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DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2550

RIN 1210-AB37

Improving Transparency into Pharmacy Benefit Manager Fee Disclosure

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: The Department is issuing a final regulation that will require providers of pharmacy benefit management services and affiliated providers of brokerage and consulting services to disclose information about their compensation to fiduciaries of large, self-insured group health plans subject to the Employee Retirement Income Security Act (ERISA). Pharmacy spending is a major driver of overall healthcare costs for employers and is growing faster than medical and surgical spending. These disclosure requirements apply for purposes of ERISA's statutory prohibited transaction exemption for service arrangements under section 408(b)(2). These disclosures are needed so that fiduciaries can assess the reasonableness of contracts or arrangements with these service providers, including the reasonableness of the service providers' compensation. As directed in section 12 of President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, the Department is issuing this rule to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers. This final rule will affect sponsors and other fiduciaries of large, self-insured group health plans and certain service providers to such plans.

DATES: This regulation is effective **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. This regulation is applicable to plan years beginning on or after July 1, 2027.

FOR FURTHER INFORMATION CONTACT: Stephen Sklenar, Office of Regulations and Interpretations, Employee Benefits Security Administration, Department of Labor, at 202-693-1000 ext. 18554, or Saliha Moore, Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Department of Labor, at 202-693-1000 ext. 12913. These are not toll-free numbers.

Customer service information: Individuals interested in obtaining general information from the Department of Labor concerning Title I of ERISA may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department's website (www.dol.gov/agencies/ebsa).

SUPPLEMENTARY INFORMATION:

A. Executive Summary

In Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, President Trump instructed the Department to propose regulations under ERISA section 408(b)(2) to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers.[1] Businesses that provide pharmacy benefit management services ("PBMs," unless otherwise specified) to ERISA-covered self-insured group health plans have acquired significant influence over prescription drug costs in recent years. By addressing the influence of PBMs and promoting transparent pricing, President Trump's Executive Order aims to create a fairer and more competitive prescription drug market

[1] 90 FR 16441 (Apr. 18, 2025).

that lowers costs and ensures accountability across the entire healthcare system.[2] This final rule responds to Executive Order 14273 and is a part of the Trump Administration's larger initiative to address rising healthcare costs for Americans.[3]

ERISA section 408(b)(2) is a statutory exemption from ERISA's prohibited transaction rules applicable to contracts or arrangements for services. ERISA section 406(a)(1)(C) provides that the furnishing of goods, services, or facilities between employee benefit plans (including group health plans) and parties in interest to the plans is a prohibited transaction.[4] A person providing services to the plan is a "party in interest" to the plan.[5] To satisfy the conditions of the exemption, ERISA section 408(b)(2)(A) provides that the service contract or arrangement must be reasonable, the services must be necessary for the establishment or operation of the plan, and no more than reasonable compensation may be paid for the services. In addition, under recent amendments to ERISA section 408(b)(2)(B) as part of the Consolidated Appropriations Act, 2026 (CAA, 2026), a broad group of service providers to group health plans including PBMs

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[2] *See* Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices (Apr. 15, 2025) ("The [Executive] Order builds off [the Administration's] critical work and reevaluates the role of middlemen by: Improving disclosure of fees that pharmaceutical benefit managers (PBMs) pay to brokers for steering employers to utilize their services . . ."), available at https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-announces-actions-to-lower-prescription-drug-prices/.

[3] *See, e.g.*, Department of Labor News Release, *Departments of Labor, Health and Human Services, Treasury Announce Move to Strengthen Healthcare Price Transparency*, available at https://www.dol.gov/newsroom/releases/ebsa/ebsa20250522 (May 22, 2025); Executive Order 14221, "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information," which directs the Secretaries of Treasury, Labor, and Health and Human Services to build on the groundbreaking transparency regulations launched during President Trump's first term. E.O. 14221 (Feb. 25, 2025); Executive Order 13877, "Improving Price and Quality Transparency in American Healthcare to Put Patients First" (June 24, 2019); Executive Order 13813, "Promoting Healthcare Choice and Competition Across the United States" (Oct. 12, 2017).

[4] *See* 29 U.S.C. § 1106(a)(1)(C). *See also Cunningham v Cornell University*, 604 U.S. 693, 697 (2025) (ERISA section 406 "supplements the fiduciary's general duty of loyalty to the plan's beneficiaries . . . by categorically barring certain transactions deemed 'likely to injure the pension plan.'") (citations omitted). If the conditions of an exemption are not satisfied, responsible plan fiduciaries entering into service arrangements with parties in interest to self-insured group health plans, and the parties in interest themselves, may be subject to enforcement action by the Department and the imposition of a civil penalty under ERISA section 502. *See* 29 U.S.C. § 1132.

[5] ERISA section 3(14)(B).

must provide specified disclosures to the group health plan for the services contract or arrangement to meet the reasonableness condition of the exemption.[6] This final rule implements ERISA section 408(b)(2)(B) for PBMs and affiliated brokers and consultants, with respect to the covered plans described in the final rule.

PBMs are the "middlemen" in the pharmaceutical supply chain.[7] For ERISA-covered self-insured group health plans, PBMs perform a wide range of services including, but not limited to, organizing pharmacy networks, negotiating pharmacy reimbursement amounts and drug rebates,[8] establishing drug formularies,[9] processing claims, and managing utilization. In connection with these services, PBMs receive compensation from self-insured group health plans as well as from other sources in the pharmaceutical supply chain. Responsible plan fiduciaries of self-insured group health plans (including plan sponsors and other fiduciaries who are responsible for prudently selecting and monitoring service providers)[10] also commonly rely on brokers or consultants to help them with advice, recommendations, and referrals regarding pharmacy benefit management services. The brokers or consultants may, in some cases, be

[6] Section 6702 of Title VII of Division B of the Consolidated Appropriations Act, 2026, amending definition of "covered service provider" in ERISA section 408(b)(2)(B).
[7] *See, e.g.*, Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.
[8] As discussed below in section B.3.2 of this preamble, rebates are discounts on drugs offered by the pharmaceutical manufacturer in return for preferred placement on a self-insured group health plan's formulary.
[9] A formulary is a list of drugs covered by the plan.
[10] It is well established that plan sponsors as defined in ERISA section 3(16)(B)(i) often wear two hats – a settlor hat and a fiduciary hat. *See, e.g., McKee Foods Corp. v. BFP Inc.*, 173 F.4th 242, 256 (6th Cir. 2026); *Reetz v. Aon Hewitt Inv. Counseling, Inc.*, 74 F.4th 171, 179–80 (4th Cir. 2023); *Bennett v. Conrail Matched Savings Plan Admin. Comm.*, 168 F.3d 671, 679 (3d Cir. 1999). Yet it is equally well established that "ERISA does require, however, that the fiduciary with two hats wear only one at a time, and wear the fiduciary hat when making fiduciary decisions." *Pegram v. Herdrich*, 530 U.S. 211, 225 (2000). Under this principle, a contract or arrangement with a covered service provider necessary for the establishment or operation of the self-insured group health plan does not evade the requirements of this proposed regulation merely because it is signed by a plan sponsor.

affiliated with a PBM. They also may receive compensation from sources other than group health plans.

Concerns have existed for many years that PBMs, including in their capacities as brokers and consultants with respect to pharmacy benefit management services, are not fully disclosing their compensation to the responsible plan fiduciaries. These concerns prompted the ERISA Advisory Council to recommend that the Department consider extending its service provider disclosure regulation to require specific disclosures by PBMs.[11] Congress took that step by amending ERISA section 408(b)(2) to specify disclosure requirements for PBMs and other covered service providers to group health plans.[12] Additionally, Congress has provided that effective for plan years beginning on or after August 3, 2028, PBMs must pass through rebates, fees, alternative discounts, and other remuneration received from drug manufacturers and other entities to the group health plans that the PBMs are providing services to (or to health insurance issuers on behalf of the plans).[13] A new ERISA section 726, added to part 7 of ERISA, will require additional, retrospective disclosures by providers of pharmacy benefit management services regarding drug spending and drug utilization under the group health plan, effective for plan years beginning on or after August 3, 2028.[14]

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[11] *See* Advisory Council on Employee Welfare and Pension Benefit Plans (ERISA Advisory Council), *PBM Compensation and Fee Disclosure* at 20 (Nov. 2014) available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf ("Plan sponsors uniformly testified about the difficulties in obtaining the disclosure of PBM compensation, and how this interfered with their efforts to negotiate and monitor PBM contracts.").

[12] Section 6702 of Title VII of Division B of the Consolidated Appropriations Act, 2026 amended subparagraph (b)(2)(B) of ERISA section 408.

[13] Section 6702 of Title VII of Division B of the Consolidated Appropriations Act, 2026 added subparagraph (b)(2)(C) to ERISA section 408.

[14] ERISA section 726, added by section 6701 of Title VII of Division B of the Consolidated Appropriations Act, 2026. Section 6701 also added parallel provisions in Public Health Service Act section 2799A-11 and Internal Revenue Code section 9826.

The Department's final rule implementing ERISA section 408(b)(2)(B) is intended to provide much needed transparency into contracts and arrangements with PBMs and affiliated brokers and consultants, so that the responsible plan fiduciaries of large ERISA-covered self-insured group health plans can fulfill their statutorily mandated role to determine whether these service contracts or arrangements are reasonable. Under the Department's final rule, these service providers must furnish detailed disclosures to responsible plan fiduciaries of large self-insured group health plans describing their compensation for such services, and advance disclosure of compensation they reasonably expect to receive. The final rule also includes audit provisions designed to ensure that the responsible plan fiduciaries of large self-insured group health plans can verify the accuracy of the disclosures. The responsible plan fiduciaries will be able to use the disclosures in their process of selecting a provider of pharmacy benefit management services, engaging an affiliated broker or consultant, and monitoring these service providers' operations and compliance with contractual obligations.

B. Background

1. Group Health Plan Prescription Drug Coverage

Approximately 136 million Americans receive health coverage through their employers (or their family members' employers) in group health plans covered by ERISA.[15] Group health plans provide healthcare benefits such as hospitalization, sickness, prescription drugs, vision, and

[15] U.S. Department of Labor, *Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2023 Annual Social and Economic Supplement to the Current Population Survey* at 6 (Aug. 30, 2024), available at https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf.

dental. Group health plans provide these benefits by purchasing insurance[16] or by self-funding[17] (also known as self-insured) benefits from the employer's general assets or from a funded trust.

Employer pharmacy spending is increasing faster than medical and surgical expenses, representing a growing concern for employers and workers about affordability and adherence. Retail prescription drug spending in the U.S. amounted to nearly $495 billion in 2024 and is projected to grow 7 percent in 2025, but to grow more slowly from 2026 to 2033.[18] Against this backdrop, employers anticipate an 11 to 12 percent increase in pharmacy costs in 2025 into 2026.[19]

For employer-sponsored group health plans, the cost of prescription drugs is usually shared between the group health plan and the individual participant, where the participant pays a fixed amount (copayment), a percentage of the drug's cost (coinsurance), or the full cost of the drug up to the amount of the annual deductible, if the group health plan applies a deductible. The group health plan's drug formulary identifies the drugs that are covered and organizes the drugs

[16] In a fully insured plan, the employer pays a fixed monthly premium to an insurance carrier that assumes all risk for paying claims. Premiums are generally fixed for a year, providing high budget predictability. Under this model, employers have more limited design flexibility, since plans are standardized by the insurance carrier. For fully insured plans, the insurer manages all claims processing, network management, and regulatory compliance and must adhere to both federal and state-mandated insurance and coverage regulations. The fully insured model may appeal more to smaller, risk-averse firms.

[17] In a self-insured plan, the employer assumes the financial risk for providing health benefits to employees, rather than paying a fixed premium to an insurance carrier. Additionally, the employer pays for claims as they are incurred. While this can save on premiums and administrative costs, it exposes the employer to volatility; thus, employers often buy "stop-loss" coverage to protect against high-cost, catastrophic claims. Under self-funding, employers have more control over the plan design, allowing them to customize coverage to employee needs. Benefits are typically managed by a Third-Party Administrator (TPA), and the plan is subject to federal ERISA regulations, but exempt from many state-mandated benefits.

[18] Centers for Medicare & Medicaid Services, *National Health Expenditure Projections 2025-2034*, available at https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf ("From 2025–27, average growth is projected to slow to 5.6 percent due to decreasing Marketplace enrollment and slower anti-obesity medication uptake. For 2028–33, growth is projected to average 4.7 percent.").

[19] Business Group on Health, *2026 Employer Health Care Strategy Survey: Executive Summary,* (Aug. 19, 2025), available at https://www.businessgrouphealth.org/resources/2026-employer-health-care-strategy-survey-executive-summary.

into tiers, with different cost-sharing requirements imposed on participants. The tiers often distinguish between generic drugs and brand-name drugs, and plans may have one or more separate tiers for "specialty drugs."[20]

Managing a group health plan's prescription drug coverage is exceedingly complex due to the vast number of drugs available on the market and the large number of drug manufacturers and pharmacies, among other reasons. Further, the pharmaceutical supply chain involves multiple entities—including drug manufacturers, drug wholesalers, pharmacies, PBMs, payors (e.g., group health plans), and participants—that interact with each other in arrangements that can be quite opaque.[21]

Due to the complexity of the pharmaceutical supply chain and the myriad players involved, responsible plan fiduciaries of group health plans often outsource pharmacy benefit management services. When group health plan benefits are obtained through insurance, pharmacy benefit management services are often integrated with the insurance contract. When group health plans are self-insured, however, the responsible plan fiduciaries may engage a PBM

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[20] Generic drugs are "medication[s] created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quantity, performance characteristics, and intended use." U.S. Food & Drug Administration, *Generic Drugs: Questions & Answers* (June 8, 2026), available at https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#q1. Specialty drugs do not have a standard definition, but some characteristics that may identify specialty drugs are special handling requirements or high costs. Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 17–18 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[21] *See* Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 1 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf ("PBM business practices and their effects remain extraordinarily opaque."); United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 65, available at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf. Many sources that discuss the pharmaceutical supply chain find it useful to include a chart to map out the parties involved. *See, e.g.*, U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 9 (GAO-24-106898, Mar. 2024), available at https://www.gao.gov/assets/gao-24-106898.pdf.

directly, or they may obtain pharmacy benefit management services through a third-party administrator (TPA) or other entity.

2. Pharmacy Benefit Managers' Services Provided to Self-Insured Group Health Plans

PBMs perform numerous services related to self-insured group health plans' prescription drug coverage, including identifying the prescription drugs that will be covered by a plan and negotiating prices with various entities in the pharmaceutical supply chain.[22]

2.1. Formulary Development and Design

PBMs develop a self-insured group health plan's prescription drug formulary,[23] which is a list of drugs (brand, generic, and specialty) that the self-insured group health plan will cover. A variety of different, tiered cost-sharing requirements may apply to the drugs in the formulary, either through coinsurance (a percentage off list price) or copayments (a fixed price not tied to

[22] *See* National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* (GAO-24-106898, Mar. 2024), available at https://www.gao.gov/assets/gao-24-106898.pdf; Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit* Managers (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921; United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (2021); available at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf; Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

[23] Some formularies are open – covering virtually all drugs – while others are more restrictive. There has been a growing trend over the last decade, however, in usage of more restrictive formularies, excluding more drugs. United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, at 71, available at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf; Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* 66-67 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

list price).[24] Formularies generally balance access to prescription drugs with managing costs, and their development is similar across PBMs in that they often follow a multi-step process involving several distinct committees.[25] For example, a pharmacy and therapeutics (P&T) committee is often used as an external body of experts who "evaluate clinical and medical literature to select the most appropriate medications for individual disease states and conditions."[26] These committees are staffed with healthcare providers including physicians, pharmacists, and patient representatives. Following their analyses, the P&T committee makes recommendations for the PBM's template formulary or for an individual client's custom formulary.[27] Notably, this is only one of several possible PBM committees that may have influence over formulary design.[28] There are also formulary review and value assessment committees which review P&T committee recommendations to make formulary placement decisions and trade relations committees which negotiate and approve rebate agreements with drug manufacturers.[29]

In connection with formulary development, PBMs and their affiliates enter into rebate contracts with drug manufacturers and negotiate for rebates and fees on prescription drugs and

[24] Tasmina Hydery & Vimal Reddy, Journal of Managed Care & Specialty Pharmacy, *A Primer on Formulary Structures and Strategies, Journal of Managed Care & Specialty Pharmacy* (Feb. 3, 2024), available at https://www.jmcp.org/doi/10.18553/jmcp.2024.30.2.206.
[25] *Id.*
[26] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 18 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf.
[27] United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 35 (2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.
[28] *Id.* at 36.
[29] *Id.* at 36, 38.

other remuneration in return for preferred formulary placement.[30] PBMs use the large number of participants across multiple self-insured group health plans to negotiate with drug manufacturers based on "covered lives," primarily where there are competing therapeutic alternatives.[31] Rebates are paid to the PBM periodically after the prescriptions are filled and may be passed through to the self-insured group health plan to the extent required by the services contract.[32]

While PBMs historically have negotiated these contracts directly with drug manufacturers, PBM-affiliated group purchasing organizations (GPOs), also known as rebate aggregators, have taken over much of the rebate negotiation function for commercial health plans in return for incremental fees, or for a portion of the rebate that is then shared with the PBM and the self-insured group health plan, pursuant to contractual terms.[33] Each of the three largest PBMs is part of a vertically integrated entity which owns and controls such GPO subsidiaries.

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[30] Federal Trade Commission, Interim Staff Report, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 10–11 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO-24-106898, Mar. 2024), available at https://www.gao.gov/assets/gao-24-106898.pdf; National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf.

[31] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 8 (April 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921; United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 29 (2021), available at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf. "Covered lives" means the total number of eligible members covered under a benefit plan. Truveris, *The Truveris Pharmacy Benefits Glossary of Terms* (Feb. 6, 2022), https://truveris.com/pharmacy-benefits-glossary/).

[32] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf; United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 39 (2021), available at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

[33] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 21 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 83 (2021), available at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

These GPOs are affiliates of their respective PBMs and perform the role of rebate aggregator, and two of these GPOs are currently headquartered outside of the United States.[34]

2.2. Drug Utilization Management

PBMs provide a range of utilization management services—such as prior authorization, step therapy, and quantity limits—to promote medication use, improve clinical outcomes, and control drug costs.[35] While formularies act as the "menu" of drugs the self-insured group health plan will cover, utilization management techniques dictate the "how" a participant may access drugs prescribed by their healthcare provider. As illustrated above, formularies typically sort drugs into tiers of cost-sharing requirements. Additionally, PBMs may require providers to obtain approval before a drug can be dispensed, a process known as prior authorization. Step therapy, on the other hand, requires participants to try and fail on a less expensive drug first before progressing to another, more expensive option. PBMs may also implement quantity limits that cap the amount of a drug a participant can receive for a particular condition within a given period.

2.3. Pharmacy Contracting and Network Design

PBMs develop pharmacy networks for self-insured group health plans which can be

[34] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 24 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[35] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 12 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO-24-106898, Mar. 2024), available at https://www.gao.gov/assets/gao-24-106898.pdf.

divided into three types of dispensing formats: retail, mail-order, and specialty.[36] Retail pharmacies, which may be part of a pharmacy chain or independent, purchase prescription drugs from drug manufacturers and drug wholesalers and make them available to self-insured group health plan participants.[37] Mail-order pharmacies dispense and deliver prescriptions directly to participants and are often utilized for prescription drugs that are taken regularly.[38] Specialty drugs that meet certain characteristics such as special handling needs or high cost may be provided through a separate pharmacy.[39]

Pharmacy networks can be open (which includes most pharmacies as in-network and apply uniform cost-sharing) or restrictive (which limit in-network status to a narrow group of pharmacies). An open network allows participants to fill prescriptions at nearly any licensed pharmacy nationwide, offering broad convenience and access. This wider access, however, often comes with higher costs for both the plan and its participants, as broader networks may reduce a plan's leverage to negotiate lower reimbursement rates. Recent analysis by the Federal Trade Commission (FTC), Congress, and others have highlighted that the largest PBMs utilize restrictive networks to steer participants to their own vertically integrated or PBM-affiliated pharmacies, even when another pharmacy may provide the same or better pricing, raising concerns about diminished competition and potential conflicts of interest.[40]

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[36] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 11 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO-24-106898, March 2024), available at https://www.gao.gov/assets/gao-24-106898.pdf;

[37] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 17 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[38] *Id.*

[39] *Id.* at 17–18.

[40] *Id.* at 11.

In developing pharmacy networks, PBMs negotiate reimbursement rates and post-sale adjustment provisions that determine the amount the pharmacy is ultimately reimbursed. The reimbursement rate is typically determined using the lowest price among various indices using the "lesser of" logic, for example, the lesser of: (1) Average Wholesale Price, (2) Wholesale Acquisition Cost, (3) Usual and Customary Price, (4) Submitted Costs, or (5) Maximum Allowable Costs (MAC).[41] MAC lists represent the amount that a group health plan will pay for generics and, in some cases, brand name drugs with generic equivalents.[42] MAC lists are often proprietary and are created, maintained, and updated by PBMs exclusively.

2.4. Claims Administration and Other Services

Finally, PBMs also perform prescription drug claims administration services, which like the other services, are important to a self-insured group health plan's pharmacy benefit program. Claims processing may involve the determination of "(1) whether an individual was an eligible participant: (2) whether the prescribed drug was covered by the plan; (3) whether the participant met his or her deductible; and (4) what the participant's co-payment would be if required by the plan."[43] PBMs have developed systems to transmit prescription information between themselves

[41] *Id.*; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 26 (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[42] U.S. Government Accountability Office*, Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 13 (GAO-24-106898, March 2024), https://www.gao.gov/assets/gao-24-106898.pdf.

[43] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 9 (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

and pharmacies, permitting the rapid processing of claims as prescriptions are being filled.[44] Other services include adjudicating appeals, plan recordkeeping and regulatory compliance.[45]

3. PBM Contracts and Arrangements with Self-Insured Group Health Plans

When engaging in a request for proposal process, responsible plan fiduciaries of self-insured group health plans receive bids to contract directly with a PBM for services, or they may contract for services with a TPA or other entity (examples discussed herein) that agrees to provide pharmacy benefit management services to the self-insured group health plan.[46] Some responsible plan fiduciaries also join coalitions or cooperatives that negotiate with PBMs on behalf of a group of employer-sponsored self-insured group health plans.[47]

Negotiating a pharmacy benefit contract is a complex process that requires specialized expertise. Responsible plan fiduciaries, especially those without internal expertise and practices to manage drug benefits, often work with a separate consultant or broker to select and negotiate a direct contractual agreement with the PBM. As a best practice, the Department is of the view that large employers should ensure that strategic financial leaders, including the company's Chief

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[44] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 13 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit* Managers at 11 (April 2025), https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[45] U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO-24-106898, Mar. 2024), available at https://www.gao.gov/assets/gao-24-106898.pdf; Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 6 (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

[46] *See* Matthew Fiedler, Loren Adler, & Richard G. Frank, *A Brief Look at Current Debates about Pharmacy Benefit Managers*, The Brookings Institution (Sept. 7, 2023), available at https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/.

[47] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 19–20, 59 (Apr. 2025), https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

Financial Officer or similarly situated individual(s), both lead and collaborate closely with internal teams in selecting, designing, and engaging in procurement for employee health benefits. This will ensure alignment of health benefits with the company's overall strategic financial plan and assist in addressing rising healthcare costs, improving benefits, and reducing administrative burdens.

Consultant or broker services can include requests for proposals (RFPs), PBM oversight, and PBM audit services.[48] In some cases, the consultants and brokers receive indirect compensation (i.e., compensation from the PBMs or other sources other than the self-insured group health plan) that create a conflict of interest with respect to their self-insured group health plan customers.[49] Consulting firms and brokerages reportedly may receive payments on a per prescription or per covered employee basis, or they may share in rebates earned by PBMs.[50] Consultants may have preferred relationships with certain PBMs which may impact their recommendations.[51]

In addition to the complexity of the negotiations, PBM contracts themselves are complex and responsible plan fiduciaries often lack knowledge of how PBMs operate and how they

[48] Milliman, Pharmacy Benefits Consulting, available at https://www.milliman.com/en/services/pharmacy-benefits-consulting.
[49] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3 (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.; Deidre S. Gifford, Connecticut Health Strategy, *Report of Pharmacy Benefit Manager Practices* at 34 (Feb. 2025), available at https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1.
[50] Bob Herman, *'It's beyond unethical': Opaque conflicts of interest permeate prescription drug benefits* (June 20, 2023), available at https://www.statnews.com/2023/06/20/pbms-consulting-firms-investigation/.
[51] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 21 (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

receive compensation.[52] For example, PBM contracts may be for one year or multiple years, and may be amended at any point during the contract period if the formulary changes. The contracts may also allow for interim "market checks."[53] As described by one source, this involves "a comparison of the aggregate program pricing terms with the market access product types/distribution channels, administrative fees, allowances, other financial guarantees, and rebates to determine if the plan sponsor is receiving competitive market rates."[54] The contracts also address the ability of the responsible plan fiduciary to audit the PBM's compliance with the contract.[55] PBMs often limit a self-insured group health plan's audit rights, however, providing only a sample of records relating to contractual performance, requiring that the auditor be approved by the PBM, or that the audit be conducted on-site at a facility chosen by the PBM.

3.1. Administrative Fees and Spread Pricing

PBM compensation arrangements with self-insured group health plans may have multiple components, but the compensation models are sometimes described as falling into two general

[52] Congress has prohibited plans and issuers from entering into contracts with healthcare providers, networks or association of providers, third-party administrators, or other service providers offering access to a network of providers that would prohibit them from electronically accessing de-identified claims and encounter information or data, including financial information, such as the allowed amount, or any other claim-related financial obligations included in the provider contract; however, such provisions do not affirmatively provide disclosure to responsible plan fiduciaries. *See* ERISA section 724; Code section 9824(a)(1)(B); PHS Act section 2799A-9.

[53] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 60 (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921; Alex Johnson & Brian N. Anderson, *PBM Best Practices Series, RFP Process*; Milliman White Paper at 4 (Sept. 2016), available at https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/Articles/Best-practices-PBM-RFP-process.pdf.

[54] Alex Johnson & Brian N. Anderson, *PBM Best Practices Series, RFP Process*; Milliman White Paper at 4 (September 2016), available at https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/Articles/Best-practices-PBM-RFP-process.pdf.

[55] Scott McEachern & Patrick Cambel, *PBM Contracts: Understand then Optimize;* Milliman White Paper (Aug. 2020), available at https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize ("PBMs normally define all audit rights and limitations in the PBM contract and plan sponsors must initiate the audit."); Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 24 (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

categories: pass through pricing and spread pricing.[56]

In a pass-through pricing model, self-insured group health plans may pay the PBM the average wholesale price (AWP) for a drug minus a negotiated discount (also referred to as the negotiated rate) plus an administrative fee, which may be structured on a per claim basis, per participant basis, flat rate, or other mechanism.[57] In a spread pricing model, self-insured group health plans may pay AWP or AWP minus a smaller negotiated discount than in a pass-through model, but will either not pay or pay only a reduced administrative fee.[58] The PBM will instead retain the spread between the price reimbursed to the pharmacy, which might be based on MAC or a different formula, and the negotiated rate with self-insured group health plans.[59]

The spread pricing model does not utilize an agreed upon AWP for a given drug. Accessing AWP data may be costly, and AWP providers use proprietary, hard-to-verify data

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[56] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf; House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 7 (2024), available at https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 2 (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[57] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 142-43 (Oct. 2024), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[58] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 119 (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[59] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf; U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 7-8 (GAO-24-106898, Mar. 2024), available at https://www.gao.gov/assets/gao-24-106898.pdf.

sources and methodologies.[60] Additionally, PBMs typically have not disclosed to the responsible plan fiduciaries either the reimbursement amount paid to pharmacies or the pharmacies' acquisition costs.[61] Even where a price guarantee is included in a PBM contract, this guarantee may apply on an aggregate basis where PBMs may use periodic true-ups to show compliance with the price guarantee, rather than ensuring each individual prescription is billed at or below the guaranteed price.[62] One testimony to the ERISA Advisory Council indicated that PBMs may also use complex pricing algorithms in aggregate calculations, which can involve including or excluding certain claims in ways that affect the calculations used to measure the fulfillment of price guarantees.[63]

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[60] AWP is "an estimate of the price wholesalers charge for drugs." National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 12 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf. AWP prices are available from third-party vendors. Andrew W. Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains: An Overview of Stakeholder Relationships, RAND Corporation at 30 (2021), available at https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf. The Department reviewed the publicly available information on the websites of AWP providers and found no methodology documents, quality control practices, or sample price lists or analysis that could validate the accuracy of the AWP.

[61] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 21 (2025) ("Pharmacy pricing is complex, and the process is not transparent. Plan sponsors are often unaware of the difference between the amount they are billed and the pharmacy reimbursement."), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf; Eastern Research Group, *An Examination of Pharmaceutical Supply Chain Intermediary Margins in the U.S. Retail Chain* at ii (Sept. 27, 2024), available at https://aspe.hhs.gov/sites/default/files/documents/db1adf86053b1fda8ae9efd01c10ddc8/Pharma%20Supply%20Chains%20Margins%20Report_Final_2024.09.27_Clean_508.pdf.

[62] Scott McEachern & Patrick Cambel, *PBM Contracts: Understand then Optimize*, Milliman White Paper (Aug. 2, 2020), available at https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize ("Contracts with PBMs typically involve guarantees in a number of pricing areas. The PBM may guarantee individual pricing by dispensing channel (retail, mail order, and specialty) as well as by drug type (brand or generic). The PBM might commit to these pricing metrics such that overall, at the end of the year, the aggregate pricing within each channel and drug type will be at least as good as the guarantees outlined in the contract. In the case that a PBM has not met a guarantee, the PBM would issue a true-up payment to the plan sponsor to make up for any deficiencies. However, some contracting language may allow the PBM to cover its underperformance by using any overperformance from other channels.").

[63] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 22 (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

Some responsible plan fiduciaries may view the spread pricing model as providing potential benefits such as smoothing fluctuations in drug costs, which could reduce unpredictability, compared to models where the full drug costs are passed through to the self-insured group health plan, without applying a price smoothing mechanism.[64] However, the spread pricing model may be less transparent to responsible plan fiduciaries if there are no disclosures of the differences between the amounts the PBM paid to pharmacies and the amounts charged to the self-insured group health plan, or if pricing guarantees are verified only in the aggregate. Comparatively, in the pass-through model, PBMs charge the plan the same amount they reimburse pharmacies, and compensation is more plainly identified, which some responsible plan fiduciaries characterize as a more "transparent" arrangement.[65] Some PBMs that offer pass-through pricing also have business models that provide customers with frequent audit opportunities and minimal limitations on access to PBM data.[66]

Additionally, as discussed in greater detail later in the Regulatory Impact Analysis, the largest PBMs have become vertically integrated with health insurance companies, pharmacies, drug manufacturers, and other entities.[67] PBMs sometimes operate affiliated pharmacies and

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[64] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit* Managers at 34 (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[65] House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 26 (2024), available at https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit* Managers at 142 (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[66] House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 26 (2024), available at https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.

[67] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 1–2 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

require plan participants to use these affiliated pharmacies for certain prescriptions such as mail-order and/or specialty drugs.[68] In some ways, the vertically integrated structure can be efficient and cost-effective, but it may affect price competition when participants are required to use a PBM-affiliated pharmacy for certain prescriptions.[69] With respect to specialty drugs, which are an increasing source of drug spending, the FTC found in a recent study that the three largest PBMs "reimbursed their affiliated pharmacies at a higher rate than unaffiliated pharmacies on nearly every specialty generic drug examined."[70]

3.2. Payments from Drug Manufacturers

Payments from drug manufacturers are another component of PBM compensation. These types of payments include, but are not limited to, rebates, administrative fees, price protection fees, and so on. These payments are often defined by reference to list price, which incentivizes PBMs to choose high-list price, high-rebate drugs when creating a self-insured group health plan's formulary.[71]

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[68] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 12 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 11 (Nov. 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf

[69] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 23 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 18 (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[70] Federal Trade Commission, *Second Interim Staff Report*, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Mangers* at 2 (Jan. 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

[71] *See* Federal Trade Commission, *FTC Secures Landmark Settlement with Express Scripts to Lower Drug Costs for American Patients* (Feb 4. 2026), available at https://www.ftc.gov/news-events/news/press-releases/2026/02/ftc-secures-landmark-settlement-express-scripts-lower-drug-costs-american-patients ("The complaint alleges that this system pushed insulin manufacturers, among others, to compete for preferred formulary coverage based on the size of rebates off the list price rather than net price, which ultimately benefitted the PBMs, including ESI, which keep a portion of the inflated rebates.").

Rebates are discounts on drugs offered by the pharmaceutical manufacturer in return for preferred placement on a self-insured group health plan's formulary; and the extent to which rebates are retained by the PBM or passed through to the self-insured group health plan is negotiated by the parties.[72] PBMs also earn administrative fees from drug manufacturers when prescriptions are filled based on the utilization of the drugs and plan design decisions made by plan sponsors, including formulary and utilization management strategies.[73] Price protection fees are an additional rebate that a manufacturer pays the PBM if list prices rise faster than inflation or another agreed upon amount.[74]

To the extent rebates, fees, and other sources of remuneration are passed through to the self-insured group health plan, such amounts can help defray the cost of the healthcare benefits being provided.[75] However, even if there are contracted obligations requiring that rebates, fees, and other sources of remuneration be passed through to the plans, the responsible plan fiduciaries

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[72] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf.

[73] United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 8 (2021), available at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 13 (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[74] United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 9 (2021), available at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf ; Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* at 13 (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.

[75] For example, rebates passed through to a trust established to fund a self-insured group health plan would be required to be used for the exclusive purposes of providing benefits to the plan's participants and beneficiaries and defraying reasonable expenses of administering the plan. *See* ERISA section 403(c)(1). *See also Deidre S. Gifford*, *Report of Pharmacy Benefit Manager Practices* at 38 (2025) ("From the plan sponsor's perspective, rebates are a valuable tool in keeping plan premiums low as most plans use rebate value to directly offset plan liability and do not share rebate value with members at the point of sale."), available at https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1.

may benefit from more transparent disclosures to ensure that such amounts are passed through as agreed to under the contract with the PBM, in part due to evolving terminology used in the contracts and or re-routing or recharacterizing of the amounts.[76] The role of rebate aggregators adds complexity to drug pricing and transparency for disclosure of rebates owed to group health plans.[77]

The rebate payment structure would also benefit from more transparent disclosure for other reasons. One commonly cited concern is that PBMs have an incentive to select certain drugs with high-list prices over others for group health plan formularies due to the size of the rebate payments from drug manufacturers.[78] In addition to providing PBMs with an incentive to select higher priced drugs for the formularies, drug manufacturers offer higher rebates to PBMs

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[76] Joanna Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs,* Yale L. & Pol'y Rev. at 382 (2020), available at https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content ("PBMs rarely disclose the rebates they receive from manufacturers, and in situations in which they've agreed to share rebate information, the PBMs may recategorize rebates as fees to circumvent disclosure obligations."); Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 22 (Nov. 2014), https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

[77] Eric Percher, *Trends in Profitability and Compensation of PBMs & PBM Contracting Entities*, Nephron Research at 2 (Sept. 18, 2023), available at https://cdn.ymaws.com/www.wsparx.org/resource/resmgr/legislative_session/2024/pbm_campaign/nephron_pbm.pdf.

[78] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 20 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdfhttps://content.naic.org/sites/default/files/pmbwhitepap.pdfhttps://content.naic.org/sites/default/files/pmbwhitepap.pdf ("The existence of rebates alone is not a problem. However, the PBM's ability to retain a percentage of the rebate creates a concern, as they are also commonly in charge of formulary design. These two factors give PBMs a financial incentive to prioritize drugs in the formulary based on the highest rebate instead of the lowest total cost to the plan sponsor or consumer."); House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 7 (2024), available at https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf; Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs,* Yale L. & Pol'y Rev. at 360 (2020), https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content; T. Joseph Mattingly II, David A Hyman, Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy,* available at https://pubmed.ncbi.nlm.nih.gov/37921745/.

to exclude competing products from the formulary.[79] Disclosure of rebates and other payments from drug manufacturers will enable responsible plan fiduciaries to evaluate the way the PBM has designed the formulary, the extent to which its composition might be influenced by financial incentives, and to determine whether the impacts of these incentives require mitigation to ensure the reasonableness of the contract or arrangement.

Rebates and related PBM formulary practices have also been shown to correspond to increases in the manufacturers' drug list prices.[80] Drug manufacturers often raise list prices to accommodate rebate demands to secure preferred formulary placement to protect market share, profits, or to recoup the costs for research and development.[81] While increases in list prices have a marginal impact on self-insured group health plans, as they generally pay a lower price due to rebates and other discounts negotiated by the PBMs, they can be detrimental to participants.[82]

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[79] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 4 (July 2024) ("We share evidence that PBMs and brand pharmaceutical manufacturers sometimes enter agreements to exclude generic drugs and biosimilars from certain formularies in exchange for higher rebates from the manufacturer."), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf; United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 8 (2021), available at https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

[80] Neeraj Sood, Rocio Ribero, Martha Ryan, & Karen Van Nuys, *The Association Between Drug Rebates and List Prices* at 3, USC Schaeffer (Feb. 2020), available at https://schaeffer.usc.edu/wp-content/uploads/2024/10/SchaefferCenter_RebatesListPrices_WhitePaper-1.pdf ("Our finding that increased rebates are positively associated with increased list prices supports the notion that PBMs' demand for rebates is at least partly responsible for increasing list prices."); United States Senate Finance Committee, *Staff Report*, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 80 (2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

[81] *See* Joanna Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs,* Yale L. & Pol'y Rev. at 362 (2020), available at https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content.

[82] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Report to Congress: Prescription Drug Spending, Pricing Trends, and Premiums in Private Health Insurance Plans* at 4 (Nov. 2024), available at https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/2024-report-to-congress-prescription-drug-spending.pdf (noting that "[f]or many drugs, however, list prices are not the prices ultimately paid to manufacturers; payers or pharmacy benefit managers (PBMs) negotiate with manufacturers over formulary placement in exchange for discounts in the form of rebates off the list price," and that "[a]s used throughout this report, the term 'rebates' includes rebates, fees, and other remuneration transferred to PBMs from drug manufacturers and pharmacies.").

To offset rising drug prices, employers are increasingly shifting towards cost-sharing structures that make participants more sensitive to list prices. Participants in self-insured group health plans often pay the full cost of the drug up to the amount of their annual deductible and a portion of prescription drug costs after the deductible is satisfied, typically in the form of coinsurance. In many self-insured group health plans, coinsurance is often based on list price, resulting in higher out-of-pocket costs for participants.[83]

3.3. Payments from Pharmacies

PBMs receive payments from pharmacies in several different circumstances. If a participant's copay is higher than the total reimbursement owed to the pharmacy, a PBM may "claw-back" the overpayment amount.[84] For example, if a participant's copayment for a generic drug is $15 dollars, but the PBM has agreed to pay the pharmacy $5, the PBM will "claw-back" the excess $10. In such cases, it is not clear whether such overpayments are generally or ever reimbursed to the self-insured group health plan (or participant).[85]

PBMs also reportedly recoup amounts paid to pharmacies for other reasons, including

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[83] Neeraj Sood, Rocio Ribero, Martha Ryan, & Karen Van Nuys, *The Association Between Drug Rebates and List Prices* at 5, USC Schaeffer (Feb. 2020), available at https://schaeffer.usc.edu/wp-content/uploads/2024/10/SchaefferCenter_RebatesListPrices_WhitePaper-1.pdf ("We find that rebates and list prices are positively related, with an increase in rebates associated with a roughly dollar-for-dollar increase in list price. This suggests that reducing or eliminating rebates could result in lower list prices, thereby decreasing out-of-pocket costs for uninsured patients and for insured patients with deductibles or coinsurance."); Joanna Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs,* Yale L. & Pol'y Rev. at 362–63 (2020), available at https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content; T. Joseph Mattingly II, David A Hyman, & Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy*, available at https://pubmed.ncbi.nlm.nih.gov/37921745/.

[84] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 21 (2025), available at https://content.naic.org/sites/default/files/pmbwhitepap.pdf. Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 23 (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

[85] Some self-insured plans have benefit-design edits that make copayments the "lesser of" the copayment amount and the acquisition cost to prevent overpayment and therefore claw-backs.

"network participation fees, fees for non-compliance or lower performance with quality measures, and reimbursement reconciliation."[86] A relatively new PBM practice is "effective rate reconciliation," in which the contractual reimbursement rate paid by a PBM to a pharmacy for dispensing a drug is determined by an aggregate effective rate, typically expressed as a percentage discount from AWP.[87] The PBM periodically reconciles the payments made to pharmacies at the point of sale with the specified effective rate and will adjust future reimbursement to the pharmacy to account for the difference between the amount paid at the point of sale and the effective rate following the reconciliation.[88] In addition to generic effective rate and brand effective rate, the PBM may also include a "dispensing fee effective rate" for the administrative cost charged by a pharmacy to dispense a drug.[89]

C. Service Provider Arrangements under ERISA

1. Prohibited Transaction Framework

Responsible plan fiduciaries of group health plans must determine that service provider relationships involving the group health plan meet certain conditions to avoid constituting a

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[86] Deidre S. Gifford, *Report of Pharmacy Benefit Manager Practices* at 17 (2025) ("Brokers earn revenues in several ways that may not be apparent to the plan sponsor, such as commissions, bonuses, fees, TPA fees paid by PBMs, per prescription fees, etc."), available at https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1. Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 11 (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[87] Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains: An Overview of Stakeholder Relationships*, RAND Corporation at 19 (2021), available at https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf.

[88] U.S. Senate Committee on Finance, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers*, Written testimony of Jonathan Levitt (2023), available at https://www.finance.senate.gov/imo/media/doc/Jonathan%20Levitt%20Testimony%20US%20Senate%20Committee%20on%20Finance%20-%20Frier%20Levitt%20-%20March%202023_Redacted1.pdf.

