December 17, 2024

Further Continuing Appropriations and Disaster Relief Supplemental Appropriations Act, 2025

Summary of Select PBM Provisions

Sec. 113. Preventing the use of abusive spread pricing in Medicaid. (pp. 65-72)

Effective date: Applies to contracts that have an effective date beginning on or after the date that is 18 months after enactment.

Included new definitions: Pharmacy Benefit Manager

Rulemaking requirements: Waives rulemaking (and application of the APA and PRA) and permits implementation by program instruction. The Secretary must develop forms for reporting on 340B drug purchases and for reporting of detailed PBM cost and payment data. The Secretary must also define the fair market value of PBM administrative services,

Overview. This section amends the Medicaid Drug Rebate Program (MDRP) statute to require a "transparent prescription drug pass-through pricing" model for any arrangements between a PBM and a state Medicaid agency or Medicaid managed care plan where the PBM is responsible for coverage of covered outpatient drugs. This section also restricts any form of spread pricing, whereby the amount charged by the PBM to the state or Medicaid MCO that exceeds the amount paid to the pharmacy is treated as unallowable for purposes of claiming Federal match.

Pass-through pricing required. Under the required pass-through pricing model, payment to a pharmacy must be limited to (1) ingredient cost; and (2) a professional dispensing fee no less than the amount provided under the state plan, and must be fully passed through to the pharmacy or provider dispensing the drug. Such payments must also comply with a range of existing Medicaid regulatory requirements otherwise imposed directly on states (upper limits, etc.).

Pass-through pricing exception for 340B-acquired drugs. In the case of a drug dispensed by a 340B covered entity to a patient of that covered entity, the payment by the PBM for the acquisition cost *may* exceed the "actual acquisition cost" if the drug is (1) a 340B drug; (2) the cost does not exceed the maximum amount that would have otherwise been paid by the PBM if the drug was not a 340B drug; and (3) the covered entity reports to the Secretary on an annual basis on payments for ingredient costs that are in excess of the actual acquisition costs for such drugs. HHS shall publish on at least an annual basis the results of such reports, without identifying any covered entity, broken out by covered entity category (e.g., FQHC, DSH hospitals).

FMV Payments to PBM. The pass-through pricing model requires that any payment to the PBM for administrative services performed is limited to an administrative fee that reflects fair market value (as defined by the Secretary).

Reporting by PBM to State and CMS. The PBM must make available to the state (and CMS on request), in a form specified by CMS, all costs and payments for drugs and administrative services broken down on a drug-by-drug basis by ingredient costs, professional dispensing fees, administrative payments, post-sale and post-invoice fees, discounts, or related adjustments (if costs are attributable on such a drug-by-drug basis).

Limitation on spread pricing. The section restricts the ability of a state to claim Federal matching payments on any amounts charged by a PBM that exceed the amount paid to pharmacies, including any post-sale or post-invoice adjustments, after allowing for permitted administrative fees).

Sec. 222. Adjustment to Medicare Part D cost-sharing reductions for low-income individuals. (pp. 106-108)

Effective date: Plan year 2027.

Included new definitions: n/a

Reductions in cost-sharing. This section eliminates generic drug cost-sharing for the Medicare Part D Low-Income Subsidy (LIS) program. Medicare beneficiaries with income up to 150% of the federal poverty level (FPL) quality for the LIS program, which provides additional cost-sharing and premium assistance to eligible beneficiaries. Under the 2025 benefit, most beneficiaries would typically pay a copayment from $1.60 to $4.90 for a generic or preferred multi-source drug, and $4.80 to 12.15 for brand, depending on income level (some who are institutionalized or receive HCBS pay nothing). Per this provision, beginning in plan year 2027, copayments for:

- Generic drugs are $0
- Multiple source preferred drug copayments are calculated based on the dollar amount for the preceding plan year increased by the annual percentage increase in the consumer price index (CPI) as of September of the preceding year.

This provision appears to be calculated to incentivize more LIS beneficiaries to pick generic drugs over brand counterparts. As MedPAC has reported, the current differential between copayments for generic and brand name drugs might not provide enough financial incentive for beneficiaries to use generics.

Sec. 226. Assuring pharmacy access and choice for Medicare beneficiaries. (pp. 129-146)

Effective date: January 1, 2028 for Any Willing Pharmacy (AWP) and Essential Retail Pharmacies. January 1, 2027 for PBM reporting of incentive payments.

Included new definitions: References "affiliate" and "pharmacy benefit manager" definitions included in MEPA.

