WAYS AND MEANS

Preventing Addiction for Susceptible Seniors (PASS) Act of 2018
H.R. 5773

Background: Many Medicare beneficiaries receive opioid prescriptions through Medicare Part D. Broadly, the Centers for Medicare & Medicaid Services' (CMS) role in Part D oversight is to provide guidance to private plans (plan sponsors) that contract with CMS to offer drug coverage to Medicare beneficiaries. Plan sponsors are encouraged to identify providers that prescribe inappropriate amounts of opioids, and in cases of fraud or abuse, refer those cases for further investigation. Accordingly, CMS has programs and processes in place to monitor overprescribing, crack down on abuse, and identify at-risk beneficiaries.

According to a July 2017 report released by the Department of Health and Human Services (HHS) Office of Inspector General (OIG), one-third of Medicare Part D beneficiaries received an opioid prescription in 2016, costing the program $4.1 billion and representing 79.4 million prescriptions.[1] The analysis also found that 501,008 Part D beneficiaries received high amounts of opioids, and 69,563 received "extreme" amounts – many as a result of "doctor shopping," a practice through which beneficiaries obtain medically unnecessary prescriptions from multiple pharmacies and prescribers.[2]

The PASS Act is the combination of several member bills that aim to prevent opioid overuse by increasing program integrity efforts and resources for beneficiaries to help ensure that they are properly adhering to their prescribed pain medications. The following bills have been included in this package:

- **Section 2: H.R. 5675, Mandatory Lock-In, Introduced by Health Subcommittee Chairman Peter Roskam (R-IL) and Health Subcommittee Ranking Member Sandy Levin (R-MI)**
- **Section 3: H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing, Introduced by Rep. David Schweikert (R-AZ) and Rep. Mike Thompson (D-CA)**

[1] OIG. Opioids in Medicare Part D: Concerns about extreme use and questionable prescribing. 2017.
[2] OIG. Opioids in Medicare Part D: Concerns about extreme use and questionable prescribing. 2017.

- **Section 4: H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act, Introduced by Rep. Jim Renacci (R-OH) and Rep. Terri Sewell (D-AL)**
- **Section 5: H.R. 5684, Protecting Seniors from Opioid Abuse Act, Introduced by Rep. Mike Kelly (R-PA) and Rep. Mike Thompson (D-CA)**
- **Section 6: H.R. 5716, Commit to Opioid Medical Prescriber Accountability and Safety for Seniors (COMPASS) Act, Introduced by Health Subcommittee Chairman Roskam (R-IL) and Social Security Subcommittee Ranking Member John Larson (D-CT)**

Section 2: Requiring Prescription Drug Plan Sponsors Under Medicare to Establish Drug Management Programs for At-Risk Beneficiaries

Background: Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 allows Medicare prescription drug plans *to voluntarily* develop a safe prescribing and dispensing program for beneficiaries that are at risk of abusing or diverting medications. The provision allows the HHS Secretary to work with plan sponsors to create "lock-in" programs, which restrict beneficiaries to certain providers or pharmacies. These programs curb fraud, abuse, and misuse of prescribed medications while at the same time ensuring legitimate access to needed medications. Such controls would prevent doctor/pharmacy shopping, as well as duplicative and inappropriate drug therapies that can lead to prescription drug abuse.

Summary: This section of the bill will *require* Medicare prescription drug plans to establish lock-in programs for seniors at-risk of opioid overuse.

Section 3: Electronic Prior Authorization for Covered Part D Drugs

Background: Prior authorization (PA) is meant to ensure that services and drugs are provided in compliance with coverage, coding, and payment rules before services are rendered and claims are paid. PA is used to prevent waste, fraud, and abuse by preventing beneficiaries from receiving (1) drugs/procedures with dangerous side effects; (2) higher cost alternative drug/procedures; (3) drugs with a high risk of abuse; and (4) drugs/procedures that are only supposed to be used for certain conditions.

Section 704 of CARA required a report by HHS on "Ways to Improve the Part D Appeals Process". In Part D, the ordering prescriber is not a party to the claim rejection transaction in the pharmacy and cannot provide additional information to resolve the coverage determination criteria. The completed report suggested that increased industry use of electronic prior authorization (ePA) transactions may help resolve issues at the pharmacy between the ordering provider and the plan, resolving denials before they enter the appeals process unnecessarily. Currently, ePA transactions are not standardized across all stakeholders. ePA standardization will help reduce abandoned prescriptions at the pharmacy counter, increase efficiencies in the appeals process by reducing claims denials, and ensure beneficiaries get the right treatment with the right cost-sharing.