[89] Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers, U.S. Senate Committee on Finance, 118th Cong. (2023) (Written testimony of Jonathan Levitt); Elevate Provider Network, *What are GERs/BERs/DFERs?*, available at https://www.alliantrx.com/wp-content/uploads/2020/05/GER-Explainer-Document.pdf Last accessed July 17, 2026.

prohibited transaction under ERISA. Specifically, unless an exemption applies, the furnishing of goods, services, or facilities between a group health plan and a party in interest to the plan is a prohibited transaction under ERISA section 406(a)(1)(C). A person providing services to the group health plan is defined by ERISA section 3(14)(B) to be a "party in interest" to the group health plan.

ERISA section 408(b)(2) exempts certain arrangements between ERISA-covered plans (including group health plans) and service providers that otherwise would constitute prohibited transactions under ERISA section 406. Section 408(b)(2) provides relief from ERISA's prohibited transaction rules for service contracts or arrangements between a plan and a party in interest if the contract or arrangement is reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid for the services.

The Department's regulation under ERISA section 408(b)(2) clarifies the exemption's "necessary service," "reasonable contract or arrangement," and "reasonable compensation" conditions.[90] The regulation also clarifies that the exemption in ERISA section 408(b)(2) does not extend to acts described in ERISA section 406(b) relating to fiduciary conflicts of interest and provides examples illustrating this principle.[91]

In 2012, the Department amended its regulation under ERISA section 408(b)(2) to require parties who are "covered service providers" with respect to pension plans to disclose specified information to a responsible plan fiduciary, in order for certain services contracts or

[90] 29 CFR 2550.408b-2(b), (c), (d).
[91] 29 CFR 2550.408b-2(e).

arrangements to be reasonable.[92] The amended regulation generally requires covered service providers to provide initial disclosure of: the services to be provided; the status of the covered service provider, an affiliate, or a subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors. The amended regulation also establishes ongoing disclosure obligations in the event of a change in the information required to be provided in the initial disclosures and disclosures to be provided upon the written request of the responsible plan fiduciary as needed for the plan to comply with the reporting and disclosure requirements of title I of ERISA. The amended regulation also carries over a provision from the initial regulation regarding termination of the contract or arrangement.[93]

The amended regulation defines a responsible plan fiduciary as a fiduciary with authority to cause the plan to enter into, or extend or renew, a contract or arrangement for the provision of services to the plan.[94] The Department's amended regulation is accompanied by an administrative class exemption for responsible plan fiduciaries, codified at paragraph (c)(1)(ix),

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[92] Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure, 77 FR 5632 (Feb. 3, 2012) (codified at 29 CFR 2550.408b-2(c)).

[93] 29 CFR 2550.408b-2(c)(3) ("No contract or arrangement is reasonable within the meaning of section 408(b)(2) of the Act and paragraph (a)(2) of this section if it does not permit termination by the plan without penalty to the plan on reasonably short notice under the circumstances to prevent the plan from becoming locked into an arrangement that has become disadvantageous. A long-term lease which may be terminated prior to its expiration (without penalty to the plan) on reasonably short notice under the circumstances is not generally an unreasonable arrangement merely because of its long term. A provision in a contract or other arrangement which reasonably compensates the service provider or lessor for loss upon early termination of the contract, arrangement, or lease is not a penalty. For example, a minimal fee in a service contract which is charged to allow recoupment of reasonable start-up costs is not a penalty. Similarly, a provision in a lease for a termination fee that covers reasonably foreseeable expenses related to the vacancy and reletting of the office space upon early termination of the lease is not a penalty. Such a provision does not reasonably compensate for loss if it provides for payment in excess of actual loss or if it fails to require mitigation of damages.").

[94] 29 CFR 2550.408b-2(c)(1)(viii)(E).

which provides prohibited transaction relief for responsible plan fiduciaries in the event a covered service provider fails to disclose information as required under the regulation. In the absence of an exemption providing otherwise, the service provider's failure to comply with the regulation will result in a prohibited transaction by the responsible plan fiduciary.[95]

In the final rule amending its regulation, the Department reserved paragraph (c)(2) for future guidance on disclosure with respect to welfare plans (including self-insured group health plans). The Department concluded that there were significant differences between service and compensation arrangements for welfare plans and those involving pension plans, and that those differences supported the development of specifically tailored disclosure requirements for welfare plans.[96]

In 2014, the ERISA Advisory Council studied PBM fee disclosures and recommended that the Department should "consider making Section 408(b)(2) Regulations applicable to welfare plan arrangements with PBMs, and thereby deem such arrangements reasonable only where PBMs disclose direct and indirect compensation, including compensation paid among related parties such as subcontractors, in a manner consistent with current Section 408(b)(2) Regulations."[97]

The report included several findings related to this recommendation, including:

- "Plan sponsors of group health plans who testified at the Council hearings were unanimous in their view that they face many challenges managing pharmacy benefits on

[95] *See* ERISA section 406(a)(1) ("Except as provided in [section 408] . . . [a] fiduciary with respect to a plan shall not cause the plan to engage in a transaction, if he knows or should know that such transaction constitutes a direct or indirect . . . furnishing of goods, services, or facilities between the plan and a party in interest.").
[96] 77 FR at 5649. The Department held a public hearing on December 7, 2010, to explore operational, disclosure, and fee transparency issues concerning welfare benefit plans. *See* https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/1210-AB37.
[97] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3 (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

a cost-effective basis. However, plan sponsors uniformly testified that PBM services are a valuable part of this effort."

- "Testimony submitted to the Council revealed that drug pricing methodologies and PBM compensation are complex and evolving, including rebates, price spreads, discounts, and other payments from retail pharmacy chains and manufacturers. Substantial evidence was submitted to the Council from ERISA plan sponsors and others that many PBMs do not fully disclose compensation in a manner which is readily understandable to even the most sophisticated plan sponsors and consultants."

- "Testimony before the Council indicated that some forms of PBM compensation have the potential for creating conflicts of interest. Sponsors of ERISA health plans may or may not be aware of these potential conflicts."

- "ERISA group health plans that contract directly with PBMs frequently use consultants to assist in negotiations with the PBM. Testimony was submitted to the Council that it is common for consultants to receive indirect compensation. The payment of indirect compensation to consultants who are advising plan sponsors in negotiations with the PBM may create the potential for conflicts of interest that may be adverse to the plan sponsor. Sponsors of ERISA health plans may or may not be informed of such indirect compensation."

- "Plan sponsors testified that disclosure of PBM compensation would better enable them to comply with their obligations to determine reasonable compensation under Section 408(b)(2). Nondisclosure creates the potential for impediments to plan sponsors' ability to comply with 408(b)(2)."

The second recommendation of the ERISA Advisory Council related to audits of a PBM's compliance with its contract with the welfare plan.[98] Specifically, the Council recommended that the Department should "consider issuing guidance to assist plan sponsors in determining whether to and how to conduct a PBM audit of direct and indirect compensation."[99]

Findings related to this recommendation included identification of the following problem areas, among others:

- "The exclusion of auditors who the PBM believes hold hostile views."

[98] The Council noted this audit should not be confused with the requirement under ERISA section 103(3)(A).
[99] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure,* at 5 (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.

- "On-site audits are required at PBM headquarters."
- "PBMs limit the auditor to transcribing notes of documents."
- "Confidentiality agreements can be overly broad and put unnecessary burdens on the parties when they prohibit disclosure of information by an auditor to its client plan."
- "PBMs will not disclose documents requested by some auditors such as PBM contracts with retail pharmacies and drug manufacturers."
- "Access to claims data is restricted."
- "Audit rights restricted to limited periods (such as 2 years)."
- "Some necessary data sources such as AWP pricing are not public and access is expensive . . . and disclosure is limited."

2. Consolidated Appropriations Act, 2021 408(b)(2) Amendment

In the Consolidated Appropriations Act (CAA), 2021, Congress amended the ERISA section 408(b)(2) statutory exemption to add a new paragraph (B) applicable to certain services arrangements with group health plans, effective December 27, 2021.[100] As part of the amendment, Congress designated the pre-existing text as ERISA section 408(b)(2)(A).[101] The requirements in ERISA section 408(b)(2)(B) as originally enacted applied to a group of covered service providers, defined as persons or entities who provide "brokerage services" or "consulting" to group health plans with respect to a list of sub-services including pharmacy benefit management services.[102]

[100] Section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.
[101] ERISA section 408(b)(2)(A) now provides an exemption for "[c]ontracting or making reasonable arrangements with a party in interest for office space, or legal, accounting, or other services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid therefor."
[102] Specifically, as originally enacted ERISA section 408(b)(2)(B)(ii)(I)(bb)(AA) defined a covered service provider as one who provides *brokerage services* "provided to a covered plan with respect to selection of insurance products (including vision and dental), recordkeeping services, medical management vendor, benefits administration

ERISA section 408(b)(2)(B) closely tracks the Department's regulation for pension plan arrangements. It requires disclosure of: the services to be provided; the status of the covered service provider, an affiliate, or a subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors. It also establishes ongoing disclosure obligations in the event of a change in the information required to be provided in the initial disclosures and disclosures to be provided upon the written request of the responsible plan fiduciary as needed for the plan to comply with the reporting and disclosure requirements of title I of ERISA.

In December 2021, the Department provided a guidance and temporary enforcement policy addressing questions about ERISA section 408(b)(2)(B).[103] In general, the policy provided that, pending future guidance or rulemaking, covered service providers and responsible plan fiduciaries would be expected to implement the ERISA section 408(b)(2)(B) requirements using a good faith, reasonable interpretation of the law.

With respect to the terms "brokerage services" and "consulting" as used in the definition of a covered service provider, the Department noted that neither term was defined and the

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(including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness services, transparency tools and vendors, group purchasing organization preferred vendor panels, disease management vendors and products, compliance services, employee assistance programs, or third party administration services." ERISA section 408(b)(2)(B)(ii)(I)(bb)(BB) as originally enacted defined a covered service provider as one who provides *consulting services* "related to the development or implementation of plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third party administration services."

[103] Field Assistance Bulletin No. 2021-03 (Dec. 30, 2021), available at https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03.

categories may overlap in some circumstances, but that the fact that a service provider did not call itself a broker or consultant would not be dispositive. Instead, the Department's enforcement policy would apply to parties who reasonably and in good faith determined their status as a covered service provider. The Department expressed that "service providers who reasonably expect to receive indirect compensation from third parties in connection with *advice*, *recommendations*, or *referrals* regarding any of the listed sub-services . . . should be prepared, if the Department is auditing their 408(b)(2)(B) compliance, to be able to explain how a conclusion that they are not covered service providers is consistent with a reasonable good faith interpretation of the statute."[104]

D. Consolidated Appropriations Act, 2026

1. ERISA Amendments

The Department issued a proposed rule entitled Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure on January 30, 2026.[105] On February 3, 2026, Congress made further changes to ERISA in the CAA, 2026. Among other things, the CAA, 2026 amended subparagraph (B) of ERISA section 408(b)(2), added a new subparagraph (C) to ERISA section 408(b)(2), and added a new section 726 to ERISA entitled "Oversight of Entities that Provide Pharmacy Benefit Management Services."

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[104] *Id.* (emphasis added). In addition to the ERISA section 408(b)(2)(B), in 2019, Congress added a distinct statutory exemption in ERISA section 408(h) for the provision of pharmacy benefit services, although in a limited context. The exemption is available to "an entity described in [ERISA section 3(37)(G)(vi)]" or any related organization or subsidiary, provides pharmacy benefit services to a group health plan sponsored by the entity or any other group health plan sponsored by a regional council, local union, or other labor organization affiliated with such entity, see Section 1302 of Division P of the Further Consolidated Appropriations Act, 2020. The Department is aware that the United Brotherhood of Carpenters and Joiners of America takes the position that it is a 501(c)(5) organization, tax exempt under Section 501(a) of the Code, and was established in Chicago, Illinois, on August 12, 1881, as referenced in ERISA section 3(37)(G)(vi). *See* Exemption from Certain Prohibited Transaction Restrictions Involving the United Brotherhood of Carpenters and Joiners of America, 90 FR 2748 n. 3 (Jan. 13, 2025).

[105] 91 FR 4348.

1.1. Amendments to ERISA section 408(b)(2)

In subparagraph (B) of ERISA section 408(b)(2), the CAA, 2026 revised the definition of covered service provider to remove the words "brokerage services" and "consulting." This change clarified that providers of pharmacy benefit management services (as well as a broad range of other service providers to group health plans, including third party administrators) are covered service providers and are required to make the disclosures under the statute to rely on the prohibited transaction exemption. Additionally, new language was added to subparagraph (B) stating that a service provider for pharmacy benefit management services that contracts with a health insurance issuer in connection with health insurance coverage for a group health plan is considered an indirect provider of services to the plan and a party in interest under ERISA. This language clarified that providers of pharmacy benefit management services that provide services to fully insured plans through an insurance contract are considered parties in interest that must comply with an exemption to avoid participating in a prohibited transaction. The CAA, 2026 amendments also specified that the Department has authority to issue regulations addressing the time, manner, and content of the disclosures identified in subparagraph (B). The amendments to subparagraph (B) were effective on February 3, 2026, upon enactment of the CAA, 2026.

New subparagraph (C) of ERISA section 408(b)(2) focuses solely on providers of pharmacy benefit management services. Under that subparagraph, which is effective for plan years beginning on or after August 3, 2028, providers of pharmacy benefit management services are required to remit to group health plans (or to the insurance company on behalf of the plan) "100% of rebates, fees, alternative discounts, and other remuneration" received from "any

applicable entity" related to the utilization of drugs or drug spending under the plan.[106] Applicable entities are defined in new ERISA section 726 and generally include: drug manufacturers, rebate aggregators, affiliated group purchasing organizations; affiliates of the plan, health insurance issuer, PBM, or drug manufacturers; and other entities that the Secretary specifies in rulemaking. Subparagraph (C) includes related disclosure and audit provisions.

1.2. New ERISA section 726

ERISA section 726 provides that certain group health plans must receive a report from providers of pharmacy benefit management services every six months (or, at the plan's request, quarterly) containing detailed information about drug spending under the plan. Relatedly, applicable entities must agree by contract with plans and providers of pharmacy benefit management services (i) not to limit or delay disclosure of information in such a manner as to prevent the provider from making the required reports and (ii) to supply the required information. ERISA section 726 is applicable to plan years beginning on or after August 3, 2028, and the Department, along with the Secretaries of the Treasury and of Health and Human Services, has authority to issue regulations necessary to implement it.

Under ERISA section 726, the report is required for self-insured plans of "specified large employers" (generally with at least 100 employees) and self-insured "specified large plans" (generally with at least 100 participants).[107] Employers with fully insured plans that meet these

[106] ERISA section 408(b)(2)(C)(vi) provides that "[n]othing in this subparagraph shall be construed to- (I) prohibit reasonable payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not described in this subparagraph, provided that such fees are transparent and quantifiable to group health plans and health insurance issuers; [and] (II) require a third-party administrator of a group health plan or covered service provider for pharmacy benefit management services under such health plan or health insurance coverage to remit bona fide service fees to the group health plan . . ."

[107] ERISA section 726(e)(8), (9).

size specifications can opt in to receive the report.[108] Under ERISA section 726, all group health plans regardless of size must also receive certain information from the entity providing pharmacy benefit management services on behalf of the group health plan. All group health plans must receive a summary document of the information required to be provided for self-insured plans of specified large employers and self-insured specified large plans, as specified by the Secretary through guidance, program instruction, or otherwise.[109] ERISA section 726 also requires that all group health plans regardless of size receive a summary document that plans can provide to participants and beneficiaries upon request by the participant or beneficiary.[110] Further, ERISA section 726 provides for a limited form of report to be defined by the Secretary for any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or any other participant in the drug supply chain, "to prevent anti-competitive behavior."[111]

The required reports for the self-insured group health plans of specified large employers and self-insured specified large plans include a list of drugs for which a claim was filed and related information about costs, compensation, and distribution channel, including information on spread compensation received by the provider of pharmacy benefit management services as well as the total amount received, or expected to be received, by the provider of pharmacy benefit management services from applicable entities in rebates, fees, alternative discounts or other remuneration.[112] The report must also include a list of each therapeutic class for which a claim was filed and related information about costs, utilization, and formulary placement; for any

[108] ERISA section 726(b)(3).
[109] ERISA section 726(b)(2)(B)(i)
[110] ERISA section 726(b)(2)(B)(ii).
[111] ERISA section 726(b)(4)(G).
[112] ERISA section 726(b)(2)(A)(i).

drug for which gross spending exceeded $10,000 during the reporting period (or the 50 drugs with the highest spending if gross spending exceeded $10,000 during the reporting period with respect to fewer than 50 drugs), information about other drugs in the same therapeutic class, rationale for formulary placement and any change in the formulary placement compared to prior year; and for plans, issuers, and providers of pharmacy benefit management services with affiliated pharmacies, information about benefit design that encourages/requires use of mail order, specialty or retail pharmacies, percentage of prescriptions dispensed by such pharmacies, and a list of drugs dispensed along with amount charged to the plan and comparative cost information from other pharmacies.[113]

2. Comments on Interaction with the Department's Rule

Upon enactment of the CAA, 2026, the Department published a notice in the Federal Register drawing the public's attention to the new amendments to ERISA and extending the comment period on the proposed rule by an additional 15 days to allow interested persons to address "whether the rule should be adjusted in light of the CAA, 2026 amendments to ERISA, and if so, what adjustments are needed."[114]

Many commenters responded to the Department on the interaction of the proposed rule and the CAA, 2026, amendments to ERISA. These commenters generally touched on whether the Department should move forward to a final rule or withdraw its proposal, as well as ways that the Department should align provisions of its regulation with the CAA, 2026 amendments.

[113] ERISA section 726(b)(2)(A)(ii)–(iv).

[114] Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure: Extension of the Comment Period, 91 FR 10033 (Mar. 2, 2026). In the notice, the Department also specifically sought comment on "whether specific provisions of the rule should be revised or whether new provisions should be added, in order to minimize complexity or align with the new statutory provisions, while continuing to fulfill the stated transparency goals of the proposal." *Id.* at 10034.

On the topic of whether the Department should move forward to a final rule or withdraw the proposal, commenters weighed in on both sides. A few commenters advocated for withdrawal of the Department's proposal based on their view that in the CAA, 2026, Congress established a disclosure framework for PBM transparency that rendered the Department's regulatory project unnecessary, or even outside its regulatory authority. Commenters said the CAA, 2026 amendments address the transparency issues that motivated the Department's rulemaking, and the Department should focus its efforts on implementing the CAA, 2026 framework under ERISA section 726 with the Departments of Treasury and Health and Human Services. Some commenters noted the Department could then evaluate whether additional regulation is warranted.

Some commenters also expressed a related concern that if the Department proceeded to a final rule at this time, the rule could end up being duplicative or even conflict with requirements under the CAA, 2026 amendments to ERISA that will become effective several years from now, resulting in compliance inefficiencies and difficulties and confusion for plan fiduciaries. One commenter said that implementing the Department's rule only to later make changes to satisfy the CAA, 2026 amendments would impose operational and financial burdens on the healthcare system. One commenter said these types of compliance burdens would particularly impact mid-market PBMs. Several commenters suggested the Department should at least repropose its rule to ensure its provisions are consistent with the CAA, 2026 amendments.

A few commenters also recognized that providers of pharmacy benefit management services are now clearly covered service providers under ERISA section 408(b)(2)(B) and expressed concern that such service providers would be required to comply with three sets of disclosure obligations: the statutory provisions of ERISA section 408(b)(2)(B), the

Department's rule, and ERISA section 726. Another commenter opposed the Department proceeding with a regulation under the prohibited transaction framework because of the potential for penalties such as excise taxes for covered service providers as well as equitable remedies which the commenter said could disrupt the provision of pharmacy benefit management services.

Many more commenters expressed strong support for the proposal and urged the Department to finalize it. Commenters expressed particular support for the proposal's focus on transparency and accountability for providers of pharmacy benefit management services. Commenters also supported supplying plan fiduciaries with disclosures necessary to assess contracts with these providers and to satisfy the fiduciaries' obligations under ERISA. Some commenters expressed the view that the proposal represented an important protection of group health plan participants' interests.

One commenter who supported finalizing the rule noted that the CAA, 2026 provision that amended ERISA to add section 726 did not contain any preemptive language, did not rescind or prohibit rulemaking under ERISA section 408(b)(2), and did not state that the section 726 provisions are exclusive. Commenters also highlighted the distinct purpose of ERISA section 408(b)(2) as a statutory prohibited transaction exemption that requires group health plan fiduciaries to determine the reasonableness of services contracts or arrangements as a reason for the Department to proceed to a final rule. Some commenters identified the initial disclosures in particular as helpful to fiduciaries in discharging this obligation at the time they are entering into a contract and noted there is no counterpart in ERISA section 726. A few commenters also described how certain specific disclosures in the proposed rule would complement, not conflict with, those in ERISA section 726. For example, one commenter said that the pre-contract disclosure of spread pricing at the formulary level in the Department's proposed rule along with

the post-transaction drug level reporting on spread under ERISA 726 would work together to allow for prospective fiduciary review as well as retrospective transaction verification. One commenter said the Department's adoption of a final rule at this time would provide impacted parties the opportunity to implement and gain experience with the disclosures in preparation for implementation of the CAA, 2026 amendments.

Regardless of their views on whether the Department should withdraw its proposal or proceed to a final rule, there was consensus among many commenters that if the Department determined to proceed to a final rule, it should align with the CAA, 2026 amendments to the extent possible. Many such commenters focused on alignment with the ERISA section 726 disclosures, including areas of scope, definitions, and timing.

Commenters also discussed the impact of the new subparagraph (C) of ERISA section 408(b)(2) on service provider arrangements. As that provision will require covered service providers to pass through to the group health plans "100% of rebates, fees, alternative discounts, and other remuneration" received from "any applicable entity," commenters asserted that some of the contractual practices disclosed under the Department's rule would no longer persist after subparagraph (C)'s effective date. One commenter suggested sunsetting some of the disclosures while leaving in place robust audit rights to ensure that compensation is not recharacterized or shifted to avoid the pass-through requirements. Other commenters suggested disclosures would still be needed with respect to any compensation not passed through to the group health plan. One commenter said that the definition of "applicable entity" does not specifically include pharmacies and therefore – unless the Department (with the Departments of Treasury and Health and Human Services) uses its regulatory authority to include them within the definition –

revenue streams from pharmacies would continue to exist after the rebate-pass through provision takes effect.

3. The Department's responses

The Department has carefully considered the interaction of its proposal with the CAA, 2026 amendments to ERISA, as well as comments urging withdrawal of the rule, but has determined that it would not be appropriate or prudent to withdraw its proposal in favor of a disclosure regime based solely on ERISA section 726. In making this determination, the Department acknowledges that the disclosures required under new ERISA section 726 have areas of overlap with the disclosures the Department had proposed under ERISA section 408(b)(2). However, the Department believes that, for many of the reasons cited by supportive commenters, it is appropriate to proceed to a final rule on its proposal.

Chiefly, the Department believes that the ERISA section 408(b)(2) disclosures serve a function that is distinct from those in ERISA section 726. First and foremost, the Department's regulation is designed to improve transparency in large self-insured group health plan contracting practices involving providers of pharmacy benefit management services. It will ensure responsible plan fiduciaries can determine the reasonableness of the contract or arrangement by providing them a description of each pharmacy benefit management service to be provided to the covered plan and disclosure of the direct and indirect compensation that service providers contracting for pharmacy benefit management services receive. This is achieved through initial disclosures, at the time of contracting, extension or renewal, as well as semiannual disclosures and audit rights that will support the fiduciaries' ongoing monitoring of the services contract or arrangement. Section 726, on the other hand, is a retrospective disclosure containing detailed

information about drug spending and drug utilization under the group health plan that goes beyond the disclosure requirements of the Department's final rule.

Congress' amendments to ERISA section 408(b)(2)(B) clarified that providers of pharmacy benefit management services are covered service providers, and the legislation also provided specific authority to the Department to issue regulations addressing time, manner, and content of the disclosures. The fact that Congress added disclosure obligations for providers of pharmacy benefit management to both ERISA section 408(b)(2) and new ERISA section 726 in a single piece of legislation detailing separate, albeit related, disclosure regimes compels the conclusion that Congress meant for both disclosure regimes to coexist. In the Department's view, these two regimes complement each other.

In sum, the Department issues this final rule to implement disclosure obligations under ERISA section 408(b)(2)(B) with respect to the covered service providers and covered plans described in the rule, thus satisfying the provisions of section 408(b)(2)(B) for those covered service providers and responsible plan fiduciaries. The Department is operating under the authority granted in section 408(b)(2)(B) to regulate the time, manner, and content of those disclosures, applying the statutory framework. The Department has added a provision to the regulation in paragraph (a) to confirm this position.

The Department also acknowledges, as some commenters noted, that the new subparagraph (C) of ERISA section 408(b)(2) requiring pass-through to group health plans of "100% of rebates, fees, alternative discounts, and other remuneration" received from "any applicable entity" is likely to result in changes to pharmacy benefit manager compensation arrangements. The Department considered whether to sunset related disclosure obligations but, as discussed in greater detail below, determined that it would be preferable to retain the

disclosure obligations generally as proposed to ensure transparency regarding how the payments are being handled. In this regard, the Department notes that, once in effect, ERISA section 408(b)(2)(C) will require the rebates, fees, alternative discounts, and other remuneration not only to be passed through to the group health plan but also to be fully disclosed to such plan.[115]

Overall, the Department concurs with commenters who stressed the importance of aligning with the CAA, 2026 amendments to avoid inefficiencies and potential confusion on the part of plan fiduciaries. The Department has made a number of changes to the text of the rule to achieve alignment. These changes, which are discussed in greater detail below, include:

- *Limitation to large self-insured group health plans*: The final rule applies only to self-insured plans of specified large employers and self-insured specified large plans, defined in the same way that such plans are defined in ERISA section 726. This is consistent with the approach in ERISA section 726(b)(2) in which the detailed information about drug spending will be provided to these plans.
- *Disclosure period*: The final rule provides for disclosures on a semiannual basis or, at the request of the group health plan, quarterly, for consistency with the reporting period in ERISA section 726(b)(1).
- *Manufacturer payments*: The final rule's disclosures regarding payments from drug manufacturers use the terminology "rebate[s], fee[s], alternative discount[s], or other remuneration" for consistency with the reporting obligation in ERISA section 726(b)(2)(A)(i)(X) and (XI).

[115] ERISA section 408(b)(2)(C)(ii)(I)(bb).

- *Spread compensation*: The final rule's disclosures regarding spread compensation define spread compensation consistently with ERISA section 726(b)(2)(A)(i)(I)–(III).
- *Drug pricing methodology:* The final rule's disclosures regarding drug pricing methodology use terminology from ERISA section 726(b)(2)(A)(i)(VII).

The Department sought and received thoughtful comments on the extent to which this rule should align with the CAA, 2026. Comments on legal arguments regarding the Department's authority to issue the final rule in light of the CAA, 2026 are discussed along with the Department's responses, in section E.14 of this preamble.

The Department has not aligned the effective date of this final rule with the August 3, 2028 effective date of the CAA, 2026 amendments, as some commenters requested. The Department concurs with commenters who expressed concern about unduly delaying the introduction of much needed transparency in the area of group health plans' contracts with providers of pharmacy benefit management services. Implementing this final rule without delay will benefit responsible plan fiduciaries of self-insured group health plans by providing timely access to the more detailed information required to be disclosed. It will also provide timely guidance to covered service providers regarding their compliance with ERISA section 408(b)(2)(B), as amended effective February 3, 2026, who may use the guidance in this final rule to determine their own disclosure obligations.

Furthermore, as noted earlier in this preamble, the addition of new subparagraph (C) of ERISA section 408(b)(2) and the addition of section 726 of ERISA under the CAA, 2026 do not take effect until 30 months after the date of enactment. In contrast, Congress' amendments to ERISA section 408(b)(2)(B), establishing statutory disclosure requirements for pharmacy benefit management service providers wishing to take advantage of the exemption, became effective

upon enactment of the CAA, 2026 on February 3, 2026. In the Department's view, this indicates Congress' intent that responsible plan fiduciaries should have the required disclosures to evaluate the contracts or arrangements with pharmacy benefit management service providers on an earlier timetable. The provisions in this final rule implement the statutory disclosure requirements in section 408(b)(2)(B), dictating against delaying applicability longer than necessary to allow parties to develop compliance structures. Accordingly, the Department has made the final rule effective **[INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** and applicable to plan years beginning after July 1, 2027.

4. ERISA Section 408(b)(2)(B) Compliance

Several commenters urged the Department to acknowledge and highlight that the amendments to ERISA section 408(b)(2)(B) are in effect currently. The Department concurs with these commenters that the broader range of service providers to group health plans must make the disclosures outlined in the statute to rely on the exemption, for contracts or arrangements, extensions or renewals, effective as of February 3, 2026. As specified in ERISA section 408(b)(2)(B), as amended, covered service providers include, in addition to providers of brokerage services and consulting, providers of: pharmacy benefit management services, third-party administration services, insurance services and insurance product selection services (including vision and dental), recordkeeping services, and others.[116]

[116] *See* ERISA section 408(b)(2)(B)(ii)(I)(bb) ("The term 'covered service provider' means a service provider that enters into a contract or arrangement with the covered plan and reasonably expects $1,000 (or such amount as the Secretary may establish in regulations to account for inflation since December 27, 2020, as appropriate) or more in compensation, direct or indirect, to be received in connection with providing one or more of the following services, pursuant to the contract or arrangement, regardless of whether such services will be performed, or such compensation received, by the covered service provider, an affiliate, or a subcontractor: (AA) Services (including

This final rule implements the requirements of ERISA section 408(b)(2)(B), as amended, for the covered service providers and covered plans identified herein. Although the statutory provisions apply to all ERISA-covered group health plans, the Department believes the detailed descriptions of compensation streams and arrangements in this rule that are tailored to the pharmaceutical supply chain will provide particularly valuable information to responsible plan fiduciaries of large, self-insured group health plans. Furthermore, to demonstrate alignment with the statutory disclosures as appropriate following the CAA, 2026 amendments, and in response to commenters requesting additional clarity regarding the application of the disclosure obligations to indirect compensation, the Department has revised the rule to categorize the disclosures in the final rule as either "direct" or "indirect" compensation.[117]

Some commenters asked the Department to offer an enforcement policy for all covered service providers identified in the amended ERISA section 408(b)(2)(B), which was effective as of February 3, 2026, as these providers work to come into compliance with the statutory

brokerage services), for which the covered service provider, an affiliate, or a subcontractor reasonably expects to receive indirect compensation or direct compensation described in item (dd), provided to a covered plan with respect to selection of insurance products (including vision and dental), recordkeeping services, medical management vendor, benefits administration (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness services, transparency tools and vendors, group purchasing organization preferred vendor panels, disease management vendors and products, compliance services, employee assistance programs, or third party administration services. (BB) Other services, for which the covered service provider, an affiliate, or a subcontractor reasonably expects to receive indirect compensation or direct compensation described in item (dd), including any of the following: plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third-party administration services, or consulting services related to any such services.").

[117] *See* ERISA section 408(b)(2)(B)(iii)(III) and (IV) ("A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures) . . . (III) A description of all direct compensation, either in the aggregate or by service, that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services . . . [and] (IV)(aa) A description of all indirect compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services . . .").

disclosure obligations. Commenters also asked for safe harbors for responsible plan fiduciaries who demonstrate good faith efforts to comply with their obligations with respect to determining the reasonableness of the service contract or arrangement.

The Department concurs that enforcement relief under ERISA section 408(b)(2)(B) is appropriate as parties develop mechanisms to comply with obligations that became effective when the CAA, 2026 was enacted on February 3, 2026, and believes the appropriate period for a temporary enforcement policy should end on the final rule's applicability date of plan years beginning on or after July 1, 2027. This temporary enforcement policy will apply to all covered service providers and responsible plan fiduciaries of covered plans, each as defined in ERISA section 408(b)(2)(B), regardless of whether they are covered service providers and plan fiduciaries of covered plans addressed in this final rule. Accordingly, from the period from February 3, 2026 to the applicability date of the final rule, the Department will not treat a covered service provider as defined in ERISA section 408(b)(2)(B) as having failed to make the required disclosures to a responsible plan fiduciary under ERISA section 408(b)(2)(B) as long as the covered service provider made disclosures in accordance with a good faith interpretation of ERISA section 408(b)(2)(B), as amended. Further, prior to the applicability date of the final rule, the Department will not treat a responsible plan fiduciary of a covered plan as defined in ERISA section 408(b)(2)(B) as having engaged in a prohibited transaction in entering into a contract or arrangement with a covered service provider as long as the fiduciary acted in accordance with a good faith interpretation of their obligations under ERISA to determine the reasonableness of the contract or arrangement.

E. Description of the Final Rule

1. Scope of the Final Rule

1.1. General – Paragraph (a)

As discussed above in section C of this preamble, ERISA section 408(b)(2) provides an exemption for services contracts and arrangements with ERISA-covered plans, provided that the contracts or arrangements are reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid. Paragraph (a) of the final rule[118] provides that no contract or arrangement for services between a "covered plan" and a "covered service provider," nor any extension or renewal, is reasonable unless the requirements of ERISA section 408(b)(2)(B) are satisfied.[119] Paragraph (a) includes additional language that was not in the proposal, specifying that this final rule implements ERISA section 408(b)(2)(B) with respect to the covered service providers defined herein, and further that a contract or arrangement between a covered plan and a covered service provider, as defined in the final rule, that satisfies the requirements of the final rule also satisfies the requirements of ERISA section 408(b)(2)(B). These sentences were added to clarify the relationship between the statutory exemption and the final rule.

[118] 29 CFR section 2550.408b-22(a).

[119] Title I of ERISA sets forth various requirements for covered plans, which, subject to certain specific exceptions, "apply to any employee benefit plan if it is established or maintained . . . by any employer . . . or . . . by any employee organization . . . or . . . by both." ERISA section 4(a); 29 U.S.C. 1003(a). However, Title I of ERISA specifically does "not apply to any employee benefit plan if . . . such plan is a governmental plan." ERISA section 4(b); 29 U.S.C. 1003(b). "Governmental plan" is defined for purposes of this exclusion as "a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing." ERISA section 3(32); 29 U.S.C. 1002(32).

1.2. Covered Plan – Paragraph (b)

As provided in paragraph (b) of the final rule,[120] covered plans are generally defined to include large ERISA-covered self-insured group health plans. Specifically, a covered plan for purposes of this rule is a group health plan as defined in ERISA section 733(a) that is offered by a specified large employer or that is a specified large plan, each as defined in paragraph (m) of the final rule, with two exceptions. One is a group health plan in which all of the benefits are provided exclusively through a contract or policy of insurance issued by a health insurance issuer as defined in 29 CFR section 2590.701-2. The second is a group health plan established by a plan sponsor that is in the drug supply chain, as discussed in further detail in section E.1.2.4 of this preamble. The definition of covered plans includes excepted benefits, such as limited scope dental and vision plans.[121] ERISA section 733(a)(1) expressly excludes qualified small employer health reimbursement arrangements from the definition of group health plan, and therefore such arrangements are not covered plans under the final rule.

While the proposed rule applied to all self-insured group health plans, the final rule further limited the scope to large self-insured group health plans and included a new exception for group health plans established by a plan sponsor that is, or that is affiliated with, a drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), as discussed in the next sections of the preamble.

[120] 29 CFR section 2550.408b-22(b).

[121] *See* Field Assistance Bulletin No. 2021-03, Q&A 3, available at https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03 ("ERISA section 733(c)(2) provides that certain benefits are not subject to certain requirements of Part 7 of ERISA if offered separately, including limited scope dental or vision benefits . . . . The view of the Department is that limited scope dental and vision plans, although excepted from certain requirements in Part 7 of ERISA, are 'covered plans' subject to the requirements of ERISA section 408(b)(2)(B). The definition of a "covered plan" in ERISA section 408(b)(2)(B) refers to ERISA section 733(a), without any indication that the definition is further limited by ERISA section 733(c)(2).").

1.2.1. Limitation to Large, Self-insured Group Health Plans

The final rule applies only to self-insured group health plans offered by "specified large employers" and self-insured group health plans that are "specified large plans." These terms are defined in paragraph (m)[122] and are generally consistent with those terms in ERISA section 726. A specified large employer means, in connection with a group health plan established or maintained by a single employer, with respect to a calendar year, an employer who employed an average of at least 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the calendar year. For purposes of counting employees to determine whether an employer is a specified large employer, employees must be counted in accordance with the rules for counting employees and employer aggregation under section 4980H of the Internal Revenue Code and its implementing regulations at 26 CFR 54.4980H. A specified large plan means a group health plan established or maintained by a plan sponsor described in ERISA section 3(16)(B)(ii) or (iii) that had an average of at least 100 participants on business days during the preceding plan year. Whether a group health plan is a specified large plan is determined by taking the sum of the total number of participants (not including beneficiaries) for each calendar month in the preceding plan year, and dividing by 12. The result, if not a whole number, is then rounded to the next lowest whole number. Self-insured group health plans that are not described in those definitions are not covered plans for purposes of the final rule, but they are covered plans for purposes of the application of the statutory exemption in ERISA section 408(b)(2)(B) to entities providing pharmacy benefit management services. Accordingly, covered service providers not addressed in this rule must provide the

[122] 29 CFR section 2550.408b-22(m).

generalized compensation disclosures specified in the statute to rely on the prohibited transaction exemption.

The Department determined to limit the scope of the final rule in response to several different types of comments. First, commenters asked the Department to align the covered plan definition with ERISA section 726. Under ERISA section 726, the larger group health plans (i.e., offered by a specified large employer or a specified large plan) receive a report with detailed information about drug spending while smaller group health plans will receive a summary document that includes information "that the Secretary determines useful to group health plans for purposes of selecting pharmacy benefit management services, such as an estimated net price to group health plan and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary."[123] In the Department's view, aligning the definition of a covered plan so that only the larger self-insured group health plans receive the detailed disclosures under this final rule is responsive to those comments and is consistent with the Secretary's authority to specify the time, manner and content of the section 408(b)(2)(B) disclosures. Based on that same authority, the Secretary has determined that the smaller self-insured group health plans should receive the generalized compensation disclosures pursuant to ERISA section 408(b)(2)(B).

Limiting the detailed disclosures under the final rule to large, self-insured group plans is also responsive to other comments on the proposal. Commenters expressed the view that smaller employers with limited resources may face substantial challenges analyzing the detailed disclosures in the proposal, and having received the detailed disclosures, may face increased

[123] ERISA section 726(b)(2)(B).

litigation risk second guessing their disclosure-related decisions. Other commenters said that providing the detailed disclosures in the proposal would unduly burden smaller providers of pharmacy benefit management services who commonly serve smaller employers.

The Department believes that increased transparency in the area of pharmacy benefit management services is critical but it recognizes that, as a practical matter, the detailed disclosures required under the final rule may be most useful to responsible plan fiduciaries of larger employers, who are more likely to have compliance staff and sufficient resources to analyze the disclosures and take appropriate action. Proceeding with the more limited scope in the final rule is intended to avoid unintended negative consequences for smaller employers as described by some commenters while ensuring they receive disclosures under the statute to determine the reasonableness of the contracts or arrangements, including their covered service providers' compensation.[124]

This approach will not result in the smaller self-insured group health plans receiving no disclosures to assist them in selecting a provider of pharmacy benefit management services. These group health plans are covered plans under the statutory exemption in ERISA section 408(b)(2)(B) and would receive the disclosures required under the statute from covered service providers – including providers of pharmacy benefit management services – wishing to take advantage of the exemption. The disclosures are required at the time of the initial contract or arrangement and any extension or renewal, and include, for example, the services to be provided; the status of the covered service provider, an affiliate, or a subcontractor as a fiduciary, if applicable; and the direct and indirect compensation reasonably expected to be received by the

[124] Providing at least some disclosures is important for smaller employers because, as one commenter highlighted, their average deductible for individual coverage is $2,631—significantly higher than the $1,670 average deductible for larger employers—and half of the nation's smallest employers do not offer health insurance at all.

covered service provider, their affiliates and their subcontractors. The statute also provides for disclosure in the event of a change in the information required to be provided in the initial disclosures and for disclosures to be provided upon the written request of the responsible plan fiduciary, as needed for the plan to comply with the reporting and disclosure requirements of Title I of ERISA. Simply put, the covered service providers of these smaller self-insured group health plans, alongside those that serve fully-insured entities through a health insurance issuer, will not be required to provide the disclosures described in the final rule, which are more specific, prescriptive, and detailed with respect to the compensation streams than the disclosure provisions in the statute, but they will still need to follow the statute. As such, after considering comments, the Department believes that these more detailed disclosures are appropriately directed to the responsible plan fiduciaries of larger self-insured group health plans.

1.2.2. Fully Insured Plans

The definition of "covered plan" in the final rule excludes fully insured group health plans because the Department is reserving for future action more detailed regulatory disclosure obligations with respect to these plans. However, these group health plans remain covered plans under ERISA section 408(b)(2)(B) and therefore covered service providers serving fully insured plans that wish to rely on the statutory prohibited transaction exemption are required to provide the generalized statutory disclosures.

In the proposal, the Department had reserved regulatory disclosure obligations with respect to fully insured group health plans for future action based on the preliminary view that responsible plan fiduciaries may focus on different considerations when contracting with an insurance company for health insurance coverage that integrates prescription drug coverage, as opposed to self-insuring medical care and contracting for pharmacy benefit management

services. Specifically, the Department questioned whether responsible plan fiduciaries would find the specific disclosures proposed in the regulation useful when negotiating a fully insured arrangement as to justify the costs associated with the detailed disclosures (both to the covered service provider providing the disclosures and the responsible plan fiduciary reviewing and analyzing the disclosures). The Department also noted its understanding that, in some instances, other relevant reporting and disclosure requirements may apply under State law to the health insurance issuer, either independently under the applicable insurance code, or as part of the issuer's routine form filing review.