Rulemaking requirements: Waives rulemaking (and application of the PRA) and permits implementation by program instruction. CMS must develop a standard template for pharmacy submissions of allegations related to standard terms and conditions.

Standard Contract Terms and Conditions. This section amends the existing Any Willing Pharmacy requirement in the Part D statute to require that beginning January 1,2028 a Part D plan sponsor include as a "network" pharmacy any pharmacy that meets the "standard contract terms and conditions" under the plan. Under current law, Part D plans are permitted to define their own terms and conditions, although CMS' regulations require such terms be "reasonable and relevant." By April 1, 2026 CMS must issue an RFI on a broad range of standards for reasonable and relevant contract terms and conditions, and by the first Monday in April of 2027, the Secretary is required to establish standards for reasonable and relevant contract terms and conditions.

Essential Retail Pharmacies. This section also establishes a new category of pharmacy termed "essential retail pharmacy" defined as a retail pharmacy that: (1) is not an affiliate of a PBM or PDP sponsor; and (2) is either located in a medically underserved area (MUA), a rural area with no retail pharmacy within 10 miles, a suburban area with no retail pharmacy within 2 miles, or an urban area with no retail pharmacy within 1 mile. Beginning January 1, 2028, CMS must publish a list of essential retail pharmacies on a publicly available website. Also beginning January 1, 2028, Part D sponsors must submit to CMS a list of pharmacies that are affiliates of the plan sponsor.

Beginning January 1, 2028, and at least once every two years through 2034, CMS must publish a report on: (1) trends on reimbursement, fees, and payments to essential retail pharmacies and those that are not essential; (2) trends on amounts paid to Part D sponsors by essential retail pharmacies and those that are not essential (3) trends in network pharmacy participation by both pharmacy types; (4) trends in the number of essential retail pharmacies by geography; (5) a comparison of cost-sharing for drugs dispensed at network essential retail pharmacies and those that are not essential; (6) a comparison of the volume of drugs dispensed by both pharmacy types located in similar geographies, including by type of drug dispensed; and (7) a comparison of the information provided above broken down by standalone Part D plans and MA-PD plans.

Reporting on Incentive Payments. Beginning January 1, 2027, Part D sponsors must submit information to CMS on incentive payments and other fees to pharmacies not otherwise reported to CMS.

Enforcement Regarding Standard Terms and Conditions. Beginning January 1, 2028, the Secretary must establish a process and standard template to allow a pharmacy to submit an allegation of a violation (not more than once per plan year per contract, except to the extent the pharmacy contract is modified) of the standards for reasonable and relevant contract terms and conditions. A Part D sponsor subject to an allegation shall submit to CMS documents and materials requested by CMS and may not prevent the pharmacy from also submitting documentation. To the extent CMS determines a pharmacy has submitted frivolous allegations on a routine basis, CMS may temporarily prohibit such a pharmacy from using the process. Allegations are exempt from disclosure under FOIA.

CMS may impose civil monetary penalties where it determines that a Part D sponsor has violated the standards for reasonable and relevant contract terms and conditions.

Biennial Report on Pharmacy Access Requirements. Not later than two years after enactment and every two years after, CMS shall publish a report on enforcement and oversight of the requirements of this section, except that it shall not disclose identifiable information about individuals or entities, or contain trade secret information.

Sec. 227. Modernizing and Ensuring PBM Accountability Act (pp. 146-182)

Effective date: January 1, 2028.

Included new definitions: Affiliate, Bona Fide Service Fee, Pharmacy Benefit Manager

Rulemaking requirements: Waives rulemaking (and application of the PRA) and permits implementation by program instruction. However, the Secretary's defining of fair market value for purposes of defining a "bona fide service fee" is subject to notice-and-comment rulemaking.

Overview. The legislation establishes stricter requirements for Pharmacy Benefit Managers (PBMs) under Medicare Part D, aiming to address transparency, improper remuneration, and potential conflicts of interest, beginning with plan years on or after January 1, 2028. Of note, this section "delinks" PBM compensation from the utilization of covered Part D drugs, requiring instead that PBM compensation consist only of flat, fair market value bona fide service fees.

