Pharmacy DIR Reform to Reduce Senior Drug Costs Act

Section-by-Section Summary

H.R. 3554 / S. 1909

Overview

In the Medicare Part D program there are payments made to Part D sponsors, including rebates and pharmacy price concessions. These payments are known as Direct and Indirect Remuneration (DIR). When pharmacy price concessions (pharmacy DIR fees) are applied at the point-of-sale of a drug to a Medicare beneficiary, they are used to reduce the cost of the drug. However, today the majority of pharmacy DIR fees are applied after a drug is dispensed to a beneficiary. Often times these fees are clawed back from pharmacies by plans/PBMs a year or longer after a drug is dispensed to a beneficiary, and the DIR fees collected do not reduce the cost of a drug for a Medicare beneficiary. A 2020 report showed that pharmacy DIR fees grew from $229 million in 2013 to an estimated $9.1 billion in 2019.[1] The Centers for Medicare and Medicaid Services (CMS) documented an extraordinary 45,000 percent increase in DIR fees paid by pharmacies from 2010-2017. More concerning, CMS has indicated that the growth of pharmacy DIR fees based on so-called pharmacy performance assessments has skyrocketed by 225% from 2012 to 2017. [2] These pharmacy performance assessments used by plans and their PBMs are arbitrary, lack transparency, and have no oversight.

Thus, pharmacy DIR fee reform is needed. ***The Centers for Medicare and Medicaid Services (CMS) has stated that eliminating pharmacy DIR claw back fees and ensuring pharmacy DIR fees are applied at the point-of-sale of a drug will save beneficiaries an estimated $7.1-$9.2 billion in reduced cost sharing.[3]***

Sec. 1 – SHORT TITLE
Pharmacy DIR Reform to Reduce Senior Drug Costs Act

Sec. 2 – REQUIRING PHARMACY-NEGOTIATED PRICE CONCESSIONS, PAYMENT, AND FEES TO BE INCLUDED IN NEGOTIATED PRICES AT THE POINT-OF-SALE UNDER PART D OF THE MEDICARE PROGRAM

This section would redefine "negotiated price," under statute. Beginning January 1, 2022, negotiated price under the Medicare Part D program would include all pharmacy price concessions (pharmacy DIR fees) at the point-of-sale to a Medicare beneficiary, so that a senior's cost-sharing for drugs under Medicare Part D will reflect all possible discounts. This will reduce beneficiary cost-sharing on drugs and eliminate the post-point-of-sale clawing back of fees applied by plans/PBMs on pharmacies, providing increased price transparency for patients and pharmacies.

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[1] Drug Channels Institute. February 13, 2020.

[2] . 83 Fed. Reg. 62152, 62174 (November 30, 2018).

[3] 83 Fed. Reg. 62154. (Nov. 30, 2018)

Sec. 3 – DISCLOSURE TO PHARMACY OF POST-POINT-OF-SALE PHARMACY PRICE CONCESSIONS AND INCENTIVE PAYMENTS

This section would require prescription drug plans (PDP) and Medicare Advantage prescription drug plans (MA-PD) to report any pharmacy price concession or incentive payment they apply after the point-of-sale to a pharmacy on at least an annual basis. Reporting must be provided in a manner that improves transparency in the fees that are applied and payments that are made to a pharmacy.

Sec. 4 – ESTABLISHMENT OF PHARMACY PERFORMANCE MEASURES UNDER MEDICARE PART D

This section would establish a new pharmacy performance evaluation system that is overseen by the Department of Health and Human Services (DHHS) and established in collaboration with multi-stakeholder consensus organization(s). The new system would begin during the plan year that begins no later than January 1, 2022.

This section would ensure that if a prescription drug plan (PDP) and Medicare Advantage prescription drug plan (MA-PD) uses measures to assess pharmacy performance, that those measures are reliable, fair and transparent. DHHS shall establish or adopt standardized, evidence-based measures that will be used to assess the performance of a pharmacy in a manner that is specific to the pharmacy type (specialty, retail, etc.) and the drugs a pharmacy dispenses and manages. Any payments to or received from pharmacies by plans following performance evaluations will be considered outside of the pharmacy DIR process. Plans and PBMs will no longer be permitted to use their own arbitrary performance measures that do not appropriately assess the work of a pharmacy in its network. DHHS shall maintain a single list of measures and ensure that measures are evaluated and updated on an ongoing basis through consensus stakeholder organizations and that they are transparent, achievable, and clinically meaningful.

In statute and regulation there is no definition for “specialty pharmacy,” which creates a challenge in verifying whether performance measures are being appropriately applied against a specialty pharmacy. This section would have DHHS work with stakeholders to define “specialty pharmacy” in regulation by December 31, 2022 in order to support the development and application of the new pharmacy performance measure system.

This section would also have DHHS develop new measures to apply in the star ratings system that is currently used to assess prescription drug plan (PDP) and Medicare Advantage prescription drug plan (MA-PD) performance. These new measures will assess plan/PBM use of the new standardized pharmacy performance measures, providing oversight and the opportunity for plans to be recognized and rewarded for their use of the new pharmacy performance measurement system.