THE PEW CHARITABLE TRUSTS

2005 Market Street, Suite 1700 215.575.9050 Phone
Philadelphia, PA 19103-7077 215.575.4939 Fax

901 E Street NW, 10th Floor 202.552.2000 Phone
Washington, DC 20004 202.552.2299 Fax
www.pewtrusts.org

January 12, 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 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 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.

As noted at the MedPAC meeting on October 9, 2014, there is growing concern about potential overuse of opioids among Medicare Part D beneficiaries. Analyses conducted by the Centers for Medicare & Medicaid Services (CMS) and Government Accountability Office (GAO) have sought to quantify the extent of opioid overuse in this population. Differences in the thresholds these evaluations set for the number of prescriptions, prescribers, and pharmacies resulted in variability in the overall number of beneficiaries defined as at-risk for opioid over-utilization. However, findings from these evaluations echo results from a preliminary analysis of 2011 data presented by Shinobu Suzuki at the MedPAC meeting, which found an average of 23 prescriptions per year among the top five percent of opioid users (approximately 500,000 beneficiaries).[i] Further, each of these evaluations identified similar subpopulations in which opioid utilization was the highest. These studies, which will be described in detail here, highlight the need to ensure the safe and appropriate use of opioids in these patient populations. To achieve this goal, **Pew encourages MedPAC to recommend that Congress provide Part D plan sponsors the authority to implement patient review and restriction (PRR) programs to address potentially inappropriate opioid use.**

In the CMS evaluation, investigators used quantity thresholds for opioid dispensing as well as an assessment of the dosage and duration of therapy to assess prescribing for 8.8 million beneficiaries who received opioids according to 2011 claims data.[ii] As with the MedPAC analysis, beneficiaries with cancer and those receiving hospice care were excluded from the analysis. Potentially unsafe opioid use, which was defined as doses that exceeded 120 mg daily morphine equivalent dose (MED) for 90 or

more consecutive days, was found in approximately 225,000 beneficiaries. Those under the age of 65 years were three times more likely to be included in this population compared with those between 75 and 85 years of age. Further, those receiving a Medicare Low-Income Cost-Sharing (LIS) subsidy and those who were disabled or had end-stage renal disease were more likely to be in this group of high opioid utilizers compared with other segments of the Part D population. Among the 225,000 beneficiaries defined as having potentially unsafe opioid use, 28.3 percent obtained prescriptions from four or more prescribers and nearly 18 percent used four or more pharmacies. When the number of prescribers, number of pharmacies, and the dose and duration were analyzed together, a subset of 22,000 Part D beneficiaries was found to have received doses that exceeded 120 mg daily MED for 90 or more consecutive days from four or more prescribers and four or more pharmacies.

An evaluation of 2008 claims data conducted by the GAO identified 170,000 Part D beneficiaries who visited at least five, and as many as 87, medical professionals in a year to obtain prescriptions for opioids or other drugs from 14 classes of abusable drugs.[iii] Individuals with cancer and those receiving hospice care were excluded. Seventy-one percent of these beneficiaries were eligible for Part D benefits based on a disability and 72 percent received a LIS subsidy. This rate is similar to the 66 percent of highest opioid utilizers in the MedPAC analysis that received a LIS. Data from these three evaluations highlight segments of the Part D population that are at greatest risk. However, there is a need to ensure appropriate use of opioid therapies in the entire Part D population. Data from the Substance Abuse and Mental Health Services Administration indicate that the number of seniors who reported misusing a pain reliever during the past year increased 155 percent between 2002 and 2012.[iv,v]

Existing strategies that Part D plan sponsors employ to address inappropriate opioid use include drug utilization reviews and point-of-sale edits, which allow plans to deny prescriptions or impose quantity limits at the point of dispensing when abuse is suspected. As noted by several commission members at the MedPAC meeting, these strategies represent retrospective interventions, which may be limited in their effectiveness. In addition, point-of-sale edits can delay or prevent access to medications for those with legitimate pain. A PRR program is another tool that can be used prospectively to improve opioid use. However, this tool is not currently available to Medicare Part D plan sponsors. PRRs, also known as "lock-in" programs, are designed to identify and intervene in instances when patients over-utilize narcotics and other prescription drugs that are subject to abuse. These programs can increase care coordination by requiring that individuals use a single pharmacy or physician for controlled substance prescriptions. 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. Finite enrollment periods and appeals processes are additional mechanisms used to provide beneficiary protections. A clinical review is also recommended to augment prescription and prescriber thresholds and other criteria (e.g., MED or drug combinations) that are used to identify patients for enrollment in these programs.

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] However, current law does not permit the use of PRRs in Medicare Part D plans, despite the fact that officials from the CMS and other government agencies have indicated a willingness to explore the use of these programs.[vii,viii] Authorizing the use of PRRs in Part D would expand the options available to plan sponsors to address opioid overuse and improve continuity of care among at-risk patients, including those with disabilities.

The effectiveness of PRRs has led to their adoption in the public and private sector, with major insurers operating these programs in their state-sponsored Medicaid and employer-based plans. According to a recent review of state Medicaid programs, most PRRs restrict beneficiaries to a single pharmacy and single prescriber.[ix] However, program structure may vary depending on requirements defined by the state in which these programs are administered. For example, a PRR using a pharmacy-only restriction is used to manage Medicaid beneficiaries in Florida. In the absence of access to medical records, plans have used prescription histories as a proxy to prevent enrollment of patients who should be exempt from PRRs (e.g., patients with cancer and those receiving hospice care). For example, concurrent prescriptions for oncology medications can be used to identify patients with a cancer diagnosis. Pew has also received feedback from plan sponsors about strategies for implementing PRRs. In these discussions, plan sponsors have noted the use of prescriber letters and other communications to increase awareness and improve coordination of care, even in pharmacy-only PRRs. While they currently lack authority to use PRRs in Medicare Part D, plan sponsors have reported also using prescriber outreach to increase awareness of potential overutilization prior to implementing point-of-sale edits.

Thank you for the opportunity to provide input to inform the development of strategies to address 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

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[i] 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

[ii] Centers for Medicare & Medicaid Services. Supplemental guidance related to improving drug utilization controls. Correspondence from Cynthia G. Tudor, Director, Medicare Drug Benefit and C & D Data Group, September 6, 2012. Available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf

[iii] Government Accountability Office (GAO). Medicare Part D. Instances of questionable access to prescription drugs. Report to congressional requesters (2011). Available at http://www.gao.gov/assets/590/585424.pdf

[iv] Substance Abuse and Mental Health Services Administration (SAMHSA). Table 1.18A – Nonmedical use of pain relievers in lifetime, past year, and past month, by detailed age category: numbers in thousands, 2011 and 2012. Available at http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect1peTabs1to46-2012.htm#Tab1.18A

[v] SAMHSA. Table 1.26A: Nonmedical use of any pain reliever in lifetime, past year, and past month, by detailed age categories: numbers in thousands, 2002 and 2003. Available at http://media.samhsa.gov/data/nhsda/2k3tabs/Sect1peTabs1to66.htm#tab1.26a

[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] GAO. 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

[viii] 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

[ix] 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