Agreements with Pharmacy Benefit Managers**.** PDP sponsors and MA-PDs would be required to include the following provisions in their contracts with PBMs and any affiliates of such PBMs:

- *Bona Fide Service Fees***:** PBMs can only receive remuneration in the form of bona fide service fees, defined as flat fees reflecting fair market value for specific services.
    - *Incentive Payments*. Incentive payments are deemed "bona fide service fees" notwithstanding the above definition if such incentive payments are (1) a flat dollar amount, (2) consistent with fair market value, (3) related to services actually provided by the PBM or its affiliate on behalf of the PDP sponsor in connection with the utilization of Part D drugs, and (4) meets any other requirements determined appropriate by the Secretary.
    - *Rebates Passed-Through To PDP Sponsor*. Rebates, discounts and other price concessions received by the PBM and fully passed through to a PDP sponsor are not subject to the bona fide service fee limitation described above. Such pass-through arrangements must comply with all direct/indirect remuneration requirements, including in cases where a PDP sponsor is acting as a PBM on behalf of a PDP offered by such PDP sponsor.
- *Evaluation of Remuneration Arrangements*. The Secretary is granted express authority to review components of subsets of remuneration arrangements between PBMs and their affiliates and other entities involved in the dispensing or utilization of covered Part D drugs, including PDP sponsors, manufacturers, pharmacies, and other entities as determined appropriate by the Secretary. The Secretary shall conduct this review in consultation with the OIG of HHS, as determined appropriate by the Secretary. This review would examine whether remuneration such arrangements is consistent with fair market value (as specified by the Secretary) through reviews and assessment of such remuneration.
- *Disgorgement*. The PBM must disgorge any remuneration found inconsistent with the above requirements.
- *Additional PBM Requirements***:**
    - *PBMs and Affiliates*. PBMs must include disgorgement clauses in their written contracts with their affiliates who must identify and disgorge any remuneration identified above. The PBM must attest that it has implemented these clauses in their affiliate contracts.
    - *Transparency Regarding Guarantees and Cost Performance Evaluations*. PBMs must define, interpret, and apply in a "fully transparent and consistent manner" certain key definitions relating to the PBMs pricing guarantees or similar cost performance

measurements related to rebates, discounts, price concessions, or net costs, including:

- Generic drug, which should be defined in accordance with 42 CFR 423.4.
- Brand name drug, which should be defined consistent with 42 CFR 423.4 along with "specialty drug," "rebate," and "discount".

Further, when a pricing guarantee or other cost performance measure is based on a pricing benchmark other than WAC, the PBM shall calculate and provide a WAC-based equivalent to the pricing guarantee or other cost performance measure.

- *PBM Transparency Requirements*. Not later than July 1 of each year, beginning in 2028, PBMs must submit to PDP sponsors and the Secretary a report (at no cost and in a format specified by the Secretary). Each report should contain the following data from the previous plan year with respect to each PDP sponsor and each plan offered by such sponsor:
  - *Drug Utilization And Cost Data*. A list of all drugs covered by the plan and with respect to *each* drug the following information:
    - Drug Identifiers: Brand name, generic name, and National Drug Code (NDC).
    - Utilization Metrics: Number of plan enrollees, prescription claims (including refills), and total dosage units dispensed, including a breakdown by dispensing channel (e.g., retail, mail order, specialty pharmacy).
    - Pricing Information: Average Wholesale Acquisition Cost (WAC), Average Wholesale Price (AWP), and National Average Drug Acquisition Cost (NADAC).
    - Out-of-Pocket Costs: Total enrollee spending, including copayments, coinsurance, and deductibles.
    - Rebates and Remuneration: Total manufacturer rebates and other direct/indirect remuneration (DIR).
    - Revenue Retained: Manufacturer-derived revenue retained by the PBM and affiliates.
  - *Affiliate Pharmacy Data*. If a PBM affiliate dispenses drugs, the PBM must report the percentage of total prescriptions dispensed by the affiliate, compare costs (per unit, course, or supply) for drugs dispensed by affiliates versus non-affiliates, provide acquisition cost differences for affiliate-dispensed drugs, and identify drugs subject to 340B pricing agreements with covered entities.
  - *Generic and Biosimilar Coverage*. For brand drugs versus generic or biosimilar alternatives, the PBM must list generic or biosimilar drugs not covered or subject to higher cost-sharing, estimate beneficiary cost-sharing for alternatives if they were equally covered on the same formulary tier, and provide a written justification for the preferential coverage of brand drugs or reference products over lower-cost alternatives.
  - *Plan Spending*. Total gross and net spending on Part D drugs and an explanation of any benefit design features (e.g., mail order programs) that

encourage enrollees to use PBM-affiliated pharmacies. This includes all a list of brokers, consultants, advisors, and auditors receiving compensation for services related to pharmacy benefit management, the amount of compensation provided to each entity, the methodology used to calculate such compensation, a list of all PBM affiliates, and a summary document in a standardized template (determined by the Secretary) outlining the required information.

