May 7, 2015

Dear Congressional Leaders:

We, the undersigned organizations representing research and policy organizations, healthcare plan sponsors, and managed care pharmacy providers are writing to urge Congress to expand the tools available to tackle the Nation's prescription drug abuse epidemic by authorizing the use of Patient Review and Restriction programs in Medicare. Prescription drug abuse has become an epidemic, with 16,000 people dying in the United States each year from opioid-related prescription drug overdoses.[i] According to the Centers for Disease Control and Prevention, such deaths have increased more than 300 percent since 1998, while prescribing rates for these drugs quadrupled between 1999 and 2010. Deaths connected to prescription drug misuse now exceed those from heroin and cocaine combined.[ii]

A critical tool for addressing the Nation's prescription drug abuse epidemic, Patient Review and Restriction (PRR) programs, also known as "lock-in" programs, require patients at risk of drug abuse to utilize designated pharmacies and prescribers to obtain all prescriptions for opioids and other controlled substances. The use of these drug management programs can improve continuity of care among at-risk patients by providing improved drug therapy management while ensuring patients with legitimate medical needs have access to effective pain control and making an additional tool available to plan sponsors to combat prescription drug abuse. A Centers for Disease Control and Prevention expert panel evaluation found that PRRs used in state Medicaid programs have reduced narcotic prescriptions, abuse, and visits to multiple doctors and emergency rooms, while also generating cost savings.[iii] These drug management programs are used in state Medicaid as well as in commercial plans. However, current law does not permit the use of PRRs in Medicare. Legislation is needed to allow for the use of PRRs in Medicare.

There is broad bipartisan support for legislation authorizing the use of these programs in Medicare, with policy proposals put forward on both sides of the Capitol as well as in the FY 2016 Budget request for the Department of Health and Human Services. This ongoing collective action reflects the shared interest in advancing this policy as an effective tool to decrease prescription drug abuse.

To maximize the impact of PRRs and to ensure the policy works as intended, we, the undersigned organizations, urge Congress to include the principles specified below in PRR legislation.

Legislation should:

Provide plan sponsors with the option to restrict beneficiaries to both a designated prescriber and pharmacy

Designating a single prescriber to oversee the beneficiary's pain management, in conjunction with a single pharmacy, can improve effectiveness of PRRs by coordinating care for the beneficiary and ensuring access to medically necessary prescription drugs. Most existing PRR programs in state Medicaid programs restrict beneficiaries to both a single prescriber and a single pharmacy. While sponsors of Medicare Part D plans lack direct oversight of prescribers, many plans have had success identifying individual prescribers who agree to coordinate pain management for these patients.

Include a requirement that plan sponsors perform an internal clinical assessment before beneficiaries identified as at-risk are enrolled in a PRR

Once beneficiaries are identified as potentially abusing prescription drugs through prescription fill records and other data sources, plan staff should complete a clinical assessment of available information (e.g., patient diagnosis, concomitant therapies) to determine if the patient's drug use is appropriate. If the assessment determines that the prescribed medications and dosages are medically necessary, the individual will not be enrolled in a PRR.

Provide beneficiaries written notification of enrollment in a PRR

Beneficiaries should be notified in writing of their identification as a beneficiary at-risk for prescription drug abuse and their proposed inclusion in a PRR. Notification should include the meaning and consequences of their identification as at-risk and plan sponsor contact information. Notification should include the beneficiary's right to submit preferences for prescriber and pharmacy selection. Notification will also include information about their right to appeal.

Include the ability for beneficiaries to appeal enrollment in a PRR

Beneficiaries should have the right to appeal plan sponsors' identification as at-risk and subsequent enrollment in a PRR.