In the proposal, the Department sought comments on the relevance of the proposed disclosures to responsible plan fiduciaries of fully insured group health plans. In these arrangements in which services are fully bundled with insurance, the Department assumed that responsible plan fiduciaries discharged their obligation to ensure that the contract or arrangement is reasonable by focusing on premiums, covered benefits, coverage limits, exclusions, and cost-sharing requirements. The proposal further assumed that responsible plan fiduciaries would not, in these circumstances, benefit from the specific disclosures required under the proposal because when the pharmacy benefit management services are fully bundled with insurance, the responsible plan fiduciary has a clearer understanding of the total compensation paid for the services.

Some commenters supported the Department's proposed exclusion of fully insured group health plans as covered plans under the regulation. Commenters said a contract of insurance is different from the services arrangements involving self-insured plans and involves state insurance law oversight (i.e., Medical Loss Ratio requirements). A few commenters also took the position that extending the proposed disclosures to responsible plan fiduciaries of fully insured

group health plans would not be legally supportable. One commenter said that, in the case of a fully insured group health plan, the provider of pharmacy benefit management services is a vendor to the insurer and therefore does not have a contractual relationship with the plan. This commenter further argued that, in a fully insured group health plan, the insurer (not the plan) assumes financial risk, administers the benefits, and is responsible for all components of the insurance product. The same commenter also suggested that Congress addressed the mechanisms for fully insured arrangements to receive prescription drug reporting under ERISA section 726.

Many other commenters on the proposal said the Department should extend disclosure obligations under the final rule to covered service providers of fully insured group health plans. Many of these commenters said that excluding fully insured plans would leave fiduciaries without the benefit of the disclosures in the rule despite those fiduciaries having an obligation under ERISA to assess the reasonableness of contractual arrangements. Further, commenters believed that a consistent approach to transparency across self-insured plans and fully insured plans was desirable. Some commenters specifically referenced concerns about transparency in connection with the vertical integration of the largest PBMs and health insurance issuers. Other commenters noted that fully insured plans that are offered by specified large employers or that are specified large plans can receive the detailed report required under ERISA section 726 (although such plans must specifically opt in to do so). One commenter said the Department's stated rationale for excluding fully insured plans – which was based on integration with a health insurance contract – was not compelling, on the basis that the rule would apply to other cases where the commenter believed that pharmacy benefits are integrated with medical services, such as in arrangements offered by TPAs.

A few commenters who supported extending disclosure obligations to covered service providers of fully insured group health plans asked the Department to conduct a future rulemaking for these products, acknowledging the differences between fully insured and self-insured contracts and arrangements. One commenter said the Department would have flexibility to tailor disclosures to reflect differences in the fully insured group health plan context. A commenter opposing the expansion of this rule to include fully insured group health plans also expressed the view that fiduciaries making decisions about an insurance contract would not act on the particular disclosures in the Department's proposal.

The Department has carefully considered comments encouraging the Department to extend the final rule's disclosure obligations to covered service providers with respect to fully insured plans. In the Department's view, some of these commenters argued for disclosures to be made to fully insured plans as a matter of policy, without addressing whether the proposed disclosures would be meaningful for responsible plan fiduciaries of fully insured group health plans. The Department believes that arrangements in which pharmacy benefit services are bundled with insurance are distinct from self-insured arrangements offered by TPAs in which pharmacy benefit management services are integrated with medical services, as referenced by one commenter. The bundling with health insurance raises different issues because of the insurance guarantees. When an employer self-insures a group health plan, the employer bears the financial risk of paying claims and managing the plan. To assist with managing the plan, these employers often contract with service providers such as TPAs to process claims and provide other plan administration services. For a fully insured plan, generally the employer purchases a pre-packaged insurance product where the issuer bears the financial risk of covering costs. These differences in financial risk and plan management require a different approach for developing

meaningful disclosures for plan fiduciaries of fully insured plans. The Department is persuaded by the commenters who believe further work would need to be done before developing a framework for disclosures to responsible plan fiduciaries of fully insured group health plans.

The Department notes however that, contrary to an assertion by one commenter, providers of pharmacy benefit management services that contract with health insurers providing coverage to fully insured plans are in fact parties in interest and covered service providers, as clarified by the CAA, 2026.[125] Accordingly, these covered service providers have disclosure obligations under the statute that must be satisfied if they wish to rely on the exemption set forth in ERISA section 408(b)(2).

1.2.3. Other Types of Group Health Plans

Some commenters asked the Department to exclude excepted benefits such as limited scope dental and vision plans from the definition of covered plan. The commenters said that including excepted benefits is inconsistent with the CAA, 2026 amendments to ERISA. A few commenters also asked the Department to clarify whether the rule would apply to Taft-Hartley plans or welfare benefit plans under ERISA section 3(1).

The final rule applies to covered plans which are defined as group health plans under ERISA section 733(a) that are offered by a specified large employer or that are specified large plans, each as defined in paragraph (m), other than a group health plan in which all of the benefits are provided exclusively through a contract or policy of insurance issued by a health

[125] *See* ERISA section 408(b)(2)(B)(i) ("For purposes of applying section 1106(a)(1)(C) of this title with respect to a transaction described under this subparagraph or subparagraph (C), a contract or arrangement for services between a covered plan and an entity providing services to the plan, including a health insurance issuer providing health insurance coverage in connection with the covered plan, in which such entity contracts, in connection with such plan, with a service provider for pharmacy benefit management services, shall be considered an indirect furnishing of goods, services, or facilities between the covered plan and the service provider for pharmacy benefit management services acting as the party in interest.").

insurance issuer. Although excepted benefits are not subject to certain requirements in Part 7 of ERISA, such benefits are "covered plans" subject to the requirements of ERISA section 408(b)(2)(B) to the extent that such benefits satisfy the definition of "group health plan" under ERISA § 733(a)(1). The Department notes that in accordance with ERISA section 732(b) and (c), the market requirements of part 7 of ERISA do not apply to a group health plan or a health insurance issuer in the group or individual market in relation to the provision of excepted benefits described in ERISA section 733(c). However, ERISA section 408(b)(2)(B) provides that covered plan means a group health plan as defined in ERISA section 733(a). Under ERISA section 733(a) a group health plan is defined as "an employee welfare benefit plan to the extent that the plan provides medical care…to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise." Section 733(a)(1) of ERISA specifically excludes qualified small employer health reimbursement arrangements.

The definition of a group health plan in ERISA section 733(a) does not exclude excepted benefits, which are defined under ERISA section 733(c)(2). Therefore, excepted benefits are not excluded from the disclosure requirements under this final rule. To the extent that a covered service provider enters a contract or arrangement with an excepted benefit plan, the disclosure obligations required to qualify for a prohibited transaction exemption may apply. Similarly, the definition of group health plan does not exclude Taft-Hartley plans, and such plans are covered plans under ERISA section 408(b)(2)(B) and this regulation if they meet the size criteria.

1.2.4. Group Health Plans of Sponsors in the Drug Supply Chain

A few commenters raised the potential for anticompetitive harm associated with detailed disclosures to responsible plan fiduciaries of self-insured group health plans sponsored by drug manufacturers or other employers in the drug supply chain. Commenters pointed to a special

provision in ERISA section 726 directing the Secretary (along with the Secretaries of Treasury and Health and Human Services) to define through rulemaking a limited form of report for any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or other direct participant in the drug supply chain, "to prevent anti-competitive behavior."[126] The commenters said the Department should include a similar limited initial disclosure and semiannual disclosure for these group health plans.

No commenters articulated why plan fiduciaries of self-insured group health plans sponsored by drug manufacturers or other employers in the drug supply chain should receive detailed disclosures under this final rule. Commenters highlighted that, in recent years, multiple cases have been brought by plan participants claiming that their plan fiduciaries did not fulfill their fiduciary responsibilities regarding PBM services by incurring excessive fees, failing to negotiate better pricing terms for prescription drugs, and not behaving prudently when selecting the plan's PBM.[127] One of these cases involved a pharmaceutical manufacturer, highlighting that employers in the drug supply chain are also expected to scrutinize the agreements they enter into with PBMs.

Although the disclosures under the final rule would assist employers in the drug supply chain in satisfying their fiduciary obligations, the Department is persuaded that Congress' inclusion of this special provision in CAA, 2026 reflects a deliberate judgement that anticompetitive harm could result from those with a direct financial stake in the drug supply chain receiving detailed disclosures. Therefore, the definition of covered plan in the final rule

[126] ERISA section 726(b)(4)(G).
[127] *See Knudsen v. MetLife Grp., Inc.*, 117 F.4th 570 (3d Cir. 2024); *Navarro v. Wells Fargo & Co.*, No. 24-cv-3043 (LMP/DTS), 2025 WL 897717, (D. Minn. Mar. 24, 2025); *Lewandowski v. Johnson & Johnson*, No. CV 24-671 (ZNQ) (RLS), 2025 WL 288230 (D.N.J. Jan. 24, 2025).

was revised from the proposal to exclude group health plans established by a plan sponsor that is, or that is affiliated with, a drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates). Plan sponsors that are considered direct participants in the drug supply chain for purposes of exclusion under this final rule include but are not limited to drug manufacturers, market authorization holders (if different than the manufacturer) that retain control over the drug's list price; distributors or wholesalers, pharmacy benefit managers; rebate aggregators, including GPOs; and affiliated pharmacies, including retail, mail-order, and specialty pharmacies. While group health plans of these sponsors would not receive disclosures under this final rule, they would receive the disclosures required under ERISA section 408(b)(2)(B) from those wishing to take advantage of the exemption as well as ERISA section 726 once the Secretaries define through rulemaking a limited form report.[128]

1.3. Covered Service Providers – Paragraph (c)

Paragraph (c) of the final rule[129] defines the entities that are covered service providers under the final rule and therefore have disclosure and related audit obligations. The final rule identifies two types of covered service providers: (i) providers of pharmacy benefit management services (as defined in paragraph (d) of the final rule) and (ii) providers of advice, recommendations, or referrals regarding pharmacy benefit management services who are themselves providers of pharmacy benefit management services or their affiliates.[130] In each case, to be a covered service provider, the entity must reasonably expect to receive $1,000[131] or

[128] ERISA section 726(b)(4)(G).
[129] 29 CFR section 2550.408b-22(c).
[130] Non-affiliated brokers and consultants remain subject to the ERISA section 408(b)(2)(B) disclosures.
[131] This $1,000 threshold is consistent with the thresholds in the statute (ERISA section 408(b)(2)(B)(ii)(I)(bb)) and the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b-2(c)(1)(iii)).

more in compensation, direct or indirect, in connection with providing the services.[132] These provisions in the definition of covered service provider in the final rule are consistent with the definition in the Department's proposal.

Some commenters asked the Department to clarify whether the $1,000 threshold figure would be calculated on a per claim basis or based on total aggregate earnings within a year. Commenters also asked whether the threshold applies to any combination of the services identified in the definition of pharmacy benefit management services. In response, the Department confirms the $1,000 is measured against total aggregate earnings within the year and applies to any combination of the pharmacy benefit management services.

1.3.1. Other Types of Service Providers

In the proposal, the Department noted that it was focusing on pharmacy benefit managers in response to President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, which instructed the Department to propose regulations to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers. However, the Department recognized that self-insured group health plans have other service providers that were not covered by the proposal. These service providers include TPAs, health insurers, and others involved in the administration of self-insured group health plans' medical claims, such as for hospital stays, surgeries, and chronic treatment, but whose services are unrelated to pharmacy benefit management. Stakeholders had indicated that group health plan fiduciaries may not have access to all claims data, payments to providers, and

[132] Under proposed paragraph (m)(3), compensation is defined as "anything of monetary value but does not include any item or service valued at $250 or less, in the aggregate, during the term of the service contract or arrangement." The $250 threshold in this context is consistent with the definitions in the statutory provision (ERISA 408(b)(2)(B)(ii)(I)(dd)(AA)) and the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b-2(c)(1)(viii)(B)).

fee and pricing data that could enable negotiation for cost savings to group health plans and participants.[133] The Department sought comment on whether it should expand the proposed disclosures to cover additional service providers beyond providers of pharmacy benefit management services; and if so, which service providers should be covered. Additionally, the Department sought comment on whether the disclosures in the proposal would be sufficient to bring transparency into arrangements with those additional service providers or whether additional disclosures would be needed, such as claims data, payments to providers, and other fee and pricing data.

As discussed in section D. of this preamble, shortly after the Department published its proposed rule, Congress amended ERISA section 408(b)(2)(B) in the CAA, 2026, which in part clarified which service providers are covered service providers for purposes of the prohibited transaction exemption. The phrase "Brokerage services" was removed and replaced with "Services (including brokerage services)," in subparagraph (AA) of section 408(b)(2)(B)(ii)(I)(bb). The term "Consulting" was removed and replaced with "Other services" in subparagraph (BB) of section 408(b)(2)(B)(ii)(I)(bb). Additionally, in subparagraph (BB) of section 408(b)(2)(B)(ii)(I)(bb), the phrase "related to the development or implementation of" and the list of services that followed were removed and replaced with "including any of the following" and an updated list of services that includes consulting services.

In response to the CAA, 2026, the Department extended the comment period for the proposed rule to allow stakeholders to address how to harmonize the proposed rule with the new

[133] *See* letter to The Honorable Donald J. Trump from Cynthia A. Fisher, PatientRightsAdvocate.org (November 25, 2025), available at https://www.patientrightsadvocate.org/lettertopresidentonaffordabilityandhealthcare.

statutory requirements.[134] Many commenters said the Department should expand the definition of covered service provider to include additional types of service providers. They mentioned TPAs, independent brokers and consultants, insurers, and network vendors, for example. Commenters said the need for transparency was not limited to the context of pharmacy benefit management services, with some commenters also stating that arrangements with other service providers also suffered from undisclosed conflicts of interest, misaligned incentives, and indirect compensation streams that may not be known by the responsible plan fiduciaries. A few commenters said that the compensation flows among various group health plan service providers are inseparable, especially due to vertical integration of service providers and expressed concern that failure to expand the definition of covered service provider would allow parties to evade disclosure obligations and undermine the transparency goals of the rulemaking. Some commenters noted expansion to other types of service providers would be consistent with Congress' action clarifying the broader definition of covered service provider in ERISA section 408(b)(2)(B).

Some commenters provided information on the types of disclosures that should be required should the Department expand the final rule to include other covered service providers, especially TPAs with respect to medical claims. Commenters mentioned compensation retained on provider reimbursements; shared savings or gainsharing arrangements; network access or discount fees; repricing or claims-editing fees; and many others. Commenters raised the point that TPAs often receive compensation from network lessors, specialty vendors, and utilization management companies by routing business through those entities, for the plans the TPA serves.

[134] Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure: Extension of the Comment Period, 91 FR 10033 (Mar. 2, 2026). In the notice, the Department also specifically sought comment on "whether specific provisions of the rule should be revised or whether new provisions should be added, in order to minimize complexity or align with the new statutory provisions, while continuing to fulfill the stated transparency goals of the proposal."

These indirect sources of compensation may not be known to plan sponsors as they are not always identified in the contracts between TPAs and plans. Commenters also identified brokers and consultants who advise plans on service provider selection and may receive compensation from selected providers.

Other commenters said the Department should not expand the definition of covered service providers to other types of service providers beyond providers of pharmacy benefit management services. One commenter said that TPA and claims administration services are fundamentally different from pharmacy benefit management services and disclosure issues would not be able to be addressed by expanding the disclosures in the Department's rule which had been developed for providers of pharmacy benefit management services. Another commenter noted that TPAs are included in the proposed rule to the extent they provide pharmacy benefit management services. Commenters also said that Congress had made clear that there is a broader set of covered service providers in the statutory exemption but did not single them out for detailed disclosure obligations.

The Department concurs with commenters who said that broader transparency encompassing additional covered service providers to group health plans would be beneficial and consistent with law. As discussed above, a broad range of covered service providers are now covered service providers for purposes of the statutory exemption in ERISA section 408(b)(2)(B), including TPAs. Commenters identified multiple types of service providers that contract with group health plans to provide a wide array of services with multiple sources of direct and indirect compensation that group health plan service providers, such as TPAs, may utilize. However, based on the comments identifying the compensation streams that should be disclosed, the Department believes disclosures for the expanded group of covered service

providers would best be addressed in a separate regulatory or subregulatory guidance project tailored to those other types of service providers, and will consider adding this project to a future regulatory agenda.

For now, although not covered by this final rule, the Department expects this expanded group of covered service providers to make a good-faith effort to comply with their disclosure obligations under ERISA section 408(b)(2)(B), in line with the Department's temporary enforcement policy announced herein, in order to rely on the exemption. For example, a TPA providing services to a group health plan for medical management should disclose, pursuant to ERISA section 408(b)(2)(B), direct and indirect compensation. This includes direct or indirect compensation such as administrative fees, per-employee-per-month fees, or 340B-related income; provider and network compensation; affiliate, subcontractor, and vertically integrated compensation; data monetization compensation; and payment and recovery compensation.

1.3.2. Compensation of Individuals who are Officers, Directors, Employees or Partners

Some commenters noted that the definition of an "affiliate" includes officers, directors, employees, and partners of the covered service provider. These commenters said the final rule should not require disclosure of any individual's compensation in connection with providing pharmacy benefit management services. The Department agrees that compensation of individuals is not the focus of this regulatory project and notes that ERISA section 408(b)(2)(B) specifically provides that the requirement to disclose indirect compensation does not extend to compensation received by an employee from an employer on account of work performed by the employee.[135] The Department has added a similar provision in paragraph (c) of the final rule that specifies that

[135] ERISA section 408(b)(2)(B)(iii)(IV)(aa)(BB).

the regulation does not require disclosure of the compensation of individuals who are officers, directors, employees and partners.

1.4. Providers of Pharmacy Benefit Management Services – Paragraph (c)(1)(i)

Paragraph (c)(1)(i) of the final rule defines, as covered service providers, service providers who enter into a contract or arrangement with a covered plan to provide pharmacy benefit management services. Like the proposed rule, the final rule clarifies that this would be the case regardless of whether the services will be performed by the covered service provider, an affiliate, an agent, or a subcontractor.[136] Thus, the final rule recognizes that the pharmacy benefit management services may be performed by the covered service provider, or they may be performed by an affiliate, an agent, or a subcontractor of the covered service provider. Likewise, the final rule recognizes that compensation in connection with the services may be received by the covered service provider or it may be received by an affiliate, an agent, or a subcontractor of the covered service provider.

Under this framework, paragraph (c)(1)(i) of the final rule focuses on the entity that has a contract or arrangement with the covered plan to provide any pharmacy benefit management services to that plan – that party is the covered service provider. The Department believes that the service provider directly responsible to the covered plan for the provision of pharmacy benefit management services is the appropriate party to ensure that the required disclosures under the regulation are made. This approach is consistent with ERISA section 408(b)(2)(B) as

[136] The definition of pharmacy benefit management services in paragraph (d) of the final rule is discussed in the next subsection of this preamble. The terms affiliate, agent, and subcontractor are defined in paragraph (m) of the final rule and are discussed in the following subsection of this preamble.

well as the Department's service provider regulation applicable to pension plans (29 CFR 2550.408b-2(c)(1)).[137]

In this regard, the Department understands that responsible plan fiduciaries to covered plans may take a number of different approaches in identifying and selecting a provider of pharmacy benefit management services. The covered plan may ultimately contract directly with the entity that will perform the services, or it may enter into a contract with a different entity that agrees to provide the services to the covered plan through an affiliate, an agent, or a subcontractor. It is common, for example, for responsible plan fiduciaries to work with a consultant or broker to conduct a request for proposal and to assist in negotiations with the providers of pharmacy benefit management services. In that case, the covered plan will enter a contract directly with the PBM.

On the other hand, the Department understands that TPAs may contract directly with covered plans to provide a range of health-care related services, such as creating networks of healthcare providers, negotiating payments rates, and processing and paying health claims. One component of these services may be pharmacy benefit management services. If the TPA contracts with the covered plan to provide pharmacy benefit management services, the TPA would be a covered service provider under this regulation, even if it intends to rely on another provider to perform those services. In that event, the TPA would be responsible for making the disclosures to the responsible plan fiduciary required under the final rule and therefore must be

[137] ERISA section 408(b)(2)(B)(ii)(I)(bb) ("The term 'covered service provider' means a service provider that enters into a contract or arrangement with the covered plan . . ."); Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure; Interim Final Rule, 75 FR 41600, 41606 (July 16, 2010) ("In the view of the Department, the service provider directly responsible to the plan for the provision of services is the appropriate party to ensure that the required disclosures under the regulation are made.").

able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

Covered plans may access pharmacy benefit management services through other similar types of arrangements, where the provider may or may not refer to itself as a TPA. For example, it is common for group health plans to enter level-funded arrangements that have stop-loss policies to emulate characteristics of fully insured arrangements, such as predictable spending, but that are actually self-funded arrangements. These arrangements commonly include pharmacy benefit services and the entity that contracts with the covered plan to provide those services would be the covered service provider. As in the TPA example, even if the entity contracting or arranging with the covered plan is not providing the services itself, it nonetheless would be responsible for making the disclosures to the responsible plan fiduciary required under the final rule, and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

Questions may arise regarding which party is the covered service provider and which party is the responsible plan fiduciary in the context of a multiple employer welfare arrangement (MEWA).[138] For MEWAs that are considered single ERISA plans, the responsible plan fiduciary for the covered plan would receive the disclosures from the party that contracts with the covered plan to provide pharmacy benefit management services. In the case of a MEWA that is not considered a single ERISA plan but rather involves a number of covered plans each sponsored by an employer individually, the party operating the MEWA is likely to be the covered service provider that contracts with the individual covered plans to provide pharmacy benefit

[138] For more information on MEWAs, see *MEWAs Multiple Employer Welfare Arrangements under the Employee Retirement Income Security Act (ERISA): A Guide to Federal and State Regulation*, available at https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/mewa-under-erisa-a-guide-to-federal-and-state-regulation.pdf.

management services. In that case, the MEWA operator would have the responsibility to make the disclosures required by the final rule to the responsible plan fiduciaries (i.e., the employers or other fiduciary responsible for entering into the contract or arrangement to provide such services),[139] and therefore must obtain the necessary information from the provider (e.g., as a subcontractor) performing the pharmacy benefit management services.

Covered plans alternatively may access pharmacy benefit management services through employer consortiums or other types of employer groups. The analysis of who the covered service provider is in those arrangements would depend on the details of the arrangement and, specifically, which entity contracts with the covered plan to provide the pharmacy benefit management services. If the consortium or other group assists in negotiating with the provider of pharmacy benefit management services but the covered plan contracts directly with the provider—which the Department believes is the predominant approach—the provider of pharmacy benefit management services would be the covered service provider. However, if the consortium or other employer group were to contract to provide the services to the covered plan, the consortium or other group would be the covered service provider.

Finally, a covered plan may directly contract with more than one entity for pharmacy benefit management services as such services are defined in paragraph (d) of the rule. In such circumstances, the covered plan would thus have more than one PBM, each of which would be a covered service provider and responsible for making its own disclosures with respect to services under its contract or arrangement with the covered plan.

[139] *See* paragraph (m)(4) defining "responsible plan fiduciary."

1.4.1. Definition of Pharmacy Benefit Management Services – Paragraph (d)

Paragraph (d) of the final rule[140] defines pharmacy benefit management services as services necessary for the management or administration of a covered plan's prescription drug benefits (including the covered plan's provision of prescription drugs through the plan's medical benefit), regardless of whether the person, business, or entity performing the service identifies itself as a "pharmacy benefit manager." The definition includes a list of examples of such services, as follows:

- acting as a negotiator or aggregator of rebates, fees, discounts and other price concessions for prescription drugs;
- establishing or maintaining prescription drug formularies;
- establishing or maintaining pharmacy networks, through contract or otherwise, including a mail order pharmacy, a specialty pharmacy, a retail pharmacy, a nursing home pharmacy, a long-term care pharmacy, and an infusion or other outpatient pharmacy, to provide prescription drugs;
- performing utilization review and management, including the instituting and processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic and biosimilar substitution programs.

The definition also includes examples of other services that, in conjunction with any of the services described above, are considered pharmacy benefit management services. These services are:

- processing and payment of claims for prescription drugs;
- adjudicating appeals or grievances related to the covered plan's prescription drug benefits;
- recordkeeping related to the covered plan's prescription drug benefits; and

[140] 29 CFR section 2550.408b-22(d).

- performing regulatory compliance with respect to the covered plan's prescription drug benefits under the contract or arrangement.

As discussed above, pharmacy benefit management encompasses a number of services related to developing drug formularies, negotiating with drug manufacturers for rebates and other discounts, negotiating with pharmacies, and processing claims and other functions for covered plans. The examples provided in the definition are intended to describe the services expansively to ensure comprehensive disclosures are made. Consequently, the definition specifies that whether the person providing the services identifies itself as a PBM is not dispositive of the requirement to disclose. Additionally, a person will be a covered service provider by virtue of performing any of the services identified in the definition; covered service provider status does not depend on comprehensively providing all the services set forth in the definition.

The definition in the final rule was revised from the proposal based on comments stating that certain examples included in the proposed definition were too broad. Commenters identified the following examples as ones that in isolation may identify service providers that should not be considered to provide pharmacy benefit management services: "processing and payment of claims for prescription drugs;" "adjudicating appeals or grievances related to the covered plan's prescription drug benefits;" "recordkeeping related to the covered plan's prescription drug benefits;" and "regulatory compliance with respect to the covered plan's prescription drug benefits under the contract or arrangement." One commenter, for example, said that health reimbursement account (HRA) service providers may process and pay claims for prescription drugs as part of their account administration, but the commenter did not believe the Department should cover HRA service providers as providers of pharmacy benefit management services.

The Department is persuaded by the examples provided by these commenters that the examples may be too broad in isolation, and has accordingly revised the definition of pharmacy benefit management services. Under the revised definition, certain services described in the examples will, standing alone, be considered pharmacy benefit management services. Those services are: acting as a negotiator or aggregator of rebates, fees, discounts, and other price concessions for prescription drugs; establishing or maintaining prescription drug formularies; establishing or maintaining pharmacy networks, through contract or otherwise, including a mail order pharmacy, a specialty pharmacy, a retail pharmacy, a nursing home pharmacy, a long-term care pharmacy, and an infusion or other outpatient pharmacy, to provide prescription drugs; and performing utilization review and management, including the instituting or processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic and biosimilar substitution programs. These services can be considered core pharmacy benefit management services.

The Department revised the example regarding utilization review and management based on comments suggesting that the example should be expanded to be comprehensive. In the final rule, the words "instituting or" were added before "processing of prior authorization requests for drugs," so that the example extends to "*instituting or* processing of prior authorization requests for drugs" and the word "biosimilar" was added to the phrase regarding administering generic substitution programs, so that the example reads "administering generic *and biosimilar* substitution programs."

Other examples in the definition will be considered pharmacy benefit management services only if they are performed "in conjunction with" the core services. Those services are: processing and payment of claims for prescription drugs; adjudicating appeals or grievances

related to the covered plan's prescription drug benefits; recordkeeping related to the covered plan's prescription drug benefits; and performing regulatory compliance with respect to the covered plan's prescription drug benefits under the contract or arrangement. Under this approach, entities who provide these services along with the core pharmacy benefit management services would consider the compensation from these services when determining if the $1,000 threshold is met for status as a covered service provider. Compensation received in connection with these services would be disclosed under the various disclosure provisions in the final rule.

Some commenters focused on the example regarding "performing regulatory compliance" and asked whether, under that example, providers of legal services would be considered covered service providers. The revised definition should make clear that attorneys and other providers of legal services would generally not be considered providers of pharmacy benefit management services under the final rule. The definition is intended to encompass entities that perform any of the core services described above and also provide regulatory compliance – for example, ensuring compliance with the rebate pass through requirements of ERISA section 408(b)(2)(C) when that section takes effect. Under the definition of pharmacy benefit management services in the final rule, it is not necessary for an entity to provide all the services described in the examples. One commenter said the word "and" connecting the examples might suggest that all such examples must be satisfied for the definition to apply. The Department has replaced "and" with "or" and, under the language of the definition as revised, the Department does not believe there is potential for confusion.

Commenters suggested that the Department make other changes to this definition in the final rule. One commenter said that the example "acting as a negotiator or aggregator of rebates, fees, discounts and other price concessions for prescription drugs" is unnecessarily broad and

could encompass negotiators of price concessions whose services are separate from the procurement and management of prescription drug coverage traditionally associated with pharmacy benefit management services. The commenter also said any definition should be clear that pharmacies themselves are not pharmacy benefit management service providers. In the Department's view, acting as a negotiator or aggregator of rebates, fees, discounts and other price concessions for prescription drugs is a core component of pharmacy benefit management services so it has retained that aspect of the definition as proposed. The Department understands that pharmacies do not perform the core services as described above and therefore agrees that they would not be considered providers of pharmacy benefit management services under the final rule.

Several commenters asked for specific items to be added to the definition. Suggestions included adding a reference to administration of a pharmacy benefit, in whole or in part, to the definition; adding a reference to establishing or maintaining prescription drug formularies that require beneficiaries to apply to manufacturer patient assistance-related programs and adding a reference to activity of a provider of pharmacy benefit management services or an affiliate that manages, co-manages, or private-labels pharmaceutical products. The Department has not adopted these changes because it believes the existing language in the definition is adequate to cover the activities suggested by commenters. For example, administration of a pharmacy benefit is specifically referenced in the general language in paragraph (d)(1), which states "the term 'pharmacy benefit management services' means services necessary for the management or administration of a covered plan's prescription drug benefits (including the covered plan's provision of prescription drugs through the plan's medical benefit) . . ." Paragraph (d)(2)(ii) provides that pharmacy benefit management services include "[e]stablishing or maintaining

prescription drug formularies" which the Department believes is broad enough to cover establishing or maintaining prescription drug formularies that require beneficiaries to apply to manufacturer patient assistance-related programs as well as selecting PBM-affiliated pharmaceutical products for the formulary.

One commenter suggested the definition of pharmacy benefit management services should include a rebuttable presumption under which a health plan service provider providing what generally may be considered pharmacy benefit management services as illustrated by the examples would be presumed to be a covered service provider unless reasonably determined not to be by the applicable group health plan fiduciaries. Another commenter suggested a special rule under which pharmacy benefit management services would not include activities performed by "an integrated health care delivery system that includes a nonprofit health insurance issuer in which enrollees primarily use pharmacies that are entirely owned and operated by the nonprofit health insurance issuer." The Department has not adopted the rebuttable presumption because it does not believe a responsible plan fiduciary should be in a position to excuse a particular entity from being considered a covered service provider. The Department also has not adopted the special rule for the nonprofit health insurance issuer described by the commenter because it was not persuaded that covered plans entering into that arrangement would not benefit from the disclosures under the final rule.

There were additional comments on how the definition of pharmacy benefit management services should be phrased. One commenter suggested that the definition should reference subsidiaries, parents, and affiliates of the entity providing pharmacy benefit management services. The Department does not believe that is necessary because the final rule has a definition of "affiliate" that includes these entities.

One commenter believed that the final rule should clarify that the definition of pharmacy benefit management services relates to prescription drugs reimbursed under the medical benefit, and specifically that the following compensation streams are covered: compensation received by PBMs, TPAs, carriers, specialty pharmacies, and affiliated entities in connection with medical-benefit drugs; rebates, administrative fees, and other payments tied to physician-administered or specialty drugs; provider-side revenue, including markups, reimbursement differentials, and site-of care-related compensation; and any other direct or indirect remuneration arising from the management, distribution, or reimbursement of such drugs.

The Department believes the definition in the final rule adequately includes that reference in the language. In paragraph (d)(1) of the final rule, the definition states: "the term 'pharmacy benefit management services' means services necessary for the management or administration of a covered plan's prescription drug benefits (*including the covered plan's provision of prescription drugs through the plan's medical benefit*). . . ." (Emphasis added).

1.4.2. Affiliates, Agents and Subcontractors – Paragraph (m)

The final rule's defined terms "affiliate," "agent," and "subcontractor" identify parties other than the covered service provider that may perform pharmacy benefit management services and may receive compensation in connection with the contract or arrangement that the covered service provider has with a covered plan for pharmacy benefit management services. The services and compensation of these entities are required to be disclosed under the final rule. As noted above, the final rule places the obligation on the covered service provider to make the disclosures, including to seek any required information from these parties as needed for the disclosure. Paragraph (c)(2) clarifies that affiliates, agents, and subcontractors of covered service

providers do not, themselves, become covered service providers as a result of providing services pursuant to the contract or arrangement.[141]

Under paragraph (m)(1) of the final rule, an affiliate is an entity that "directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with such person or entity; or is an officer, director, or employee of, or partner in, such person or entity." The definition states that unless otherwise specified, an "affiliate" in the regulation refers to an affiliate of the covered service provider. In other contexts, the Department has said "control" refers to the power to exercise a controlling influence over the management or policies of a person other than an individual.[142]

Paragraph (m)(5) defines a subcontractor as a "person or entity (or an affiliate of such person or entity) that is not an affiliate of the covered service provider and that, pursuant to a contract or arrangement with the covered service provider or an affiliate, reasonably expects to receive $1,000 or more in compensation for performing one or more services described pursuant to paragraph (d) of this section provided for by the contract or arrangement" with the covered plan. Accordingly, under the definition, an affiliate of a subcontractor would also be considered a subcontractor for purposes of the regulation, including the disclosure requirements. This means that compensation to a subcontractor's affiliate must be disclosed if received in connection with the pharmacy benefit management services provided to the covered plan.

The definitions of the terms "affiliate" and "subcontractor" are generally consistent with the definitions of these terms in ERISA section 408(b)(2)(B) and the Department's service

[141] This clarifying provision is also in ERISA section 408(b)(2)(B)(ii)(III) and the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b-2(c)(1)(iii)(D)).
[142] *See, e.g.*, 29 CFR 2550.404c-1(e)(3).

provider disclosure regulation for pension plans (29 CFR 2550.408b-2(c)).[143] The Department believes they are well understood by stakeholders.

The final rule also includes, in addition to "affiliates" and "subcontractors," the term "agent," defined in paragraph (m)(2) as "any person or entity authorized (whether that authorization is expressed or implied) to represent or act on behalf of another person or entity." Unless otherwise specified, an "agent" for purposes of the regulation refers to an agent of the covered service provider. Although parties performing services provided for under the contract or arrangement on behalf of the covered service provider should generally fall within the broad term "subcontractor," the additional defined term "agent" is included based on the concern that, in the context of pharmacy benefit management services, entities that receive undisclosed compensation in connection with a covered service provider's contract or arrangement with a covered plan for pharmacy benefit management services may not technically fall within the definition of an "affiliate" or a "subcontractor," or may take the position that they do not. As one example, the Department is aware that some providers of pharmacy benefit management services have formed rebate aggregators or GPOs outside of the laws of the United States.[144] The Department intends that any compensation received by these entities in connection with a covered service provider's contract or arrangement with a covered plan for pharmacy benefit management services would be disclosed under the final rule.

The Department requested comments on the proposed definitions of affiliate, agent, and subcontractor, including whether parties such as rebate aggregators or GPOs (or any other parties

[143] *See* ERISA section 408(b)(2)(B)(ii)(I)(cc) and (ff); 29 CFR 2550.408b-2(c)(1)(viii)(A) and (F).
[144] *See, e.g.*, Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

that fell within the proposed definition of agent) would be likely to be covered by either of the other proposed definitions (i.e., affiliate or subcontractor).

Many commenters supported an approach in the regulation that would result in comprehensive disclosure of compensation associated with pharmacy benefit management services. Some commenters specifically referenced challenges to transparency associated with vertically integrated providers of pharmacy benefit management services.

Regarding the goal of comprehensive disclosures, some commenters said the phrasing of the definitions of "affiliate," "subcontractor," and "agent" might have loopholes, particularly with respect to rebate aggregators, GPOs, and similar entities. For example, some commenters said the definition of "affiliate" referenced common control but might not cover entities that have contractual relationships with a provider of pharmacy benefit management services. Some commenters suggested that the Department should specifically identify rebate aggregators, GPOs, and similar entities as entities for which compensation must be reported, regardless of their relationship with the covered service provider. Other commenters believed that the term "agent" in the final rule would be critical to ensuring disclosure of compensation received by rebate aggregators, GPOs, and similar entities, as that defined term does not require any ownership or control. One commenter said the Department should align with ERISA section 726 and use the "applicable entity" definition.

Other commenters said the Department should eliminate affiliates and agents from the disclosure obligations altogether or narrow them so that they are covered only if performing pharmacy benefit management services. These comments appeared to be based on the perception that, absent this change, the rule would require disclosure of compensation received by these entities unconnected to the performance of pharmacy benefit management services. One

commenter said that if the Department did not narrow the definitions of these entities, it should provide a safe harbor for affiliates and subcontractors that receive compensation solely in the form of arm's length, market-rate fees for discrete services performed under separate commercial contracts, without discretion to influence formulary placement, plan design, or compensation structures applicable to the covered plan.

After considering comments on these definitions, the Department decided to retain the definitions as proposed, based on the view that they will ensure comprehensive disclosure of compensation received in connection with a covered service provider's contract or arrangement with a covered plan for pharmacy benefit management services, consistent with the goals of this rulemaking and the language of section 408(b)(2)(B), as amended. The Department did not eliminate the definitions of affiliates and subcontractors, or switch to the defined term "applicable entity," because ERISA section 408(b)(2)(B) specifies that affiliates' and subcontractors' services and compensation must be disclosed. The Department additionally agrees with commenters who believed that the term "agent" is needed in the context of a rule requiring disclosure of compensation in connection with a covered service provider's contract or arrangement with a covered plan for pharmacy benefit management services. The term "agent" is needed to ensure that compensation received by rebate aggregators, GPOs, and similar entities would be disclosed, even if such parties may take the position that they are not "affiliates" or "subcontractors." As one commenter described, these entities act on behalf of providers of pharmacy benefit management services in negotiating, aggregating, and receiving manufacturer remuneration.

With respect to commenters who believed that the final rule might require disclosure of compensation of affiliates who do not have any involvement in the pharmacy benefit

management services, the Department points to the regulatory text that provides for disclosure of the various forms of compensation received by the covered service provider, an affiliate, an agent, or a subcontractor "in connection with" the service contract or arrangement. As discussed in greater detail below, the Department intends that "in connection with" will be interpreted broadly to cover compensation that is received based in whole or in part on the service contract or arrangement. If the standard is not satisfied with respect to compensation received by an affiliate, then disclosure is not required.

Some commenters addressed proposed paragraph (c)(2) which stated that "no person or entity is a 'covered service provider' solely on the basis of providing services as an affiliate, an agent, or a subcontractor of the covered service provider." Some commenters supported this provision as providing clarity regarding which party has the obligation to provide the required disclosures. Another commenter asked the Department to delete this provision to ensure that all such parties will provide the required disclosures, noting that it was not clear what recourse covered plans would have if such parties did not provide the required information and data. A few other commenters also expressed concern about whether covered service providers would be able to obtain information from other parties in the pharmaceutical supply chain to supply the required disclosures to the covered plan.

The Department has retained paragraph (c)(2) in the final rule, as proposed, as a matter of consistency with ERISA section 408(b)(2)(B) which also places the responsibility for disclosure on the entity with the direct relationship with the covered plan. This structure does not, however, absolve affiliates, agents, and subcontractors from supplying the information required by ERISA section 408(b)(2)(B) or this regulation. For the covered service provider to participate in and receive compensation in connection with these contracts and arrangements, these parties must all

be prepared to make the required disclosures so that contracts and arrangements with covered plans do not result in prohibited transactions. Responsible plan fiduciaries of covered plans that do not receive required disclosures under the final rule may take advantage of the administrative exemption that involves notifying the Department about covered service providers' failures to meet their disclosure obligations.[145]

The Department has considered comments about the potential burden on smaller covered service providers obtaining the information and providing the detailed disclosures under the final rule. In response, the Department notes that ERISA section 408(b)(2)(B) does not provide an exemption from the disclosure requirements for small service providers. Also, to the extent that these smaller covered service providers provide services to smaller employers or smaller self-insured group health plans, the Department believes these burdens are alleviated by the more limited scope of the final rule extending the regulatory disclosure requirements only to larger self-insured group health plans.

1.5. Affiliated Providers of Brokerage or Consulting Services – Paragraph (c)(1)(ii)

Paragraph (c)(1)(ii) of the final rule identifies as covered service providers parties described in paragraph (c)(1)(i) or their affiliates that enter a contract or arrangement with a covered plan to provide advice, recommendations, or referrals of pharmacy benefit management services. These covered service providers have the obligation under the final rule to disclose their services and compensation and to allow for an audit, as discussed below. This provision in the final rule is unchanged from the proposal.

[145] *See* paragraph (n) of the final rule.

The Department's stated purpose in the proposal for including these entities as covered service providers was to address concerns about brokers and consultants receiving payments from parties they are recommending, which may be undisclosed to their covered plan clients. The Department stated that these arrangements have high potential for conflicts of interest that warrant disclosure. The Department further stated that to the extent that PBMs as described in paragraph (c)(1)(i) of the proposal, or their affiliates, also provide "brokerage services" or "consulting" to self-insured group health plans regarding pharmacy benefit management services, the Department had determined that special provisions under the rule would be needed. The Department said that these entities should be included in the definition of covered service providers under the rule to ensure that conflicts associated with the affiliation are disclosed and, further, to allow affiliated brokers and consultants to determine the extent of their obligations under the statutory exemption in ERISA section 408(b)(2)(B).

Commenters who addressed inclusion of brokers and consultants as covered service providers suggested that a meaningful approach to disclosures for these parties would involve disclosure of the total net cost of the entire benefit for the upcoming year. Commenters expressed that this would provide a simple data point that would allow responsible plan fiduciaries to easily compare competing service provider bids even across different business models that may, or may not, incorporate rebate guarantees. The Department considered these comments but determined not to add a total net cost type of disclosure to the final rule. These comments and the Department's responses are discussed in section E.3.11.1 of this preamble.

2. Overview of Covered Service Provider Obligations under this Final Rule

2.1. General

Under this final rule, covered service providers will be required to provide specified disclosures to responsible plan fiduciaries of covered plans and also permit the responsible plan fiduciaries to conduct an audit for accuracy of the disclosures. The disclosures will generally focus on the services provided, the compensation received, and the arrangements with other parties in the pharmaceutical supply chain.[146] The disclosures will be provided on an initial basis prior to the covered plan entering into the service contract or arrangement, or an extension or renewal, and then on a semiannual basis thereafter (or quarterly, at the plan's request).