- *Agreements with Manufacturers***.** PBMs must provide a PDP sponsor, within 30 days of executing a contract with a manufacturer, a written explanations for contracts or agreements with drug manufacturers that include rebates, discounts, or financial incentives tied to coverage, formulary placement, or utilization management of Part D or other prescription drugs. The explanation must include (1) the manufacturer and covered drugs involved, (2) a high-level description of the contract terms and their application to the drugs, (3) certification by a senior officer (CEO, CFO, General Counsel) or a delegated individual reporting to the officer of the PBM, and (4) "Other prescription drugs", which includes supplemental benefits or drugs paid outside of Part D, that are subject to the agreement between the PBM and manufacturer.

- *Audits***.** PBMs must permit audits at least once per year upon request from PDP sponsors. PDP sponsors can choose the auditor without restrictions from the PBM. PBMs must provide all necessary records, contracts, and data (including from affiliates) to verify compliance, subject to "reasonable" safeguards against unauthorized disclosure. PBMs must supply this information within 6 months of the audit's start and respond to additional requests within 30 days.

Enforcement and Confidentiality. PDP sponsors must enforce PBM compliance, return improperly retained funds to the Secretary, certify annual compliance, and adhere to anti-retaliation protections, while the Secretary must maintain a confidential reporting system for PBM violations. Specifically:

- *PDP Sponsor Responsibilities*. PDP sponsors must return any amounts improperly retained by PBMs to the Secretary. PDP sponsors must require PBMs through contract to reimburse any civil penalties caused by their non-compliance, including punitive remedies for contract breaches related to these requirements. PDP sponsors must annually certify compliance with these provisions, which the Secretary can further implement through subregulatory guidance.
- *Reporting System*. The Secretary must make available and maintain a mechanism that allows manufacturers, PDP sponsors, pharmacies, and other entities to report PBM violations confidentially.
- *Anti-Retaliation*. PDP sponsors are prohibited from retaliating, coercing, or intimidating individuals or entities reporting violations.

Rule of Construction. Nothing in any of these requirements imposed on PBMs and PDP sponsors should be construed to prohibit industry-standard dispensing fees, reimbursement for ingredient costs, or industry-standard discounts retained by pharmacies or wholesalers.

Standard Formats. The Secretary must establish standardized, machine-readable formats by June 1, 2027, for pharmacy benefit managers (PBMs) to submit required annual reports. The Secretary has the authority to implement this requirement through program instructions.

Confidentiality. Information disclosed by PBMs affiliates, PDP sponsors, or pharmacies that is not publicly available must remain confidential. However, the Secretary may share the information for specific purposes, including reviews by the Comptroller General, CBO Director, MedPAC Executive Director, Attorney General, and the HHS Inspector General for oversight and enforcement. The disclosed information cannot be made public in a way that identifies specific PBMs, affiliates, pharmacies, manufacturers, PDP sponsors, or plans, nor can it reveal prices, rebates, or discounts tied to specific drugs or parties.

Definitions. The legislation defines several key terms that govern the implementation of the above requirements, including:

- *Affiliate*. An "affiliate" is broadly defined to encompass any entity related to a PBM or PDP sponsor. Two pathways are specified to determine an entity's affiliation: (1) Ownership and Control–the entity owns, is owned by, controls, or is controlled by the PBM or PDP sponsor; or (2) Contractor, Principal, or Agent Role—the entity acts as a contractor, principal, or agent to a PBM or PDP sponsor.
- *Bona Fide Service Fee*. A "bona fide service fee" is narrowly defined and must meet specific criteria:
    - *Reflective of Fair Market Value*. The fee must represent fair market value (FMV) for a legitimate, itemized service performed on behalf of an entity. FMV will be determined by the Secretary through notice and comment rulemaking.
    - *Actual Service Requirement*. The service must be itemized and something the entity would otherwise perform itself (or contract for) if the service agreement did not exist.
    - *Not Passed Through*. The fee cannot be passed on, directly or indirectly, to a client or customer, regardless of whether the entity takes ownership of the drug.
    - *Flat Fee Requirement*. The fee must be a flat dollar amount and cannot be tied to the following:
        - Drug price benchmarks (e.g., Wholesale Acquisition Cost (WAC) or Average Wholesale Price (AWP)).
        - Discounts, rebates, fees, or remuneration linked to covered Part D drugs dispensed to enrollees, except as explicitly permitted under paragraph (1)(A)(ii).

