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The PBM Oversight Act of 2023

Introduced by Senator Carper (D-Del.) and Senator Chuck Grassley (R-Iowa)
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Across the nation, families experience several barriers to getting their prescription drugs from the pharmacy. In 2023, the American Medical Association reported cost being a major barrier to patients picking up their medications and adhering to their therapy regimen prescribed by their health care providers. Cost of medications result from how they are included, or not included, on a patient health plan's formulary, or the list of covered drugs. When it is not, the out-of-pocket expense can be exorbitant because they are paying for the total unsubsidized cost of the medication(s). However, when the medication is on the health plan's formulary, the patient is only responsible for the copay. Unfortunately, copays have increased substantially over time and this is largely rooted in Pharmacy Benefit Mangers' (PBM) practices.

The Pharmacy Benefits Mangers (PBM) Steering and Accountability Act of 2023:

The PBM Oversight Act of 2023 establishes the authority for the Centers for Medicare and Medicaid Services (CMS) to oversee how PBMs decide to include, exclude, or change inclusion and exclusion of new drugs to their formulary. This is intended to steer practices back to the original goal of a Pharmacy & Therapeutics (P&T) Committee's role without it being overridden by practices that pursue profit.

Specifically, the PBM Oversight Act of 2023 would require that:

1. Prescription drug plan sponsors or PBMs submit detailed information to CMS every year, including documented interactions with the recommendation committees.
2. The Government Accountability Office will study and report findings to Congress on the role of the P&T Committee and other committees in the development and review of formularies under Medicare part D.

BACKGROUND

The Role of PBMs:

PBMs perform a variety of services for health plans or payers. These services include negotiating drug prices with pharmaceutical manufacturers; developing prescription drug formularies, or list of covered drugs; contracting with pharmacies that agree to dispense drug for established reimbursement rate; and operating their own mail-order and specialty drug pharmacies.

The negotiations that occur between PBMs and manufacturers are intended to establish a rebate percentage to a drug's list-price with the intent for those cost-savings to be realized by the patient. That realization could appear in lower premium rates or reduced copays. Instead, PBMs have often profited by these rebates.

The Role of the P&T Committee:

The Pharmacy & Therapeutics Committee (P&T Committee) is an advisory committee comprised of physicians, pharmacists, and other multidisciplinary health experts who are responsible for evaluating clinical evidence to assess a medication's clinical value.

After reviewing the scientific evidence related to a drug, P&T Committees make formulary recommendations for the PBM's national formularies, a type of formulary that is designed to be offered to PBMs or multiple plan sponsors, or for an individual's custom formulary.

According to CVS Caremark, Express Scripts, and OptumRx (3 out of the 4 largest PBMs), the P&T Committee neither has access to, nor does it consider, financial factors such as rebates, discounts, or net costs.

The P&T Committee also meets annually to review final formulary recommendations. This is often an opportunity to ensure that formularies include products for a wide-range of therapeutic classes and, if necessary, to make final adjustments to plan formularies. This activity allows P&T committees to design formulary structure in terms of drug tiers, exclusions, and copays.

PBMs and Health Plans' Recommendations Made by P&T Committees:

PBMs often maintain additional internal committees to develop formularies that are separate from the P&T Committee. These formulary development committees raise concern because they have authority to modify or reverse the recommendations of P&T committees. The development of drug formularies has a major financial impact not only on pharmaceutical companies, but also on health insurers and PBMs. Because PBMs are too often interested in protecting and increasing their profits, if the recommendations of P&T committees do not support their earnings, the PBM may override the guidance when convening their formulary development committees.

The Finance Committee's 2021 report that reviewed PBM-manufacturer contracts related to insulin uncovered specific examples of P&T committee overrides. For example, Optum Rx's "Formulary Management Committee" (FMC) on multiple accounts had presentations that referred to the financial evaluation of different insulin products, and how these drugs would impact Optum Rx financially. FMC reported on metrics such as how Humalog, a type of insulin, would impact net cost and the annual impact on rebates caused by moving Tresiba, another form of insulin, to a different formulary tier. FMC then issued guidance about structuring formularies that considered P&T Committee analysis, in addition to other influences, to include OptumRx staff and "other supporting financial, business, and benefit strategy analyses."