With respect to brokers and consultants that are affiliated with providers of pharmacy benefit management services and recommend those services (covered service providers under paragraph (c)(1)(ii)), the required disclosures under the final rule will ensure that the responsible plan fiduciaries that may hire these brokers or consultants for their advice, recommendations, and referrals, are aware of the other sources of compensation that the brokers and consultants may be receiving, also so as to evaluate the potential impact on their services to the plan and the reasonableness of their compensation.

2.2. Breadth of Disclosure Obligation

Throughout the final rule, the disclosure obligation is phrased in terms of compensation "in connection with" the service contract or arrangement. This language largely mirrors the corresponding provisions in ERISA section 408(b)(2)(B) which require disclosure of direct

[146] The term "compensation" is defined in paragraph (m)(3) of the proposed regulation as anything of monetary value but does not include any item or service valued at $250 or less, in the aggregate, during the term of the contract or arrangement.

compensation and indirect compensation reasonably expected to be received "in connection with" the services provided.[147]

The Department intends that the language "in connection with" will be construed broadly and consistently with how the Department construes the language in its service provider disclosure regulation for pension plans (29 CFR 2550.408b-2(c)(1)). The Department stated in the preamble to that rule that: "[t]o the extent a covered service provider reasonably expects that compensation will be received, which is based in whole or in part on its service contract or arrangement with the covered plan, the compensation will be considered 'in connection with' such contract or arrangement."[148]

Some commenters on the Department's proposal said that a broad and comprehensive disclosure obligation was critical and suggested additional language that they thought would be needed to ensure the intended breadth, such as using "as a result of" instead of "in connection with." Some commenters suggested a string of words such as "in connection with, as a result of, or in any way connected with, services provided to the plan" to ensure broad disclosure.

The Department has considered these comments but has determined to retain the proposed language "in connection with" to describe the breadth of the disclosure obligation. The Department believes there is value to using language like that of ERISA section 408(b)(2)(B) as well as the service provider disclosure regulation for pension plans (29 CFR 2550.408b-2(c)(1)). The Department believes the interpretive position stated above, under which compensation will be required to be disclosed if it is (or will be) received, based in whole or in part on its service contract or arrangement with the covered plan, is appropriate to ensure comprehensive

[147] ERISA section 408(b)(2)(B)(iii)(III) and (IV)(aa).
[148] Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure, 77 FR 5632, 5637 (Feb. 3, 2012).

disclosure. The Department does not think that "as a result of" or other suggested wording is clearly broader.

Relatedly, in the preamble to the proposal, the Department requested comment on payments from drug manufacturers that may be based on a structure of incentives not solely related to the contract or arrangement with the self-insured group health plan.[149] The Department sought comment on whether the final rule should specify that such disclosures would be made on a pro-rata basis.

Several commenters said that it is common for providers of pharmacy benefit management services to negotiate rebates and other manufacturer payments on the basis of participants across multiple plan sponsors, so these commenters supported a pro-rata approach as a way for responsible plan fiduciaries to assess the compensation the provider is receiving in connection with a particular covered plan. One commenter said the Department should specify that pro-rata allocation based on an objective and consistently applied metric—such as enrollment share, utilization share, or claims volume—constitutes a compliant disclosure methodology. A few other commenters thought that a pro-rata disclosure might not relate to the actual rebate structure with respect to a particular covered plan and therefore may have limited value as a disclosure to responsible plan fiduciaries. In response, the Department has added text to the final rule in paragraph (e)(3) and paragraph (g)(2) clarifying that indirect compensation includes "compensation based on a structure of incentives not solely related to the contract or arrangement with the covered plan[.]" Thus the Department confirms that such compensation

[149] *See also* ERISA section 408(b)(2)(B)(iii)(IV)(aa) (requiring a description of all indirect compensation "including compensation from a vendor to a brokerage firm based on a structure of incentives not solely related to the contract with the covered plan").

must be disclosed, but has not further specified that it must be disclosed on a pro-rata basis versus another reasonable method.

2.3. Disclosure of Monetary Amounts

Paragraph (k) of the final rule[150] provides information about the manner of disclosure, including a requirement that disclosures must be "clear and concise, free of misrepresentation, and contain sufficient specificity to permit evaluation of the reasonableness of the service contract or arrangement." For required descriptions of compensation amounts, paragraph (k) provides that these descriptions must be expressed as a monetary amount and may be estimated to the extent that the actual amount is not reasonably ascertainable but shall contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, an affiliate, an agent or a subcontractor.

The Department intends that disclosures of a monetary amount (even if estimated) in this context, furnished with the specificity required under paragraph (k), will further the transparency goals of this rulemaking which are intended to facilitate a responsible plan fiduciary's assessment of reasonableness of compensation and potential for or existence of conflicts of interest in the provision of pharmacy benefit management services. This would also foster a fairer prescription drug market that lowers costs.

Several commenters strongly supported this aspect of the proposal with one commenter taking the position that the disclosure of a monetary amount is the most important provision in the rulemaking. Some commenters said that formulas and percentages can be used by providers of pharmacy benefit management services to obscure compensation received. One commenter

[150] 29 CFR section 2550.408b-22(k).

said that the Department should specifically provide that compensation estimates should be "grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience or other information reasonably available at the time of disclosure." Other commenters supported flexibility to use alternative methodologies and said this is how compensation arrangements are structured. A commenter said there would be no greater need to finalize this more prescriptive standard for PBM disclosures than in other contexts.

The Department agrees with the commenters who said that disclosure of a monetary amount is preferable to a formula or other methodology and has finalized that provision in paragraph (k) as proposed. The Department believes that the responsible plan fiduciaries of the large self-insured group health plans that are covered plans under the final rule will have sufficient resources to analyze the more detailed disclosures of monetary amounts. The Department believes that the commenter's suggested language (that the estimates should be "grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience or other information reasonably available at the time of disclosure") provides helpful guidance to covered service providers and has added it to paragraph (k) in the final rule.

2.4. Structure of the Final Rule

The specific elements of the disclosure and audit provisions are discussed in greater detail below. Paragraph (e) of the final rule establishes initial disclosure requirements. Paragraph (f) is reserved for initial disclosure requirements for fully insured group health plans. Paragraph (g) establishes semiannual disclosure obligations. Paragraph (h) is reserved for semiannual disclosure obligations for fully insured group health plans. Paragraph (i) establishes a

requirement for the covered service provider to provide certain information upon request of the responsible plan fiduciary of the covered plan. Paragraph (j) establishes the audit rights that must be provided to the covered plan under the service contract or arrangement. Paragraph (k) addresses the manner of disclosure and paragraph (l) addresses disclosure errors. Paragraph (m) provides definitions for certain terms used in the regulation.

Overall, the disclosures are intended to provide responsible plan fiduciaries of covered plans with a fuller picture of the terms under which the services will be provided, so they can assess both the reasonableness of the compensation in light of the services being (or to be) provided and the potential for or existence of conflicts of interest that may impact the quality of services provided. The Department believes that these disclosures will provide necessary information to responsible plan fiduciaries of these larger self-insured group health plans who are required to determine that the services contract or arrangement meets the standards for an exemption under ERISA section 408(b)(2).

3. Initial Disclosure Requirements – Paragraph (e)

Paragraph (e) of the final rule[151] sets forth the initial disclosure requirements. Covered service providers of pharmacy benefit management services are required under the final rule to produce these disclosures to the responsible plan fiduciary, in writing, no later than the date that is reasonably in advance of the date on which the contract or arrangement is entered, extended, or renewed. For extensions and renewals, 90 calendar days is deemed "reasonably in advance," absent an agreement between the covered service provider and the plan to a longer timeframe.

[151] 29 CFR section 2550.408b-22(e).

The final rule, in some instances, requires disclosure of amounts reasonably expected to be paid to the covered service provider or an affiliate, an agent, or a subcontractor. As noted above, paragraph (k) requires descriptions of compensation to be expressed as a monetary amount—for example, $1,000. The amounts can be provided as an estimate, to the extent that the actual amount is not reasonably ascertainable; but in any event, the disclosures must contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation to be received by the covered service provider, an affiliate, an agent, or a subcontractor. Estimates shall be grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience, or other information reasonably available at the time of disclosure.

3.1. Time Period for Initial Disclosure, Extensions and Renewals

The Department proposed that a reasonable period of time for responsible plan fiduciaries to receive the initial disclosure in the context of extensions and renewals of the contract or arrangement would be 30 days. This timeframe was intended to align with to other disclosure requirements in the Title XXVII of the Public Health Service (PHS) Act, Chapter 100 of the Internal Revenue Code, and Part 7 of ERISA that require 30-day timelines for disclosures, including the summary of benefits and coverage (SBC) requirements under PHS Act section 2715, as added by the Affordable Care Act and incorporated into ERISA section 715 and Code section 9815, for renewals, reissuances and reenrollments.[152] Aligning the timing requirements with other disclosures that group health plans and issuers already provide was intended to minimize compliance burdens by streamlining the collection of similar data and disclosure for

[152] *See* 29 CFR 2590.715-2715.

multiple purposes during the same cadence. The Department sought comment on the proposed timing requirements for the initial disclosure including whether additional specificity would be needed for the timing of the disclosure outside of the context of contract extensions and renewals.

While one commenter supported the proposed 30-day time frame, a few other commenters said that plan fiduciaries would need disclosure at an earlier date to inform initial contract negotiations. Commenters offered different suggested longer time frames, including 60 or 90 days in advance of the date of contract, extension or renewal; 60 days from request of the responsible plan fiduciary; or, for extensions and renewals, sufficiently in advance of the earliest contractual deadline by which the plan fiduciary must act to avoid automatic renewal. A few commenters suggested timeframes that would allow disclosures after execution of the contract, while others emphasized that the disclosures must be prospective to assist responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement.

The final rule provides that 90 days in advance of the extension or renewal is reasonable, to ensure that plan fiduciaries have sufficient time to review the disclosures as part of the contracting process. The Department agrees with the commenters who said that initial disclosures should be provided in advance of the contract to be useful to responsible plan fiduciaries. The Department selected a specific number of days (i.e., 90 days) prior to the extension or renewal because it has an advantage of simplicity over some of the other commenters' suggestions and would allow time for plan fiduciaries to solicit competing bids and evaluate information in the disclosures to prudently select a service provider. Under the final rule, parties remain free to negotiate for a longer period.

The Department did not propose any specific time frame for what would be deemed reasonable in the context of new contracts or arrangements. Although some commenters suggested some specific time frames, as noted above, the Department does not believe it is necessary to establish a default timeframe as that timing can be more easily managed by the responsible plan fiduciary who is considering entering into a contract or arrangement with a new covered service provider.

3.2. Description of Services

Under paragraph (e)(1), the initial disclosure must include a description of each pharmacy benefit management service, or of the advice, recommendations, or referrals regarding the provision of pharmacy benefit management services to be provided to the covered plan pursuant to the contract or arrangement. This provision mirrors the provision in ERISA section 408(b)(2)(B)(iii)(I).[153]

Full disclosure of the services is essential so that the responsible plan fiduciary can satisfy its duties under ERISA at the outset of the contract or arrangement and its ongoing duty to monitor. Full disclosure helps ensure that both parties have a common understanding of the services to be performed as part of the contract or arrangement. Absent full disclosure of services, questions may arise as to whether a responsible plan fiduciary has effectively approved otherwise discretionary behavior by the covered service provider.

Full disclosures are also important for covered service providers. Depending on the pharmacy benefit services being provided, if they are not performed in accordance with

[153] "A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures): (I) A description of the services to be provided to the covered plan pursuant to the contract or arrangement."

parameters established under the contract or arrangement with the covered plan, the provider may have assumed discretionary authority or control over the administration of the covered plan. Providers who exercise such discretionary authority or control fall within the definition of a fiduciary under ERISA section 3(21)(A) and are subject to ERISA's fiduciary duties in section 403 and 404, and the prohibited transaction provisions in ERISA section 406. Therefore, it is crucial that disclosures be complete and accurate and carefully written in a manner that conforms with the plain language requirements in paragraph (k) of the final rule. When disclosures meet these standards, both parties to the contract or arrangement are more likely to have a common understanding of their roles and limitations under the contract or arrangement and the law.

Relatively few commenters addressed the general requirement in the proposal to provide a description of services to be provided to the covered plan pursuant to the contract or arrangement. One commenter asked the Department to add specificity regarding the level of detail required, after further stakeholder input. Another commenter suggested that the description should have increased granularity to specify which entity (i.e., the covered service provider, an affiliate, an agent, or a subcontractor) will be providing the services and the compensation to be received by service. The Department believes that the requirement in the final rule is clear and straightforward, and it determined not to increase complexity by adding further requirements specifying the level of detail to be provided or requiring the disclosures to identify which entity will be providing the services. Therefore, the Department is finalizing the description of services disclosure as proposed.

Some commenters identified certain policies and practices that may be implemented and administered by providers of pharmacy benefit management services that the commenters believed should be disclosed under the final rule. Examples include utilization management; cost

sharing policies; and use of copay accumulators, copay maximizers or alternative funding programs. The Department views these as examples of services that are offered by providers of pharmacy benefit managers and agrees that initial disclosure under the final rule of the services to be provided would include disclosure of these types of services that will be implemented and administered by covered service providers with respect to a covered plan.

3.3. Direct Compensation

Under paragraph (e)(2), the initial disclosure must include a description of direct compensation the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with the pharmacy benefit management services under the contract or arrangement. Specifically, the final rule requires a description of the amount of all direct compensation, both in the aggregate and by service, that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive on a semiannual (or quarterly, upon the covered plan's request) basis in connection with pharmacy benefit management services under the contract or arrangement. An example is an administrative fee calculated on a per-participant, per-month basis. ERISA section 408(b)(2)(B)(iii)(III) likewise provides for a description of direct compensation reasonably expected to be received by the covered service provider, an affiliate, or a subcontractor.[154]

For purposes of paragraph (e)(2) of the final rule, the term "direct compensation" means compensation received directly from the covered plan or from the plan sponsor on behalf of the

[154] "A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures) . . . (III) A description of all direct compensation, either in the aggregate or by service, that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services described in subclause (I)."

covered plan regardless of whether such compensation is paid from plan assets. It is important to ensure that all direct compensation is disclosed, regardless of the source of the payment, to avoid frustrating the purposes of this final rule because service providers to covered plans sometimes are paid, in whole or in part, directly from the general assets of the employer sponsoring the covered plan as opposed to a plan asset trust. Consequently, responsible plan fiduciaries may find it challenging to assess the overall reasonableness of the covered service provider's compensation if this source of revenue is excluded from disclosure.

The Department revised paragraph (e)(2) of the final rule so that the reporting period is semiannual or, at the request of the covered plan, quarterly. This change was made in other paragraphs throughout the final rule to align with the reporting period in ERISA section 726.

3.3.1. Bundled Services Arrangements

In the proposal, the Department requested comments as to whether the requirements under the proposed rule for disclosure of direct compensation as defined in paragraph (e)(2) would ensure sufficient disclosure of information for bundled services, or whether the description of direct compensation under paragraph (e)(2) for a bundled services option should include additional information, such as the bundled discounted value along with a description of services provided in the bundle.

A number of commenters said the Department should require covered service providers to unbundle and disclose compensation attributable to each discrete service, rather than permitting a single aggregate figure. Some commenters provided examples of scenarios that they believed necessitated unbundling. For example, one commenter asserted that bundled service arrangements may be used to obscure the cost of the services and that unbundling is especially important to uncover potential preferential pricing to affiliates. Another commenter believed that

it is important for plan fiduciaries to understand the portion of a bundled service fee attributable to administrative fees to ensure that the plan is not paying twice for the same administrative service.

Other commenters were less sure that unbundling would be helpful or appropriate. One commenter stated that pharmacy benefit services are commonly offered on a full-service basis and requiring unbundling would be hypothetical and could mislead plan fiduciaries. A different commenter supported permitting covered service providers to disclose an aggregate figure with respect to direct compensation on the basis that the commenter believed this is the approach permitted by ERISA section 408(b)(2)(B).

Upon consideration of these comments, the Department determined to add a provision in paragraph (e)(2) of the final rule stating that bundled services or aggregated compensation arrangements must include a reasonable and good faith allocation of the compensation associated with each service in the bundle. This is consistent with the overarching standard in paragraph (e)(2) which provides that the disclosure must include a description of the amount of all direct compensation "both in the aggregate and by service" that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive. This standard is more specific than the statutory provision in ERISA section 408(b)(2)(B) but in the Department's view it is appropriate for the large self-insured group health plans that are covered plans under the final rule to receive more detailed information. The Department also believes it is appropriate for covered service providers to make a reasonable and good faith allocation of the compensation associated with each of the services, despite the fact that these services may commonly be offered on a full-service basis. The Department does not share the commenter's concern about the potential for misleading plan fiduciaries; rather, unbundling may benefit group health plans

by giving them the opportunity to consider a competitive bidding approach for each service, allowing them to design a plan that meets their unique needs to deliver costs savings and efficiencies. Allowing bundled services or aggregated compensation arrangements without specificity about the compensation associated with each service in the bundle, on the other hand, risks creating an unwarranted loophole for certain arrangements.

3.4. Indirect Compensation

The final rule includes a new paragraph (e)(3) entitled "Indirect Compensation" under which there are four subparagraphs listing disclosure obligations as follows: (i) payments from drug manufacturers, (ii) spread compensation, (iii) pharmacy recoupment, and (iv) price protection agreements. Subparagraphs (i)–(iv) correspond to proposed paragraphs (e)(3)–(6). These subparagraphs are discussed in the next sections of the preamble. Disclosure of indirect compensation is required under ERISA section 408(b)(2)(B)(iii)(IV), which provides that disclosures must include a description of indirect compensation reasonably expected to be received by the covered service provider, an affiliate, or a subcontractor in connection with the services disclosed under the statute, as well as a description of the arrangement pursuant to which the indirect compensation is paid, the services for which the indirect compensation will be received, and an identification of the payer of the indirect compensation.[155]

[155] "A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures): . . . '(IV)(aa) A description of all indirect compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services described in subclause (I)-(AA) including compensation from a vendor to a brokerage firm based on a structure of incentives not solely related to the contract with the covered plan; and (BB) not including compensation received by an employee from an employer on account of work performed by the employee. (bb) A description of the arrangement between the payer and the covered service provider, an affiliate, or a subcontractor, as applicable, pursuant to which such indirect compensation is paid. (cc) Identification of the services for which the indirect compensation will be received, if applicable. (dd) Identification of the payer of the indirect compensation.'"

The Department introduced the paragraph heading "Indirect Compensation" in the final rule for consistency with ERISA section 408(b)(2)(B) – which distinguishes direct versus indirect compensation – and also in response to comments that asked for clarification of the distinction between the two.

Paragraph (e)(2) of the final rule includes a definition of "direct compensation" which is compensation received directly from a covered plan or from the plan sponsor on behalf of the plan (regardless of whether such compensation is paid from plan assets). The disclosures identified in paragraph (e)(3) of the final rule would be considered indirect compensation. Paragraph (e)(3) also makes clear that indirect compensation includes amounts based on a structure of incentives not solely related to the contract or arrangement with the covered plan.[156] As discussed above, this language is intended to ensure disclosure of rebates and other payments that may be based on a number of participants across multiple plan sponsors.

3.5. Payments from Drug Manufacturers

Under subparagraph (e)(3)(i), the initial disclosure must include a description of the monetary amount of any rebate, fee, alternative discount or other remuneration reasonably expected to be received from any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates) by the covered service provider, an affiliate, an agent, or a subcontractor, in the aggregate and for each drug on the formulary, in connection with the contract or arrangement with the covered plan. The disclosure

[156] *See* ERISA section 408(b)(2)(b)(iii) ("A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures): . . . (IV)(aa) A description of all indirect compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with the services described in subclause (I)-(AA) including compensation from a vendor to a brokerage firm based on a structure of incentives not solely related to the contract with the covered plan . . .").

must cover each semiannual period (or quarter) under the contract or arrangement and must disclose both amounts reasonably expected for claims incurred during the period and amounts reasonably expected that are related to utilization of such drug spending. For example, this disclosure will include any amounts the covered service provider reasonably expects to receive based on achieving utilization thresholds like volume-based rebates. The disclosure must specify both the amount that is reasonably expected to be passed on to the covered plan and, if applicable, the plan sponsor, and the amount that will be retained by the covered service provider, affiliate(s), agent(s), or subcontractor(s).

Under subparagraph (e)(3)(iv), the initial disclosure also must also include a description of any inflation protection or price protection agreements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), regarding prescription drugs dispensed under the service contract or arrangement with the covered plan. The disclosure must specify the amount reasonably expected to be retained by the covered service provider, an affiliate, an agent, or a subcontractor in connection with each prescription drug product and under each such contract or arrangement and the price protection amount that will be passed on to the covered plan and, if applicable, plan sponsor, for each semiannual period (or quarter). The disclosure must cover amounts reasonably expected to be received for claims reasonably expected to be incurred during the period and amounts reasonably expected to be received related to utilization of such drug or spending on such drug. The Department separated the disclosure required under subparagraph (e)(3)(iv) from the disclosure required under subparagraph (e)(3)(i) because of the contingent nature of inflation and price protection.

The disclosure required by these provisions would be intended to cover any and all payments reasonably expected to be received from drug manufacturers, distributors, wholesalers, or rebate aggregators (or other purchasing entities designed to aggregate rebates), by the covered service provider, an affiliate, an agent, or a subcontractor in connection with their services to the covered plan, regardless of how they are characterized. The term "agent" is intended to capture rebate aggregators and GPOs, to the extent they may take the position that they do not fall within the definition of affiliate or subcontractor, so that reasonably expected payments to those entities in connection with the services contract or arrangement would be part of the initial disclosures.

In the proposal, the disclosure obligation was phrased in terms of "payments" from drug manufacturers and aggregators. The Department sought comments on whether the provisions in proposed paragraph (e)(3) and proposed paragraph (e)(6) adequately described the type of payments that may be received in this respect. The Department also sought comment on whether the broad term "payments" would be sufficient to define the disclosure obligation or whether more specificity would be needed to ensure full disclosure.

Many commenters responded to the proposed requirement for disclosure of payments from drug manufacturers and aggregators to a covered service provider. Commenters expressed both support and concern as to the forms of compensation to be disclosed as a manufacturer payment, the granularity of information reported, and the interaction of the disclosures with other requirements introduced by the CAA, 2026.

Several commenters said the Department should adopt the proposed disclosure of manufacturer payments in both the aggregate and for each drug on the formulary, with some commenters suggesting that additional granularity in disclosures would be necessary. These commenters generally encouraged the Department to broadly construe the types of compensation

to be disclosed under this provision to ensure the disclosure would cover all manner of compensation paid by drug manufacturers. While many commenters supported use of broad and general language to describe the disclosure obligation, some also suggested either exemplary or enumerated breakouts delineating information into categories of compensation such as the common types of payments (e.g., administrative fees, data fees, and access fees), discounts, and other compensation structures, to avoid the possibility that the disclosure requirements could be evaded through reclassification of manufacturer payments as various types of fees or alternative forms of compensation not explicitly in connection with the service contract or arrangement. A few commenters emphasized the need to ensure that disclosure obligation included amounts retained by GPOs, which the Department confirmed in an earlier preamble paragraph describing the disclosure obligation.

Several commenters suggested that additional disclosure elements be added. A few commenters suggested that disclosure include information about the manufacturer's net price, which would assist fiduciaries in evaluating the components of drug costs including remuneration to providers of pharmacy benefit management services. One commenter recommended that the final rule should require disclosure of information related to the specific manufacturer rebate contract the covered service provider would apply to claims for drugs submitted to a plan and the amount of rebates, on a per-National Drug Code basis, applicable to such rebate contract. Another commenter said that the final rule should require disclosure of manufacturer payments to break out the amounts retained and passed through at the level of each entity in the supply chain; require disclosure of the ownership, governance, and compensation structure of all entities involved in negotiations for manufacturer rebates or price concessions;

and break out manufacturer payments made to the covered service provider and its affiliated entities separately.

The Department has finalized the provisions regarding disclosure of payments from drug manufacturers in subparagraphs (e)(3)(i) and (e)(3)(iv) with modifications. In the final rule, the requirement to disclose manufacturer payments in subparagraph (e)(3)(i) is phrased in terms of rebates, fees, alternative discounts or other remuneration. Further, both subparagraph (e)(3)(i) and (e)(3)(iv) refer to payments from drug manufacturers, distributors, wholesalers, or rebate aggregators (or other purchasing entities designed to aggregate rebates). These changes provide additional specificity as to the type of payments and the types of payors that would result in the required disclosures. This terminology also aligns with terminology in ERISA sections 408(b)(2)(C) and 726.[157] Additionally, the reporting period is a semiannual period or, at the request of the plan, a quarter, which aligns with the reporting period in ERISA section 726(b).[158]

The Department did not identify any additional specific payment types in the regulatory text as requested by some commenters (e.g., administrative fees, data fees, and access fees) based on the view that "other remuneration" is a broad term that would encompass all such payments and that it was desirable to use the same terms as ERISA sections 408(b)(2)(C) and

[157] ERISA section 726(b)(2)(A)(i) provides for reports regarding drugs for which a claim was filed for the applicable period including: "(X) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration; (XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities-(aa) for claims incurred during the reporting period; and (bb) that is related to utilization of such drug or spending on such drug." ERISA section 726(e)(1) provides a definition of applicable entity as follows: "The term 'applicable entity' means-(A) an applicable group purchasing organization, drug 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); or (C) such other entity as the Secretary may specify through rulemaking."

[158] ERISA section 726(b)(1) provides for disclosures "not less frequently than every 6 months . . . or, at the request of a group health plan, not less frequently than quarterly . . ."

726. The Department also did not add a requirement to disclose the specific rebate contract associated with the payments as one commenter suggested. Such contracts would be available as part of an audit, which the Department believes strikes the correct balance in terms of the burden of the disclosure requirements.[159]

Some commenters said that an initial disclosure of manufacturer payments reasonably expected on a per-drug basis, as had been proposed, would be speculative and thus of limited use to responsible plan fiduciaries assessing the reasonableness of compensation for a contract or arrangement under ERISA section 408(b)(2). The commenters also said this approach was burdensome and generally misaligned with the comparable provisions regarding payments from drug manufacturers introduced by the CAA, 2026, which were only on a retrospective basis, and risked exposing sensitive information to be used for anti-competitive purposes. Some commenters said the Department should permit the disclosure in the aggregate, or by therapeutic category or formulary tier, rather than at the per-drug level using the requirements set forth in that section. A few commenters said that the new subparagraph (C) of ERISA section 408(b)(2), as added by the CAA, 2026 amendments, will require full rebate pass-through to group health plans and thereby will address concerns about a potential misalignment of incentives between covered service providers and group health plans related to manufacturer payments. Commenters said this obviated the necessity for the granular disclosure of such payments under the Department's rule.

The Department did not eliminate the initial disclosure of manufacturer payments altogether or revise the rule to permit an aggregate initial disclosure based on therapeutic

[159] The Department believes that the disclosure of drug pricing methodology in paragraph (e)(7) is responsive the commenters who suggested disclosing manufacturer net price information.

category or formulary tier, as some commenters suggested. The fact that ERISA section 726 is limited to a retrospective disclosure does not indicate that the Department's final rule should have a similar scope. Rather, the Department believes that the prospective disclosures are consistent with ERISA section 408(b)(2)(B) because they serve a distinct purpose in assisting responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of contracting and in monitoring these contracts or arrangements thereafter. This disclosure of manufacturer payments for each drug on the formulary is important to assess the compensation to providers of pharmacy benefit management services and their affiliates, agents and subcontractors for each such drug.[160] An aggregate disclosure, on the other hand, might permit a covered service provider to obscure the covered service provider's financial incentives to select a particular prescription drug for the formulary.

It is important to note that in the final rule, these detailed disclosures are required only for covered plans, which are generally the larger self-insured group health plans (i.e., the plans of specified large employers and the specified large plans) but also do not include group health plans established by a plan sponsor that is, or that is affiliated with, a drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates). As discussed elsewhere, the Department has mirrored the approach Congress took in the CAA, 2026 amendments regarding which responsible plan fiduciaries should receive the detailed disclosures. The more limited scope of the final rule should mitigate some concerns

[160] In requiring disclosure of all direct compensation and all direct compensation that a covered service provider, an affiliate, and a subcontractor "reasonably expect[]" to receive, Congress in ERISA section 408(b)(2)(B) clearly contemplated a prospective disclosure. ERISA section 408(b)(2)(B)(iii)(III) and (IV).

regarding the administrative burden to covered service providers of providing information on manufacturer payments and to responsible plan fiduciaries of reviewing such information as well as concerns about anti-competitive behavior.

To assist covered service providers that will need to make the detailed initial disclosures under subparagraphs (e)(3)(i) and (iv), the Department also added a new sentence to paragraph (k)(2) providing guidance on the methodology of developing the estimate, as suggested by a commenter. That sentence provides that "estimates shall be grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience, or other information reasonably available at the time of disclosure." The final rule also includes confidentiality provisions that are designed to address concerns about redisclosure of rebate information and use of such information for purposes unrelated to the covered plan's contract or arrangement, as discussed in section E.8 and E.9 of this preamble.

A few commenters directly addressed disclosure of price-protection agreements, with one commenter in favor of the disclosure as a measure of informing fiduciaries about how these agreements may influence behavior of providers of pharmacy benefit management services regarding higher list prices even when net price is offset by rebates. A few other commenters said the CAA, 2026 amendments did not require disclosure of these agreements, indicating Congress' view that disclosure would not be necessary for responsible plan fiduciaries in their review and evaluation of pharmacy benefit manager services arrangements. The Department believes that disclosure of these agreements is likely to provide insight regarding drug pricing-related incentives to responsible plan fiduciaries of the larger self-insured group health plans and is necessary to assess the reasonableness of compensation under the contract or arrangement required under the statutory exemption contained in ERISA section 408(b)(2). Therefore, the

Department has retained this requirement in the final rule. The Department is also of the view that the disclosure of these agreements will help responsible plan fiduciaries analyze the full impact on participant costs and promote the use of lower cost alternatives.

Finally, the Department acknowledges that when the rebate pass-through provision in ERISA section 408(b)(2)(C) becomes effective, there likely will be increased transparency into rebate arrangements and other payments from drug manufacturers, and possibly reduced reliance on them. The Department does not see that potential development as a reason to eliminate the disclosure altogether. The Department believes it is still important to require transparency regarding how the payments are being handled for responsible plan fiduciaries to satisfy their fiduciary duties and the reasonableness assessment required under the statutory exemption. In this regard, the Department notes that ERISA section 408(b)(2)(C) will require the rebates, fees, alternative discounts, and other remuneration not only to be passed through to the covered plans but also to be fully disclosed to such plans.[161] The Department anticipates that requiring those disclosures in this regulation will make the transition to that disclosure process smoother, once those provisions (under section 408(b)(2)(C)) become fully effective, and envisions that it will leverage such disclosures in any future rulemaking or guidance implementing section 408(b)(2)(C) to minimize duplicative regulatory requirements.

3.6. Spread Compensation

Subparagraph (e)(3)(ii) of the final rule includes several disclosure requirements related to spread compensation. Under this subparagraph, the initial disclosure must include a list of drugs on the formulary, and for each drug: the contracted compensation to be paid by the

[161] ERISA section 408(b)(2)(C)(ii)(1)(bb).

covered plan for the drug to the covered service provider or an affiliate, an agent, or a subcontractor; the contracted compensation to be paid to the pharmacy by the covered service provider, or an affiliate, an agent, or a subcontractor, on behalf of the group health plan; and the difference between the two. This difference is defined in the final rule as spread compensation. Subparagraph (e)(3)(ii) further requires a description of the amount of spread compensation reasonably expected to be received by the covered service provider, an affiliate, an agent and a subcontractor in connection with the service contract or arrangement, for claims filed during each semiannual period (or quarter), both in the aggregate and for each drug on the formulary, and for each pharmacy channel (i.e., retail pharmacy, mail order pharmacy, and specialty pharmacy) available under the contract or arrangement. The subparagraph additionally requires the disclosure to include a description of arrangements, incentives, contractual provisions, and policies that will be implemented under the service contract or arrangement that direct patients to pharmacies that are affiliates of the covered service provider.

The Department sought comments on the requirements under the proposed rule for disclosure of spread compensation, including whether the provision required disclosure of information sufficient to assess reasonableness and what challenges would arise from a covered service provider providing, or a responsible plan fiduciary reviewing, this level of disclosure. The Department also sought comments on whether arrangements with retail, mail order, and specialty pharmacies are sufficiently similar to one another so that dividing disclosures into these three channels is efficient, and whether greater transparency would incentivize the use of a pass-through pricing or a flat-fee compensation model.

Many commenters said the spread pricing disclosure provisions should be adopted in the final rule as a means of improving transparency into this historically opaque PBM revenue

stream. Commenters expressed the view that the availability of such information would allow plan fiduciaries to better assess compensation arrangements consistent with their obligations under ERISA. A few commenters believed that transparency into spread compensation would incentivize the adoption of pass-through pricing and flat fee models with one commenter suggesting the Department should consider exempting or requiring reduced disclosure for providers using those models. One commenter observed that incorporating drug-level spread disclosure in the final rule could be consistent with and complementary to the requirement in ERISA section 726, enabling fiduciaries to perform both prospective review and retrospective verification of such amounts. Another commenter observed that spread compensation may not be addressed by the rebate-pass through provision in ERISA section 408(b)(2)(C), so disclosure will be important to understand this revenue stream that will continue to exist after the rebate-pass through provision takes effect.

Several commenters agreed with the Department's designation of three pharmacy channels – retail, mail order and specialty – in the proposal for spread pricing disclosure. However, some commenters believed it would also be important to break out PBM-affiliated versus non-affiliated pharmacies within these channels. Commenters said this would allow responsible plan fiduciaries to identify incentives in these arrangements and assess their impact on plan costs. Several commenters said the Department should require disclosure of arrangements, incentives, and contractual provisions that may direct patients to affiliated pharmacies or higher-spread channels. Another commenter said that the Department should also break out disclosure of spread by drug category (generic, brand, and specialty).

Other commenters said that the Department's proposal to require disclosure with respect to spread compensation reasonably expected for all formulary drugs across each pharmacy

channel would impose extreme administrative burden upon covered service providers. Commenters said responsible plan fiduciaries would be overwhelmed with the expanse of data, could not meaningfully process such information to evaluate the overall reasonableness of the arrangement, and could face increased litigation risk based on having received such detailed information. Several commenters said they would support disclosure of aggregate amounts of spread compensation by pharmacy channel. Commenters also suggested that the Department permit disclosure of spread compensation as a percentage of drug spend rather than a dollar amount.

Commenters also made recommendations that they said would better align the final rule with the CAA, 2026 amendments. A few said the Department should not require any initial disclosure of spread pricing on the basis that initial disclosures are not part of the CAA, 2026 statutory framework. One commenter said if the Department proceeded with this element of the initial disclosure, it should clarify methodologies for initial estimations and provide specific guidance to clarify "reasonably expected."

In the final rule, the Department has revised the disclosure of spread compensation to align with the structure and phrasing of the similar requirement in ERISA section 726(b)(2)(A)(i)(I)–(III).[162] Thus subparagraph (e)(3)(ii)(A) requires a list of drugs on the formulary; the contracted compensation to be paid by the covered plan to the covered service

[162] Requiring reports to group health plans offered by a specified large employer or that are specified large plans including "(i) a list of drugs for which a claim was filed and, with respect to each such drug on such list-(I) the contracted compensation paid by the group health plan or health insurance issuer for each covered drug (identified by the National Drug Code) to the entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer; (II) the contracted compensation paid to the pharmacy, by any entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer, for each covered drug (identified by the National Drug Code); (III) for each such claim, the difference between the amount paid under subclause (I) and the amount paid under subclause (II)[.]"

provider, an affiliate, an agent, or a subcontractor for each drug (identified by National Drug Code); the contracted compensation to be paid to the pharmacy by the covered service provider, an affiliate, an agent, or a subcontractor for each such drug (identified by National Drug Code); and the difference between the two. To align with ERISA section 726, the Department also revised the reporting period so that it is a semiannual period (or at the request of the plan, a quarter).

Although the final rule requires disclosure of spread by pharmacy channel (retail, mail order, and specialty), the Department did not differentiate PBM-affiliated pharmacies versus non-affiliated pharmacies for purposes of the spread compensation disclosure provisions in the final rule because the Department was not convinced that this additional disclosure regarding spread compensation would be the easiest way for responsible plan fiduciaries to evaluate the potential for steering or pricing variations involving affiliated pharmacies. Rather, the Department believes that a more direct, narrative disclosure as suggested by some commenters may assist responsible plan fiduciaries; so for that reason, subparagraph (e)(3)(ii)(C) was added to the final rule requiring disclosure of arrangements, incentives, contractual provisions and policies that will be implemented under the service contract or arrangement that direct patients to pharmacies that are affiliates of the covered service provider. Additionally, as discussed below in section E.3.9 of this preamble, compensation reasonably expected to be received by pharmacies that are affiliated with a covered service provider when a covered plan's participants fill prescriptions at that pharmacy would be disclosed to the covered plan's responsible plan fiduciary as part of the category of "other" compensation. The Department did not require the disclosure to be categorized by drug category (generic, brand, and specialty) because that did not appear to be necessary in light of the disclosure at the individual drug level.

To address anticipated burdens in preparing the disclosures, some commenters requested limiting the disclosure obligation in the final rule to aggregate amounts of spread compensation by pharmacy channel. Other commenters suggested allowing disclosure of spread compensation as a percentage of drug spend rather than a dollar amount. The Department did not make these revisions because the Department believes that concerns about administrative burden and utility to responsible plan fiduciaries are alleviated by the more limited scope of the final rule to the larger self-insured group health plans.

The Department also did not eliminate the initial disclosure regarding spread pricing altogether. Even though ERISA section 726 does not include initial disclosures, the Department determined that an initial disclosure of this important compensation stream was consistent with ERISA section 408(b)(2)(B) and needed for responsible plan fiduciaries of covered plans evaluating the services contract or arrangement at the time of contracting. The Department included guidance on methodology in paragraph (k)(2) of the final rule which provides that "estimates shall be grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience or other information reasonably available at the time of disclosure."

The Department did not expressly exempt covered service providers using pass-through pricing and flat fee models as suggested by one commenter, but notes that covered service providers who do not reasonably expect to receive spread compensation would have no disclosure under this subparagraph of the final rule. PBM compensation models can change over time and be referred to by different names. By not providing a categorical exemption for certain models, the Department ensures that covered service providers provide disclosure under paragraph (e)(3)(ii) if they reasonably expect to receive such compensation.

3.7. Pharmacy Recoupment

Under subparagraph (e)(3)(iii) of the final rule, the initial disclosure must include a description of amounts of copay claw-back compensation and other retroactive adjustment to pharmacy reimbursement reasonably expected to be recouped from a pharmacy by a covered service provider, an affiliate, an agent, or a subcontractor in connection with prescription drugs dispensed under the contract or arrangement, for each semiannual period (or quarter). The final rule defines a copay claw-back as the dollar amount of the difference between a copayment or coinsurance amount paid to the pharmacy by a plan participant or beneficiary and the reimbursement to the pharmacy. Under subparagraphs (e)(3)(iii) and (k)(2), the disclosure must be expressed as a monetary amount per semiannual period (or quarter) and must specify the anticipated total number of transactions.

Where a covered service provider, an affiliate, an agent, or a subcontractor claws back any portion of a payment to a pharmacy made at point-of-sale and does not pass along the full amount recouped to the covered plan, information as to the value of any such amount recouped may not be otherwise available to a responsible plan fiduciary assessing the reasonableness of compensation under the contract or arrangement. For example, where the pharmacy's reimbursement price for dispensing a drug is less than the copayment made to the dispensing pharmacy by a participant or beneficiary and the covered plan's cost share for the drug is zero dollars, the responsible plan fiduciary may be unaware of the difference between the cost of the drug and the copayment that results in compensation to the covered service provider, an affiliate, an agent, or a subcontractor recouping such difference. The Department believes that additional disclosure of the total number of transactions reasonably expected to occur in the reporting period would provide the responsible plan fiduciary key information needed to assess the

pervasiveness of this practice and whether adjustments to the plan's cost sharing structure may be appropriate.

The Department sought comments on this disclosure element in the proposed rule, including whether the proposed provision's scope of required disclosure of information for copay claw-back payments would be sufficient to assess reasonableness and whether other types of recouped payments should be included. If commenters believed the final rule should require disclosure of information for recouped payments other than copay claw-backs, the Department asked the commenters to describe the type(s) of recouped payments recommended to be included and how disclosure of this information is necessary to assess the reasonableness of the compensation under the contract or arrangement.

A number of commenters said the initial disclosure of copay claw-backs would be an important compensation element for responsible plan fiduciaries to be aware of in connection with their assessment of a contract or arrangement. Several commenters asked the Department to take additional steps in the final rule related to recoupment of compensation from pharmacies – either to require disclosure of all types of retroactive payments imposed by pharmacy benefit management service providers on pharmacies or to outright prohibit such retroactive payments under ERISA. Commenters also asked the Department to expand the disclosure to cover additional types of recoupment mechanisms that generate compensation. Several commenters mentioned effective rate reconciliation, which they described as a practice whereby PBMs periodically adjust pharmacy reimbursement to match an "aggregate effective rate," clawing back amounts previously paid. Commenters asking the Department to prohibit these payments pointed to the negative impact on plan participants and pharmacies. One commenter said the disclosure of copay claw-backs should be broken out by affiliated and non-affiliated pharmacies.

Other commenters said the proposed disclosure of copay claw-backs should not be adopted in the final rule because this type of compensation was not included in the disclosures outlined by Congress in the CAA, 2026 amendments. One such commenter said this was not a common feature of group health plan contracts or arrangements, so the Department should allow covered service providers to provide a simple negative response to that required disclosure category.