        - Coverage decisions, formulary placement, or the volume/value of referrals or business generated between the parties.
        - Any other amounts or methodologies prohibited by the Secretary.

- *Pharmacy Benefit Manager*. A "pharmacy benefit manager" (PBM) includes any person or entity that performs PBM-related functions, whether directly or through an intermediary. PBM-related functions encompass:
    - Price negotiation or acting as a group purchaser on behalf of a PDP sponsor or prescription drug plan.
    - Management of prescription drug benefits, which includes:
        - Processing and paying claims for prescription drugs.
        - Performing drug utilization review (DUR).
        - Processing prior authorization requests.
        - Adjudicating appeals or grievances related to prescription drug benefits.
        - Contracting with network pharmacies.
        - Controlling the cost of covered Part D drugs.
        - Providing related services connected to drug benefits.

GAO Study. The Comptroller General of the United States (GAO) is tasked with conducting a comprehensive study on compensation and payment structures tied to prescription drug prices within the retail prescription drug supply chain under Medicare Part D. The GAO will submit a report to Congress within 2 years of enactment with legislative and administrative recommendations. The GAO's the study will focus on the following key elements:

1. *Types and Features of Price-Related Compensation Structures.* The GAO will examine type, magnitude, prevalence, and other features of compensation structures, including pricing benchmarks (e.g., fees calculated as a percentage of drug prices). Entities included in the analysis:
    - Pharmacy Benefit Managers (PBMs).
    - PDP sponsors and Medicare Advantage Organizations offering MA-PD plans.
    - Drug wholesalers.
    - Pharmacies
    - Manufacturers.
    - Pharmacy Services Administrative Organizations (PSAOs).
    - Brokers, auditors, consultants, and other entities that:
    - Other service providers that contract with any of the above, including rebate aggregators.

2. *Business Models and Compensation Structures.* The study will identify and analyze the primary business models and compensation structures used by each intermediary.

3. *Variation Between Affiliates and Unaffiliated Entities*. The GAO will evaluate differences in compensation structures between affiliated entities (e.g., those with common ownership or subsidiary relationships) and unaffiliated entities.
4. *Conflicts of Interest*. The study will assess potential conflicts of interest caused by price-based compensation structures.
5. *Differences Across Time and Market Segments*. The study will explore any notable differences in the use and prevalence of price-related compensation structure over time across different market segments such as Medicare Part D and Medicaid.
6. *Effects on Federal Health Care Programs and Beneficiaries*. The GAO will analyze the impact of price-based and alternative compensation structures on Federal health care programs, with a specific focus on the impact on program beneficiaries relating to Cost-sharing, premiums, federal expenditures, adoption and utilization of biosimilar and generic drugs, risks of drug shortages, and incentives for higher-priced drugs due to fees tied to drug prices.
7. *Other Relevant Issues*. The GAO may include other issues it deems relevant and appropriate to the study.

MedPAC Report. MedPAC must submit two reports to Congress analyzing PBM agreements for PDPs and MA-PD plans. An initial report (due 2 years after receiving data) discussing trends and patterns in PBM agreements, impacts on enrollee out-of-pocket costs and pharmacy reimbursements, and recommendations. 2 years after the initial report, MedPAC must updates its report on changes and offer further recommendations. $1 million are allocated to MedPAC for fiscal year 2025, available until expended to carry out this section.

Sec. 901. Oversight of pharmacy benefit management services. (p. 448-533)

Applicability: New reporting requirements in this section are applied to entities providing PBM services for all group health plans, whether fully or self-insured, regulated under Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.), Subtitle B of title I of ERISA, and Chapter 100 of the Internal Revenue Code (IRC).

Reporting requirements are less substantial and detailed for PBM services to an insured group health plan (as opposed to a self-insured plan), unless the plan is a specified large plan or offered by a specified large employer *and* elects to receive more detailed reports from its insurer's PBM.

Effective date: Applies to contracts for plan years beginning on after the date 30 months after the date of enactment.

Rulemaking requirements: Within 18 months of enactment, the Secretary shall specify through notice-and-comment rulemaking a standard format for the reporting required of entities offering PBM services, as well as any other regulations necessary to implement the section.

Section-specific definitions:

- "Applicable entity" means (A) any "applicable GPO" (meaning associated with PBM), manufacturer, distributor, wholesaler, "rebate aggregator (or other purchasing entity designed to aggregate rebates)" or associated third party; (B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that

provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A)"; and any other entity the Secretary "may specify" in rulemaking.