Allow beneficiary input on prescriber and pharmacy selection

Beneficiaries should be able to submit their preferences for a designated prescriber(s) and pharmacy(ies) to obtain their controlled substances once enrolled in a PRR. Allowing for beneficiary preferences in the selection process ensures that beneficiaries will have reasonable access to their designated providers and reduces possible disruptions to continuity of care. Plan sponsors should review beneficiary choices before provider assignment to verify that these prescribers and pharmacies have not been previously involved in abusive or fraudulent activity. If the review reveals abusive or fraudulent activity, the plan sponsor should notify the beneficiary of the alternative providers that are selected, along with information about how the beneficiary can submit a request for reassignment of the designated providers. If the beneficiary does not provide input, plan sponsors can assign a prescriber and pharmacy for the beneficiary; however, the beneficiary reserves the right to submit input on suggested providers to be reviewed by the plan sponsor if the assignment is not preferred. The designated prescriber and pharmacy should also receive notification of their designation as the beneficiary's prescriber and pharmacy. Beneficiaries should be able to use other prescribers and pharmacies for any medical needs other than their prescriptions for controlled substances.

Exclude certain patient populations from enrollment

When plan staff complete a clinical assessment of available information (e.g., patient diagnosis, concomitant therapies) to determine if the patient's drug use is appropriate, the clinical assessment will identify hospice, long-term care patients in skilled nursing and assisted living facilities, and other patients (e.g. oncology and sickle cell anemia) to be excluded from enrollment in a PRR.

Provide a mechanism to share information regarding beneficiary plan switches between Part D sponsors

There is concern that identified beneficiaries may switch plans and effectively avoid enrollment in the PRR. This concern is heightened among dual eligible beneficiaries who are allowed to switch plans on a monthly basis. Further, an evaluation completed by the Centers for Medicare &

Medicaid Services reported that dual eligible beneficiaries are three times more likely to over-utilize prescription opioids than the general Medicare population.[iv] The legislation should establish an effective mechanism to share information between plans in the event a beneficiary identified for, or enrolled, in a PRR switches plans so that this status follows the beneficiary to the new plan. Information sharing would be consistent with Health Insurance Portability and Accountability Act (HIPAA) privacy guidelines.

The legislation should define frequently abused drugs to include controlled substances in Drug Enforcement Agency (DEA) schedules II-V, and other drugs that the Secretary determines to be at-high-risk for diversion or abuse.

Inclusion of controlled substances drugs in DEA schedules II through V, which include narcotics, benzodiazepines, muscle relaxants, and other frequently abused drugs, would allow for flexibility to address current and future patterns of drug abuse. It would also reduce potential beneficiary harm by allowing designated providers to monitor and coordinate the use of all controlled substances. "Other drugs" would be identified through a comment and rulemaking process.

Address the need for processes for the termination of beneficiary enrollment in a PRR

The legislation should require that plan sponsors establish procedures for terminating beneficiary enrollment in a PRR. This ensures that beneficiaries are not enrolled in a PRR for an indefinite amount of time or when prescription drug misuse or abuse is no longer occurring.

We urge Congress to pass legislation that authorizes PRR programs in Medicare and thank you for the opportunity to provide input in the development of legislation to advance this important public health policy. We look forward to continued collaboration with Congress to ensure that PRRs work as intended and offer our support and resources to advance this policy as a valuable tool to help address the Nation's prescription drug abuse epidemic. Should you have any questions on this policy or desire additional information, please contact Lindsey Berman at the Pew Charitable Trusts at lberman@pewtrusts.org or (202) 540-6958.

Sincerely,

Academy of Managed Care Pharmacy
Alliance of Community Health Plans
Anthem, Inc.
Blue Cross Blue Shield Association
CVS Health
The Pew Charitable Trusts
National Coalition on Health Care
Pharmaceutical Care Management Association
Prime Therapeutics LLC
Express Scripts

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[i] Centers for Disease Control and Prevention, "Opioids Drive Continued Increase in Drug Overdose Deaths" (2013), accessed June 16, 2014, http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html

[ii] CDC. Vital Signs: Overdoses of Prescription Opioid Pain Relievers—United States, 1999-2008. MMWR 2011; 60: 1-6

[iii] 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

[iv] 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/HPMSSupplementalGuidanceRelatedtoImprovingDURcontrols.pdf