Modernizing and Ensuring PBM Accountability Act

Section-By-Section Summary

Section 1. Short Title; Table of Contents.

This section sets out the name of the bill - the "Modernizing and Ensuring PBM Accountability Act" - and lists the Table of Contents of the Act, including all eight of its sections.

Section 2. Arrangements with Pharmacy Benefit Managers with Respect to Prescription Drug Plans and MA-PD Plans.

This section would require each contract Medicare enters into with a Part D plan (PDP) sponsor to offer outpatient prescription drug benefits provides that any pharmacy benefit manager (PBM) acting on behalf of a plan sponsor has an agreement with the plan sponsor to meet the requirements of the provisions outlined below. All requirements would apply to MA–PD plans, as well as PDPs.

Delinking PBM Income from Prescription Drug Prices

This provision would prohibit PBMs and their affiliates from deriving income or remuneration for covered Part D drugs based on a manufacturer's price for the drug. Specifically, PBM remuneration must be in the form of a "bona fide service fee" for services provided and such fees must reflect the fair market value for such services. A bona fide service fee would be required to be a flat dollar amount, rather than based or contingent upon the manufacturer list price or other related drug price benchmarks and factors. Part D plan sponsors could continue to accept rebates, discounts, or price concessions that lower net cost for covered Part D drugs.

Consistency in Terms for Pricing Guarantees & Cost Performance Evaluations

This provision would require PBMs to define and apply drug and drug pricing terms in contracts with Part D plan sponsors in a transparent and consistent manner for purposes of calculating or evaluating PBM performance against pricing guarantees or similar cost performance measurements.

Enhanced PBM Reporting Requirements

This provision would set out new requirements for PBMs to annually report drug price and other information to Part D plan sponsors and to the Secretary of Health and Human Services (HHS). PBMs would be required to include information related to several categories, such as information related to covered Part D drugs, drug dispensing, drug costs and pricing, generic and biosimilar formulary placement, PBM affiliates, financial arrangements with consultants, and potential PBM conflicts of interest. The HHS Secretary would be barred from publicly disclosing information obtained from these reports, except in limited circumstances. The information also could not be disclosed in a way that would identify a specific supply chain stakeholder or prices for specific drugs.

Audits & Enforcement

This provision would permit Part D plan sponsors to audit their PBM for compliance with contract requirements, including under these provisions. The Part D plan sponsor would have the right to select the auditor. The PBM would be required to provide information to the auditor necessary to perform the audit and confirm the accuracy of PBM reporting, including information owned or held by a PBM's affiliate, in a timely manner.

If a PBM is found to be out of compliance with these provisions, the PBM would be required to: (1) disgorge remuneration that violates the delinking provisions; (2) reimburse the PDP sponsor for any civil monetary penalties imposed as a result of violations of these provisions; and (3) be subject to punitive remedies for breach of contract with the PDP sponsor for failing to comply with these provisions. An annual certification of compliance with the provisions outlined above must also be provided by Part D plan sponsors to the HHS Secretary.

Effective Date

The provisions in Section 2 would take effect starting plan year 2026.

Section 3. Ensuring Fair Assessment of Pharmacy Performance and Quality under Medicare Part D.

This provision would require the HHS Secretary to institute standard Part D measures for assessing network pharmacy performance. Under the provision, PDP plan sponsors may only use pharmacy performance measures that are: (1) established or adopted by the HHS Secretary; and (2) relevant to the pharmacy. The HHS Secretary would be required to establish or adopt standardized pharmacy performance measures that were: (1) evidence-based and reasonable; and (2) focused on pharmacy performance related to patient health outcomes and other areas that pharmacies can impact. Rather than establishing some or all of the required performance measures, the HHS Secretary may adopt measures endorsed by a multi-stakeholder consensus organization (such as the Pharmacy Quality Alliance), that has participation from pharmacies, health plans, PBMs, and CMS. This provision would take effect starting plan year 2025.

Section 4. Promoting Transparency for Pharmacies under Medicare Part D.

This provision would establish a process by which Part D plan sponsors provide their network pharmacies with comprehensive information about pricing prescription drug claims to help increase predictability in pharmacy reimbursement. These provisions would take effect starting plan year 2025.