- "Contracted compensation" means "the sum of any ingredient cost and dispensing fee for a drug (inclusive of the out-of-pocket costs to the participant or beneficiary), or another analogous compensation structure that the Secretary may specify through regulations."
- "Gross spending" means spending by the plan before rebates/fees/alternative discounts/other remuneration.
- "Net spending" means spending by the plan after rebates/fees/alternative discounts/other remuneration.
- "Remuneration" shall be defined by the Secretary through rulemaking, reevaluated every 5 years.
- "Plan sponsor" has the definition provided in section 3(16)(B) of ERISA.
- "Specified large employer" means an employer with at least 100 employees I the previous year.
- "Specified large plan" means a group health plan established or maintained by an employer with eat least 100 participants in the previous year, or a group health insurance coverage offered in connection with such a plan.
- WAC is defined by reference to Section 1847A of the Social Security Act.

Restrictions on contracts: PBMs, group health plans, or health insurance issuers may only enter into contracts that:

- Do not limit or delay disclosure of information to the issuer/health plan in a way that prevents the entity providing PBM services from making the reports required by this section.
- Provide the entity providing PBM services with the information needed to complete reports required by the section.

Reports required: For plan years beginning on or after the effective date, the entity providing PBM services must, at least every 6 months (or, at the request of a group plan, not less than quarterly on request) submit a report to the plan in plain language, machine-readable format, and any other format as the Secretary may require, containing information regarding drugs covered by the plan:

For self-insured group health plans that are "specified large plans" or offered by a "specified large employer" or involving a paragraph 3 election (see below):

- List of drugs for which a claim was filed, with the following information about each such drug:
  - Contracted compensation paid by the plan/issuer to the entity providing PBM services, broken down by National Drug Code (NDC).
  - Contracted compensation paid to the pharmacy by any entity providing PBM services or other applicable entity, broken down by NDC.
  - The difference, for each such claim, between the amount in the two previous bullets.

  - Broken down by type of dispensing channel (retail, mail order, specialty pharmacy) for each drug dispensed:
    - Whether the drug is brand or generic.
    - For brand name drugs, WAC by per days supply and per days dosage unit on date of dispensing.
    - For generics, AWP by per days supply and per dosage unit, on date of dispensing.
    - Total number of prescription claims.
    - Total number of beneficiaries.
    - Dosage units and dosage units per fill.
    - Days supply of each drug per fill.
  - Net price per course of treatment or single fill after rebates, fees, alternative discounts, or other remuneration from applicable entities.
  - Total amount of OOP spending on the drug, except for non-covered drugs or drugs for which a claim was not submitted.
  - Total net spending on the drug.
  - Total amount received or expected to be received by the plan from any applicable entity in rebates, fees, alternative discounts, or other remuneration.
  - Total amount received by the entity providing PBM services from the applicable entity in rebates, fees, alternative discounts, or other remuneration for claims during the reported period related to utilization or spending on the drug.
  - "To the extent feasible," information on total amount of remuneration for the drug provided by manufacturers (including, copay cards, etc.)
- A list of each therapeutic class (defined by the Secretary) for which a claim was filed and, with respect to such classes:
  - Total gross spending to the class before rebates/price concessions/alternative discounts/other remuneration from applicable entities.
  - Net spending in such class after rebates/price concessions/alternative discounts/other remuneration from applicable entities.
  - Total amount received or expected to be received by the entity providing PBM services from applicable entities in rebates/price concessions/alternative discounts/other remuneration for claims during the reporting period related to utilization or spending on the drug.
  - Average net spending per 30 day and 90 day supply by the plan on such coverage among all drugs within the class.
  - Number of participants/beneficiaries who filled a prescription for a drug in the class, broken down by NDC.

    - As applicable, a description of formulary tiers and utilization management (UM) such as prior authorization (PA) or step therapy (ST) for drugs in the class.
    - Total out of pocket spending on drugs in the class by participants/beneficiaries, excluding non-covered drugs or drugs with no claim filed.
- For any drug with gross spending exceeding $10,000 during the reporting period, or a minimum of the 50 highest spending drugs:
    - A list of all other drugs in the same therapeutic class.
    - The rationale for the formulary placement of such drug, selected from a set of standard rationales developed by the Secretary in consultation with stakeholders.
    - Any change in formulary placement versus the prior plan year.
    - Where the entity providing PBM services has an affiliated pharmacy or pharmacy under common ownership (including home delivery, mail order, etc.):
        - Explanation of any benefit design parameters to encourage participants/beneficiaries to use mail order, specialty, or retail pharmacies.
        - Percentage of total prescriptions dispensed by affiliated pharmacies to participants/beneficiaries.
        - List of all drugs dispensed by affiliated pharmacies to plan participants/beneficiaries, including:
            - Amount charged per dosage unit, 30 day supply, or 90 day supply (as appliable) to the plan and to participants/beneficiaries.
            - Median amount charged to the plan and interquartile range of such costs per dosage unit, 30 day supply, *and* 90 day supply, including amount charged to participants/beneficiaries, when the drug is filled at a non-affiliated pharmacy that is in-network.
            - Lowest cost per dosage unit. 30 day supply, and 90 day supply for each drug, including amount charged to participants/beneficiaries, from any in-network pharmacy.
            - Net acquisition cost per dosage unit, 30 day supply, and 90 day supply if the drug is subject to a "maximum price discount."