The Department believes that compensation recouped from pharmacies should be disclosed to responsible plan fiduciaries of covered plans for purposes of assessing the reasonableness of a contract or arrangement to provide pharmacy benefit management services. The Department was persuaded by commenters that, to ensure comprehensive disclosure, the requirement should be expanded to include any other retroactive adjustment to pharmacy reimbursement reasonably expected to be recouped from a pharmacy in connection with prescription drugs dispensed under the service contract or arrangement. In response to the commenter who believed this to be uncommon, the Department confirms that a covered service provider who does not reasonably expect to receive this type of compensation would not make a disclosure under this subparagraph of the final rule.

The Department did not revise the requirement in the final rule to require a breakdown of pharmacy recoupments from affiliated versus nonaffiliated pharmacies. The Department has determined to address the issues associated with PBM-affiliated pharmacies in subparagraph (e)(3)(ii)(C) which requires a description of arrangements, incentives, contractual provisions and policies that will be implemented under the service contract or arrangement that direct patients to pharmacies that are affiliates of the covered service provider.

The Department did not eliminate this disclosure element of the rule even though the CAA, 2026 amendments do not include specific disclosures regarding recoupment of compensation from pharmacies. The Department believes that such disclosures are appropriate under ERISA section 408(b)(2) because they will assist responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of contracting and in monitoring these contracts or arrangements thereafter. Moreover, comprehensive disclosure is consistent with ERISA section 408(b)(2)(B), which requires disclosure of "all direct compensation" and "all indirect compensation" reasonably expected to be received by covered service providers, affiliates, and subcontractors.

3.8. Compensation for Termination of Contract or Arrangement

Under paragraph (e)(4) of the final rule, the initial disclosure must include a description of any compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with termination of the contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination. The provision on termination of compensation mirrors ERISA section 408(b)(2)(B)(iii)(VI).[163]

In the Department's view, a determination of reasonableness necessitates that a responsible plan fiduciary be aware upfront of any termination costs or potential costs to a covered plan. Without this information, a responsible plan fiduciary cannot sufficiently evaluate the economic consequences of such termination to the covered plan. Paragraph (e)(4) will, for

[163] "A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary addressing time, manner, and content of such disclosures) . . . . (VI) A description of any compensation that the covered service provider, an affiliate, or a subcontractor reasonably expects to receive in connection with termination of the contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination."

example, enable the responsible plan fiduciary to understand and ensure proper treatment of any rebates owed at the time of the termination. While covered service providers may recoup reasonable amounts for actual losses upon early termination of the contract or arrangement, no contract or arrangement is reasonable if it does not permit termination by the covered plan without penalty on reasonably short notice under the circumstances to prevent the covered plan from becoming locked into a contract or arrangement that has become disadvantageous.[164]

Commenters on the Department's proposal generally did not address termination fees in any detail but several expressed the view that the comprehensive approach to disclosure in the proposal – including the termination fees – would assist responsible plan fiduciaries in fulfilling their statutory obligations. One commenter said visibility into costs of termination are needed for fiduciaries to understand the financial implications of ending the arrangement. Another commenter asked the Department to expand the disclosure to specify certain elements would be covered such as different impacts for different types of terminations, whether the compensation is direct or indirect, and the details of what entity is paying the compensation, what entity is receiving it, and how the compensation relates to the covered plan's arrangement. A few commenters on the other hand said the Department should not include this disclosure in the final rule because it is not a compensation element specified for disclosure in ERISA section 726, with one commenter expressing concern that this provision would invite regulatory scrutiny of lawful contractual provisions negotiated at arm's-length.

The Department agrees with commenters who said that disclosure of compensation reasonably expected in connection with termination of the contract or arrangement is a necessary

[164] 29 CFR 2550.408b-2(c)(3).

component of comprehensive disclosure for responsible plan fiduciaries of covered plans determining the reasonableness of the contract or arrangement. Further, this disclosure element is consistent with ERISA section 408(b)(2)(B), so the Department believes that including it in the final rule will not materially increase the likelihood regulatory scrutiny of these contractual provisions. As stated elsewhere, the Department believes that ERISA section 408(b)(2) assists responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of contracting and in monitoring these contracts or arrangements thereafter. On the other hand, the Department is not persuaded that there is value commensurate to the burden associated with adding additional specific elements to the disclosure of termination compensation, such as whether the compensation is direct or indirect, and the details of what entity is paying the compensation, what entity is receiving it, and how the compensation relates to the covered plan's arrangement, as suggested by one commenter. For these reasons, the Department has adopted this disclosure in the final rule as proposed.

3.9. Other Compensation

Paragraph (e)(5) provides a catch-all provision for any compensation not disclosed under paragraphs (e)(1)–(4). The disclosure must include a description of any such compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with the contract or arrangement for the semiannual period (or quarter), regardless of whether such compensation is paid regularly or irregularly or from plan assets or is subject to any contingency or other condition. The disclosure must also include an identification of the payer of such compensation, an identification of the services for which such compensation will be received, and a description of the arrangement between the payer and the covered service

provider, an affiliate, an agent, or a subcontractor, as applicable, pursuant to which such compensation is paid.

Several commenters who supported comprehensive disclosure under the Department's rule expressed uncertainty that this aspect of the proposal would achieve the desired result. In particular, some thought the Department intended an aggregate disclosure that would not require specification of the particular amount of compensation and the source. A few other commenters did not think "other" was an appropriate category of compensation to be included in the final rule based on the fact that ERISA section 726 does not include that category of compensation, and the commenters were concerned that the category could be overbroad and interpreted to require disclosure of compensation from services other than pharmacy benefit management services.

In response to comments, the Department revised the wording of the "other compensation" category to make clear it is not an aggregate disclosure; the requirement is now to disclose "any" compensation not already disclosed under paragraphs (e)(1)–(4), along with the payer of the compensation, the services for which it will be received, and a description of the arrangement pursuant to which it will be received. This specific disclosure is what the Department had intended. The Department also added the language "regardless of whether such compensation is paid regularly or irregularly or from plan assets or is subject to any contingency or other condition" to underscore the breadth of the disclosure obligation.

The Department did not eliminate the category of "other" compensation altogether in response to comments regarding alignment with the CAA, 2026 amendments. The Department believes that ERISA section 408(b)(2) serves a distinct purpose in assisting responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of

contracting and in monitoring these contracts or arrangements thereafter. Further, comprehensive disclosure is consistent with ERISA section 408(b)(2)(B), which requires disclosure of "all direct compensation" and "all indirect compensation" reasonably expected to be received by covered service providers, affiliates, and subcontractors. Under ERISA section 408(b)(2)(B) as amended by the CAA 2026, the Department has authority to address time, manner, and content of the disclosures.

In connection with this category of "other" compensation, the Department sought comments on whether it should specify any other type of compensation that may be received by covered service providers instead of having those items disclosed in the catch all "other" category. The Department specifically asked about disclosure requirements related to compensation received by entities providing pharmacy benefit management services in connection with copay maximizer, copay accumulator, or alternative funding programs. Many commenters said that the final rule should include a specific disclosure regarding these programs, as the commenters said copay maximizer, copay accumulator, and alternative funding programs generate an increasing amount of compensation to providers of pharmacy benefit management services, including in the form of per-claim or per-enrollee fees; administration or technology fees; spreads or retained margins; and gain-share or savings-based payments for the design, implementation, or administration of these programs. Commenters suggested that use of such programs should be disclosed to permit the responsible plan fiduciaries to make decisions regarding their use. A few other commenters suggested the programs should be prohibited.

Commenters also suggested that the final rule should identify other examples of compensation streams that should be disclosed, including compensation from float (i.e., interest on funds held or transferred on behalf of the plan); compensation from PBM-affiliated

pharmacies; compensation received from pharmacy benefit manager-affiliated prescription drugs that are dispensed to the covered plan under the service contract or arrangement; compensation from rebate claw-backs (for seeking a lower cost or clinically superior drug); compensation associated with prescription drugs covered by the plan but reimbursed under the medical benefit, such as rebates, administrative fees and other payments tied to physician-administered or specialty drugs; and others.

The Department carefully considered commenters' suggestions regarding additional disclosure categories but determined that a robust list of additional disclosure items would overly complicate the regulatory text. The Department determined that the broad category of "other" compensation would be preferable to avoid creating any definitional loopholes or other unforeseen consequences associated with adding additional disclosure categories. However, based on the list of additional compensation streams commenters identified, the Department is persuaded that the other compensation category is critical to ensuring full disclosure and therefore did not eliminate it as requested by some commenters.

3.10. Formulary Placement Incentives

Paragraph (e)(6) requires the initial disclosures to include specified information regarding formulary placement incentives. The purpose of paragraph (e)(6) is to assist responsible plan fiduciaries in evaluating the covered service provider's formulary selections and how the selections might be influenced by incentives, arrangements, and payments. While paragraph (e)(3)(i) requires covered service providers to provide a description of the *amounts of payments* reasonably expected to be paid by drug manufacturers or rebate aggregators in connection with the contract or arrangement, paragraph (e)(6) requires a *description of the arrangements* so that the responsible plan fiduciary can gain additional insight as to their impact. The disclosures are

set forth in three subparagraphs, each of which address different aspects of formulary design and maintenance.

3.10.1. Subparagraph (e)(6)(i)

Under subparagraph (e)(6)(i), the initial disclosure must include a description of any formulary placement incentives and arrangements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer in connection with the contract or arrangement with the covered plan. The disclosure must also include an explanation of how the incentives and arrangements affect services to and are aligned with the interests of, the covered plan and/or its participants and beneficiaries, such as by controlling prescription drug costs, providing clinically superior drugs, or both.

Formulary incentives or arrangements widely reported on in industry literature include concessions made by a drug manufacturer for including its drugs in a formulary, for tiering of drugs within a formulary, for excluding or tiering of other manufacturers' drugs within a formulary, and for treating a drug differently than therapeutically equivalent drugs (including biosimilar biological products) under a utilization management protocol. In addition, adding to a formulary a drug that is manufactured or co-manufactured by the PBM or an affiliate, in the view of the Department, would be a formulary placement incentive that triggers the disclosure required under subparagraph (e)(6)(i).

Under subparagraph (e)(6)(i), the covered service provider is required to provide an explanation of how the formulary placement incentives and arrangements affect services to and align with the interests of the covered plan and/or its participants and beneficiaries. The concept of alignment is inherently dependent on the specific facts and circumstances of the incentive or arrangement in question. However, examples of incentives or arrangements that are aligned with

the interests of the covered plan and/or its participants and beneficiaries are those that aim to control prescription drug costs, provide clinically superior drugs, or both. In this regard, the Department notes that any given formulary placement incentive or arrangement can be aligned with the interests of the covered plan and/or its participants and beneficiaries based on a combination of the clinical value and cost-effectiveness of the associated drug, even though the drug is not necessarily clinically superior to all alternatives.

The Department anticipates that, in connection with developing these disclosures, covered service providers will carefully review the incentives and arrangements to determine how the incentives and arrangements would impact services to the covered plan. Likewise, covered service providers are required to determine that they could accurately disclose how the incentives and arrangements are aligned with the interests of the covered plan and/or its participants and beneficiaries, whether by contributing to controlling prescription drug costs, by providing clinically superior drugs, or both.

In the proposal, the Department requested comments on the proposed requirement to explain how formulary incentives and arrangements affect services to and are aligned with the interests of the covered plan and/or its participants and beneficiaries, and in particular whether commenters believed this requirement would contribute to the elimination of incentives and arrangements that are not aligned with the interests of the covered plan and/or its participants and beneficiaries. Further, to ensure that the final rule appropriately protects the interests of the participants in covered plans, the Department sought comment on whether any assertions of clinical superiority provided in the disclosure should be required to be accompanied by evidence. The Department also asked whether there are other examples of incentives or arrangements that align with the interests of the covered plan and/or its participants and beneficiaries (other than by

controlling prescription drug costs, providing clinically superior drugs, or both) that should be specified in the regulatory text.

The Department received comments supporting the proposed requirement to disclose formulary incentives as a means of allowing responsible plan fiduciaries to understand incentives of pharmacy benefit management service providers associated with formulary decisions that may affect access to, and costs of, prescription drugs under the service contract or arrangement. Several commenters suggested that the final rule should specify that the required disclosure extends to how drug manufacturer payments impact tier placement, prior authorization, or step therapy, and may require drugs to be excluded from the formulary.

With respect to the proposed requirement to provide an explanation of how the incentives and arrangements affect services to and are aligned with the interests of the plan and/or its participants and beneficiaries, for example by controlling drug prices, providing clinically superior drugs, or both, some commenters agreed with the concept but believed that covered service providers may provide conclusory responses that might be of limited use. One commenter said that assertions of clinical superiority should be accompanied by peer-reviewed evidence or FDA recognized clinical data, and another commenter believed that evidence to support the assertion should be available upon request. However, several other commenters believed such claims could be supported by other methods such as a short evidentiary basis or a detailed analysis.

Other commenters expressed concerns about the burdens to the covered service provider and the potential market impact of the proposed disclosures. These commenters said that the disclosures may impact pharmacy benefit management service providers' ability to maintain competitive rebate leverage. Some commenters asked the Department to permit a narrative

qualitative type of disclosure regarding formulary design principles rather than the disclosure of the incentive arrangements. Commenters also asked the Department to align with the approach taken by Congress in ERISA section 726, which focuses on a retrospective disclosure regarding the plan's highest spend drugs and involves standardized formulary placement rationales developed by the Secretary (along with the Secretary of Treasury and Health and Human Services).[165]

After considering these comments, the Department determined to finalize this paragraph as proposed, and has redesignated it as subparagraph (e)(6)(i) in the final rule. The Department believes there is value in covered service providers carefully reviewing the incentives and arrangements in light of the requirement to provide an explanation of how the incentives and arrangements affect services to and are aligned with the interests of the covered plan and/or its participants and beneficiaries. The Department did not require assertions of clinical superiority to be accompanied by any specific type of justification, to avoid additional costs and burden to covered service providers. The type of justification provided will be evaluated for persuasiveness by the responsible plan fiduciaries, who may seek additional information as they determine appropriate. The Department did not revise subparagraph (e)(6)(i) specifically to require the disclosure to address how incentives may address tier placement, prior authorization, and step therapy, and may result in drugs being excluded from the formulary and other related matters

[165] ERISA section 726(b)(2)(A)(iii) (Requiring disclosure of, "with respect to any drug for which gross spending under the group health plan or health insurance coverage exceeded $10,000 during the reporting period or, in the case that gross spending under the group health plan or coverage exceeded $10,000 during the reporting period with respect to fewer than 50 drugs, with respect to the 50 prescription drugs with the highest spending during the reporting period-(I) a list of all other drugs in the same therapeutic class as such drug; (II) if applicable, the rationale for the formulary placement of such drug in that therapeutic category or class, selected from a list of standard rationales established by the Secretary, in consultation with stakeholders; and (III) any change in formulary placement compared to the prior plan year").

because the Department believes that the language of the required disclosures in subparagraph (e)(6)(i) and (ii) (discussed below) is broad enough to capture such information.

One commenter said that the final rule also should specify that formulary placement driven by lowest net cost to the plan and participant combined, after all compensation to the pharmacy benefit management service provider, would be most aligned with plan and participant interests. The Department did not add this additional language to the regulatory text because cost was already addressed in the language of subparagraph (e)(6)(i) regarding controlling prescription drug costs.

The Department decided to retain the disclosure of the incentive arrangement rather than a narrative qualitative type of disclosure regarding formulary design principles, as suggested by some commenters, because the Department was not convinced that a narrative would allow the responsible plan fiduciary to assess the incentives associated with formulary decisions that may affect access to, and costs of, prescription drugs under the service contract or arrangement.

The Department did not eliminate this disclosure altogether to align with ERISA section 726, as some commenters suggested. The Department believes this disclosure has value as a component of the initial disclosure so that plan fiduciaries will have the information at the time of contracting, which is key to making the reasonableness determination required under ERISA section 408(b)(2)(B). The Department believes that the burden described by commenters will be alleviated by the more limited scope of the final rule to the larger self-insured group health plans

and that concerns about potential market impact are addressed by the confidentiality provision in paragraph (k)(4).[166]

One commenter said the formulary incentive disclosures and other disclosures in paragraph (e)(6) would not be necessary in the future because of the newly added ERISA section 408(b)(2)(C) that will require pass-through of rebates, fees, alternative discounts and other remuneration to covered plans; at that time, the commenter said the covered plans will receive the full benefit of such payments. The Department has considered this comment but determined that a disclosure of formulary placement incentives will nevertheless have value in revealing to plan fiduciaries whether these arrangements may affect covered plan participants' access to, and costs to them of, prescription drugs under the service contract or arrangement. Adding this to the initial disclosures now also will provide plan fiduciaries a better sense of the accuracy of those future pass-through amounts and how they are calculated.

3.10.2. Subparagraph (e)(6)(ii)

Under subparagraph (e)(6)(ii), the initial disclosure also must include an identification of reasonably available therapeutically equivalent alternatives (including biosimilar biological products) for any drug on the formulary with respect to which the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive any payment by the manufacturer or rebate aggregator that is not passed through to the covered plan. This provision also requires the covered service provider to explain the reason for omitting such alternatives from the covered plan's formulary.

[166] One commenter said, in connection with the proposed paragraph on formulary incentives, that the final rule must require disclosure of compensation received by a provider of pharmacy benefit management services when a PBM-affiliated product is preferred on a formulary or dispensed under the service contract or arrangement. This comment is discussed in the section on "other" compensation under paragraph (e)(5).

The purpose of this provision is to provide the responsible plan fiduciary with information on the constitution of the formulary and the extent to which its overall composition was influenced by lower cost and/or clinical efficacy, as discussed above, as opposed to financial incentives. For instance, when the formulary contains a drug for which the covered service provider will receive a payment from the drug manufacturer (and not pass the payment through to the covered plan), subparagraph (e)(6)(ii) requires the subject disclosure to identify reasonably available therapeutically equivalent alternatives or biosimilar biologic products that do not similarly compensate the covered service provider. This disclosure thus will enable responsible plan fiduciaries to evaluate the way the covered service provider has designed the formulary and the extent to which its composition might be overly influenced by conflicts of interests that impact the quality or performance of services and that require mitigation. The mere fact that alternatives without manufacturers' payments may exist in the marketplace is not dispositive of an unreasonable contract or arrangement; therefore, subparagraph (e)(6)(ii) requires the disclosure to explain the reason for their omission from the formulary, such as the alternatives having lower clinical efficacy, higher pricing, or inadequate supply.

In the final rule, the Department has required identification of reasonably available therapeutically equivalent alternatives modifying the proposal to include "*biosimilar biological products*," based on several comments that said that as used by the Food and Drug Administration, the term "therapeutically equivalent alternatives" applies to small molecule drugs, and not biological products.

Subparagraph (e)(6)(ii) of the final rule does not define "identification" with respect to reasonably available alternatives. At a minimum, however, this identification must include enough information about the alternatives that the responsible plan fiduciary is able to consult a

publicly available directory to complete a prudent analysis.[167] Typically, this will include the manufacturer's name, the generic or trade name of the drug, and dosage form. The disclosure is required to include only a reasonable number of alternatives, not every alternative on the market.

The Department requested comments on whether the final rule should contain an explicit standard with respect to the number of alternatives versus allowing the contracting parties the leeway to establish parameters on their own. One commenter said the rule should have a minimum standard such as requiring identification of at least three therapeutically equivalent alternatives with the lowest net cost available on the market, rather than leaving this to negotiation. Another commenter supported leaving this to the contracting parties but said the final rule should provide that defining therapeutic equivalents by reference to the Orange Book maintained by the Food and Drug Administration would be considered a reasonable approach. Based on limited commenter feedback, the Department determined that requiring a specific number of alternatives to be identified may prove too prescriptive, so it determined to allow the contracting parties to determine parameters. The Department agrees with the commenter who suggested that reference to the Orange Book maintained by the Food and Drug Administration would be considered a reasonable approach.

Other commenters on the proposal also said the Department should align its approach with that of ERISA section 726(b)(2)(A)(iii), which will require notification of changes in the formulary placement compared to the prior year, or should withdraw its proposed disclosure altogether in light of that statutory provision. The Department did not adopt a provision in which

[167] *See, e.g.*, U.S. Food and Drug Administration's National Drug Code Directory, available at https://dps.fda.gov/ndc (last accessed July 31, 2025); U.S. Food and Drug Administration's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, available at https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm (last accessed July 31, 2025).

the disclosure focused on formulary placement compared to the prior plan year because a change in a formulary placement is not the focus of subparagraph (e)(6)(ii) and that type of disclosure would not yield any information in the case of a new contract or arrangement. The Department did not eliminate this disclosure altogether as a means of aligning with ERISA section 726 because the Department believes this disclosure has value as a component of the initial disclosure so that plan fiduciaries will have the information at the time of contracting in order to conduct a reasonableness assessment under ERISA section 408(b)(2)(B).

3.10.3. Subparagraph (e)(6)(iii)

Under subparagraph (e)(6)(iii), if the covered service provider, an affiliate, an agent, or a subcontractor retains authority to modify the formulary during the term of the contract or arrangement – such as by adding or removing drugs or changing their tiering – the initial disclosure must include an explanation of the reasons for retaining such authority and the expected frequency of such changes. Further, the disclosure must state that the responsible plan fiduciary will be notified reasonably in advance of any modifications that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the contract or arrangement. The disclosure also must notify the responsible plan fiduciary of the covered plan's right to terminate the contract or arrangement on reasonably short notice under the circumstances.

The purpose of the advance disclosure requirement is to notify the responsible plan fiduciary sufficiently in advance of the upcoming formulary modification so that the responsible plan fiduciary can either consent or raise an objection. Modifying the formulary is an act of plan administration, with important consequences to the covered plan and its participants. The responsible plan fiduciary could not properly carry out its responsibilities under ERISA without

this advance notice, and likewise the covered service provider might be exercising discretionary authority or responsibility in the administration of the covered plan if it unilaterally effected the modifications without the responsible plan fiduciary's consent.

With respect to this advance notice requirement, the proposed regulation did not specify a number of days "in advance" for the notice to be provided. The Department stated that ideally, the notice would be given sufficiently in advance so that responsible plan fiduciary has a reasonable period to consider the modification and consent or raise an objection. The Department requested comments on whether the final rule should provide more specificity regarding the timing of this advance notice, and stated that it was considering whether to require the notice to be furnished at least 75 days in advance of the change, to allow the covered plan to provide notice to plan participants at least 60 days prior to the date the upcoming material modification becomes effective, if required.[168]

While several commenters supported the 75-day advance notice timeframe as providing responsible plan fiduciaries with sufficient time to evaluate the change before it takes effect, another commenter opposed the advance notice requirement stating that it could delay patient access to newly approved drugs. The commenters opposed to 75-day advance notice timeframe did not propose alternative timeframes. The Department determined, in light of concerns about prompt patient access to newly approved drugs, that it would not specify a timeframe for the advance notice provision in the final rule. Instead, it would leave the decision up to the responsible plan fiduciary and the covered service provider.

[168] *See* 29 CFR 2590.715-2715(b).

The advance notice requirement is triggered only with respect to formulary modifications that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the contract or arrangement. In this way, the trigger is carefully tied to matters of compensation – the chief topic of ERISA section 408(b)(2).

For this purpose, subparagraph (e)(6)(iii) provides that the term "material" means an amount that is 5 percent or more, or such lower percentage or dollar amount that may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement, of the aggregate compensation (on a semiannual basis, or at the request of the covered plan, quarterly basis) disclosed pursuant to subparagraph (e)(3)(i) of the final rule, adjusted for any increases previously disclosed under paragraph (e)(6). Thus, the base amount on which the materiality of the modification is judged would initially be the amount disclosed pursuant to subparagraph (e)(3)(i), but it would increase by the amount of any modifications disclosed under subparagraph (e)(6)(iii).

The following example illustrates how the base amount subparagraph (e)(6)(iii) adjusts as material modifications are made to the formulary. Assume that in advance of entering a contract with a covered plan, a covered service provider discloses pursuant to subparagraph (e)(3)(i) reasonably expected payments on a semiannual basis of 100 dollars. After entering the contract, a contemplated modification in the first semiannual period would result in an increase in compensation above the initially-disclosed amount (100 dollars) by two percent. Advance disclosure of this modification would not be required by subparagraph (e)(6)(iii), unless the parties had agreed to a two percent threshold. A contemplated modification in the second semiannual period would result in an increase in compensation above the initially-disclosed amount (100 dollars) by four percent. Because the aggregate of the second semiannual period

modification (four percent increase to initially-disclosed amount) and the first semiannual period modification (two percent increase to initially-disclosed amount) collectively are expected to exceed five percent, advance notice of the second semiannual modification would be required under subparagraph (e)(6)(iii). The disclosure would need to describe the aggregate (six percent) increase to the initially-disclosed amount. Going forward, the five percent threshold in subparagraph (e)(6)(iii) would apply to the initially disclosed amount (100 dollars) plus the amount disclosed under paragraph (e)(6) (six dollars, or six percent of 100 dollars).

The Department proposed a materiality standard as a trigger to balance the amount of disclosure provided to responsible plan fiduciaries of covered plans. Without a materiality standard, the Department was concerned that responsible plan fiduciaries might be inundated with advance notices of formulary modifications. This concern was based on the understanding that PBMs make frequent changes to formularies.

The materiality standard has two components: it includes a ceiling of a five percent impact over the base amount, and it also allows for the covered service provider and responsible plan fiduciary to negotiate a lower threshold (dollar or percentage).[169] The Department understands that in other contexts, materiality is determined based on the significance to the impacted parties.[170] However, the Department also believes that covered service providers and responsible plan fiduciaries may appreciate a bright line rule as an alternative.

In the proposal, the Department sought comments on the proposed definition of materiality and whether commenters believed the approach taken in the proposal is workable and

[169] The parties may agree to other changes to the formulary that would trigger advance notification to the responsible plan fiduciary. It is a best practice but also on the part of the fiduciary a matter of prudent dealing on behalf of the plan to memorialize in writing any such negotiated advance notice thresholds or triggers.
[170] *See, e.g.*, *Basic Inc. v. Levinson*, 485 U.S. 224, 240 (1988).

identifies an appropriate test for materiality. The Department asked whether the test for materiality in the proposal, which was based on a 5 percent increase over the estimated amount of expected rebates from manufacturers or aggregators, should be broadened to include other compensation, such as spread. The Department also asked about alternative tests for materiality, including whether it would be better to trigger advance disclosure on "any non-trivial changes in the formulary that could affect the covered service provider's own compensation."

Several commenters suggested changes to the proposed approach to the materiality standard. A few commenters said the provision should be broadened to apply to material increases in other compensation such as spread. Other commenters said that the provision should also apply to material increases in plan costs, cost-sharing, or utilization management structure.

A few commenters said the Department should eliminate the general materiality standard (i.e., "the responsible plan fiduciary must be notified in advance of any modifications that, individually and in the aggregate, *are reasonably expected to have a material impact on* the reasonableness of compensation under the service contract or arrangement") and instead use only a percentage threshold.

After considering comments on this paragraph, the Department decided to finalize it as proposed with a focus on formulary changes that materially impact rebates, fees, alternative discounts and other remuneration from drug manufacturers, distributors, wholesalers, and rebate aggregators (or other purchasing entities designed to aggregate rebates) that will be received by the covered service provider, an affiliate, an agent, or a subcontractor. The Department did not expand the provision to apply to material increases in other compensation such as spread because it was not convinced that spread compensation is necessarily a driver of formulary changes such that changes should be brought to the attention of the responsible plan fiduciary in advance;

rather, it is appropriate for material increases in spread compensation to be subject to the overage explanation in paragraph (g)(4). The Department did not require a disclosure based on material increase in plan costs or other factors such as cost-sharing because it determined that changes that will increase compensation for covered service providers (and affiliates, agents, or subcontractors) should be the focus of this disclosure under ERISA section 408(b)(2). The Department also did not replace the general standard that "the responsible plan fiduciary must be notified in advance of any modifications that, individually and in the aggregate, *are reasonably expected to have a material impact on* the reasonableness of compensation under the service contract or arrangement" with a percentage threshold, because it preferred to leave responsible plan fiduciaries the opportunity to negotiate a lower materiality threshold.

A few commenters opposed the disclosure in subparagraph (e)(6)(iii) as they said it was inconsistent with the statutorily mandated framework in the CAA, 2026. The Department disagrees that this provision exceeds its authority. As set forth above, modifying the formulary is an act of plan administration. To rely on the exemption when contracting with a plan to provide pharmacy benefit management services, ERISA section 408(b)(2)(B) as amended by the CAA, 2026 in fact requires that PBMs as covered service providers make disclosures sufficient to permit the responsible plan fiduciary to assess the reasonableness of the compensation that is to be received. Without notice to the responsible plan fiduciary so that the fiduciary can monitor the service contract or arrangement and the covered service provider can avoid exercising discretionary authority or responsibility in the administration of the covered plan, the exemption cannot function, and a fiduciary cannot meet its duties under ERISA section 404.

3.11. Drug Pricing Methodology

Under paragraph (e)(7), the initial disclosure must include a description of the net price per course of treatment or single fill, such as a 30-day or 90-day supply, to the covered plan of each drug on the formulary, as defined by National Drug Code, after rebates, fees, alternative discounts, or other remuneration received from applicable entities, for each pharmacy channel, expressed as a monetary amount. If a monetary amount is not ascertainable, the covered service provider must disclose the methodology used by the covered service provider, an affiliate, an agent, or a subcontractor, under the contract or arrangement, to determine the net price the covered plan will pay for each drug on the formulary, for each pharmacy channel, along with an objective means to verify the accuracy.

The final rule therefore requires the covered service provider to disclose the net price to the covered plan of each drug on the formulary by pharmacy channel, including mail order pharmacy, retail pharmacy, and specialty pharmacy. The net price refers to the total cost to the covered plan after rebates, fees, alternative discounts, or other remuneration received by applicable entities would be applied to the price paid by the plan. The covered service provider would disclose to the responsible plan fiduciary the net price of each drug as a monetary amount when such figures can be ascertained by available information.

In instances where a monetary amount cannot be ascertained by the covered service provider, the paragraph (e)(7) disclosure requirement may be satisfied if the covered service provider instead discloses the methodology that will be used to determine the cost to the covered plan and an objective means to verify the accuracy of that methodology. An example of this methodology would be a price determined by reference to AWP, and a direction to the plan as to where the AWP that will be used may be located. Depending on the specific pricing

methodology being used, other examples of information that may be provided by the covered service provider, enabling the responsible plan fiduciary to verify the accuracy of the disclosed drug pricing methodology, could include pricing indices, rate schedules, benchmark formulas, or similar objective data sources.

The Department has no single specific list or benchmark in mind to satisfy this verification requirement. The covered plan and covered service provider are best situated, on a case-by-case basis, to establish solutions that meet their individual needs. The intent of this provision is to address the reported opacity in the pharmaceutical supply chain and to remedy the imbalance in bargaining power between covered plans and large providers of pharmacy benefit management services.

The paragraph (e)(7) disclosure requirements serve to establish price transparency to ensure a responsible plan fiduciary can effectively evaluate whether the contract or arrangement with the covered service provider is reasonable. The responsible plan fiduciary gains clear and upfront awareness of drug costs and can assess the fairness and predictability of such prices, preventing arbitrarily inflated net costs and enabling the selection of pricing models most aligned with the interests of the covered plan. Additionally, the (e)(7) provision limits opportunities for covered service providers to use non-transparent discretionary pricing formulas that could obscure the true costs of drugs on the formulary.

Commenters who supported this provision in the proposal said it would assist fiduciaries in evaluating drug pricing arrangements and formulary policies, and it would also ensure that pharmacy benefit managers do not implement discretionary pricing methodologies. One commenter particularly supported the ability of fiduciaries to verify the pricing information.

The Department had proposed disclosure of "net cost" to the covered plan of each drug on the formulary, for each pharmacy channel. The Department revised the language in the final rule to use the phrasing "the net price per course of treatment or single fill, such as a 30-day or 90-day supply to the plan . . . after rebates, fees, alternative discounts, or other remuneration" received from drug manufacturers, distributors, wholesalers, or rebate aggregators (or other purchasing entities designed to aggregate rebates). The Department believes this is clearer than the phrasing "net cost" and the terminology aligns with ERISA section 726(b)(2)(A)(i)(VII).

One commenter who supported the disclosures recommended aligning pricing disclosure requirements under the rule with pricing disclosures required under ERISA section 726 and requested the Department clarify that the net cost of each drug be disclosed as the "average net unit cost." The commenter did not describe how the average net unit cost related to the net cost language in ERISA section 726, so the Department declined to adopt that additional language.

In the proposal, the Department requested comments on whether the language in the proposed price disclosure provision provided sufficient clarity to covered service providers regarding their disclosure obligations or whether adjustments should be made. The Department asked whether, for example, the provision should specify how the term "drug" will be defined, and if so, the Department asked commenters to please provide suggested language. Several commenters suggested that the term drug be identified by reference to the National Drug Code. Some commenters specified that it should be at the 11-digit level (as opposed to the 5-digit or 9-digit level), which a commenter said is the standard identifier throughout the pharmaceutical supply chain and is necessary to prevent PBMs from aggregating disclosures and obscuring individual drug pricing. The Department has added a reference to the National Drug Code to paragraph (e)(7) in the final rule. The Department expects the disclosure to include the 11-digit

code, as the industry standard, but has not included that specification in the final rule to avoid the potential that such specification could become outdated. Additionally, ERISA section 726 includes National Drug Code reporting without specifying the 11-digit code.

Commenters suggested additional changes that the Department did not accept. Several commenters suggested aggregate reporting of drug pricing information, including specific information by therapeutic category or pharmacy channel; and one commenter supported it as an addition to individual drug pricing, while another commenter suggested it as an alternative. The commenter who suggested it as an alternative to individual drug pricing said aggregate price disclosure would have the benefit of advancing transparency in a more targeted way while avoiding transmittal of commercially sensitive individual drug pricing information. A few commenters also said that this rule should require disclosure of net cost to include breakouts identifying whether a prescription was filled at a pharmacy owned by or affiliated with the covered service provider. The Department believes the disclosure of pricing information at the individual drug level in the final rule is appropriate as an initial disclosure to responsible plan fiduciaries contracting for pharmacy benefit management services. Additional disclosures such as aggregate disclosure by therapeutic category, pharmacy channel, or pharmacy affiliation would increase the burden to covered service providers.

Some commenters said that drug level disclosure would not be necessary for effective fiduciary oversight; would possibly overwhelm responsible plan fiduciaries; and would exceed the framework established by Congress in ERISA section 726, which requires pricing disclosure only for drugs for which a claim was filed. As discussed above, the Department believes that the paragraph (e)(7) disclosure requirements will assist responsible plan fiduciaries in their assessments of contracts or arrangements with providers of pharmacy benefit management

services, including by allowing them to select drug pricing models most aligned with the interests of the self-insured group health plan, and limiting opportunities for covered service providers to use non-transparent discretionary pricing formulas that could obscure the true costs of drugs on the formulary. The Department believes disclosures under ERISA section 408(b)(2) assist responsible plan fiduciaries in assessing the reasonableness of the contract or arrangement and the compensation of the covered service provider and its affiliates, agents, and subcontractors at the time of contracting and in monitoring these contracts or arrangements thereafter.

Finally, commenters expressed concern about confidentiality of disclosures related to drug prices and drug pricing methodologies. The Department has adopted paragraph (k)(4) in the final rule that permits covered service providers to require responsible plan fiduciaries to require third parties and their subcontractors to execute reasonable confidentiality provisions preventing redisclosure by such parties and limiting use of such information to purposes related to the covered plan's contract or arrangement.

3.11.1. Net Effective Cost Disclosure

Several commenters recommended that the Department add a new provision to the final rule requiring covered service providers defined in paragraph (c)(1)(ii) (i.e., brokers and consultants) to disclose information using a net effective cost model for bids to provide pharmacy benefit management services furnished as part of a request for proposal. These commenters said that bids submitted as part of a request for proposal for pharmacy benefit management services which focus on the value of rebates or other price concessions from drug manufacturers can obscure the total net cost incurred by a plan for providing its pharmacy benefit, as bids structured on securing sizable rebates for high-list-price drugs may still result in a

higher cost to the plan than an option structured on using lower-list-price drugs, generics, or biosimilars. These commenters also said that requiring disclosure of bids using a net effective cost model would align the incentives of all parties in the supply chain and present competing models in a simple and comparable manner while preserving the various mechanisms used by covered service providers for negotiating price concessions and other factors to reduce the ultimate cost to the plan for providing a pharmacy benefit. The commenters proposed a definition of "net effective cost" for use in the regulatory text.

The Department considered these comments and concluded that a disclosure that is simple and would allow responsible plan fiduciaries to compare competing bids could be a helpful tool for responsible plan fiduciaries. However, the suggestion centered around a detailed and technical definition of net effective cost, and the Department was reluctant to adopt this disclosure as a requirement in the final rule based on limited comments.

3.12. Statement of Fiduciary Status

Under paragraph (e)(8), the initial disclosure must include, if applicable, a statement that the covered service provider, an affiliate, an agent, or a subcontractor will provide, or reasonably expects to provide, services pursuant to the contract or arrangement directly to the covered plan as an ERISA fiduciary.

As relevant to this final rule, ERISA provides that a person is generally a fiduciary with respect to a covered plan to the extent he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, or do so, or has any discretionary authority or

discretionary responsibility in the administration of such plan.[171] In complying with paragraph (e)(8), therefore, the covered service provider should carefully consider whether it, or an affiliate, an agent, or a subcontractor, will meet this definition in its services to the covered plan.

The Department has previously explained in this respect that a person who performs "purely ministerial functions . . . within a framework of policies, interpretations, rules, practices and procedures made by other persons" is not a fiduciary under this test.[172] To avoid fiduciary status, a covered service provider should ensure that its services to the covered plan, and the services of its affiliates, agents, and subcontractors, are not discretionary, but instead operate within policies and procedures disclosed to and approved by the responsible plan fiduciary.[173]

Multiple commenters expressed support for the proposal's broad disclosure requirement, indicating that transparency regarding fiduciary roles is essential to helping plan sponsors and fiduciaries clearly understand whether covered service providers or their affiliates have legal obligations to act in the best interest of the plan as required under ERISA. In their view, without knowing when fiduciary duties apply, plan sponsors cannot properly evaluate whether covered service provider's decisions are loyal fiduciary judgments or if financial incentives are influencing decision-making that may not be in the best interest of the plan.

Multiple other commenters generally opposed the statement of fiduciary status required under the proposal. A commenter noted that a statement of fiduciary status is not required under the disclosure provisions of the CAA, 2026, and that the statement seems to exceed the statutory

[171] ERISA section 3(21)(A)(i) and (iii) (29 USC 1002(3)(21)(A)(i) and (iii)). ERISA section 3(21)(a)(ii) (29 USC 1002(3)(21)(A)(ii)) is not described in the text as it pertains to the provision of investment advice for a fee.
[172] Interpretive Bulletin 75-8, 29 CFR 2509.75-8 (Q&A D-2).
[173] The test for fiduciary status under section 3(21) of ERISA is a functional test. While effective policies and procedures enable service providers to act ministerially and thereby avoid discretionary acts described in section 3(21) of ERISA, express disclaimers of fiduciary status, standing by themselves, have no such effect.

purpose of ERISA section 408(b)(2). According to the commenter, it is immaterial to the framework under section 408(b)(2) whether or not the covered service provider believes it is a fiduciary. Some commenters suggested that the fiduciary status disclosure may cause confusion about ERISA's definition of fiduciary, which is well-understood to be a functional test. The commenters noted that disclosing a statement as to fiduciary status does not, by itself, create such status if the person does not meet the functional test, and that meeting the function test confers fiduciary status even without a statement. According to commenters, the initial disclosure could therefore mislead a responsible plan fiduciary into believing that a covered service provider is a fiduciary even if the purported fiduciary does not actually meet the functional test described in ERISA section 3(21).

A commenter suggested that the fiduciary statement should instead focus on those duties that the plan and covered service provider have separately and expressly agreed are fiduciary in nature. The commenter explained that any arrangement under which a plan fiduciary intends to confer on another entity the role of fiduciary would be the subject of a separate, explicit, and specific written undertaking agreed to by all parties. Another commenter similarly suggested that the statement should identify whether the covered service provider will provide services to the plan in a fiduciary capacity, or has entered into any agreement that could be construed as conferring discretionary authority or control over plan management or plan assets, which result in fiduciary status under ERISA section 3(21)(A). Another commenter suggested that the proposal should be modified to additionally require a negative disclosure when a covered service provider does not believe it is a fiduciary.

Commenters also requested several other clarifications and changes to the proposed requirement. A commenter requested clarification that a plan fiduciary, other than the PBM, is

not liable for any failure of the PBM to provide the statement required by the regulation. Another commenter requested confirmation that the functional fiduciary test under ERISA section 3(21)(A) would still generally apply to pharmacy benefit service arrangements. A commenter also requested confirmation that ERISA makes clear that when a fiduciary is acting in a non-fiduciary capacity, such as when a PBM sells services to a plan, such activities are not a conflict of interest so long as they do not relate to the party's fiduciary role.

A commenter suggested that a covered service provider should be required to update their statements whenever there is a material change to the provider's fiduciary status or conflicts of interest or compensation, with materiality defined explicitly in relation to the affected plan sponsor. The commenter also recommended the fiduciary status statement requirement be changed to require semiannual and material event restatements, explaining that annual or even semiannual updates would be insufficient given the dynamic nature of PBM operations, vertical integration, and the frequency with which formulary and network changes can alter fiduciary analysis. The commenter also recommended that the regulation should be revised to indicate that the failure to acknowledge that the PBM is acting as a fiduciary is, itself, a breach of its fiduciary duty.