Section 5. Preventing the Use of Abusive Spread Pricing in Medicaid.

This provision would ban PBM spread pricing in the Medicaid program. Spread pricing occurs when a PBM reimburses a pharmacy at a lower amount than the amount charged to the PBM's health plan client, with the PBM pocketing the difference. Specifically, this provision requires pass-through pricing for covered outpatient drugs reimbursed under Medicaid, including when

services are provided under contract with managed care organizations. Payment for PBM services would be limited to the ingredient cost for the drug (i.e.: an amount that approximates pharmacy acquisition costs) and a professional dispensing fee. This amount must be passed through in its entirety from the PBM to the pharmacy. These provisions would take effect 18 months after enactment.

Section 6. Ensuring Accurate Payments to Pharmacies Under Medicaid.

This provision would require participation by retail community pharmacies in the National Average Drug Acquisition Cost (NADAC) survey. The NADAC survey measures pharmacy acquisition costs and is often used in the Medicaid program to help inform reimbursement to pharmacies. This provision would take effect 18 months after enactment.

Section 7. HHS OIG Study and Report on Drug Price Mark-Ups in Medicare Part D.

This provision would require the HHS Office of Inspector General (OIG) to investigate the impact of vertical integration between Part D plans, PBMs, and pharmacies including effects on beneficiary out-of-pocket costs and Medicare spending under the Part D program. The OIG must submit a report with its findings to Congress within a specified timeframe.

Section 8. P&T Committee Conflicts of Interest

This provision would amend Section 1860D-4 of the Social Security Act (SSA) to require that at least one practicing physician and one practicing pharmacist is independent and free of conflict with respect to any pharmacy benefit manager.

Section 9. Enhancing PBM Transparency Requirements.

This provision would amend Section 1150A of the SSA to expand the type of entities that must report data to the HHS Secretary to include certain PBM affiliates, to add data elements that would be required to be reported (to include fees received from manufacturers), and to add a requirement for CMS to produce an annual report with confidentiality protections.

Section 10. Facilitating Midyear Formulary Changes for Biosimilars.

This provision would allow PDP sponsors to change the preferred or tiered cost-sharing status of a reference biological product if such sponsor adds a biosimilar for such reference product to the formulary. The PDP sponsor would need to submit a request to the Secretary in order to make such a change. This provision would take effect beginning in plan year 2025.

Section 11. Strengthening Pharmacy Access for Seniors.

This provision would mitigate PBM steering to PBM-owned pharmacies for medicines that do not qualify as “limited access drugs” by codifying a portion of the Part D manual. The provision would also increase transparency of PBM practices in the prescription drug supply chain related to the dispensing of limited access drugs.

Section 12. Initiating Meaningful Patient Review of Various Existing Part D Regulations.

This provision would direct CMS to conduct beneficiary-focused listening sessions open to the public on potential Medicare Part D improvements.

Section 13. Reporting on Enforcement and Oversight of Pharmacy Access Requirements.

This provision would require the HHS Secretary to publish biennial reports on enforcement actions and oversight activities undertaken by the Department with respect to the pharmacy access requirements under section 1860D-4(b)(1) of the Social Security Act.

Section 14. Study on Price-Linked Compensation Across the Supply Chain.

This provision would require GAO to complete a study of compensation and payment structures related to drug prices in the retail prescription drug supply chain.

Section 15. Reports on Inappropriate Pharmacy Rejections.

This provision would require the Secretary to publicly post a biennial report related to preventing, identifying, or addressing inappropriate pharmacy rejections and inappropriate coverage denials under Part D.

Section 16. Study on Drug Shortages.

This provision would require GAO to complete a study of factors across the outpatient prescription drug supply chain that influence prescription drug shortages.

Section 17. Report on Biosimilar and Generic Access Under Part D.

This provision would direct HHS OIG to conduct a study and generate a report on biosimilar and generic drug access under Part D, including with respect to Part D plan features that discourage or encourage low-priced biosimilar and generic drug adoption and utilization under the program, along with trends in such adoption and utilization.

Section 18. Medicare Improvement Fund.

This provision would direct the $1.947 billion in savings from the Modernizing and Ensuring PBM Accountability Act to the Medicare Improvement Fund.