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December 2, 2016

Mr. Chad Buskirk
Centers for Medicare and Medicaid Services
Mail Stop C1-24-23
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-4183-N: Medicare Program; Listening Session Regarding the Implementation of Certain Medicare Part D Provisions in the Comprehensive Addiction and Recovery Act of 2016

Dear Mr. Buskirk:

The Pew Charitable Trusts is pleased to offer comments on the implementation of provisions in the Comprehensive Addiction and Recovery Act (CARA) intended to prevent prescription drug misuse in Medicare. Pew is an independent, nonpartisan research and policy organization dedicated to serving the public. Our work to address substance use disorders focuses on developing and supporting policies that 1) reduce the inappropriate use of prescription drugs while ensuring that patients have access to effective pain management and 2) expand access to effective treatment for substance use disorders, including through the increased use of medication-assisted treatment (MAT).

Section 704 of CARA allows Medicare plan sponsors to establish drug management programs to identify and intervene in instances when beneficiaries misuse opioid pain relievers. These programs, which are also known as patient review and restriction (PRR) programs, increase care coordination by assigning at-risk patients to obtain these drugs from a designated prescriber and pharmacy. PRR programs are valuable tools that plan sponsors can use to proactively improve patient safety and reduce harm.

Pew has conducted research on the use of PRR programs in Medicaid, including a nationwide survey that provides an overview of the characteristics and structures of these programs as they are used to prevent prescription drug misuse; 38 Medicaid programs operating PRRs in their fee-for-service population provided input.[i] Pew has also convened Medicaid staff members who oversee these programs in eleven states to discuss program variability and develop recommendations for improving PRR programs.[ii] Based on this research, we offer the following recommendations to help ensure these programs work as intended to reduce patient harm while ensuring that Medicare beneficiaries have access to effective pain management.

Statutory topic 1: Developing clinical guidelines that indicate misuse of frequently abused drugs

The Secretary should use the authority provided in the legislation to include on the list of drugs subject to these program all controlled substances in Drug Enforcement Administration (DEA) schedules II through V. This would ensure that plan sponsor have the ability to address the full spectrum of frequently misused drugs, including opioids, benzodiazepines, and muscle relaxants. For example, misuse of benzodiazepines has increased over the past two decades and nearly a third of all prescription overdose deaths now involve this class of drugs.[iii] Of note, 92 percent (35 of 38) of Medicaid fee-for-service PRR programs that responded to Pew's survey require patients to receive all controlled substances from designated providers.[iv] Allowing Medicare plan sponsors to similarly address the misuse of all DEA scheduled controlled substances will assist in efforts to reduce patient harm.

Beneficiaries should be identified for enrollment in PRR programs using a variety of criteria including, at a minimum, the number of pharmacies visited, the number of prescribers visited, and the number of controlled substance prescriptions obtained over a certain period of time. Seventy-six percent of Medicaid fee-for-service programs (29 of 38 programs) use all three of these criteria.[v] 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. Roughly three quarters of fee-for-service Medicaid PRR programs (28 of 38 programs) use at least five criteria and 13 percent (5 programs) use more than 10 criteria to identify at-risk beneficiaries. Using a variety of enrollment criteria helps to identify those patients most at risk for harm, while avoiding false positives (i.e., patients who are identified but not appropriate for enrollment in PRR programs). While additional research is needed, use of more clinically relevant measures, such as a maximum threshold for morphine milligram equivalents (a standardized measure that can be used to assess dose-related risk of overdose) may be most effective in reducing harm.

More research is needed to determine the optimal time period for terminating a beneficiary's at-risk status; however, Pew's research found that PRR enrollment for Medicaid fee-for-service beneficiaries ranges from 1 to 2 years.[vi] Forty-one percent of PRR programs (16 programs) enroll beneficiaries for 24 months, while 31 percent (12 programs) enroll at-risk patients for 12 months. At the end of these time periods, an assessment is conducted to determine if a patient's controlled substance use still requires PRR enrollment to prevent inappropriate use or harm. Only two states enroll Medicaid beneficiaries in a PRR for an indefinite period of time.

Statutory topic 3: Assessing the impact of drug management programs for at-risk beneficiaries on cost sharing and accessibility to prescription drugs for enrollees who are considered at-risk.

