making it clear that Medicare has the authority to implement PRRs, Medicare would provide plan sponsors with a proactive strategy to address opioid overuse and improve continuity of care among at-risk patients.

CMS has successfully used OMS to identify patients with potentially inappropriate use of opioids. However, this program requires that plan sponsors use retrospective interventions, including drug utilization reviews and point-of-sale edits that deny prescriptions or impose quantity limits at the point of dispensing when abuse is suspected (i.e., when beneficiaries have used cumulative morphine equivalent doses (MED) in excess of 120 mg for at least 90 consecutive days and obtained these prescriptions from three prescribers and three pharmacies.[iv] OMS has demonstrated some effectiveness in addressing overuse of opioids based on the assessment described in the 2016 Advance Notice and Draft Call Letter. This analysis, which compares data from the fourth quarter of 2013 and the third quarter of 2014, found an overall 8 percent reduction in the number of beneficiaries, or outliers, who exceeded the established MED–prescriber–pharmacy threshold for identification of potential opioid over-utilization.[v] This reduction is commendable, but the subset of beneficiaries with a repeat occurrence of exceeding the threshold increased by 26 percent during the same time period. The high frequency at which beneficiaries have repeated exceeding the established threshold following an intervention by the plan sponsor indicates that currently available mechanisms have limited effectiveness. The proposed expansion of the OMS that would add an edit based on the threshold of a cumulative MED of 200 mg/day from two or more prescribers may enhance identification of patients at risk for prescription drug abuse. However, the effectiveness of OMS would continue to rely on retrospective interventions, whereas PRRs would permit plan sponsors to designate a prescriber and pharmacy to proactively coordinate care for these patients. **Therefore, Pew urges CMS to work with Congress to ensure CMS has the authority to implement PRRs in Medicare.** The President's FY 2016 Budget request for the Department of Health and Human Services proposes these programs and there is broad bipartisan support in Congress with PRR programs included in the Protecting the Integrity of Medicare Act of 2015 and 21st Century Cures discussion draft.

Thank you for the opportunity to inform the development of strategies to address potentially inappropriate opioid use by Medicare Part D beneficiaries. Should you have any questions or if we can be of assistance with your work, please contact me by phone at 202-540-6916 or via email at creilly@pewtrusts.org.

Sincerely,

Cynthia Reilly
Director, Prescription Drug Abuse
The Pew Charitable Trusts

[i] Centers for Disease Control and Prevention; National Center for Injury Prevention and Control. Patient review & restriction programs. Lessons learned from state Medicaid programs. Available at http://www.cdc.gov/homeandrecreationalsafety/pdf/PDO_patient_review_meeting-a.pdf

[ii] Government Accountability Office. Medicare Part D. Instances of questionable access to prescription drugs. Testimony of Gregory D. Kutz before the Subcommittee of the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate, October 4, 2011. Available at http://www.gao.gov/assets/590/585579.pdf

[iii] Office of the Inspector General. Part D beneficiaries with questionable utilization patterns for HIV drugs (2014). Available at http://oig.hhs.gov/oei/reports/oei-02-11-00170.pdf

[iv] Centers for Medicare & Medicaid Services (CMS). Medicare Part D Overutilization Monitoring System. Correspondence from Cynthia G. Tudor, Director, Medicare Drug Benefit and C & D Data Group, July 5, 2013. Available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMS-memo-Medicare-Part-D-Overutilization-Monitoring-System-07-05-13-.pdf

[v] CMS. Advance notice of methodological changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) capitation rates, Part C and Part D payment policies and 2016 call letter. Attachment VI: 2016 draft call letter. Note to Medicare Advantage organizations, prescription drug plan sponsors, and other interested parties, February 20, 2015. Available at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2016.pdf