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April 10, 2015

Mark E. Miller, Ph.D.
Executive Director
Medicare Payment Advisory Commission
425 I Street, Suite 701
Washington, D.C. 20001

RE: Patient Review and Restriction Programs as a Policy Option to Address Polypharmacy and Potentially Inappropriate Opioid Use in Medicare Part D

Dear Dr. Miller:

The Pew Charitable Trusts is pleased to offer comments to the Medicare Payment Advisory Commission (MedPAC) on strategies to address polypharmacy and potentially inappropriate opioid use in Medicare Part D. 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 encourages MedPAC to recommend that Congress provide Medicare Part D the authority to implement patient review and restriction (PRR) programs to address potentially inappropriate opioid use. Pew submitted a letter to the Commission in January encouraging similar action.[i] Information presented at the April 2, 2015 meeting reinforced the need for these programs. Shinobu Suzuki presented an analysis of 2012 data, which found that approximately 500,000 Part D beneficiaries accounted for nearly 70% of total opioid spending in 2012.[ii] These beneficiaries were more likely to obtain opioids from four or more prescribers and three or more pharmacies. This analysis provided an update of 2011 data that Ms. Suzuki reported at the October 2014 MedPAC meeting, which demonstrated similar results.[iii]

PRRs identify patients suspected of abusing prescription opioids and designate a single pharmacy or physician for patients' controlled substance prescriptions, thereby allowing plan sponsors to better coordinate patient care and prevent inappropriate access to medications that are susceptible to abuse. PRRs are structured to allow beneficiary 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. Additional beneficiary protections include clinical review of all identified patients, finite enrollment periods, and appeals processes.

There are other tools to address inappropriate opioid use in Medicare Part D. The Centers for Medicare & Medicaid Services (CMS) has successfully used the overutilization monitoring system (OMS) to identify patients with potentially inappropriate use of opioids. OMS provides quarterly reports to Part D plan sponsors on beneficiaries with potential opioid or acetaminophen overutilization issues. 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.[v] 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. 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. CMS proposed an expansion to the OMS in the 2016 Advance Notice and Draft Call Letter that would add an edit based on the threshold of a cumulative MED of 200 mg/day from two or more prescribers. This proposed expansion 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.

An evaluation performed by a Centers for Disease Control and Prevention expert panel found that PRRs used in state Medicaid programs have generated savings and reduced narcotic prescriptions, abuse, and visits to multiple doctors and emergency rooms.[vi] The effectiveness of PRRs has led to their adoption in the public and private sector, with major insurers operating these programs in their Medicaid managed care and employer-based plans. About 46 state Medicaid programs currently operate PRRs.[vii]

However, current law does not permit the use of PRRs in Medicare Part D plans, despite the fact that officials from CMS and other government agencies have indicated a willingness to explore the use of these programs.[viii,ix] There is significant bipartisan support for change with legislation authorizing PRRs in Medicare under consideration in both the Ways & Means and Energy & Commerce Committees in the House of Representatives. The President's FY 2016 budget request for the Department of Health & Human Services also proposes to establish PRRs in Medicare.

Thank you for the opportunity to provide input to inform the continuing discussion on strategies to address polypharmacy and potentially inappropriate opioid use in Medicare Part D. 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] The Pew Charitable Trusts. Comments to the Medicare Payment Advisory Commission (MedPAC) on strategies to address potentially inappropriate opioid use in Medicare Part D. Correspondence from Cynthia Reilly, Director, Prescription Drug Abuse Project, January 12, 2015. Available at http://www.pewtrusts.org/~/media/Assets/2015/01/Pew_MedPAC__Comments.pdf

[ii] Suzuki S. Polypharmacy and Medicare beneficiaries with a focus on opioid use in Part D. Presentation by Shinobu Suzuki, Policy Analyst, MedPAC, April 2, 2015. Available at http://www.medpac.gov/documents/april-2015-meeting-presentation-polypharmacy-and-medicare-beneficiaries-with-a-focus-on-opioid-use-in-part-d.pdf?sfvrsn=0

[iii] Suzuki S. Potentially inappropriate opioid use in Medicare Part D. Presentation by Shinobu Suzuki, Policy Analyst, MedPAC, October 9, 2014. Available at http://www.medpac.gov/documents/october-2014-meeting-presentation-potentially-inappropriate-opioid-use-in-medicare-part-d-.pdf?sfvrsn=0

[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

[vi] Centers for Disease Control and Prevention; National Center for Injury Prevention and Control. Patient review & restriction programs. Lessons learned from state Medicaid programs (2012). Available at http://www.cdc.gov/homeandrecreationalsafety/pdf/PDO_patient_review_meeting-a.pdf

[vii] Roberts AW and Skinner AC. Assessing the present state and potential of Medicaid controlled substance lock-in programs. *J Manag Care Pharm*. 2014;20(5):439-46c. Available at http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=18019

[viii] 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

[ix] 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