The selection of designated prescribers and pharmacies should reflect beneficiary preferences to ensure that patients have reasonable access to their health care providers and to reduce possible disruptions to continuity of care. Overall, 95 percent of Medicaid fee-for-service PRR programs (36 of 38 programs) allow beneficiaries to have input on the selection of providers, with 58 percent (22 programs) allowing beneficiaries to submit preferences before these designations are made.[vii] Twenty-eight percent (11 programs) assign prescribers and pharmacies based on the beneficiaries most frequently visited providers. Beneficiary preferences should drive the selection process, but if the plan sponsor identifies and verifies that the selected prescribers and pharmacies have been involved in abusive or fraudulent activity, the plan sponsor should be able to notify the beneficiary that alternate providers have been selected, so long as that notification also provides information about how the beneficiary can submit a request for reassignment.

Statutory topic 4: How should the appeals process be used so that the enrollee may appeal or contest being identified as an at-risk beneficiary for prescription drug abuse?

PRR programs should have strong beneficiary protections, including the right to appeal, and access to an expedited appeals process to ensure access to effective pain management. Most Medicaid fee-for-service PRR programs allow patients to appeal their at-risk identification and subsequent PRR enrollment, including providing the right to a fair hearing. Eighty-six percent of responding programs (32 of 37 programs) give the beneficiary at least 30 days from notification to appeal the decision; 27 percent (10 programs) provide at least 60 days. Fifty-three percent (18 of 34 programs that responded) will not enroll the beneficiary in the PRR during the appeals process, and 32 percent (11 of 34 programs) will enroll the beneficiary only if the individual does not appeal within 10 days of receiving written notification of PRR program enrollment.

Pew supports the expedited review of appeals and is concerned that automatic escalation to external review may result in delays that place the beneficiary at ongoing risk of overdose or other harms while that process is conducted. **Efforts to streamline and improve the efficiency of existing internal review processes should be explored prior to determining whether there is a need for automatic escalation to an external entity.**

Statutory Topic 7: What information should be included in the notices sent to the at-risk beneficiary?

Written notification to the beneficiary should include information on the meaning and consequences of their identification as at-risk, instructions for submitting preferences for prescriber and pharmacy selection, information about the appeals process, and contact information for the plan sponsor. To the extent possible, plan sponsors should also provide at-risk beneficiaries with information about resources available to aid the beneficiary in addressing the misuse of controlled substances. However, requiring the plan sponsor to include information in the notification that describes all state and federal public health resources, as described in the legislation, is out of the scope of what plan sponsors are reasonably able to provide. While the Centers for Medicare and Medicaid Services (CMS) does not have the authority to remove this requirement, **Pew recommends that CMS and plan sponsors together develop a list of common resources available to all or most beneficiaries.**

Statutory Topic 9: The responsibility for the implementation of the program of the plan sponsor that establishes a drug management program for at-risk beneficiaries

While it outside the scope of the proposed regulations, plan sponsors should have access to state prescription drug monitoring programs (PDMPs).[viii] These databases can be used to optimize and inform PPR program enrollment, prevent beneficiaries from circumventing the program through the use of out-of-pocket payments, and monitor the compliance of patients, prescribers, and pharmacy staff. However, as of September 2015, only 32 of 50 states allow insurers to access PDMP data.[ix] Without access to the PDMP, the ability of plan sponsor to address overuse of controlled substances is limited to information about services billed through that insurer.

Thank you for the opportunity to inform the development of regulations for 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
Director, Substance Use Prevention and Treatment Initiative

[i] The Pew Charitable Trusts (2016). Curbing Prescription Drug Abuse with Patient Review and Restriction Programs: Learning from Medicaid Agencies, accessed November 18, 2016, http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2016/03/curbing-prescription-drug-abuse-with-patient-review-and-restriction-programs

[ii] The Pew Charitable Trusts (2016, in press). Patient Review and Restriction Programs in Medicaid. Expert Panel Recommendations to Help Curb Misuse of Prescription Drugs.

[iii] Bachhuber MA, Hennessy S, Cunningham CO, Starrels JL (2016). Increasing Benzodiazepine Prescriptions and Overdose Mortality in the United States, 1996-2013, *Am J Public Health,*106(4):686-8.

[iv] The Pew Charitable Trusts (2016), Curbing Prescription Drug Abuse with Patient Review and Restriction Programs: Learning from Medicaid Agencies.

[v] Ibid.

[vi] Ibid.

[vii] Ibid.

[viii] The Pew Charitable Trusts (2016, in press). Patient Review and Restriction Programs in Medicaid. Expert Panel Recommendations to Help Curb Misuse of Prescription Drugs.

[ix] National Alliance for Model State Drug Laws (2015). Types of Authorized Recipients—Medicaid, Medicaid, State Health Insurance Programs, and/or Health Care Payment/Benefit Provider or Insurer, accessed November 18, 2016, http://www.namsdl.org/library/1810E284-A0D7-D440-C3A9A0560A1115D7/