Summary: This section requires the Secretary to establish a standard, secure ePA system no later than January 1, 2021. The bill further expresses the sense of Congress that increased use of ePA will reduce access delays by resolving coverage issues before prescriptions for such drugs are transmitted and that a greater priority should be placed on increasing the adoption of ePA use.

Section 4: Program Integrity Transparency Measures Under Medicare Parts C and D

Background: Currently, CMS requires Medicare Advantage (MA) and Part D plan sponsors to adopt and implement their own compliance programs to prevent fraud, waste, and abuse in the Part D program. Plans are also required to conduct investigations based on evidence of provider fraud and misconduct. Although CMS encourages the reporting of potential fraud and abuse, it does not require it.

There are a number of systems CMS may use to combat possible instances of fraud, waste and abuse. CMS uses a contractor, the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC), which conducts analyses of Part D overutilization, fraud, and abuse, including oversight of opioid prescriptions. The NBI MEDIC works with law enforcement officials in the OIG to respond to instances of fraud and abuse. The Predictive Learning Analytics Tracking Outcome (PLATO) is another system CMS, the NBI MEDIC, and Part D plan sponsors use to identify potential fraud schemes, such as prescribers who provide certain controlled substances to patients without a valid medical need. This system has the ability to access live claims data to assist in monitoring at-risk providers and patients. Though these systems exist, the Committee has received a number of complaints that plans are not receiving enough information from CMS to help with future investigations.

Summary: This section of the bill requires the Secretary, no later than two years after the date of enactment, to establish a secure Internet website portal (or other successor technology) that would allow for a secure communication between the Secretary, plans, and the MEDIC regarding certain program integrity activities. The Secretary is required to use the portal to notify plans of providers that have program integrity violations. The Secretary is required to report to plans information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. Lastly, plans are required to submit to the Secretary, on or after January 1, 2021, information on the investigations and other actions taken by such plans related to providers who prescribe a high volume of opioids.

Section 5: Expanding Eligibility for Medication Therapy Management Programs Under Part D

Background: Established by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, the Medication Therapy Management (MTM) Program is a patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence. In general, each program should include prescriber interventions to promote coordinated care, an interactive comprehensive medication review and discussion with the beneficiary to assess his or her medication therapies that results in the

creation of a written summary in CMS' standardized format, and frequent monitoring and follow-up of the beneficiary's medication therapies. Beneficiaries are engaged by both their physicians and pharmacists to talk about how well their medications are working, whether or not their medications have side effects, if there might be interactions between the drugs they are taking, and other problems beneficiaries might be having with their drug regimens. Beneficiaries also receive written summaries of this discussion, including an action plan that recommends what beneficiaries can do to make the best use of their medications, and a medication list which describes the drugs beneficiaries are taking and why they are taking them.

Currently, the MTM Program is only available to certain beneficiaries who meet all three of the following criteria:

1. Have multiple chronic diseases (plans may set a minimum threshold at two or three);
2. Are taking multiple Part D drugs (plans may set a minimum threshold at any number equal to or between two and either); and
3. Are likely to incur annual costs for covered Part D drugs that are greater or equal to a specified amount (the cost threshold for 2018 is $3,967).

Comment [DG1]: What is this supposed to mean? A little unclear

Summary: This section of the bill would require beneficiaries defined as "at-risk" for opioid overuse to be eligible for the benefits provided under the MTM Program, beginning January 1, 2021.

Section 6: Medicare Notifications to Outlier Prescribers of Opioids

Background: Currently, CMS provides comparative billing data to an individual health care provider through Comparative Billing Reports. These reports compare provider billing and payment patterns to those of their peers on both a national and state level in Medicare Parts A and B. These reports help communicate to physicians what their prescribing patterns are like in relation to their peers.

Summary: This section requires the Secretary, no later than two years after the date of enactment, to annually notify Medicare Part D prescribers that they have been identified as outlier prescribers of opioids compared to other prescribers in their specialty and geographic area. The Secretary may exclude the following individuals and prescribers from the analysis: (1) individuals receiving hospice services, (2) individuals with a cancer diagnosis, and (3) prescribers who are subjects of an investigation by the Inspector General. The Secretary may also expand notifications to concurrent prescriptions used in combination with opioids that are considered to have adverse side effects when used in such combination.