After reviewing the public comments, the Department has decided to include the disclosure of fiduciary status in the final regulation, and to not limit it to instances where fiduciary status is expressly agreed upon contractually. The Department agrees with commenters that argued the importance of responsible plan fiduciaries knowing whether a party will be providing or reasonably expects to provide services to the plan as an ERISA fiduciary, given the provider's heightened level of responsibility under ERISA. In the Department's view, this importance does not change based on whether a person is a functional fiduciary or expressly

agrees by contract to perform fiduciary functions. The Department is not persuaded that disclosure of fiduciary status is inconsistent with section 408(b)(2) of ERISA. As indicated in both the proposal and elsewhere in this final rule, the statutory basis for this regulation includes section 408(b)(2)(B) of ERISA, which also contains a requirement to disclose if a covered service provider will provide, or reasonably expects to provide, services as a fiduciary within the meaning of section 3(21) of ERISA.

The Department does not share the concern of some commenters that an initial disclosure may mislead responsible plan fiduciaries into believing a covered service provider is a fiduciary even if the service provider does not actually meet the functional test described in section 3(21). As some commenters noted, the functional test for fiduciary status under section 3(21) is well understood. The Department's guidance and numerous court decisions make clear that a person is a fiduciary only to the extent it meets the functional definition in the statute.[174] The disclosure requirement in the final regulation does not change the functional test for identifying fiduciaries. We also note that if a covered service provider fails to provide the statement of fiduciary status, the exemption at paragraph (n) of the final regulation is available for the responsible plan fiduciary.

The Department agrees with the commenter who said the statement of fiduciary status should be updated and has added a requirement to update this statement in the semiannual disclosure, in paragraph (g)(5) of the final rule. With respect to other suggestions to require additional disclosure of information, and updates to the information disclosures, the Department

[174] *See, e.g.*, Advisory Opinion 2001-02A (Feb. 15, 2001), available at https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/advisory-opinions/2001-02a; Pegram v. Herdrich, 530 U.S. 211 (2000).

did not receive sufficient information from commenters for consideration. The Department has not made any changes in response to these comments.

3.12.1. Examples

A number of commenters supporting the proposal's statement of fiduciary status also suggested that the final rule include examples illustrating fiduciary status that may be taken on by PBMs. According to some, the proposal effectively allows PBMs, rather than responsible plan fiduciaries, to determine when they are acting as fiduciaries for purposes of the disclosure requirement. They indicated that the fiduciary status of a PBM performing PBM services is not always clear-cut in practice, and, as a result, similarly situated PBMs and responsible plan fiduciaries may reasonably reach different conclusions about whether specific conduct gives rise to fiduciary status that must be disclosed. Commenters cautioned that PBMs may adopt unduly narrow interpretations of fiduciary status, allowing activities that involve discretion or meaningful influence over plan assets, plan administration, or plan management to be characterized as non-fiduciary by default. Some also opined that PBMs often have evaded ERISA fiduciary duties by asserting they perform only "ministerial" functions, with one commenter suggesting that the Department provide further guidance on "ministerial" functions.

Some commenters said that the regulation could be strengthened if it includes examples of how PBMs function as fiduciaries. In their view, this would promote consistent application of the disclosure requirement and help responsible plan fiduciaries identify PBM fiduciary functions that are inconsistent with PBM pricing arrangements and increase the cost of medicines. Some commenters identified as possible examples for the regulation activities related to designing utilization management plans, designing pharmacy benefit networks, and

developing other formulary changes that they believe can cause PBMs to operate as fiduciaries under ERISA.

With respect to fiduciary status, the proposal explained that ERISA provides that a person is generally a fiduciary with respect to a self-insured group health plan to the extent he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, or has any discretionary authority or discretionary responsibility in the administration of such plan.[175] However, a person who performs "purely ministerial functions . . . within a framework of policies, interpretations, rules, practices and procedures made by other persons" is not a fiduciary under this test.[176] Whether a person is a fiduciary under the function test depends on the surrounding facts and circumstances. Because the test is based on function, a person may be a fiduciary with respect to some activities, but not others. For example, as noted in the proposal, a covered service provider that unilaterally modifies a self-insured group health plan's formulary may be exercising discretionary authority or responsibility in the administration of the plan.[177] The Department believes providing more comprehensive guidance on fiduciary status, as requested by commenters, is beyond the scope of this regulatory project.

3.12.2. Conflicts Disclosure

In the proposal, the statement of fiduciary status also included a conflict-of-interest disclosure. Specifically, the proposal included a requirement to "disclose any activity or policy

[175] ERISA section 3(21)(A)(i) and (iii).
[176] Interpretive Bulletin 75-8, 29 CFR 2509.75-8 (Q&A D-2).
[177] 91 FR at 4367 ("Modifying the formulary is an act of plan administration, with important consequences to the self-insured group health plan and its participants. The responsible plan fiduciary could not properly carry out its administrative responsibilities under ERISA without [the proposed] advance notice, and likewise the covered service provider might be exercising discretionary authority or responsibility in the administration of the self-insured group health plan if it unilaterally effected the modifications without the responsible plan fiduciary's consent.").

that may create a conflict of interest, including, for example, if such entity will benefit financially from drug substitution, from incentivizing use of affiliated pharmacies when other network pharmacies offer lower costs, or from step therapy or 'fail first' protocols that require participants and beneficiaries to use drugs that generate greater manufacturer rebates than other therapeutically equivalent drugs on the formulary."

A commenter questioned the need for the separate conflicts disclosure and the proposal's examples of potential conflicts in light of the CAA, 2026. The commenter explained that while the proposal suggested that such a conflict could include the use of a step therapy protocol requiring beneficiaries to use specific drugs to "generate higher manufacturer rebates than other therapeutically equivalent drugs," manufacturer rebates are a means to lower plan costs. The commenter asserted that it is difficult to see how that scenario could be a "conflict of interest" because under the CAA, 2026's 100% rebate pass-through requirements, manufacturer payments associated with the plan's drug utilization flow entirely to the plan. The commenter observed that if a step therapy protocol results in greater manufacturer rebates, the plan receives 100% of that value. The commenter requested that the Department clarify that the conflict-of-interest disclosures relate to those areas in which the covered service provider serves as a fiduciary. In the commenter's view, that clarification would help avoid potential confusion around the types of examples provided in the proposal. Another commenter suggested that the conflicts disclosure should apply only to activities ancillary to the covered service provider's role as an expressly agreed upon fiduciary. Another commenter suggested that the conflicts of interest disclosure should be strengthened to require a description of the processes to identify and mitigate conflicts of interest, such as objective third-party evaluation of identified conflicts and management of recusals.

The Department decided not to include the conflict disclosure in the final rule. The Department had intended that the conflict disclosure would be applicable to activities and policies related to the covered service provider's services as a fiduciary. However, after consideration of comments on the proposed statement of fiduciary status and the conflict disclosure, the Department concluded that the totality of the other disclosures in the final rule – particularly disclosures regarding the indirect compensation to be received by the covered service provider and its affiliates, agents, and subcontractors – will provide responsible plan fiduciaries with meaningful information to assess the potential conflicts of interest. Additional conflict disclosure associated with the statement of fiduciary status could prove duplicative and may therefore be confusing to responsible plan fiduciaries.

3.13. Statement of Audit Right

Under paragraph (e)(9), the initial disclosure must provide a statement of the covered plan's right to the audit described in paragraph (j) of the final rule and the procedures for requesting such an audit. Among other things, paragraph (j) ensures that the contract or arrangement does not contain terms that would impede the covered plan's ability to conduct an audit. As discussed in preamble section E.8., the right to audit the completeness and accuracy of the required disclosures is an essential part of the final rule's framework for establishing transparency in the marketplace for pharmacy benefit management services. Paragraph (e)(9) ensures that the responsible plan fiduciary is aware of the audit rights that are preserved in the regulation.

Several commenters said the audit provision exceeded the Department's statutory authority, and they submitted related comments saying that the initial disclosure should not include this statement of audit right. The Department has discussed the comments on its

statutory authority below and has determined to adopt the audit provision in the final rule with modifications clarifying the scope of limitations for confidentiality agreements related to such an audit and the timing requirements for a service provider to provide the information required for the audit. Accordingly, the final rule also includes the required statement of audit right in the initial disclosure.

4. Initial Disclosure Requirements for Fully Insured Group Health Plans Reserved – Paragraph (f)

As discussed above, the regulatory initial disclosure requirements for fully insured group health plans are reserved. ERISA section 408(b)(2)(B) continues to obligate all covered service providers, including group health plan issuers and related vendors who meet that definition, to comply with the statutory disclosure requirements to rely on the exemption.

5. Semiannual Disclosure Requirements – Paragraph (g)

Paragraph (g) of the final rule[178] requires semiannual (or at the request of the covered plan, quarterly) disclosures of the actual compensation received or reasonably expected to be received for the semiannual (or quarterly) period by the covered service provider and its affiliates, agents, and subcontractors in connection with the services provided under the contract or arrangement with the covered plan. This disclosure will serve an important purpose for the responsible plan fiduciary's monitoring obligations with respect to the services contract or arrangement with the covered plan.

Under the final rule, the semiannual (or quarterly) disclosure must cover amounts actually received during the period plus any amounts that are reasonably expected to be

[178] 29 CFR section 2550.408b-22(g).

received in connection with services during the period. Language was added in the final rule to ensure full disclosure of amounts earned during the disclosure period, even if payment has not yet been received. This approach has the advantage of providing fiduciaries with a fuller picture of the compensation arrangements as compared to an approach based strictly on when compensation is received, which may be impacted by lagging payments. This also aligns with the approach in ERISA section 726, which bases certain disclosures on claims filed during the reporting period and requires disclosure of amounts received or expected to be received.[179]

While selection of these covered service providers will be made based on the initial disclosures, which require disclosure of compensation "reasonably expected" to be received, the responsible plan fiduciary's ability to evaluate compensation actually received (or earned during the period but not yet received) is intended to facilitate ongoing oversight of the service arrangement.[180] The semiannual (or quarterly) disclosures would be required to be provided no later than 30 calendar days after the end of each six-month period (or, quarter) beginning on the date the contract or arrangement is entered, with respect to the preceding reporting period.

The content of semiannual disclosures generally tracks the specific categories of compensation that were included in the initial disclosures. Thus, these disclosures would address direct compensation (paragraph (g)(1)) as well as indirect compensation (paragraph (g)(2)), including but not limited to manufacturer payments, spread compensation, copay claw-backs and other pharmacy recoupment, and price protection agreements. Like the initial

[179] ERISA section 726(b)(2)(A)(i) required information to be provided regarding drugs for which a claim was filed for the applicable period including: "(X) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration; (XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities-(aa) for claims incurred during the reporting period; and (bb) that is related to utilization of such drug or spending on such drug."
[180] As discussed above, the semiannual disclosure requirements for fully insured group health plans are reserved.

disclosures, the semiannual disclosures also contain a catch-all category for any "other compensation" not covered by the specific compensation categories (paragraph (g)(3)). The disclosure also must include an updated statement of fiduciary status, if applicable, to the extent not previously disclosed as part of the initial disclosures (paragraph (g)(5)), and would include a disclosure of the audit rights under the final rule (paragraph (g)(6)).

Unlike the initial disclosures, the semiannual disclosures would contain amounts of compensation actually received plus any amounts reasonably expected to be received for the semiannual (or quarterly) period for each of these categories. Compensation amounts should not be re-disclosed for a later period in which it is actually received. This clarification is so that covered service providers are not double reporting compensation under this final rule.

Semiannual disclosures must include an overage explanation, if applicable. Consistent with the purpose of these disclosures to assist responsible plan fiduciaries in their ongoing monitoring of the contract or arrangement, paragraph (g)(4) requires a disclosure if any category of compensation to the covered service provider, an affiliate, an agent, or a subcontractor described in paragraph (g), in the aggregate, materially exceeds the corresponding estimate described in paragraph (e). Thus, for example, if the actual amount of spread compensation disclosed in the semiannual disclosure materially exceeded the amount identified in the initial disclosure, this overage explanation requirement would be triggered.

The overage explanation provision requires an identification of the amount of the overage (in the aggregate) and the reason for the overage. For this purpose, the term "materially" means 5 percent or more, or such lower percentage or dollar amount as may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement. This definition

of materiality generally parallels the approach taken in paragraph (e)(6)(iii) (relating to the advance notification requirement for modifications to a formulary).

The overage explanation will help responsible plan fiduciaries by emphasizing areas where categories of compensation materially exceeded the parties' expectations at the outset of the contract or arrangement. A responsible plan fiduciary will be able to take the explanation into account when deciding on the continuing reasonableness of the contract and whether to continue the service relationship with the covered service provider.

The Department notes that the semiannual disclosure obligation is not directly stated in ERISA section 408(b)(2)(B); however, the statute does require disclosure of changes to the information provided in the initial disclosures,[181] and the Department has the authority to regulate the timing of these disclosures. With respect to the compensation disclosures, changes to this information must be disclosed as soon as practicable, but generally no later than 60 calendar days from the date on which the covered service provider is informed of such change.[182] The Department believes that in the pharmacy benefit management context, it is more efficient to have a semiannual (or quarterly) disclosure that would provide all the compensation received in the prior 6 month period (or quarter), rather than a requirement to disclose changes on an ongoing basis.

As indicated above, the primary purpose of paragraph (g) is to ensure that responsible plan fiduciaries have more than just the estimates provided in the initial disclosure (before the

[181] ERISA section 408(b)(2)(B)(v)(II) ("A covered service provider shall disclose any change to the information required under clause (iii) and (iv) as soon as practicable, but not later than 60 days from the date on which the covered service provider is informed of such change, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information shall be disclosed as soon as practicable.")

[182] *See id*., noting that if a disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, the information shall be disclosed as soon as practicable.

contract or arrangement was even entered) under paragraph (e) of the final rule when conducting their statutory duty to monitor the ongoing reasonableness of the covered plan's service relationship with the covered serve provider. In this way, the final rule responds to those instances of reported opacity in the pharmacy benefits management industry.

5.1. Timing of the disclosures

In the proposal, the Department asked for comments on ways to simplify or streamline the semiannual disclosure without compromising its stated purpose. The Department said it had considered and rejected the idea of proposing annual disclosures of compensation actually received, rather than semiannual disclosures, based on the understanding that pharmacy benefits management service contracts often are only one year in duration. Consequently, in such cases, a disclosure of actual compensation received after the expiration of the contract would seem to be of significantly less value to the responsible plan fiduciary than if it had been received during the term of contract, while the fiduciary's duty to monitor the reasonableness of the relationship is ongoing and, if needed, changes still can be made in response to these disclosures during the contract period.

A number of commenters supported the Department's proposal on the basis that it would facilitate monitoring by responsible plan fiduciaries and accountability of covered service providers at an appropriate interval before the parties would begin renegotiating their contract or arrangement. One commenter said the semiannual period was appropriate given that many service arrangements operate on annual contract cycles, and the semiannual disclosure would provide responsible plan fiduciaries with information that would be timely and actionable, whereas annual disclosures would occur too late to allow meaningful corrective action. Some

commenters specifically supported the semiannual time frame as being consistent with the ERISA section 726 reporting period.

A few other commenters suggested semiannual disclosures would be too frequent, with one commenter suggesting that there should be an initial disclosure and thereafter annual disclosures prior to exercising any renewal or extension option. One commenter said that the proposed requirement to provide the disclosure 30 days after the end of the semiannual period would not allow the covered service provider to account for all payments since manufacturer payments may lag due to quarterly billing practices. One commenter asked the Department to make clear that payments received in a subsequent reporting period should be reported in that period if not previously reported.

In the final rule, the Department has retained the semiannual reporting period but also provides for a quarterly reporting period upon the request of the covered plan, in alignment with the reporting periods in ERISA section 726. The Department did not receive a significant number of comments objecting to the 30-day time frame for the disclosure and believes that prompt disclosure following the end of the reporting period is important, so it did not extend the time period for the semiannual (or quarterly) disclosure to be made. The covered service provider can report any amounts in a future semiannual (or quarterly) disclosure from a prior reporting period that were not previously reported. The Department notes, however, that the requirements in paragraphs (g)(2)(i) and (iv) as well as (g)(3) are phrased in terms of compensation received or *reasonably expected to be received*.

5.2. Changes from the Proposal

Regarding the substance of the semiannual (or quarterly) disclosures, several commenters said that the Department should make changes that correspond to changes suggested for the

initial disclosures, particularly regarding alignment with ERISA section 726. The final rule does generally incorporate corresponding changes to the initial disclosures, including those designed to align with ERISA section 726, all of which were discussed previously in this preamble section E.3.

One commenter suggested that covered service providers should provide an updated statement of fiduciary status whenever there is a change to the fiduciary status or related conflicts of interest. The Department agrees that disclosure of fiduciary status should be updated, but decided to include a requirement to update them in the semiannual (or quarterly) disclosure, not whenever a change happens. This disclosure appears in a new paragraph (g)(5) and is based on the wording of paragraph (e)(8) which is the corresponding initial disclosure.

5.3. Overage Explanation

Some commenters on the Department's proposal said the proposed overage explanation was appropriate and would assist responsible plan fiduciaries in monitoring the reasonableness of the compensation and the contract or arrangement. A few supportive commenters said additional consequences and enforcement options, such as civil penalties, would be needed to ensure the overage explanations would not be incomplete or delayed.

A few commenters addressed the proposed materiality threshold of 5 percent. Some said it was appropriate, but others opined that it was either too high or too low. The commenter who said the 5 percent threshold was too high said that with six categories of compensation specified in the rule, covered service provider compensation could increase by up to 30 percent across the board with no overage explanation. A commenter who thought the 5 percent threshold was too low said that variations between projected and actual compensation are the natural result of changes in utilization and other factors over the course of the plan year. The commenter believed

that ERISA section 408(b)(2) requires the contract or arrangement to be reasonable at the time it is entered into and does not require the fiduciary to precisely track prospective estimates. The commenter said the threshold should be significantly increased to at least 20 percent and be triggered by aggregate compensation increases not variations in individual categories. Further the commenter said the overage explanation should not be applied to manufacturer payments that are subject to the rebate pass-through to the covered plan.

In the final rule, the Department revised the language in the overage explanation to make clear the focus is compensation to the covered service provider, an affiliate, an agent, or a subcontractor. The Department agrees with the commenter that the overage explanation should not be applied to payments that are passed through to the covered plan. The Department further determined that the approach in the proposal in which the materiality threshold applied to each category of compensation and required the covered service provider to explain the reason for the overage was a straightforward way to assist the responsible plan fiduciary in its monitoring of the service contract or arrangement. Providing for a disclosure based on aggregate overage across categories may result in an explanation that involves multiple reasons and is less clear.

With respect to potential enforcement or civil penalties, section E.13 of this preamble discusses consequences of noncompliance.

6. Semiannual Disclosure Requirements for Fully Insured Group Health Plans Reserved – Paragraph (h)

As discussed above, the regulatory semiannual disclosure requirements for fully insured group health plans are reserved. ERISA section 408(b)(2)(B) continues to obligate all covered service providers, including group health plan issuers and related vendors who meet that definition, to comply with the statutory disclosure requirements to rely on the exemption.

7. Reporting and Disclosure Information upon Request – Paragraph (i)

Under paragraph (i) of the final rule,[183] certain information must be provided upon written request of the covered plan's responsible plan fiduciary. The required information is any other information relating to the contract or arrangement that is required for the covered plan to comply with the reporting and disclosure requirements of Title I of ERISA and the regulations, forms, and schedules issued thereunder. The information must be provided reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information must be disclosed as soon as practicable. This paragraph is finalized as proposed.

The information that might be requested by a responsible plan fiduciary may include information needed to complete the covered plan's Form 5500 filing.[184] In 2010, the Department issued supplemental FAQs stating that certain fees received by PBMs for services to an ERISA plan that are paid with plan assets are reportable direct compensation on Schedule C of the Form 5500.[185] Further, the Department stated that discount and rebate revenue would be reportable indirect compensation to the extent the plan and the PBM agree that these payments will be used to compensate the PBM for services to the plan.[186] While information to support these Schedule C items would likely be provided as part of the semiannual disclosure in paragraph (g),

[183] 29 CFR section 2550.408b-22(i).
[184] 29 CFR 2520.103-1.
[185] Supplemental Frequently Asked Questions about the 2009 Schedule C, Q26, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/reporting-schedule-c-faq.pdf.
[186] *Id.*, at Q27.

paragraph (i) would underscore the covered service provider's obligation to provide any information that is needed to complete the Form 5500 report.

The CAA, 2021 also added annual reporting requirements (Prescription Drug Data Collection) about prescription drug and health care expenditures under Code section 9825(a), ERISA section 725(a), and PHS Act section 2799A-10(a).[187] To comply with the reporting requirement, a responsible plan fiduciary may also request information needed to comply with reporting obligations under ERISA section 725, which was added by the CAA, 2021. The information required under ERISA section 725, and parallel provisions under the Code and PHS Act, includes the 50 most frequently dispensed brand prescription drugs, the 50 most costly prescription drugs by total annual spending, and the 50 prescription drugs with the greatest increase in plan expenditures over the preceding plan year. Further, the group health plan is required to report information on rebates, fees, and any other remuneration paid by drug manufacturers to the covered plan or its administrators or service providers overall, with respect to each therapeutic class of drugs, and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year. As part of these requirements, group health plans are also required to report spread amounts retained by its PBM(s).

One commenter said that requiring the covered service provider to provide "any other information relating to the contract or arrangement" is overbroad and said the final rule should clarify that the scope of information required upon request is limited to information reasonably within the covered service provider's possession or control and reasonably related to the

[187] *See* Centers for Medicare & Medicaid Services, *Prescription Drug Data Collection (RxDC)* (Sept. 10, 2024), available at https://www.cms.gov/marketplace/about/oversight/other-insurance-protections/prescription-drug-data-collection-rxdc.

underlying disclosure obligations of this rule. The commenter also said the standard for delayed disclosure should be revised from "extraordinary circumstances beyond the covered service provider's control" to a "commercially reasonable efforts" standard. The Department has not adopted these changes as it believes that other information relating to the contract or arrangement is sufficiently limited by the purpose of the section which is for the covered plan to obtain information needed to comply with the reporting and disclosure requirements of Title I of the Act, the regulations in this chapter, and forms and schedules issued under Title I. If a covered plan requires information to comply with its reporting obligations, the covered service provider must provide it reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement under Title I of ERISA. The Department believes a "commercially reasonable" standard for supplying the information may result in covered plans not receiving required information in time to satisfy their reporting or disclosure requirements.

8. Right to Audit – Paragraph (j)

Paragraph (j)[188] establishes a right for covered plans to audit their covered service providers at least once per year. The purpose of the audit provision in the final rule is to enable responsible plan fiduciaries to verify the accuracy of the disclosures made under the final rule. In describing the scope of the audit provision, paragraph (j)(1) narrowly reflects this purpose. The Department chose not to limit a covered plan's ability to audit their covered service providers only with respect to each plan year to avoid foreclosing a covered plan's ability to cross-reference actual service delivery against compensation disclosures regardless of plan year to

[188] 29 CFR section 2550.408b-22(j).

identify issues or concerns related to the accuracy of the disclosure, such as hidden costs, billing inconsistencies, or complete disclosure failures.

The final rule provides that the parties would share the audit costs as follows. The covered plan will be responsible for compensating the auditor. The covered service provider will bear the costs of providing the auditor with the information, data, and other materials needed to perform the audit. The Department believes this shared cost approach is fair, balanced, adequately protective of covered plans, and not unduly financially burdensome to covered service providers.

Under the final rule, the covered plans have the sole authority to select the auditor, and the covered service providers are prohibited from imposing limitations on the selection process. Likewise, the final rule broadly prohibits covered service providers from imposing restrictive conditions on the auditor, such as the location of the audit or the number of records to be provided, including contracts with retail pharmacies and drug manufacturers. The final rule, however, provides that the scope of the audit is limited to the disclosures made under the final rule.

The Department considers the audit provision to be necessary to ensure a proper and meaningful audit so that the accuracy of the disclosures can be verified. A right to audit the veracity of any and all disclosures made by the covered service provider to a responsible plan fiduciary as required by this regulation, including the responsibility of the covered service provider to deliver all necessary information to conduct such an audit, is an essential part of the rule's framework for establishing transparency in the marketplace for pharmacy benefit management services. As a general matter, the Department believes that covered service providers will be mindful of the regulation's audit rights when developing their disclosures, and

the audit rights therefore are deliberately intended to result in disclosures that are more carefully constructed, robust, and transparent. Further, to the extent that an audit reveals information that was not previously disclosed or flaws in the disclosure, the responsible plan fiduciary can evaluate the additional information in assessing the reasonableness of the compensation and determining whether additional payments should have been passed through to the covered plan or whether to exercise other rights.

In this regard, responsible plan fiduciaries must periodically monitor compliance by covered service providers with the terms of their agreements and the reasonableness of their compensation under the agreements to ensure continuation of the agreement meets the requirements of ERISA section 408(b)(2) as well as the general fiduciary obligations under ERISA section 404. In satisfying its monitoring obligations, however, the responsible plan fiduciary retains discretion as to when, if at all, to request an audit of disclosures issued by the covered service provider. The right to conduct an audit does not need to be exercised. A responsible plan fiduciary may reasonably determine that the expense incurred by the plan to audit the covered service provider under this section outweighs the likely benefit to the plan resulting from such audit where additional circumstances suggesting the covered service provider is noncompliant with the terms of the contract or arrangement or the requirements of the regulation are absent.

8.1. General Comments

After considering comments on the proposal, the Department determined to finalize the audit provision with minor changes, as discussed below. Several commenters said that audits are essential for plan fiduciaries to assess the accuracy of the required disclosures. Commenters said that audits are already often standard practice, and the final rule will set expectations and

requirements for auditing across service providers and responsible plan fiduciaries. Commenters also identified issues that have arisen in the absence of a clear audit right: PBMs sometimes limit responsible plan fiduciaries' discretion in choosing auditors or do not provide material information necessary for a complete audit. The Department finds these comments persuasive because of the role audits play already, the value commenters saw in the audit rights, and the opportunity to create a baseline standard for audits to help ensure that the disclosures required by the rule are accurate.

In the proposal, the Department sought comments on the scope of the audit considering the purpose of the rulemaking. Some commenters suggested that the Department expand the audit requirement so that plan fiduciaries would be able to use an audit to assess the extent to which service providers complied with the terms of their contract rather than limiting the audit to the accuracy of their disclosures. Other commenters said maintaining the proposed scope of the audit provision would be preferable and expanding beyond verification of required disclosures would be inconsistent with the objectives of the rule. The Department is not persuaded that the audit rights should extend beyond requiring needed information to validate the disclosures required in the rule. Such a requirement would be beyond the scope of the rule, which is designed to ensure plan fiduciaries have the information they need to assess whether the contract or arrangement is reasonable.

Some commenters said the proposed audit provision exceeded the Department's regulatory authority and therefore should not be included in the final rule. They said the Department's regulatory authority under ERISA section 408(b)(2)(B) is limited to "time, manner, and content" of the disclosures. Further, the commenters said that new ERISA section

408(b)(2)(C) contains audit rights that are limited to the rebate-pass through provision, which they believed suggested that Congress did not intend broader audit rights.

The Department does not agree that the final rule's provision preserving covered plans' audit rights exceeds its regulatory authority. Congress specified the Department's authority in ERISA section 408(b)(2)(B) with respect to the time, manner, and content of disclosures. In the Department's view, shared by many commenters, the audit provisions are necessary for responsible plan fiduciaries to verify accuracy of the disclosures and thus fulfill their ERISA section 404 duties. The audit provisions also make the reasonableness determination meaningful to fulfill the purpose of the statutory exemption. The Department believes that in the context of pharmacy benefit management services, where, historically, indirect compensation streams have not been transparent, ensuring that covered plans can audit the detailed disclosures in the final rule furthers the goal of this rulemaking. Further, the Department retains authority under ERISA section 505 to issue regulations necessary or appropriate to carry out the provisions of Title I of ERISA.

8.2. Auditor Selection and Audit Costs

Some commenters asked the Department to permit covered service providers to place reasonable limits on auditor selection, including limitations related to conflicts of interest or other anticompetitive behaviors. One commenter said auditors should be prohibited from receiving contingency fees, such as compensation based on a percentage of rebate payments not remitted to the group health plan. Other commenters stressed the need for the responsible plan fiduciary to retain the right to engage the auditor of its choosing and not be subject to limitations placed by the covered service provider.

The Department agrees with commenters who said the auditor selection should be the sole responsibility of the responsible plan fiduciary. Such responsible plan fiduciaries are required under ERISA to make a prudent and loyal selection of an auditor as a plan service provider. The Department is concerned that if the final rule permitted covered service providers to impose additional limitations, such limitations could potentially be used to limit auditor selection in ways that are inconsistent with the covered plans' interests.

Some commenters also addressed the cost sharing provision in the proposal, under which the covered plan would pay for the selection and retention of the auditor and the covered service provider would pay for providing the requested information. Some commenters opposed this provision based on their interpretation that it would establish a 50-50 cost splitting requirement which they believed could involve the plan subsidizing the covered service provider's costs. Some commenters also believed that the approach in the proposal was inconsistent with the approach in new ERISA section 408(b)(2)(C) which provides that payment for the auditor shall not be made by the provider of pharmacy benefit management services. One commenter said the covered plan should bear all the costs of the audit including the cost of providing the requested information.

The Department believes these comments were based on misinterpretation of the proposed cost sharing provision. The Department did not intend to establish a strict 50-50 cost splitting requirement; rather, as stated above, the proposal provided that the covered plan would pay for the selection and retention of the auditor and the covered service provider would pay for the costs of providing the required information. The Department does not believe this approach is inconsistent with ERISA section 408(b)(2)(C) which also provides that the payment from the auditor shall not be made by the provider of pharmacy benefit management services. Therefore,

the Department decided to adopt the cost sharing provision as proposed. The Department did not adopt the commenter's suggestion for the covered plan to bear the entire cost of the audit because we are concerned that approach would create a barrier to covered plans exercising audit rights.

In the proposal, the Department asked for comments on whether there are any circumstances in which the covered service provider should bear the entire cost of the audit, such as if the audit reveals a certain level of inaccurate disclosures. If commenters agreed, the Department asked how the final rule should identify a level of disclosure inaccuracy that would trigger the obligation for the covered service provider to bear the entire audit cost.

A few commenters expressed agreement with this approach but did not suggest a materiality threshold. One commenter suggested a threshold of a 5-percent deviation between disclosed and actual compensation in any of the categories, as an incentive for accurate disclosure. In considering these comments, the Department will not adopt a materiality standard without an objective threshold, based on the view that the lack of an objective threshold would lead to disputes related to whether a covered service provider would have the obligation to bear all the audit costs in any particular case. Moreover, the Department was not persuaded that the 5 percent threshold as suggested by one commenter represented a significant enough disparity to be used in the final rule as a threshold for the covered service provider to bear all the audit costs. Although the Department has used a 5 percent threshold for materiality elsewhere in the final rule, in those cases, the 5 percent threshold triggered an additional disclosure requirement. In the Department's view, a requirement that the covered service provider bear all the audit costs should not be based on the same threshold as provided for additional disclosures. Lacking more

specific suggestions and considering the burden this would create, the Department declined to adopt a provision under which covered service providers would bear all audit costs.

8.3. Provision of Data and Confidentiality

Some commenters argued that the audit right as proposed was problematic as it could require service providers to provide sensitive or proprietary information to auditors and responsible plan fiduciaries. Several commenters suggested that the final rule explicitly provide that covered services providers may limit use of data to the group health plan's purposes, noting that the new ERISA section 408(b)(2)(C) has similar language allowing reasonable restrictions (as determined by the Secretary) on confidentiality related to rebate contracts to prevent re-disclosure of such contracts *or use of such information in audits for purposes unrelated to the section*. The Department notes that the audit provision in the proposal addressed confidentiality concerns by allowing "reasonable confidentiality agreements to prevent redisclosure of such information." However, the Department believes adding additional language may help alleviate these concerns, so it has revised the language in paragraph (j)(3) of the final rule to allow "reasonable confidentiality agreements to prevent redisclosure of such information and to limit use of such information for purposes related to the covered plan's contract or arrangement."[189]

Some commenters expressed concern about the volume of information that may be requested as part of the audit and asked the Department to confirm that statistically valid sampling methodologies would be permitted. Other commenters said that sampling could be used to obscure potentially improper transactions. For the reason cited by this commenter, the Department determined not to expressly permit sampling under the final rule; but it notes that the

[189] As discussed below, paragraph (k)(4) of the final rule makes clear that information provided in the audit may be shared with State or Federal Government regulators or with legal counsel even if unrelated to the purpose of the covered plan's contract or arrangement.

audit provision is limited to "all records, claims and transaction-level data, and other information *reasonably necessary* to confirm the accuracy of any disclosure made to comply with this section . . . ." (Emphasis added).

Several commenters addressed access to claims and payment data. Some asked the Department to ensure that auditors would not be limited from accessing claims and payment data as needed for verifying the accuracy of the disclosures. Others suggested a more affirmative obligation to provide this information. As proposed, the audit provision required the covered service provider to make available to the auditor "all records, data, and other information reasonably necessary to confirm the accuracy of any disclosure made to comply with this section, including contracts with retail pharmacies and drug manufacturers . . . ." Although the Department believes that this language preserves access to data needed to confirm accuracy of disclosure, and that the rule is sufficiently tailored to require an audit of only that information used to produce the required disclosures, a reference to claims and transaction-level data was added to the final rule for avoidance of doubt. Paragraph (j)(3) of the final rule therefore provides that the covered service provider shall make available to the auditor "all records, claims and transaction-level data, and other information . . ." In sum, plan fiduciaries' auditors need access to material information to assess the quality and accuracy of the disclosures, as required in the rule, and the comments illustrate the need for an audit right. The Department believes that the audit provision in the rule is properly scoped to meet the needs of plan fiduciaries.

8.4. Timeframes

As in the proposed rule, the audit provision in the final rule preserves the right to an audit "[n]ot less than once per year." This approach leaves it to the parties to define "year" for this purpose, e.g., contract year, calendar year, or plan year. The Department invited comments on

whether the final rule should be more prescriptive on this point. Some commenters said it would be helpful to specify whether the reference to year meant contract year, plan year, or calendar year to avoid unnecessary disputes. One commenter noted that the audit provision in new ERISA section 408(b)(2)(C) is based on a "plan year" and recommended that the Department align with that approach. Other commenters suggested that the parties should retain flexibility to define the relevant "year." The Department determined after consideration of these comments to finalize the provision as proposed. The Department believes that allowing the parties flexibility to define the relevant year is preferable to specifying an approach that may not work for all covered plans.

Another commenter asked the Department to confirm that the language in proposed paragraph (j)(6), which provided that "the scope of the audit may be limited to the period covered by the disclosures under this section," was intended to mean that the scope of the audit could be limited to the period after the effective date of the final rule as applied to the particular covered service provider arrangement. The Department agrees that is the intent of this language and has changed "may be" to "is" for additional certainty.

One commenter asked the Department to define the period within which audit materials must be produced. Under proposed paragraph (j)(5), covered service providers would be required to provide information reasonably necessary to confirm the accuracy of disclosures within a "commercially reasonable period." The commenter said the phrase "commercially reasonable period" could lead to disputes about compliance. The commenter suggested that the final rule should specify that requested audit materials must be provided within a defined outside period, such as no more than 60 calendar days after receipt of the request, absent extraordinary circumstances. The Department agrees with this commenter that it is preferable to state a specific period for compliance, coupled with an exception for extraordinary circumstances, and therefore

has adopted the suggested 60-day timeframe absent extraordinary circumstances beyond the covered service provider's control.

8.5. Compliance with the Audit Requirement

Several commenters raised issues related to compliance with the audit requirement. One commenter asked for confirmation that failure to provide information in compliance with the audit provision would result in a prohibited transaction. Another commenter asked the Department to include a safe harbor protecting covered service providers from liability when information held by affiliates, agents, or subcontractors is not produced due to circumstances outside the covered service provider's control, provided the covered service provider exercises reasonable diligence to obtain and provide such information. In response, the Department confirms that a covered service provider's failure to provide information in compliance with the audit provision would result in a prohibited transaction, absent availability of another prohibited transaction exemption. In that event, the administrative prohibited transaction exemption granted in paragraph (n) of the final rule would be available to the responsible plan fiduciary to avoid liability. The covered service provider could be subject to a civil penalty under ERISA section 502(i), which authorizes the Secretary to assess a civil penalty on a party in interest in the case of a transaction prohibited by ERISA section 406. The Department declines to offer a safe harbor for such covered service providers but notes that its authority under ERISA section 502(i) is discretionary.

9. Manner of Disclosure – Paragraph (k)

Paragraph (k)[190] includes four separate provisions regarding the manner of disclosures under the regulation. Each is discussed below.

9.1. Plain Language

Paragraph (k)(1) specifies that all disclosures must be clear and concise, free of misrepresentations, and contain sufficient specificity to permit evaluation of the reasonableness of the contract or arrangement. The paragraph further specifies that, for example, the Department will consider the use of generic industry terms, jargon, or legalese, without definition, to lack the sufficient specificity required under the preceding sentence unless the language in question specifically refers to objectively determinable definitions, standards, or other similar guidelines that are publicly available or will be provided by the covered service provider to the responsible plan fiduciary free of charge and within a reasonable period of time following the request.

Commenters said disclosures should be clear, concise, and presented in plain language so that plan fiduciaries could understand and use them. Another commenter recommended requiring PBMs and related entities to define proprietary, specialized, or industry-specific terminology in plain language or link such terms to objective definitions. The Department agrees and therefore finalized as proposed.

9.2. Description of Compensation

With respect to descriptions of compensation required under the final rule, paragraph (k)(2) requires that they must be expressed as a monetary amount (for example, $1,000) and may be estimated to the extent that the actual amount is not reasonably ascertainable. However, the

[190] 29 CFR section 2550.408b-22(k).

disclosure must contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, an affiliate, an agent, or a subcontractor. Several commenters supported the requirement that compensation be expressed as a monetary amount, describing it as the single most important provision of this rulemaking. These commenters argued that formulas, percentages, and benchmark-based descriptions could obscure actual dollar flows and hinder meaningful transparency. Some commenters noted that their individual company experience demonstrates that monetary transparency is both feasible and commercially viable.

A few commenters supported the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b-2(c)(1)) and the statutory provision at ERISA section 408(b)(2)(B) framework in lieu of a monetary amount. However, many other commenters disagreed, stressing that formulas and percentages obscure actual dollars flowing to and from a covered plan. Several commenters suggested that, if the actual amount of compensation is not reasonably ascertainable, the estimated compensation should be grounded in a good faith assumption based on contractually defined methodologies, historical utilization, and rebate experience, or other reasonable information available at the time of disclosure. The Department agrees. Comments on the proposed paragraph (k)(2) and the Department's responses are discussed in section E.2.3 of this preamble.

9.3. Machine-Readability Format

Paragraph (k)(3) of the final rule provides that upon request of a responsible plan fiduciary, descriptions of compensation must be provided in a machine-readable file within a reasonable time after such request. The rule defines "machine-readable file" as a digital representation of data or information in a file that can be imported or read by a computer system

for further processing without human intervention, while ensuring no semantic meaning is lost. This requirement is designed to ensure that a responsible plan fiduciary can obtain information in this format if the responsible plan fiduciary determines that this will aid in its evaluation of the reasonableness of the contract or arrangement. Therefore, the contract or arrangement may not foreclose responsible plan fiduciaries from selecting the machine-readable format.

The Department received comments supporting this provision in the proposal. One commenter said the "upon request" approach strikes the correct balance because not every responsible plan fiduciary will have the capacity to process machine-readable data so requiring that format for all disclosures would be too burdensome.

Several commenters supported the use of machine-readable files to help facilitate actuarial analysis, benchmarking, comparison, oversight, and access to claims detail. A few commenters, however, argued that machine-readable files impose significant technical infrastructure costs on covered service providers. Others supported alternative formats to machine-readable files such as PDF, excel (.xlsx) and .csv files. Commenters explained that plain language disclosures can improve usability and comprehension for plan fiduciaries. Some commenters suggested that covered service providers should be required to provide information in formats negotiated and agreed upon by the covered plan. Several commenters requested the Department to establish a uniform, machine-readable schema to improve comparability, reduce ambiguity, and enhance usability.

In addition, several commenters said the Department should provide technical specifications with respect to the machine-readable format, with one commenter asking the Department to clarify that the Department's Transparency in Covered (TiC) prescription drug machine-readable file requirements, once implemented, will be deemed sufficient. The

Department agrees that machine-readable files can be useful to a responsible plan fiduciary but is finalizing the "upon request" structure to balance the need for transparency against the administrative burden of requiring machine-readable files as a default for every disclosure. For those responsible plan fiduciaries who request machine-readable files, the Department is considering future guidance to adopt a standardized disclosure framework under this rulemaking.

Some commenters requested that the Departments define what is a "reasonable time" under Paragraph (k)(3). Some suggested 30 days from the close of the most recent applicable semiannual period, or thirty days from the date of request, or whichever is sooner. The Department agrees that 30 days seems commercially reasonable but is declining to adopt a definition of "reasonable time" under this rulemaking given the limited number of comments it received.

9.4. Confidentiality Agreements

Paragraph (k)(4) addresses confidentiality agreements. The paragraph states that, except as provided in paragraph (j)(3), the covered service provider and its affiliates, agents, and subcontractors may not impose restrictions on the covered plan's use of disclosures required under this section, or the contract or arrangement described in paragraph (c)(1) of this section, with specific exceptions. Namely, the covered contract or arrangement may require the responsible plan fiduciary to require third parties with whom it shares the disclosures (and any subcontractors of the third parties) to execute reasonable confidentiality agreements that prevent redisclosure and also limit use of the disclosures to purposes related to the covered plan's contract or arrangement. Further, paragraph (k)(4)(ii) of the final rule adds language clarifying that neither paragraph (k)(4) nor paragraph (j)(3) would restrict a covered plan, auditor, or a third

party hired by the plan, or their subcontractors, from sharing information with State or Federal Government regulators or with legal counsel, even if the activities of those entities are unrelated to the purpose of a covered plan's contract or arrangement.