For any group plan/issuer, including fully insured plans, regardless of large employer/specified large plan designation:

- A summary document including such information from the previous section required for large employers/plans that the Secretary determines useful, through

guidance/program instruction (not notice-and-comment rulemaking) for the purposes of selecting PBM services, such as estimated net price for drug, cost per claim, fee structure, and estimated cost per participant/beneficiary.

- A summary document for plans to provide to participants/beneficiaries, available on request, including, as specified by the Secretary through guidance/program instruction to be useful (with only aggregate information, though claims level information may be requested):
    - Total net spending by the plan for covered drugs.
    - Total amount received by the plan from any applicable entity in rebates/fees/alternative discounts/other remuneration.
    - "To the extent possible," total remuneration paid, through methods such as copay cards, form the manufacturer.
    - Amounts paid in rebates, fees, or other compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA) of ERISA) paid by the plan to brokers, consultants, advisers, or other individuals/firms for referral of business to an entity providing PBM services, consideration of the entity providing PBM services, or retention of the entity.
- Explanation of any benefit design parameters designed to encourage or require participants/beneficiaries to use affiliated pharmacies.
- Total gross spending on all drugs during the reporting period.

Paragraph 3 opt-in: Non-large employers/non-large group plans may elect to require the entity providing PBM services to provide the report with the more extensive, large employer/group plan reporting requirements if the plan is offered in connection with a plan offered by a large employer or large plan.

Privacy requirements: Information shall be reported under these requirements consistent with section 13402(a) of the HITECH Act and HIPAA privacy regulations. The entity providing PBM services shall ensure the report submitted shall include "only summary health information" as defined at 45 C.F.R. 164.504(a) or successor regulations. The plan shall comply with 45 C.F.R. 164.504(f) in comply with the reporting requirements.

Protections: A rule of construction states that nothing in the reporting section shall be construed to affect requirements for PHI under HIPAA privacy regulations or affect protections in other privacy laws, as well as GINA, the ADA, Section 504 of the Rehab Act, Section 1557 of the ACA, and Title VI and VII of the Civil Rights Act.

Written notice: Plans shall notify beneficiaries/participants of the required reporting from entities providing PBM services each year, which may be incorporated into plan documents.

HIPAA limitation on sharing information: The information in reports received by plans under this section from the entity providing PBM services may only be disclosed to the entity from which the report was received or that entity's business associates, as defined by HIPAA privacy regs, or as otherwise permitted by the HIPAA privacy regs.

Restrictions on reporting by PBM: Entities providing PBM services may place "reasonable restrictions" on the public disclosure of information reported, except that disclosure to HHS/DOL/Treasury or for the purposes of providing claim-specific information for beneficiary claim-specific access may not be prevented.

Limited report for drug supply chain participants: The Secretary shall define through rulemaking a limited form of the reporting required with respect to any plan that is a drug manufacturer, wholesaler, or other drug supply chain participant, or affiliated with such an entity, in order to prevent "anti-competitive behavior."

Beneficiary claim-specific access: Participants/beneficiaries of a plan may request the summary document specified above or the amount paid to the pharmacy by the entity providing PBM services for a drug claim paid for the participant/beneficiary.

Enforcement:

- With respect to plans regulated under the PHS Act and entities providing PBM services to those plans, the HHS Secretary shall enforce the law.
    - Penalties are:
        - Failure to provide the information required subject to CMPs of $10,000 per day for which such violation occurs.
        - False information provided subject to a CMP of up to $100,000 for each item of false information (as well as additional penalties that may be prescribed by law).
    - The CMP procedural protections of Section 1128A of the Social Security Act, except for subsections (a) and (b) and the first sentence of subsection (c)(1), apply.
    - The Secretary may waive such penalties or extend compliance with requirements for good-faith efforts at compliance.
    - Enforcement procedures may not be used to limit disclosure or access to the reporting required.
- With respect to plans regulated under ERISA, DOL may apply CMPs in similar amounts to those authorized to be assessed by the HHS Secretary in the previous section.
- With respect to plans regulated under the IRC and entities providing PBM services to those plans, requirements may be enforced using the tax imposed under 26 U.S.C. § 4980D ($100 per beneficiary per day).

Sec. 902. Full rebate pass through to plan; exception for innocent plan fiduciaries.(p. 533-545)

Applicability: This section applies to ERISA-governed health plans (both self-funded and fully-insured plans).

Effective Date: These new provisions come into effect 30 months after the date of enactment (approximately July 2027). However, the section clarifies that the new provisions would not impact any existing contract between a PBM and an employer-sponsored plan in effect on the effective date, but notes that the provisions would apply to any renewal or extension of a contract or arrangement executed after the effective date.

PBM Agreements Prohibited as "Indirect" Furnishing of Goods, Services, Etc. This section clarifies that an agreement between a plan fiduciary and a PBM constitutes prohibited "indirect furnishing of goods, services, or facilities" under the Employee Retirement Income Security Act (ERISA), which governs most employer-sponsored health plans, unless such agreement qualifies as a "reasonable arrangement" under the statute (explained below).

PBM Arrangements Considered "Reasonable." This section provides that an arrangement between a plan fiduciary and a PBM is "reasonable" and thus exempt from the prohibition described above only if the PBM remits to the plan 100% of "rebates, fees, alternative discounts, and other remuneration related to utilization of drugs or drug spending" received from an "applicable entity" by the PBM. Applicable entity is defined to include an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party.

To be considered "reasonable", such arrangement must provide that rebates will be:

- Remitted to the plan sponsor by the PBM on a quarterly basis, not later than 90 days after the end of each quarter or, in the case of underpayment in a remittance from a prior quarter, as soon as practical, but no later than 90 days after the PBM is notified of such underpayment.
- Fully disclosed and enumerated to the employer-sponsored plan; and
- Returned to the PBM if an audit finds that the rebate amounts received by the PBM are less than the amounts remitted by the PBM to the plan.

Governing Procedures. The Secretary of Labor may establish procedures governing the remittance and disclosure of rebates.

Provision of Rebates to the PBM. This section provides that, in order to ensure that a PBM can meet the remittance requirements outlined above, a rebate aggregator or group purchasing organization must remit applicable rebates to the PBM not later than 45 days after the end of each quarter.

Audits Requirements. PBMs must make records related to applicable rebates available for audit by the plan not less than once per plan year.

Furthermore, PBMs are required to make their rebate contracts with rebate aggregators or drug manufacturers available for audit by the employer-sponsored plan, subject to reasonable restrictions (as determined by the Secretary) on confidentiality to prevent re-disclosure of such contracts or use of such information in audits for purposes unrelated to this section.

Both categories of audits must be performed by an auditor selected by the plan fiduciary. Payments for such audit cannot be made, whether directly or indirectly, by the PBM.

Acceptable PBM Arrangements/Limitations. This section clarifies that it does not prohibit "reasonable payments" to PBMs for "bona fide services" using a fee structure not otherwise prohibited by the section, provided that such fees are transparent and quantifiable to the plan. This

provision can be interpreted as allowing for payments between plans and PBMs based on the rebates negotiated by the PBM – in other words, the provision would not "delink" PBM compensation from rebates or fee amounts. Under this interpretation, the PBM must remit 100% of applicable rebates to the plan, but can negotiate appropriate fees with the plan that take into account the rebates negotiated by the PBM (and passed through to the plan).

Furthermore, this section clarifies that it does not in any way require a PBM to remit bona fide services fees to the group health plan, nor does it prohibit the employer-sponsored plan from passing through applicable rebate remittances to beneficiaries.

"Innocent" Plan Fiduciaries. The section also exempts plan fiduciaries from liability under ERISA for failure to comply with the requirements governing prohibited PBM arrangements described above if:

- The plan fiduciary did not know the PBM failed or would fail to make the required remittances and reasonably believes that the PBM remitted the required amounts;
- Upon discovering that the PBM failed to remit the require amounts, the plan fiduciary requests in writing that the PBM remit the required amounts; and
- If the PBM fails to comply with the written request within 90 days, the plan fiduciary notifies the Secretary of Labor of the PBM's failure to comply.