The primary purpose of paragraph (k)(4) is to ensure that covered service providers are not able to undermine responsible plan fiduciaries' efforts to evaluate their compensation by limiting the covered plan's ability to meaningfully use information in the disclosures, for example, by restricting responsible plan fiduciaries from sharing the information with other plan service providers, such as third-party auditors, consultants, attorneys, or advisors, and such service providers' subcontractors, for quality control, evaluation, comparing, benchmarking, renegotiating, and other purposes. At the same time, paragraph (k)(4) would protect covered service providers by ensuring covered plans take steps to prevent redisclosure of the information by third parties with whom covered plans share the disclosures (and the third parties' subcontractors), and use of the disclosed information for purposes unrelated to the covered plan's contract or arrangement.

Comments on confidentiality agreements addressed both the use of the disclosures by responsible plan fiduciaries and by third parties. Some commenters believed it was very important to ensure that covered service providers did not prevent responsible plan fiduciaries from using the disclosures to compare service provider offerings, for example, and from sharing the disclosures with third party service providers, such as consultants and legal counsel, or third-party subcontractors, such as data analytics service providers. Other commenters expressed concern about how third parties may use the information in the disclosures in other contexts and asked the Department to permit covered service providers to require reasonable confidentiality agreements governing the plan's use of the disclosed information, including limiting the use for

fiduciary purposes only. Commenters also referenced confidentiality provisions in ERISA section 726 and suggested a similar approach in the final rule.

The Department believes that the approach taken in the proposal generally strikes the correct balance in ensuring that responsible plan fiduciaries may share information with third party service providers (and their subcontractors) but also preventing further redisclosure. In response to commenters' concerns about how the information might be used by third parties, the Department has added language to the final rule permitting confidentiality agreements to limit use of disclosure information "to purposes related to the covered plans contract or arrangement." This is similar to language added in ERISA section 408(b)(2)(C) which permits, in the context of the audit provision, reasonable restrictions (as determined by the Secretary) on confidentiality to prevent redisclosure of disclosed rebate contracts or use of such information in audits "for purposes unrelated to this section." Under this language, service providers would not be able to use the disclosures in contexts other than services to the covered plan (with the exception for State and Federal Government regulators). In combination with the confidentiality provisions in the final rule's audit provision (paragraph (j)(3)), the Department believes this should, in large part, address commenters' concerns about confidentiality. The Department is concerned that commenters' suggestions to limit covered plans' and responsible plan fiduciaries' use of disclosure information to fiduciary oversight purposes might allow covered service providers to unnecessarily intrude on responsible plan fiduciaries' contracting processes, or could have other unintended consequences, and therefore did not incorporate any such limits.

10. Disclosure Errors – Paragraph (l)

Paragraph (l)[191] provides a rule for disclosure errors. Under the final rule, no contract or arrangement will fail to be reasonable under the regulation solely because the covered service provider, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the information required pursuant to paragraphs (e), (g), or (j), so long as the covered service provider discloses the correct information to the responsible plan fiduciary as soon as practicable, but not later than 30 calendar days from the date on which the covered service provider knows of such error or omission. Several commenters supported the approach taken in the proposal, and it was finalized as proposed.

11. Additional suggestions

11.1. Additional Disclosures or Other Provisions

A number of commenters suggested that the final rule should identify additional specific categories of compensation that would be required to be disclosed under the final rule. As discussed in section E.3.9 of this preamble, the final rule does not identify any additional specific compensation streams for disclosure because the requirement to disclose "other compensation" received in connection with the contract or arrangement would cover all such compensation.

The Department also received other suggestions for additional disclosures. These suggestions included disclosure of biosimilar adoption rates to evaluate whether the formulary is cost-effective, disclosure of the covered plans' regulatory status and applicable patient protections, disclosure of any circumstances when the compensation received by the PBM does not reflect fair market value, and others. The Department did not expand the final rule to include

[191] 29 CFR section 2550.408b-22(l).

these commenters' suggestions because of limited information about impact of the additional disclosures and the Department determined that the focus of the final rule should remain on the disclosures that had been proposed, as the Department believes they will be the most useful to the responsible plan fiduciaries of the larger self-insured group health plans in assessing the reasonableness of the contract or arrangement with the covered plan.

Other commenters asked for substantive provisions to be added to the final rule. For example, one commenter asked the Department to put in place an exception process for step therapy requirements in ERISA plans. Another commenter asked the Department to require PBMs serving ERISA plans to preference generic drugs when available. The Department determined that substantive provisions of this type are outside the scope of the rulemaking.

One commenter offered an alternative to the approach taken in the proposed rule that would involve disclosures the commenter referred to as core disclosures. These core disclosures related to categories already in the Department's proposal, including a description of services, a statement of fiduciary status, and a disclosure of direct and indirect compensation, although some of the disclosures would be at an aggregate level. The commenter suggested additional disclosure elements that would allow responsible plan fiduciaries to compare PBM services, including a rebate collection rate, a disclosure of the percentage of rebates shared with the plan, a calculation of gross rebates expressed on a per member per month basis, the number of pharmacies in the PBM's standard retail network, formulary exceptions: number and claims impact, number of covered drugs, and utilization management turnaround times, with additional disclosure for PBMs that operate or have a financial interest in an affiliated pharmacy. The Department has discussed above that it believes that the detailed disclosures under the final rule will assist responsible plan fiduciaries of the larger self-insured group health plans in assessing

the reasonableness of contracts or arrangements, so it has not adopted this commenter's suggestions for more aggregate disclosures. However, the Department found the commenter's suggestions for additional disclosures to enable comparison of PBM services potentially useful, and it will consider whether to incorporate the suggestions into future subregulatory guidance.

11.2. Bona Fide Services Fees

A few commenters suggested that the Department should specify as part of the final rule that providers of pharmacy benefit management services and their affiliates, agents, and subcontractors should only be compensated by "bona fide service fees" which the commenters said describes fees limited to fair market value of services and that are not tied to drug prices, rebates or other financial incentives. One commenter said the Department should opine that a fee would not be reasonable unless it meets this definition. The commenter noted that this concept is included in new subparagraph (C) of ERISA section 408(b)(2), which was part of the CAA, 2026 amendments to ERISA effective for plan years after August 3, 2028.[192] Another commenter said the Department should define acceptable compensation standards that separate PBM revenue from list prices.

The Department recognizes that the rebate pass-through provision in ERISA section 408(b)(2)(C) preserves covered service providers' ability to receive "bona fide services fees," indicating that Congress intended for parties to adjust their compensation arrangements accordingly. However, the Department believes that it is premature and beyond the scope of this

[192] ERISA section 408(b)(2)(C)(vi) ("Nothing in this subparagraph shall be construed to - . . . (I) prohibit reasonable payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not described in this subparagraph, provided such fees are transparent and quantifiable to group health plans and health insurance issuers; [or] (II) require a third-party administrator of a group health plan or covered service provider for pharmacy benefit management services under such health plan or health insurance coverage to remit bona fide service fees to the group health plan[.]").

final rule to establish herein that compensation arrangements involving rebates are per se unreasonable. The Department is considering future rulemaking or subregulatory guidance addressing what is a "bona fide service fee" under ERISA section 408(b)(2)(C).

11.3. Claims and Transaction-level Data

Many commenters asked the Department to require claims data and other transaction-level data be provided to responsible plan fiduciaries. Commenters argued that claims and transactions-level data originate from the group health plan and its participants and beneficiaries and therefore should be treated as a plan asset. Some of these comments asked the Department to confirm that such information would be available under the audit provision, which the Department has addressed in section E.8. of this preamble. The Department confirms that such information must be made available under the audit provision to the extent required to verify any, or all, of the disclosures required under this rule and has added that language to the regulatory text. However, the Department declines to mandate the affirmative disclosure of such data in this final rule outside of the context of an audit to verify disclosures, to keep the final rule focused on covered service provider, affiliate, agent, and subcontractor services, compensation and compensation arrangements.

11.4. Provide the Disclosures to the Department

Several commenters suggested that the final rule should require submission of the disclosures to the Department for oversight and enforcement purposes, and that the Department consider publishing information for other stakeholders to view and use. A few commenters suggested that reporting could be accomplished through the Form 5500 *Annual Return/Report of Employee Benefit Plan.* The Department believes that this rulemaking under ERISA section 408(b)(2) is properly focused on disclosures to responsible plan fiduciaries of covered plans, and

it is not prepared as part of this rulemaking project to create a reporting structure under which information would be provided to the Department, outside of the reporting provision in the administrative exemption in paragraph (n), which is discussed in section E.13 of this preamble. Likewise, expanding the Form 5500 is outside the scope of this rulemaking.

11.5. Standardized Template

Commenters also asked the Department to create a standardized data template to assist covered service providers as well as responsible plan fiduciaries. Commenters said this approach would support responsible plan fiduciaries in comparing arrangements. Some of these commenters suggested a standardized summary of the disclosures. The Department agrees and is considering developing a standardized template of the final rule's disclosure requirements to be made available following publication of the final rule.

11.6. Guidance and Interpretive Questions

Commenters asked the Department to provide guidance for responsible plan fiduciaries regarding how to evaluate the disclosures provided under the final rule. For example, several commenters asked the Department to establish a process-based safe harbor under ERISA section 404(a) for fiduciaries who follow a structured analytics process when selecting a covered service provider to a group health plan. One commenter outlined numerous benefits with a process-based safe harbor, including upfront due diligence in contract negotiation and vendor selection, reduced compliance burdens, enhanced participant protection, and statutory alignment that would create a unified compliance framework for the responsible plan fiduciary. The Department strongly agrees and is considering separate rulemaking under ERISA section 404(a) for group health plans.

Several commenters also asked the Department to establish safe harbors for fiduciaries who act in good faith to comply with their oversight obligations. Commenters also raised some interpretive questions that they asked the Department to respond to in the final rule. These questions included the status of plan data as a plan asset, the distinction between settlor and fiduciary functions in the context of pharmacy benefits, and whether disclosures under the rule are considered plan documents under ERISA section 104(b). The Department has not responded to these interpretive questions in the final rule's preamble but will consider requests for subregulatory guidance following publication of the final rule.

Commenters also asked the Department to state that the final rule would not preempt state licensing and regulation of pharmacy benefit management provisions. The Department is of the view that the preemption of state laws would be an interpretive matter that would not be addressed by a provision in the final rule, and therefore, the Department has not added a provision or statement in the final rule regarding preemption.

12. Privacy Issues

In addition to the confidentiality provisions contained in paragraph (k)(4) addressing the ability of self-insured group health plans to disclose information to third parties (and the third parties' subcontractors) received from covered service providers, the Department has considered the level of personally identifiable information that may be contained in those disclosures. Under ERISA section 726, Congress included privacy requirements applicable to the entities providing pharmacy benefit management services.[193] Under the privacy requirements, information disclosed to group health plans from entities providing pharmacy benefit management services

[193] ERISA section 726(b)(4).

pursuant to ERISA section 726 must comply with the privacy regulations promulgated under section 13402(a) of the Health Information Technology for Economic and Clinical Health Act at 42 USC 17932(a) and the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (collectively, the HIPAA privacy regulations). Under these privacy regulations, the information provided to group health plans must contain only summary health information as defined in 45 CFR 164.504(a). The privacy regulations also restrict the group health plan's further sharing of the information disclosed under ERISA section 726 only to the entity that provided the information to the group health plan (i.e., the entity providing pharmacy benefit management services), that entity's business associates as defined in 45 CFR 160.103, or as permitted by the HIPAA privacy regulations.

Many commenters requested that the Department consider addressing privacy protections in the final rule and specifically requested that use and disclosure of the information contemplated in this rule be consistent with HIPAA. Commenters suggested the Department look to the privacy protections contained in ERISA section 726 as a framework for addressing privacy in this rule. Commenters raised that group health plans should be able to share information they receive from covered service providers with HIPAA compliant business associates they contract with such as consultants, auditors, and actuaries, to assist group health plans with analysis of the information. Some commenters requested that the Department clarify that covered service providers cannot restrict group health plans' access to protected health information under HIPAA.

As part of the Department's effort to align this rule with the CAA, 2026 amendments, the Department is applying the privacy protections contained in ERISA section 726 to the

disclosures required under this final rule. Under ERISA section 726, Congress has set forth privacy protections when entities providing pharmacy benefit management services on behalf of group health plans are required to disclose information with respect to the compensation those entities receive for those services and for the costs of drugs they place on the group health plan's formulary. As discussed in section D. of this preamble, there are similarities between ERISA section 726 and this final rule in the information required to be disclosed and in the parties disclosing and receiving the information, and thus the same privacy concerns that arise under ERISA section 726 apply to the disclosures in this final rule under ERISA section 408(b)(2) as well. Therefore, the Department is of the view that the HIPAA privacy protections contained in ERISA section 726, including the limitation to summary health information, only applies to the disclosures under this final rule. Nothing in ERISA section 726 should be construed to limit or otherwise affect a group health plan's access to claims or transaction level-data, including in respect of the audit provisions of this final rule, otherwise permitted or required under ERISA, HIPAA, or other appliable law.

13. Consequences of Non-Compliance and Proposed Administrative Class Exemption for Responsible Plan Fiduciary – Paragraph (n)

13.1. Statutory Framework

As directed by President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First*, this final rule aims to promote transparent pricing and create a fairer and more competitive prescription drug market that lowers costs and ensures accountability across the healthcare system. Responsible plan fiduciaries of covered plans will be able to use the disclosures in their process of selecting a provider of pharmacy benefit management services, engaging an affiliated broker or consultant, monitoring these service

providers' operations and compliance with contractual obligations, and in analyzing the drivers of prescription drug costs.

In this regard, responsible plan fiduciaries must determine that service provider relationships involving the covered plan meet certain conditions in an exemption to avoid constituting a prohibited transaction under ERISA. Specifically, unless an exemption applies, the furnishing of goods, services, or facilities between a self-insured group health plan and a party in interest to the plan is a prohibited transaction under ERISA section 406(a)(1)(C). A person providing services to the self-insured group health plan is defined by ERISA to be a "party in interest" to the self-insured group health plan.

ERISA section 408(b)(2) exempts certain arrangements between ERISA-covered plans (including larger self-insured group health plans) and service providers that otherwise would be prohibited transactions under ERISA section 406. Section 408(b)(2) provides relief from ERISA's prohibited transaction rules for service contracts or arrangements between a plan and a party in interest if the contract or arrangement is reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid for the services.

If the terms of an exemption are not satisfied, responsible plan fiduciaries entering into service arrangements with parties in interest to self-insured group health plans, and the parties in interest themselves, may be subject to enforcement action by the Department and imposition of a civil penalty.[194] The Department's enforcement will be aided by the requirement in the

[194] ERISA section 502(a)(5) provides that "the Secretary may bring a civil action to enjoin any act or practice which violates any provision of ERISA . . . or to obtain other appropriate equitable relief (i) to redress such violation or (ii) to enforce any provisions of this title or the terms of the plan." ERISA section 502(i) authorizes the Secretary to assess a civil penalty on a party in interest in the case of a transaction prohibited by ERISA section 406.

administrative class exemption in paragraph (n) (discussed in the next section) that plan fiduciaries report to the Department a covered service provider's non-compliance with the disclosure or audit provisions.

A number of commenters on the Department's proposed rule raised concerns that the prohibited transaction framework under which the rule was proposed would result in insufficient incentives for compliance by providers of pharmacy benefit management services and, relatedly, that the final rule placed too much responsibility on responsible plan fiduciaries to identify noncompliance. Some commenters referenced the need for civil penalties. In the Department's view, the approach in the final rule will allow the Department to be alerted to instances of noncompliance, but that is not the only means by which noncompliance could be discovered; and, the Department retains its investigative authority under ERISA. In addition, as set forth above, the Department has authority under ERISA section 502(i) to assess a civil penalty against a party in interest in the event of a prohibited transaction.

13.2. Administrative Class Exemption

The Department recognizes that there may be circumstances when a responsible plan fiduciary enters into (or extends or renews) a contract or arrangement that appears to meet the requirements of this final rule under ERISA section 408(b)(2), but the covered service provider fails to comply with its obligations, including by not disclosing the required information or failing to comply with an audit request. Without an exemption, the covered service provider's failure would result in a prohibited transaction by both the service provider and the responsible plan fiduciary.

The Department proposed an administrative class exemption in paragraph (n) to provide relief for responsible plan fiduciaries in the event covered service providers fail to comply with

the regulation, consistent with the approach in ERISA section 408(b)(2)(B)(viii) and the Department's service provider regulation for pension plans (29 CFR 2550.408b-2(c)(1)(ix)), both of which provide exemptions for responsible plan fiduciaries who do not receive necessary disclosures from covered service providers to their ERISA-covered plans or are impeded in their right to access information related to the contract or arrangement as required under the regulation.

After consideration of comments, as discussed below, the Department has determined to adopt paragraph (n) in the final rule,[195] with minor modifications. The exemption provides responsible plan fiduciaries with relief from the restrictions of ERISA section 406(a)(1)(C) and (D) if, among other things, the responsible plan fiduciary did not know that the covered service provider failed to comply with the final rule and "reasonably believed" that the regulatory requirements were satisfied.[196] Upon discovery of a failure to comply, the responsible plan fiduciary must take certain specified steps within designated timeframes, as described in paragraphs (n)(1) and (2), including notifying the Department of any failures that are not corrected within the designated timeframes. In this way, the administrative class exemption will facilitate oversight by the Department of those covered service providers that fail to comply with the regulation. Paragraphs (n)(3) and (4) set forth the timing, content and other requirements applicable to the notice required to be filed with the Department by the responsible plan fiduciary. The Department notes that parties seeking to avail themselves of the relief provided by

[195] 29 CFR section 2550.408b-22(n).

[196] The Department notes that the fact that the service transaction, for the responsible plan fiduciary, is the subject of an exemption will not relieve the covered service provider, as the other party in interest to the transaction, from ERISA's prohibited transaction provisions. Thus, regardless of the relief available to the responsible plan fiduciary pursuant to paragraph (n) of the final rule, a disclosure failure or other failure to comply with the final rule will nonetheless result in a prohibited transaction and potential civil penalty or liability on the part of the covered service provider.

the exemption would need to be able to demonstrate compliance with the conditions of the exemption.

In the proposal, the Department requested comments on the administrative class exemption. The Department received several comments in support of the administrative class exemption and its protection for fiduciaries acting in good faith. While some commenters suggested that the full burden of a covered service provider's failure to provide complete and accurate disclosures should fall on the covered service provider, many appreciated the balance between ensuring transparency and avoiding unfair liability for circumstances outside of the responsible plan fiduciary's control.

Some commenters requested that the notifications received by the Department from responsible plan fiduciaries should be used to bring enforcement actions against providers of pharmacy benefit management services that engage in noncompliance, evasion, or unreasonable compensation practices. According to a commenter, this proactive approach is necessary to deter such providers from improper disclosure. While the Department is not making any changes to the text of paragraph (n) to address this comment, the Department reiterates its position from the proposal that "[t]he Department's enforcement will be aided by the requirement . . . that plan fiduciaries report to the Department a service provider's non-compliance with the disclosure or audit provisions."[197]

One commenter supported the proposed administrative exemption but asked that it be expanded to cover third party administrators (TPAs), in addition to responsible plan fiduciaries. According to this commenter, a plan may contract with a TPA under an administrative services-

[197] Improving Transparency into Pharmacy Benefit Manager Fee Disclosure, 91 FR 4348, 4372 (Jan. 30, 2026).

only contract, and the TPA subcontracts with a PBM to administer the pharmacy benefit to the plan. If the PBM does not comply with the requirements of the regulation, the responsible plan fiduciary would be required to name the TPA under the administrative exemption. The commenter expressed concern that this exposes the TPA to liability for failures outside their control and could chill TPA-PBM subcontracting arrangements. To address this, the commenter requested an administrative exemption for TPAs that exercise due diligence and rely on a PBM for preparation of required disclosures.

The Department declines to expand the exemption in this way. As described in the proposal, the exemption is necessary for the responsible plan fiduciary to avoid engaging in a prohibited transaction when the covered service provider fails to meet its obligations.[198] In requesting additional relief, the commenter did not provide an explanation for the types of prohibited transactions in which a TPA would engage. Additionally, the commenter did not explain how additional exemptive relief for TPAs would protect plans, their participants and beneficiaries. If TPAs need relief from the prohibited transaction provisions, they can apply for an administrative exemption under the Department's Procedures Governing the Filing and Processing of Prohibited Transaction Exemption Applications.[199]

13.3. Terminating the Contract

Paragraph (n)(5) of the administrative exemption addresses the potential that the responsible plan fiduciary would terminate the contract or arrangement in connection with the covered service provider's failure to comply with its obligations under the final rule. It provides that if the covered service provider fails to comply with the written request to correct the failure

[198] "Without an exemption, the covered service provider's failure would result in a prohibited transaction by both the service provider and the responsible plan fiduciary." 91 FR at 4372.
[199] 29 CFR 2570.30–2570.52.

within 90 calendar days of such request, the responsible plan fiduciary shall determine whether to terminate or continue the contract or arrangement consistent with its duty of prudence under ERISA section 404 and shall document the basis for that determination.

This provision is based on a similar provision in ERISA section 408(b)(2)(B)(viii)(IV), and the Department's service provider regulation for pension plans, but it does not include language from these sources that suggests that a responsible plan fiduciary must always terminate a contract or arrangement with a noncompliant covered service provider if the failure to disclose relates to future services. Although the provisions in ERISA section 408(b)(2)(B)(viii)(IV) and the Department's service provider regulation for pension plans provide that the contract or arrangement must be terminated as "expeditiously as possible, consistent with the duty of prudence," the Department is wary of imposing an absolute requirement to terminate a contract as a condition of obtaining the prohibited transaction relief under paragraph (n) because it could cause concerns about the responsible plan fiduciary's ability to prudently provide for plan benefits. Such a requirement to terminate could be read as precluding a responsible plan fiduciary from continuing a contract or arrangement for some period even if, taking into account surrounding facts and circumstances, it reasonably determines that it would be prudent and in the best interest of participants and beneficiaries to do so.

The Department solicited comments on this approach in the proposal and received several comments supporting the proposed administrative exemption's flexible approach. Commenters emphasized that requiring termination of a service provider contract could harm plan participants, including by denying their continuity in access to benefits and health care services. One commenter requested the Department add a condition that, absent extraordinary circumstances, a contract or arrangement with a noncompliant service provider should not extend

beyond the end of the current plan year without corrective action. Another commenter suggested that the provisions in paragraph (n)(5) describing the termination of a services contract or arrangement should apply only when the fiduciary believes the noncompliance is material and requested that the Department confirm that a plan fiduciary is not required to terminate a service arrangement based solely on a material disclosure deficiency. The Department does not agree that there should be a specific "extraordinary circumstances" or "materiality" requirement governing whether the contract or arrangement should continue beyond the plan year, but instead thinks it is appropriate to retain the overarching requirement that a fiduciary would make this determination consistent with its duties of prudence and loyalty.

Some commenters supported the Department's flexible approach, but suggested that, in order to ensure such flexibility is not abused, the Department should add a requirement that the responsible plan fiduciary document its analysis of whether it is prudent to continue a service or arrangement with a PBM that has failed to comply with the applicable conditions. Documentation would allow the Department to monitor whether responsible plan fiduciaries do terminate contracts and thus determine whether the flexibility is being abused by fiduciaries who fail to act on disclosed non-compliance.

The Department is revising paragraph (n) to add this documentation requirement. As granted, paragraph (n)(5) reads, "If the covered service provider fails to comply with the written request under paragraph (n)(1)(ii) of this section within 90 calendar days of such request, the responsible plan fiduciary shall determine whether to terminate or continue the service contract or arrangement consistent with its duty of prudence under section 404 of the Act, and shall document the basis for that determination." This documentation should not be a mere check the box exercise, but reflect the responsible plan fiduciary's considerations, alternatives, and how the

responsible plan fiduciary will ensure no further compliance failures. Responsible plan fiduciaries should also retain the documentation in case a need arises to demonstrate to the Department compliance with the administrative class exemption.

Some commenters expressed concern about the timing requirements in the proposed administrative exemption, particularly that responsible plan fiduciaries notify the Secretary within 90 calendar days of a covered service provider's failure to comply. One commenter asked about interim protections for plans and beneficiaries during the 90-day period. Another commenter said that 90 days is an insufficient remediation period because a responsible plan fiduciary may not be able to find a replacement service provider within 90 days and would risk losing exemption protection.

The Department notes that nothing in the exemption requires plan fiduciaries to terminate or even decide whether to terminate a services contract or arrangement within 90 days. Responsible plan fiduciaries are required to request in writing that the covered service provider correct the failure "upon discovering that the covered service provider failed to meet any requirement." If the covered service provider fails to comply with that requirement within 90 calendar days of the request, then the responsible plan fiduciary must notify the Secretary of the failure and determine whether to terminate the contract. At all times, the responsible plan fiduciary must continue to act in the interests of the plan, its participants and beneficiaries.

13.4. Findings

The Department is granting the administrative class exemption in paragraph (n) pursuant to its authority under ERISA section 408(a) and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (89 FR 4662 (Jan. 24, 2024)). The attention of interested persons is directed to the following: (1) the fact that a transaction is the subject of an exemption under

ERISA section 408(a) does not relieve a fiduciary, or other party in interest with respect to a self-insured group health plan, from certain other provisions of ERISA, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404 which require, among other things, that a fiduciary act prudently and discharge his or her duties respecting the plan solely in the interests of the participants and beneficiaries of the plan; (2) the Department finds that the administrative class exemption is administratively feasible, in the interests of self-insured group health plans and their participants and beneficiaries and protective of the rights of participants and beneficiaries of the self-insured group health plans; (3) the administrative class exemption is applicable only to transactions that satisfy the conditions specified in the exemption; and (4) the administrative class exemption is supplemental to, and not in derogation of, any other provisions of ERISA, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

14. Statutory Authority for and Placement of the Final Rule

14.1. Statutory Authority

Section 408(b)(2)(A) of ERISA exempts from the prohibitions of ERISA section 406(a) "reasonable" contracts or arrangements with a party in interest, including a fiduciary, for office space, or legal, accounting, or other services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid. Section 408(b)(2)(B) of ERISA clarifies that, in the case of a covered service provider who provides services to group health plans no such contract or arrangement is "reasonable" unless the disclosure requirements in subparagraph (iii) of section 408(b)(2)(B) of ERISA are satisfied.

As originally enacted, ERISA section 408(b)(2)(B) described two categories of covered service providers to group health plans, namely providers of "brokerage services" and "consulting services" with respect to certain sub-services, although these terms were undefined. CAA, 2026 amended ERISA section 408(b)(2)(B) and broadened its scope to make clear that it encapsulated a much wider array of covered service providers who provide services to group health plans, including providers of pharmacy benefit management services.[200] It also provided specific regulatory authority to the Secretary of Labor to address time, manner, and content of disclosures under that subsection.[201] Therefore, the Department is relying on its authority to regulate entities providing pharmacy benefit management services and entities providing advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, and who are affiliated with providers of pharmacy benefit management services, pursuant to sections 505 and 408(b)(2)(B) of ERISA.

Several commenters argue the Department exceeded the statutory authority granted to it in ERISA section 408(b)(2) by extending beyond direct compensation paid by the plan for services. The Department disagrees.

As discussed in section C of this preamble, section 408(b)(2) provides relief from ERISA's prohibited transaction rules for service contracts or arrangements between a plan and a party in interest if the contract or arrangement is reasonable, the services are necessary for the establishment or operation of the plan, and no more than reasonable compensation is paid for the services. Section 408(b)(2)(B)(iii) closely tracks the Department's regulation for pension plan

[200] *See* ERISA section 408(b)(2)(B)(ii)(I)(bb) (AA) and (BB).
[201] *See* ERISA section 408(b)(2)(B)(iii) ("A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following (in accordance with regulations issued by the Secretary, addressing time, manner, and content of such disclosures) . . .").

services arrangements. It requires covered service providers to group health plans to disclose the following to take advantage of the exemption: the services to be provided; the status of the covered service provider, an affiliate, or subcontractor as a fiduciary, if applicable; the direct and indirect compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors.

Several commenters noted that Congress acted in the CAA, 2026 amendments specifically to clarify the meaning and scope of "services" under ERISA section 408(b)(2)(B). According to a comment submitted by the U.S. House Committee on Education and the Workforce in response to this rulemaking, Congress replaced the narrow "brokerage" and "consulting" terminology with a detailed and expansive list of services to confirm that ERISA section 408(b)(2)(B) reaches the full range of services that affect plan participants' access to and cost of health benefits. To put it another way, Congress made these changes to section 408(b)(2)(B) so that covered service providers performing *any* of the services enumerated in the statute must disclose both direct and indirect compensation to a group health plan.[202]

The Department is of the view that the CAA, 2026 did not alter these substantive disclosure obligations. Furthermore, in specifying that the disclosure obligation under the exemption extends to "indirect compensation," Congress clearly intended that payments from third parties and the related arrangements under which such payments are made are appropriate and necessary subjects

[202] As discussed in section D of this preamble, entities that do not provide pharmacy benefit management services and who are not affiliates of such entities that provide advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, but who otherwise provide *any* of the services enumerated under ERISA section 408(b)(2)(B) to group health plans and meet the compensation threshold are obligated to make disclosures in accordance with the statute to rely on the exemption. In this regard, EBSA is providing a temporary enforcement policy for those providers as discussed in section D.

of disclosure. The Department is well within its authority to require disclosure of payments from, and arrangements with, drug manufacturers, third party administrators, and others. For these reasons, the Department disagrees that it exceeded the statutory authority granted to it in ERISA section 408(b)(2) by extending beyond direct compensation paid by the plan for services.

Several commenters also argue that ERISA section 726, as enacted by the CAA, 2026, preempts or limits the Department's ability to engage in this rulemaking. The Department disagrees.

As discussed in section D of this preamble, Congress added ERISA section 726, as part of the CAA, 2026. ERISA section 726 establishes new disclosure and reporting obligations for entities that provide pharmacy benefit management services to group health plans and health insurance issuers in Part VII of ERISA, outside of the prohibited transaction framework in Part IV of ERISA.

As one stakeholder commented, section 726 of the CAA, 2026 contains no preemptive language; it does not prohibit the Department from rulemaking under ERISA section 408(b)(2), nor does it state that its provisions are exclusive or that other disclosure regimes are barred. Congress was aware of the E.O. 14273 (Apr. 2025) directing the Department to improve employer health plan fiduciary transparency through rulemaking. Prior to enacting the CAA, 2026, Congress could have prohibited the Department from rulemaking under ERISA section 408(b)(2)(B) or it could have included preemptive language – it intentionally did not. Instead, Congress *doubled down* and strengthened the Secretary's authority to issue regulations governing the time, manner, and content of the required disclosures by covered services providers to group health plans required under ERISA section 408(b)(2)(B)(iii).

Even so, in addition to its authority under ERISA section 408(b)(2), the Department has the express authority under ERISA section 505 to "prescribe such regulation as [it] finds necessary and appropriate" and to "define accounting, technical and trade terms." This authority is undisturbed by the new provisions of the CAA, 2026.

For these reasons, the Department disagrees that Congress preempted this rule or limited the Department's rulemaking authority by passing ERISA section 726, as enacted by the CAA, 2026.

A few commenters argued that the Department failed to provide adequate notice of its legal theory after the passage of the CAA, 2026. The Department disagrees. Contrary to commenters' assertions, the proposed rule clearly identified ERISA section 408(b)(2) and section 505 as the source of the Department's authority to prescribe these regulations.

A few commenters also asserted that the Department somehow changed its legal theory when it extended the comment period for this rule by 15 days, following the enactment of the CAA, 2026. This mischaracterizes the Department's actions. After Congress enacted the CAA, 2026, the Department extended the comment period for 15 days for the express purpose of allowing stakeholders to evaluate and comment on whether the rule should be adjusted due to the new statutory provisions. The Department chose to draw the public's attention to the CAA, 2026 and specifically seek comments on the interaction with the proposal to ensure robust public input on that matter. Commenters had notice and a full opportunity to submit comments on the interaction with the CAA, 2026, including the statutory authority, as evidenced by the substantial volume of comments addressing precisely these issues.

14.2. Placement

This final rule, establishing disclosure requirements for covered service providers to covered plans, will appear at 29 CFR 2550.408b-22. In connection with this final rule, the Department is also revising its existing service provider regulation (29 CFR 2550.408b-2(c)(2)) in the Code of Federal Regulations to cross-reference the final rule.

15. Severability

The Department proposed under paragraph (o) that if any provision of the rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof. The Department did not receive any comments on this provision. The final rules adopt this provision in paragraph (o)[203] without change.

16. Effective and Applicability Dates – Paragraph (p)

Paragraph (p)[204] provides both an effective date and an applicability date for the final rule. Under paragraph (p)(1), the final rule is effective 60 calendar days after the date of the publication in the Federal Register. Once effective, however, paragraph (p)(2) provides that the rule is applicable to plan years beginning on or after July 1, 2027. This approach is intended to balance the need for prompt action to increase transparency into contracts and arrangements with PBMs and affiliated brokers and consultants with due concern for the cost and burden associated

[203] 29 CFR section 2550.408b-22(o).
[204] 29 CFR section 2550.408b-22(p).

with revising current and future contracts or arrangements to satisfy the requirements of the final rule.

In the proposal, the Department stated that the rule would be effective 60 days after publication and applicable for plan years beginning on or after July 1, 2026. Commenters said that operational changes would be needed and that proposed timeframe would be infeasible given the likely timing of issuance of the final rule. Some commenters suggested that one year would be needed from finalization of a final rule. Other commenters urged the Department not to delay finalizing so that responsible plan fiduciaries could receive the benefits of the disclosures under the final rule as soon as possible.

The provisions in this final rule implement those statutory disclosure requirements in section 408(b)(2)(B), dictating against delaying applicability longer than necessary to allow parties to develop compliance structures. Accordingly, the Department has made the final rule effective **[INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]** and applicable to plan years beginning on or after July 1, 2027.

F. Regulatory Impact Analysis

Summary

The Department has examined the impacts of this final rule as required by Executive Order 12866,[205] Executive Order 13563,[206] Executive Order 14192,[207] the Paperwork Reduction

[205] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).
[206] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011).
[207] Unleashing Prosperity Through Deregulation, 90 FR 9065 (Feb. 6, 2025).

Act of 1995,[208] the Regulatory Flexibility Act,[209] section 202 of the Unfunded Mandates Reform Act of 1995,[210] Executive Order 13132,[211] and the Congressional Review Act.[212]

1. Executive Orders 12866, 13563 and 14192

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, "significant" regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that may:

> (1) Have an annual effect on the economy of $100 million or more
> or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as "economically significant");
>
> (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
>
> (3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

[208] 44 U.S.C. 3506(c)(2)(A). (1995).
[209] 5 U.S.C. 601–612 (1980).
[210] 2 U.S.C. 1501–1504 (1995).
[211] Federalism, 64 FR 43255 (Aug. 10, 1999).
[212] 5 U.S.C. 801–808 (1996).

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

This final rule seeks to build upon the existing provisions of ERISA section 408(b)(2), as amended, including the 2012 final regulation and relevant provisions of the CAA, 2021 and CAA, 2026. Based on the Department's estimates, OMB's OIRA has determined this rulemaking is economically significant per Executive Order 12866 section 3(f)(1) as it is likely to have an impact of $100 million or more in any one year. The Department has provided an assessment of the potential costs, benefits, and transfers, associated with this final rule, and OMB has reviewed this final rule.

Executive Order 14192, titled "Unleashing Prosperity Through Deregulation," was issued on January 31, 2025. Section 3(a) of Executive Order 14192 requires an agency, unless prohibited by law, to identify at least ten existing regulations to be repealed when the agency issues a new regulation. In furtherance of this requirement, section 3(c) of Executive Order 14192 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with prior regulations. A significant regulatory action (as defined in section 3(f) of Executive Order 12866) that would impose total costs greater than zero is considered an Executive Order 14192 regulatory action. The final rule would require covered service providers, including PBMs, to provide fee and compensation structure disclosures to responsible plan fiduciaries of large self-insured group health plans. As such, this final rule is considered regulatory and is expected to contribute to the Department's regulatory burden under Executive Order 14192.

2. Introduction and Need for Regulation

The rising cost of pharmaceutical drugs has been an increasing concern for the U.S. healthcare system in recent years. Between January 2022 and January 2023, nearly 5,900 prescription drug products in the National Drug Code Directory reported a price change, with more than 70 percent (4,300) of these products experienced an increase in their manufacturer list price, and 46 percent (2,000) of those price increases exceeded the rate of inflation.[213] While the annual average rate of prescription price increase has fallen in recent years, prescription drug spending in the U.S. still increased by 7.9 percent in 2024 to $467.0 billion, driven by increased utilization and the entry of new drugs.[214] Despite this growth, the share of total health spending on prescription drugs has remained relatively stable over time (increasing from 7.4 percent in 1970 to 8.8 percent in 2024).[215]

However, an increasing share of these costs appears to have shifted from individuals directly to insurance. According to the National Health Expenditure Accounts (NHEA) data, public and private health insurance accounted for only 16 percent of national prescription drug spending in 1970, increasing to 87 percent in 2024, with out-of-pocket and other third-party payers and programs making up the balance.[216] Moreover, a survey of large employers reported that pharmacy costs are consuming an increasing share of their healthcare budgets, with a

[213] Arielle Bosworth, Steven Sheingold, Kenneth Finegold, Bisma A. Sayed, Nancy De Lew, Benjamin D. Sommers, Changes in the List Prices of Prescription Drugs, 2017–2023, ASPE Office of Health Policy, October 6, 2023.
[214] Centers for Medicare & Medicaid Services, *National Health Expenditure Data*, *NHE Fact Sheet*, available at https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet
[215] Centers for Medicare & Medicaid Services , *National Health Expenditure Accounts, National Health Expenditures Data, National Health Expenditures by Type of Service and Source of Funds, CY 1960–2024*, available at https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical
[216] Centers for Medicare & Medicaid Services , *National Health Expenditure Accounts*, National Health Expenditures *Data, Table 16. Retail Prescription Drugs Expenditures 1970–2024*, available at https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical.

median of 24 percent of employer healthcare spending in 2024 and employers expecting an 11 to 12 percent annual increase in pharmacy costs in 2025 and 2026.[217]

Due to the complexity of the pharmaceutical supply chain and the multitude of players involved in the sourcing, manufacturing, distribution, and delivery of pharmaceutical products to end-users, responsible plan fiduciaries of self-insured group health plans often outsource pharmacy benefit management services to intermediaries, such as PBMs. PBMs manage and administer prescription drug benefits between the self-insured group health plans, pharmacies, pharmaceutical companies, and other intermediaries. In this capacity, PBMs develop prescription drug formularies and benefit designs for self-insured group health plans, negotiate rebates with drug manufacturers for placement on those formularies, establish preferred pharmacy networks, and process prescription drug claims. As a result, PBMs influence multiple aspects of self-insured group health plans' prescription drug benefit design, affecting costs and fees, while responsible plan fiduciaries are charged with monitoring the PBMs' actions to ensure the service contract or arrangement is reasonable.

2.1. Fiduciary Challenges of Monitoring PBMs

Under ERISA, the persons responsible for hiring the self-insured group health plan's service providers are plan fiduciaries. In the PBM context, these "responsible plan fiduciaries" may be the self-insured group health plans' sponsor or another fiduciary such as a committee made up of plan sponsor employees. Responsible plan fiduciaries are required to act solely in the interests of plan participants and their beneficiaries when administering plan benefits and to ensure that plan assets are used exclusively to provide benefits and pay plan expenses. While

[217] Business Group on Health, *Executive Summary: 2026 Employer Health Care Strategy Survey,* (Aug. 19, 2025), available at https://www.businessgrouphealth.org/resources/2026-employer-health-care-strategy-survey-executive-summary.

they may engage service providers to provide benefits for the plan, plan fiduciaries are responsible for prudently negotiating terms when entering a contract, so that only reasonable and necessary costs are paid, and conflicts of interest are disclosed and mitigated. They are also required to monitor service providers' performance. Moreover, for these responsible plan fiduciaries to avoid a prohibited transaction by relying on ERISA section 408(b)(2), they must determine, among other things, that the contract or arrangement is reasonable.

In the prescription drug space, these responsibilities can be particularly challenging, as plan fiduciaries often contract with a PBM to administer the self-insured group health prescription drug coverage, create the self-insured group health plan's formulary with varying cost-sharing amounts, and manage participant claims and appeals. In doing so, PBMs may separately enter into agreements with multiple entities, including with pharmacies to dispense drugs and with manufacturers for rebates to guarantee preferred placement on the self-insured group health plan's formulary. As a result of those independent relationships, PBMs may have numerous conflicts of interest related to providing prescription drug services as well as several different payment streams that responsible plan fiduciaries are required to monitor in accordance with their fiduciary duties to ensure that the compensation related to these services is reasonable.

Failure to adequately fulfill their responsibility risks legal action for responsible plan fiduciaries. In recent years, multiple cases have been brought by plan participants claiming that their plan fiduciaries did not fulfill their fiduciary responsibilities regarding PBM services by incurring excessive fees, failing to negotiate better pricing terms for prescription drugs, and not behaving prudently when selecting the plan's PBM.[218] These cases highlight the plaintiffs'

[218] See Knudsen v. MetLife Grp., Inc., 117 F.4th 570 (3d Cir. 2024); Navarro v. Wells Fargo & Co., No. 24-CV-3043 (LMP/DTS), 2025 WL 897717 (D. Minn. Mar. 24, 2025); Lewandowski v. Johnson & Johnson, No. CV 24-671 (ZNQ) (RLS), 2025 WL 288230 (D.N.J. Jan. 24, 2025).

expectation that responsible plan fiduciaries scrutinize the agreements they enter into with PBMs, including by analyzing compensation disclosures, rooting out conflicts of interest, and auditing PBM's performance to ensure that prescription drug benefits are managed transparently, in accordance with the health plan documents and ERISA, and in the best interest of plan participants.

Often, though, the underlying agreements that PBMs negotiate on behalf of self-insured group health plans with drug manufacturers and pharmacies for these services are not shared with the self-insured group health plans themselves, nor are the relationships between PBMs and their affiliates. Contracts between PBMs and self-insured group health plans often include savings guarantees based on list prices rather than net prices, the latter of which are not disclosed. These contracts may fail to disclose the size of rebates or rebate terms, and limit the self-insured group health plan's right to audit.[219] Such an arrangement, which prevents self-insured group health plans' responsible plan fiduciaries from evaluating drug utilization and spending, the cost effectiveness of the formulary, and the gross profit of the PBM, "deprives employers of the ability to completely understand the drug benefit design, evaluate the efficiency of their drug utilization, and assess the PBM's performance."[220] According to the 2024 KFF Employer Health Benefits Survey, of employers with 500 or more workers that offer health benefits, 37 percent did not know how much was received in rebates negotiated by their PBM or

[219] Robin Feldman, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers Testimony* (Mar. 30, 2023), at the U.S. Senate, Finance Committee, available at https://www.finance.senate.gov/imo/media/doc/Feldman%20Written%20Testimony%20.pdf.
[220] Ge Bai, Mariana P. Socal, & Gerard F. Anderson, *Policy Options to Help Self-Insured Employers Improve PBM Contracting Efficiency*, Health Affairs Blog (May 29, 2019), available at https://www.healthaffairs.org/content/forefront/policy-options-help-self-insured-employers-improve-pbm-contracting-efficiency.

health plan,[221] suggesting that many plans and their sponsors have little insight into PBM rebate practices.[222]

Even when pharmacy benefit consultants are used to select PBMs and assess their contract proposals, responsible plan fiduciaries can struggle to evaluate the arrangements, as drug classifications are inconsistent across PBMs, making it difficult to compare competing PBM bids or secure favorable contract terms.[223] Exacerbating matters further, many pharmacy benefit consultants receive undisclosed compensation from the same PBMs that they are tasked with evaluating, including bonuses, shares of rebates, and per-prescription fees. For example, it has been reported that consultants can receive anywhere from $1 to $5 per prescription from the largest PBMs.[224]

This creates conflicts of interest, where consultants may be incentivized to recommend PBMs offering the highest payouts to them, rather than PBMs that deliver the best value for self-insured group health plans and their participants, which makes the fiduciary task of selecting and monitoring PBMs to protect the interests of the self-insured group health plan and its participants even more challenging. The transparency created by this final rule would help plan fiduciaries to be aware of this conflict and to consider its impact on decisions being made.

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[221] KFF, *2024 Employer Health Benefits Survey* (Oct. 9, 2024), available at https://www.kff.org/report-section/ehbs-2024-section-13-employer-practices-provider-networks-coverage-for-glp-1s-abortion-and-family-building-benefits/.
[222] Arthur Allen, *Employers Haven't a Clue How Their Drug Benefits Are Managed*, KFF Health News (Oct. 9, 2024), available at https://kffhealthnews.org/news/article/employer-drug-benefits-pbms-survey-kff/.
[223] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive? International Journal of the Economics of Business* (June 26, 2015), available at https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.
[224] United States District Court for the District of New Jersey, *Lewandowski v. Johnson & Johnson*, *No. 1:24-cv-00671* (D.N.J. Feb. 5, 2024), available at https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/02/lewandowski-v-johnson-and-johnson_2.5.24_Complaint.pdf.

2.2. PBM Revenue-Generating Practices and the Impact on Self-insured Group Health Plan Costs

PBMs utilize several practices to generate revenue when providing services to self-insured group health plans, including but not limited to rebates, price protection, spread pricing, copay claw-backs, specialty drugs administration, steering patients toward PBM-owned mail-order and specialty pharmacies, and high markups on generic drugs. Responsible plan fiduciaries, to fulfill their obligations regarding the selection and monitoring of service providers, need to know and understand the financial interests of PBMs and their relationships with other actors when providing these services. Additionally, when relying on ERISA section 408(b)(2) to avoid a prohibited transaction, they need to determine that the contract or arrangement is reasonable. The following sections discuss common PBM practices in greater detail, the lack of transparency surrounding these practices, and how they can impact the costs and services provided to self-insured group health plans.

2.2.1. Rebates

PBMs generate a significant portion of their revenues through their negotiated share of rebates, which are payments made by the drug manufacturers to issuers or PBMs to receive preferential placement on the formulary, the list of drugs covered by the self-insured group health plan.[225] Many contracts do not require PBMs to disclose the rebates that they receive—therefore self-insured group health plans often are unaware if monies are being refunded;[226]

[225] Nicole Rapfogel, *5 Things to Know About Pharmacy Benefit Managers*, Center for American Progress (Mar. 13, 2024), available at https://www.americanprogress.org/article/5-things-to-know-about-pharmacy-benefit-managers/#:~:text=Rebate:%20A%20price%20concession%20paid,in%20part%20or%20in%20full.

[226] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive*? International Journal of the Economics of Business (June 26, 2015), available at https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.

however, a frequently cited industry estimate is that "PBMs achieve rebates of 30 percent off list price, accounting for all discounts and fees."[227] While Part D plan sponsors and their PBMs are required to disclose rebates retained by PBMs to the Centers for Medicare & Medicaid Services (CMS),[228] PBM contracts with issuers and self-insured group health plans often do not directly disclose the magnitude of rebates.[229] This in turn allows PBMs to retain rebates received from manufacturers, unless their service contracts explicitly require sharing of any rebates.[230] Smaller self-insured group health plans, in particular, are less likely to receive any share of rebates due to weaker negotiating power compared to large self-insured group health plans.[231]

Further obscuring the actual rebate amount, the three largest PBMs, which account for roughly 80 percent of the prescription drug market, have created affiliated entities known as rebate aggregators, which serve as intermediaries between PBMs and drug manufacturers to negotiate and collect rebates. While PBMs argue that these entities provide greater bargaining power and savings, because rebate aggregators retain a share of the rebate themselves, depending on the terms of the contract between the self-insured group health plan and the PBM, they effectively reduce any rebate the PBM might be required to share with an issuer or self-insured group health plan, while, as an affiliated entity, still maximizing the PBM's profits. Additionally,

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[227] Health Affairs, *Health Policy Brief: Pharmacy Benefit Managers* (Sept. 2017), available at https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf.
[228] Social Security Act section 1150A.
[229] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive*? International Journal of the Economics of Business (June 26, 2015), available at https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.
[230] Frier Levitt, *Pharmacy Benefit Manager Expose: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, and Employers, and Taxpayers, The Community Oncology Alliance* (Feb. 2022), available at https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf.
[231] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?* International Journal of the Economics of Business (June 26, 2015), available at https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.

according to a 2024 Federal Trade Commission (FTC) report, two of the three largest PBMs' rebate aggregators were found to be offshore entities, further limiting oversight and transparency.[232]

The lack of transparency surrounding net prices has harmful effects on costs. For self-insured group health plans that rely on benefit consultants in their selection process, PBM proposals are often presented comparing the rebate guarantees, which encourages selection of the PBM with the highest rebate revenue. These guarantees are presented in aggregate across all impacted prescriptions regardless of which drugs are dispensed. As argued by the National Formulary Council, this "obscures" group health plan sponsors' visibility into the actual net prices of drugs on their formularies as well as the size of the rebates and other revenue (e.g., administrative fees, formulary placement fees, inflation penalties) that PBMs receive from manufacturers." [233] This can incentivize PBMs to prioritize drugs with higher rebates, such as brand-name prescription drugs, over lower-cost but equally effective alternatives, increasing overall pharmacy costs. Moreover, while responsible plan fiduciaries generally receive notice of formulary changes, the disclosures typically do not include data to inform a responsible plan fiduciary of the financial impact of such changes or their effect on the self-insured group health plan participants.[234] This lack of transparency limits self-insured group health plans' ability to

[232] Federal Trade Commission, *Interim Staff Report*: *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.
[233] Rochelle Henderson, Julie Patterson, and John Michael O'Brien, *Prescription Rebate Guarantees: Employer Insights,* 30 American Journal of Managed Care 574–80 (July 19, 2024), available at https://www.ajmc.com/view/prescription-rebate-guarantees-employer-insights.
[234] Linda Nilsen, *Written Testimony for the ERISA Advisory Council Hearing on PBM Compensation and Fee Disclosure*, (Aug. 20, 2014), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-nilsen-08-20.pdf.

assess the reasonableness of the changes, which can result in unintended consequences for plan participants.

Rebates received by self-insured group health plans can offset premiums and other healthcare costs. Without transparent disclosures providing detailed descriptions of rebates, responsible plan fiduciaries are unable to assess whether the underlying fees for PBM services are reasonable, particularly given the potential harm to self-insured group health plan participants and beneficiaries.

2.2.2. Price Protection

PBMs can further negotiate with drug manufacturers to receive additional rebates to protect them from price increases, known as price or inflation protection. In such instances, the manufacturer agrees to a maximum price paid for the drug so that if the wholesale acquisition cost (WAC) exceeds the agreed upon threshold, the PBM receives an additional rebate from the manufacturer, beyond the existing rebates and discounts.[235] This practice is similar to the inflationary rebate provisions included in the Inflation Reduction Act (IRA) of 2022, which require manufacturers to pay rebates to Medicare if they increase prices beyond the rate of inflation.[236]

Rather than discouraging price hikes, price protections can incentivize manufacturers to raise list prices more strategically. The Senate Finance Committee found that manufacturers timed their WAC price increases to avoid paying additional rebates under the price protection

[235] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021), available at https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.
[236] Center for Medicare and Medicaid Services, *Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Policies in the Calendar Year 2025 Physician Fee Schedule Final Rule* (Nov. 2024), available at https://www.cms.gov/files/document/medicare-prescription-drug-inflation-rebate-program-final-fact-sheet.pdf.

terms in the PBM contracts.[237] As such, while both PBMs and self-insured group health plans could potentially benefit from price protection rebates, rebate practices also add an additional layer of complexity to contracts which can make it hard to determine if the arrangements are reasonable.

2.2.3. Spread Pricing

Under a spread pricing model, payments for individual prescription claims received by the PBM from self-insured group health plans or issuers often exceeds the reimbursement amount it pays to the pharmacy, allowing the PBM to retain the difference, or "spread" without disclosing this additional revenue to self-insured group health plans.[238] One source found that spread pricing accounted for an estimated 10 to 15 percent of a PBM's revenue.[239] Separately, the FTC observed combined spread pricing income for the three largest PBMs totaling $1.4 billion between 2017 and 2022 on just 51 drugs.[240] Spread pricing may provide benefits such as price predictability. However, its lack of transparency can make it difficult for plan sponsors to determine whether such arrangements provide better value than available alternatives.

PBMs' failure to disclose the actual spread makes it difficult, if not impossible, for self-insured group health plans to know whether they are unwittingly paying unreasonable costs for medications and treatment. Consequently, this practice has led to an increased number of State

[237] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021), available at https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.
[238] KFF, *Medicaid Pharmacy Benefits State Fact Sheets* (Aug. 6, 2020), available at https://www.kff.org/statedata/medicaid-pharmacy-benefits-state-fact-sheets/.
[239] Colorado Health Institute, *Pharmacy Benefit Managers: As Drug Prices Soar, Policymakers Take Aim* (Aug. 2018), available at https://www.coloradohealthinstitute.org/research/understanding-pharmacy-benefit-managers .https://www.coloradohealthinstitute.org/sites/default/files/file_attachments/Pharmacy%20Benefit%20Managers.pdf
[240] Federal Trade Commission, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers*, (Jan. 2025), available at https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

lawsuits that stem from allegations of deceptive practices resulting in financial losses.[241] For example, in 2018, the Ohio Office of Attorney General reported that Centene Corporation, which oversaw Ohio's Department of Medicaid prescription drug program, had engaged in spread pricing which cost the State program nearly $225 million in excess payments.[242,,] Ohio brought a lawsuit against Centene, who ultimately agreed to pay $88.3 million to the State[243,244] and also switched to a pass-through pricing contract, which increased payments to pharmacists by 5.7 percent, though this was significantly less than the "spread" of 31.4 percent on generic drug claims from April 2017 to March 2019.[245] These findings suggest that a lack of transparency in PBM pricing can make it difficult for group health plans to determine the true cost of pharmacy benefit services.

2.2.4. Copay Claw-backs

PBMs also generate profits through copay claw-backs, which can occur when the copayment an insured individual pays at a pharmacy exceeds the total cost of the drugs purchased. This practice results in patients paying more for prescriptions by using their insurance rather than purchasing them directly from the pharmacy, with the excess amount going to the PBMs. Self-insured group health plans' responsible plan fiduciaries are generally unaware of this

[241] None of the discussed lawsuits have occurred in states that have banned spread pricing.
[242] Ohio Auditor of State, *Ohio's Medicaid Managed Care Pharmacy Services* (Aug. 16, 2018), available at https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.
[243] Ohio's Office of Attorney General, *Centene Agrees to Pay a Record $88.3 Million to Settle Ohio PBM Case Brought by AG Yost* (June 14, 2021), available at https://www.ohioattorneygeneral.gov/Media/News-Releases/June-2021/Centene-Agrees-to-Pay-a-Record-$88-3-Million-to-Se#:~:text=(COLUMBUS%2C%20Ohio)%20%E2%80%94%20Centene,for%20pharmacy%20services%20it%20provided.
[244] Centene has made settlements with 18 states worth $964.8 million. James Drew, Centene PBM Settlement with South Carolina Raises Total Payout to $964.8M, St. Louis Business Journal (Jan. 4, 2024), available at https://www.bizjournals.com/stlouis/news/2024/01/04/centene-pbm-settlement-south-carolina-raises-total.html.
[245] Health Data Plan Solutions, *Ohio Department of Medicaid (ODM) Analysis of Pass-Through Pricing Implementation* (Sept. 10, 2019), https://medicaid.ohio.gov/wps/wcm/connect/gov/8c7214d2-2215-4b30-a03f-9df486ff1fe5/ODM-HDS-Qtr1-Analysis.pdf?MOD=AJPERES.

practice and the resulting revenue, however, since the net drug prices that PBMs negotiate with pharmacies are often not disclosed to self-insured group health plan responsible plan fiduciaries.

A 2018 study using pharmacy claims data and National Average Retail Price (NARP) data, which contained drug prices paid by issuers as reported by pharmacists, found that commercially insured patients' copayments for generic prescriptions exceeded the total cost of the medicine 23 percent of the time. [246] This means that nearly a quarter of the time, patients would find it cheaper to pay the out-of-pocket cost rather than to rely on their insurance. In one particularly egregious example, a patient paid a $285 copay in 2016 for a prescription whose cash cost was only $40, resulting in the PBM retaining a profit of $245.[247]

The practice had been exacerbated by prohibitions on pharmacies from disclosing lower cash prices to patients due to "gag clauses" in their contracts with issuers and PBMs.[248] Congress outlawed such gag clauses through the *Patient Right to Know Drug Prices Act* in 2018, though the Federal law did not resolve all transparency issues in drug pricing.[249] While the legislative changes may have curtailed the practice, NARP data collection was discontinued after six months, which has made it difficult to continue monitoring the issue to assess whether it is still pervasive.

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[246] This data includes self-insured group health plans. *See* Karen Van Nuys, Geoffrey Joyce, Rocio Ribero, & Dana P. Goldman, *Overpaying for Prescription Drugs: The Copay Clawback* (Mar. 13, 2018), available at https://schaeffer.usc.edu/research/overpaying-for-prescription-drugs/.
[247] Megan Thompson, W*hy a Patient Paid a $285 Copay for a $40 Drug*, (Aug. 19, 2018), available at https://www.pbs.org/newshour/health/why-a-patient-paid-a-285-copay-for-a-40-drug.
[248] Karen Van Nuys, Geoffrey Joyce, Rocio Ribero, & Dana P. Goldman, *Overpaying for Prescription Drugs: The Copay Clawback* (Mar. 13, 2018), available at https://schaeffer.usc.edu/research/overpaying-for-prescription-drugs/.
[249] 132 Stat. 3672 - Public Law No. 115-263.

2.2.5. Specialty Drugs

PBMs have also utilized their management and distribution of specialty drugs to increase their profits. Specialty drugs are typically defined by (1) their complex handling, administration, or formulation requirements; (2) the severity or rarity of the condition being treated; and (3) their high cost.[250] However, there is no standard definition of a specialty drug. These drugs are often used to manage complex, chronic conditions, such as HIV, cancer, hepatitis, and cystic fibrosis. Not surprisingly, specialty drugs are among the most expensive. Although fewer than two percent of the population uses specialty drugs, those prescriptions account for 51 percent of total pharmacy spending.[251]

The high prices associated with specialty drugs can translate into larger manufacturer rebates, which may incentivize PBMs to design formularies that classify more prescription drugs as specialty drugs. A 2016 study found that, between 2003 and 2014, the share of specialty prescription products filled by commercially insured patients increased from 3.0 to 11.8 percent.[252] Moreover, once a drug is added to a PBM's specialty drug list, it can trigger exclusivity provisions in contracts that require the use of the PBM's affiliated specialty pharmacy.[253] While some of this increase may reflect the evolving characteristics of innovative

[250] Huseyin Naci & Aaron S. Kesselheim, *Specialty Drugs – A Distinctly American Phenomenon,* The New England Journal of Medicine (June 4, 2020), available at https://eprints.lse.ac.uk/105102/4/nejmp1909513.pdf.
[251] NAIC, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation, (*2023), available at https://content.naic.org/sites/default/files/inline-files/PBM%20White%20Paper%20Draft%20Adopted%20B%20Committee%2011-2-23_0.pdf.
[252] Stacie B. Dusetzina, *Share of Specialty Drugs in Commercial Plans Nearly Quadrupled, 2003–2014,* Health Affairs (July 2016), available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1657?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.
[253] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

drugs, the lack of a uniform definition and transparency regarding specialty drug classifications may create incentives for PBMs to classify drugs based on financial considerations.

Since PBMs often benefit financially from the placement of specialty drugs on formularies, this may create a conflict of interest in formulary design. Such a conflict could lead to the exclusion of lower-cost, equally effective alternatives, which would further limit access to prescription drugs.[254]

2.2.6. High Markups on Generic Drugs

Compared to branded or specialty drugs, generic manufacturers rarely negotiate rebates with PBMs. Instead, PBMs can generate profits by basing reimbursement amounts to pharmacies on their own proprietary price lists for generic drugs, in a process known as maximum allowable costs (MAC) pricing. While pharmacies purchase prescription drug products from various wholesalers directly, they are reimbursed by PBMs at the MAC price, which may be below the average wholesale price. Moreover, MAC prices are updated frequently – often on a weekly basis – and so pharmacies do not know the reimbursement amount until they submit a claim.[255]

Pharmacy reimbursement rates are often compared to the National Average Drug Acquisition Cost (NADAC), which is a commonly used benchmark for pharmacy acquisition costs based on data reported by pharmacies to CMS.[256] While PBMs offer lower cost-sharing on generics, PBMs can still steer patients toward affiliated pharmacies and give those pharmacies

[254] Trevor J. Royce, Caroline Schenkel, Kelsey Kirkwood, Laura Levit, Kathryn Levit, & Sheetal Kircher, *Impact of Pharmacy Benefit Managers on Oncology Practices and Patients*, *JCO Oncology Practice* (Apr. 20, 2020), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC7351331/.
[255] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.
[256] Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences*, National Bureau of Economic Research (March. 2023), available at https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.

preferential reimbursement rates. This practice allows PBM-affiliated pharmacies to earn revenues for generics that significantly exceed their estimated drug acquisition costs. A 2024 FTC report examining reimbursement rates for two generic cancer drugs found that PBMs reimbursed affiliated pharmacies at rates 20 to 40 times higher than the NADAC. For example, in 2022, commercial health plans reimbursed affiliated pharmacies for one generic prostate cancer drug over $5,800 per month, approximately 25 times the $229 NADAC. This pattern was observed across both commercial and Medicare Part D payer groups, leading to nearly $1.6 billion in excess dispensing revenue for affiliated pharmacies.[257]

2.3. Summary

The previous sections illustrate the various practices that PBMs use to generate revenue and how these practices can impact access and costs of prescription drugs for self-insured group health plans, participants and beneficiaries. Moreover, these practices are often designed to mask how revenue is generated, making it difficult for responsible plan fiduciaries of self-insured group health plans to make informed decisions when selecting a PBM, as well as to monitor its activities once they have entered into an agreement. These practices underscore the importance of greater transparency and accountability in the operations of PBMs. Transparent disclosures to responsible plan fiduciaries of self-insured group health plans regarding payments, compensation, arrangements between the PBM and affiliates, agents, and subcontractors, and the right to audit and access information are needed to enable responsible plan fiduciaries to make prudent decisions when selecting and monitoring PBMs and to ensure that the contract or arrangement, and the fees charged to self-insured group health plans, are reasonable. These

[257] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

decisions are crucial in ensuring patients have access to timely and affordable prescription drugs.[258]

3. Regulatory State

3.1. History of 408(b)(2) Regulations

In December 2007, the Department issued a proposed regulation requiring service providers to disclose specified information before a contract was entered into that would allow responsible plan fiduciaries to assess whether a contract or arrangement was "reasonable" under Section 408(b)(2) of ERISA. The required disclosures included information on all compensation to be received and any conflicts of interest that may adversely affect the service provider's performance of the contract or arrangement. The Department proposed that this information was necessary for responsible plan fiduciaries to make informed assessments and decisions about the services, costs, and the providers, in accordance with their responsible plan fiduciary obligations.[259]

Under that proposed regulation, all employee benefit plans subject to Title I of ERISA were subject to the regulation's disclosure requirements, including both pension and welfare plans. However, the Department received a number of comments arguing against the inclusion of welfare plans, asserting that the disclosures contemplated were already made available to responsible plan fiduciaries through State regulatory processes. Additionally, the Department received comments suggesting that the inclusion of PBMs under the rule was contrary to the rationale for the rule itself. In particular, commenters argued that PBMs should be excluded from

[258] U.S. House Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* (2024), available at https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.
[259] 72 FR 70988 (Dec. 13, 2007).

the rule because the FTC, at the time, had determined that market forces provide sufficient information to responsible plan fiduciaries, that excessive mandatory disclosure could weaken competition, and that this would negatively affect the delivery of prescription drugs to group health plan participants and beneficiaries.[260]

While the view of the Department was that fiduciaries and service providers to welfare benefit plans would similarly benefit from regulatory guidance in this area, it acknowledged that there are significant differences between service and compensation arrangements of welfare plans and those involving pension plans. As such, the Department expressed its intention to develop separate, and more specifically tailored, disclosure requirements for welfare benefit plans, and excluded them from the final rule.[261]

The 408(b)(2) disclosures required by the 2012 final regulation provided responsible plan fiduciaries of retirement plans with necessary information about the compensation arrangements of their service providers, enabling them to better assess whether those compensation arrangements were reasonable.[262] As a result, these disclosures helped responsible plan fiduciaries make more cost-effective investment choices, such as opting for cheaper share classes. Flows into the cheapest share classes of open-end mutual funds that indicated they distributed to retirement channels more than doubled from 2011 to 2013, indicating a substantial increase after the final rule took effect.[263] However, the fees charged to plan participants had

[260] 75 FR 41600 (July 16, 2010).
[261] *Id.*
[262] 77 FR 5632 (Feb. 3, 2012).
[263] Based on internal analysis performed by EBSA.

been declining both before and after the final rule took effect, making it difficult to isolate the specific benefits that resulted from this regulation.[264]

Building on this regulatory framework, Congress expanded similar requirements to a portion of the group health plan market. In the CAA, 2021, Congress amended the ERISA section 408(b)(2) statutory exemption to add a new paragraph (B) applicable to certain services arrangements with group health plans, effective December 27, 2021.[265] As part of the amendment, Congress designated the pre-existing text as ERISA section 408(b)(2)(A).[266] The requirements in ERISA section 408(b)(2)(B) as originally enacted in CAA, 2021 applied to a group of covered service providers, defined as persons or entities who provide "brokerage services" or "consulting" to group health plans with respect to a list of sub-services including pharmacy benefit management services.[267]

ERISA section 408(b)(2)(B) closely tracks the Department's regulation for pension plan arrangements. It requires disclosure of: the services to be provided; the status of the covered service provider, an affiliate, or subcontractor as a fiduciary, if applicable; the direct and indirect

[264] Investment Company Institute, *The Economics of Providing 401(k) Plans: Services, Fees, and Expenses*, *2023* (July 2024) at 11, available at https://www.ici.org/system/files/2024-07/per30-06.pdf.
[265] Section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.
[266] ERISA section 408(b)(2)(A) now provides an exemption for "[c]ontracting or making reasonable arrangements with a party in interest for office space, or legal, accounting, or other services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid therefor."
[267] Specifically, as originally enacted ERISA section 408(b)(2)(B)(ii)(I)(bb)(AA) defined a covered service provider as one who provides *brokerage services* "provided to a covered plan with respect to selection of insurance products (including vision and dental), recordkeeping services, medical management vendor, benefits administration (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness services, transparency tools and vendors, group purchasing organization preferred vendor panels, disease management vendors and products, compliance services, employee assistance programs, or third party administration services." ERISA section 408(b)(2)(B)(ii)(I)(bb)(BB) as originally enacted defined a covered service provider as one who provides *consulting services* "related to the development or implementation of plan design, insurance or insurance product selection (including vision and dental), recordkeeping, medical management, benefits administration selection (including vision and dental), stop-loss insurance, pharmacy benefit management services, wellness design and management services, transparency tools, group purchasing organization agreements and services, participation in and services from preferred vendor panels, disease management, compliance services, employee assistance programs, or third party administration services."

compensation reasonably expected to be received by the covered service provider, their affiliates and their subcontractors; as well as allocations of compensation reasonably expected to be made among the covered service providers and its affiliates and subcontractors. It also establishes ongoing disclosure obligations in the event of a change in the information required to be provided in the initial disclosures, and disclosures to be provided upon the written request of the responsible plan fiduciary as needed for the plan to comply with the reporting and disclosure requirements of title I of ERISA.

Congress continued to expand the transparency and fiduciary oversight of PBM services under the CAA, 2026. Specifically, CAA, 2026 amended ERISA section 408(b)(2) in several ways relevant to providers of pharmacy benefit management services, including by revising the definition of covered service provider to remove the words "brokerage services" and "consulting," clarifying that providers of pharmacy benefit management services (as well as a broad range of other service providers to group health plans, including third party administrators) are covered service providers and are required to make the disclosures under the statute to rely on the prohibited transaction exemption, and by adding disclosure requirements, requirements to pass through to the plan rebates received from certain parties in the pharmaceutical supply chain, and related audit requirements.[268] It requires providers of PBM services to disclose direct and indirect compensation, including administrative fees, network fees, spread pricing and rebates, to plan fiduciaries. It further requires that PBMs pass 100 percent of all rebates, fees, alternative discounts, and other manufacturer remuneration directly back to the group health plans. Plan

[268] Consolidated Appropriations Act, 2026, Division J, Title VII, section 6702.

sponsors are also granted the statutory right to conduct annual compliance audits using an independent auditor of their choosing, legally stripping PBMs of their ability to veto the auditor.

CAA, 2026 also amended ERISA to add section 726, *Oversight of Entities that Provide Pharmacy Benefit Management Services.*[269] Section 726 requires that entities that provide pharmacy benefit management services to certain group health plans (including through health insurance issuers) provide not less frequently than every 6 months reports to the large group health plans that include specified information with respect to drugs covered by the group health plan. These reports must break down gross and net drug spending, manufacturer rebates, spread pricing, and pharmacy compensation. A summary of the required information is to go to all plans. To further ensure transparency, ERISA-covered plans must issue an annual notice to participants regarding these PBM reporting requirements and provide detailed, claim-level pricing data upon request.

Finally, Executive Order 14273 directed the Department to propose regulations to improve employer health plan fiduciary transparency into the direct and indirect compensation received by PBMs.[270]

3.2. Current Regulatory Action

Like the Department's 2012 final pension disclosure regulation, the final rule is intended to ensure transparency by requiring covered service providers to make adequate disclosures to the responsible plan fiduciaries so that they can perform their duties under ERISA in assessing the reasonableness of the arrangement with the service provider. The specific disclosure requirements are explained in detail in the preamble.

[269] Consolidated Appropriations Act, 2026, Division J, Title VII, section 6701.
[270] Lowering Drug Prices by Once Again Putting Americans First, 90 FR 16441 (Apr. 15, 2025).

Overall, the disclosures are intended to provide responsible plan fiduciaries with a fuller picture of the terms under which the services will be provided, so they can assess both the reasonableness of the compensation in light of the services being provided, and the potential for or existence of conflicts of interest that may impact the quality of services provided. The Department believes that these disclosures will provide necessary information to responsible plan fiduciaries who are required to determine that the services contract or arrangement meets the standards for an exemption under ERISA section 408(b)(2).

4. Baseline

The baseline for this analysis reflects the current legal and regulatory framework, including the existing provisions of ERISA section 408(b)(2), as amended, and applicable provisions of the CAA, 2021. The CAA, 2021 effectively extends the disclosure requirements from the 2012 final regulation to include "brokerage services" or "consulting" to group health plans with respect to a list of sub-services including pharmacy benefit management services. The CAA, 2021 amendments require disclosure of certain information including services to be provided and a description of the direct and indirect compensation to be received by specified parties in connection with the services. These disclosures are to be made not later than the date that is reasonably in advance of the date on which the contract or arrangement is entered into, extended or renewed. As a result, the baseline includes burden for disclosure requirements for covered service providers that provide pharmacy benefits management services to group health plans sent before a contract is entered into, extended or renewed, but does not include burden for additional content for the initial disclosure and burden for other new disclosures.

As discussed in the section of the preamble titled "Consolidated Appropriations Act, 2026" most of the requirements for the CAA, 2026 are new and therefore are not included in the

baseline. Additionally, many of the requirements of the CAA, 2026 are not codified by the final rule, so their burden is not included in this analysis. The CAA, 2026 provisions amend ERISA section 408(b)(2) subparagraph (B) to explicitly apply to all pharmacy benefit management services. This analysis interprets the changes to who is a covered service provider under 408(b)(2) as a clarification of prior congressional intent under the CAA, 2021. Therefore, this analysis does not attribute additional burden to who is a covered service provider beyond what was estimated in the proposed rule's analysis, as the burden estimates in the proposed rule already included these entities.

The final rule may overlap with some requirements from the CAA, 2026, including some requirements for disclosure under Section 726. To the extent those requirements align, their burden is accounted for in this RIA. If they do not align, the burden for the requirements from the CAA, 2026 is not included. Burden for non-aligning requirements of the CAA, 2026, while not included in the burden estimates here, could be included in future rulemaking related to Section 726. So, to the extent the requirements of CAA, 2026 differ from the requirements of 408(b)(2) as amended by CAA 2021 or the final rule, those requirements are not included in this analysis.

These requirements are expected to impose costs for PBMs and may potentially impose new costs on other service providers that assist plans in their compliance. The final rule provides meaningful benefits to self-insured group health plans, participants, and beneficiaries. Benefits, costs, and transfers associated with the final rule are measured as changes relative to the baseline.

5. Summary of Impacts

The final rule is expected to increase transparency in PBM compensation arrangements, helping self-insured group health plans' responsible plan fiduciaries and other stakeholders to better understand PBM practices and make more cost-effective choices. This transparency would increase competition in the market for PBM services, enable responsible plan fiduciaries to compare offerings across PBMs, empower responsible plan fiduciaries to negotiate more favorable contract terms, reduce impacts on the self-insured group health plan and participants resulting from PBMs' conflicts of interest, and encourage PBMs to accurately classify prescription drugs, resulting in lower costs to both self-insured group health plans and participants.

Self-insured group health plans, third-party administrators (TPAs), and PBMs will incur costs to review this rule and comply with the additional disclosure requirements in the final rule. However, the Department has determined that the benefits of the final rule justify the costs. In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Department's assessment of the benefits, costs, and transfers associated with these regulatory actions. The Department is unable to quantify all benefits, costs, and transfers of the final rule, but has sought, where possible, to describe these non-quantified impacts. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of the final rule.

TABLE 1. Accounting Statement

Benefits:	Estimate (Primary)	Estimate (Low)	Estimate (High)	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($million/year)	$293.0	$146.5	$586.0	2026	7 percent	2026–2035
	$293.0	$146.5	$586.0	2026	3 percent	2026–2035

Quantified Benefits using Willingness to Pay:

- Improved welfare due to lower cost prescription drugs will result in an average undiscounted benefit of $293.0 million annually.

Non-Quantified Benefits and/or Mechanisms Yielding Quantified Benefits:

- Improved understanding of PBMs by self-insured group health responsible plan fiduciaries.
- Reduced administrative burden on self-insured group health plans due to lower search and preparation costs for PBM selection and contract negotiations.
- Greater ability for self-insured group health responsible plan fiduciaries to compare offerings across PBMs, fostering competition, and improving drug pricing.
- More favorably negotiated contracts for self-insured group health responsible plan fiduciaries with PBMs, resulting in lower costs and more appropriate coverage.
- Reduced conflicts of interest that currently influence PBMs' key decisions regarding rebates, formulary design, and prescription drug pricing.
- Reduced costs to self-insured group health plans and employers, allowing them to shift resources to other benefits or priorities.
- Improved health outcomes for participants and beneficiaries arising from increased adherence to medication as a result of lower cost prescription drugs.

Costs:	Estimate	Year Dollar	Discount	Period Covered
Annualized Monetized ($million/year)	$60.95	2026	7 percent	2026–2035
	$59.43	2026	3 percent	2026–2035

Quantified Costs:

- For familiarization with the final rule, ERISA covered self-insured group health plans, TPAs, and PBMs will incur approximately $20.8 million in the first year.
- For developing and maintaining the IT infrastructure systems, PBMs will incur $80.3 million in the first year and $21.9 million in subsequent years.
- For preparing the required disclosures, PBMs and ERISA covered self-insured group health plans will annually incur approximately $12.5 million.
- For ERISA-covered self-insured group health plans preparing audit requests, and PBMs providing requested information to plans, will annually incur approximately $16.0 million.

Transfers:	Estimate (Primary)	Estimate (Low)	Estimate (High)	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($million/year)	$818.4	$409.2	$1,636.9	2026	7 percent	2026–2035
	$818.4	$409.2	$1,636.9	2026	3 percent	2026–2035

Quantified Transfers:

- Transfers from PBMs to self-insured group health plans and health plan participants of $818.4 million annually due to reduced prescription prices.

Non-Quantified Transfers:

- Potential transfers from traditional PBMs to transparent PBMs like fully pass-through PBMs as self-insured group health responsible plan fiduciaries are better able to evaluate compensation structures.
- Potential transfers from affiliated to unaffiliated pharmacies, as PBMs remove preferential treatment of affiliated pharmacies, resulting in increased use of unaffiliated pharmacies.

Perpetual Time Horizon Costs:

- Annualized Cost (in 2024 dollars) (E.O. 14192 accounting): $53.9 million.

6. Affected Entities

Table 2 summarizes the number of self-insured group health plans, TPAs, pharmacies, manufacturers, wholesalers, and PBMs that would be affected by the final rule. These estimates and their sources are discussed in greater detail later in Section 6 of the RIA.

TABLE 2. Affected Entities

	Total
Large, self-insured Group Health Plans with 100 to 999 participants and beneficiaries	113,226
Large, self-insured Group Health Plans with 1,000 or more participants and beneficiaries	17,876
PBMs	73
Issuers	373
Issuers/State combinations in group market	809
TPAs	205
Pharmaceutical Manufacturers	1,436
Pharmaceutical Wholesalers	1,427

6.1. Self-insured Group Health Plans

The final rule applies only to a subset of ERISA-covered group health plans, which are self-insured group health plans. Fully insured ERISA plans are not subject to the final rule and are therefore excluded from the estimates. As discussed in the preamble, the final rule applies only to self-insured plans of specified large employers and self-insured group health plans that are specified large plans. A specified large employer generally means an employer that employed an average of at least 100 employees on business days during the preceding calendar year or plan year, as applicable, and that employs at least one employee on the first day of the calendar year or plan year. A specified large plan generally means a group health plan that had an average of at least 100 participants on business days during the preceding calendar year or plan year, as

applicable. Self-insured plans with 100 or more participants are used as a proxy for identifying an affected plan.

Additionally, the final rule also excludes group health plans whose sponsors are in the drug supply chain. The Department does not have a sense of how many plans would be directly impacted by this exclusion, but anticipates that it would not constitute a significant number as they would be limited to large, self-insured plans whose sponsors are in drug supply chain. As a result, the Department assumes that the impact of this exclusion is negligible.

The Department estimates that there are 113,226 self-insured group health plans with 100 to 999 participants and beneficiaries, and 17,876 self-insured group health plans with 1,000 or more participants and beneficiaries.[271] While all 131,102 of these plans are considered self-insured group health plans, the Department uses this distinction to categorize self-insured group health plans by size and other unique features. The 2025 KFF Employer Health Benefits Survey also found that nearly all covered workers (99 percent) are at firms that provide prescription drug benefits to enrollees in their group health plans.[272,273] As such, the Department assumes that all large, self-insured group health plans will be affected by the final rule.

[271] The Department estimated that there are 113,226 self-insured ERISA-covered group health plans with 100 to 999 participants and 17,876 self-insured ERISA-covered group health plans with 1,000 or more participants using the 2024 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2022 County Business Patterns from the Census Bureau.
[272] KFF reported this estimate for large firms only, as small firm respondents had a high percentage of "don't know" responses to these questions.
[273] KFF, *2025 Employer Health Benefits Survey* (Oct. 22, 2025), https://www.kff.org/report-section/ehbs-2024-section-9-prescription-drug-benefits/.

6.2. TPAs and Issuers

The Department also estimates that the final rule will affect 205 TPAs and 373 issuers (i.e., health insurance companies) in the group market with 809 issuers/State combinations[274] that provide services such as plan management to self-insured group health plans. The Department assumes that these TPAs and issuers will provide their services to self-insured group health plans with fewer than 1,000 participants and beneficiaries. TPAs and issuers are typically hired by self-insured group health plans to perform key administrative and compliance functions, including claims processing, formulary design, and oversight of pharmacy benefits. These service providers will offer economies of scale in regulatory compliance by leveraging their expertise and infrastructure to implement the final rule's requirements on behalf of multiple self-insured group health plans. While responsible plan fiduciaries remain ultimately responsible for ensuring compliance, they rely on TPAs and issuers to manage the day-to-day operations of the self-insured group health plan and fulfill the requirements of the final rule. Plans may contract with the TPAs or issuers, who in turn sub-contract with PBMs. In that case, the TPAs or issuers would be covered service providers. The TPAs or issuers would be responsible for making the disclosures to the self-insured group health plan as required under the final rule and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

[274] An "issuer/state combination" refers to a health insurance issuer and the state in which it offers coverage, such that the same issuer operating in multiple states is treated as separate issuer/state combinations. Data source: Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data*, https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.

6.3. Participants and Beneficiaries

There are approximately 72.4 million participants and beneficiaries enrolled in ERISA-covered, large, self-insured group health plans. Of these, approximately 69.7 million are under the age of 65. [275] According to the 2024 Center for Disease Control's (CDC) National Center for Health Statistics, United States, 67.8 percent of individuals under the age of 65 with private health insurance used a prescription medication in the past year[276] or 47.2 million covered participants and beneficiaries.[277]

6.4. PBMs

According to the Pharmaceutical Care Management Association (PCMA),[278] there were 70 full-service PBMs in 2021. Between 2021 and 2023, six new full-service PBMs entered the marketplace. During this same time, eight PBMs were acquired by other PBMs, primarily through mergers between small or mid-size companies. Furthermore, five PBMs that were previously not classified as "full-service" have expanded their services. As a result, the net number of full-service PBMs in the marketplace was 73 in 2023.[279]

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[275] Estimate is based on the Department's tabulations *of the March* 2025 *Current Population Survey*https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf (CPS) Auxiliary Data.

[276] Centers for Disease Control and Prevention, National Center for Health Statistics, *Prescription Medication Use Among Adults* (2025), available at https://nchsdata.cdc.gov/DQS/?topic=prescription-medication-use-among-adults&subtopic=&group=health-insurance-coverage-younger-than-65-years&subgroup=private&range=2019-to-2024.

[277]https://nchsdata.cdc.gov/DQS/?topic=prescription-medication-use-among-adults&subtopic=&group=health-insurance-coverage-younger-than-65-years&subgroup=private&range=2019-to-2023 This estimate was calculated in the following manner: 69.7 million participants and beneficiaries in ERISA-covered, large, self-insured group health plans x 67.8 percent = 47.2 million individuals.

[278] The PCMA is a national trade association representing the PBM industry. *See* Pharmaceutical Care Management Association, *About PCMA* (2026), https://www.pcmanet.org/about/.

[279]https://www.pcmanet.org/rx-research-corner/the-pbm-marketplace-is-more-competitive-not-less/05/08/2023/ Pharmaceutical Care Management Association, *The PBM Marketplace Continues to Evolve* (Apr. 11, 2023).

6.5. Brokers and Consultants

To the extent PBMs or their affiliates also act as brokers or consultants for large, self-insured group health plans with respect to pharmacy benefit management services, they are covered service providers under the final regulation. The Department requested comments on the number of brokers and consultants that are PBMs or affiliates of PBMs, as well as on their arrangements with large, self-insured group health plans and PBMs, and on costs, if any, that they will incur in complying with the requirements of the regulation.

The Department received several comments regarding the definition of the pharmacy benefit management services and the entities that would be covered under the regulation. Some commentators raised concerns that because Congress had not defined pharmacy benefit management services in CAA, 2026, the Department's proposed definition was too broad and would include unintended services. Other commenters, however, raised concerns about the potential exclusion of PBM-owned or PBM-affiliated rebate aggregators and related entities under a narrower definition. These entities may participate in rebate flow arrangements and other compensation structures associated with PBM operations that would fall under the final rule's disclosure and audit provisions. However, they could potentially evade reporting requirements by using offshore rebate aggregators and group purchasing organizations (GPOs) unless the Department includes them as related parties. Although the Department did not receive sufficient information or data to estimate the number of rebate aggregators or related entities that may be affected, the Department acknowledges that such entities may incur costs to comply with the disclosure and audit requirements under the final rule.

6.6. Drug Manufacturers, Wholesalers and Pharmacies

According to the U.S. Census Bureau, there were 1,436 drug manufacturers in 2023[280] and 1,427 pharmaceutical drug wholesaler distributors in 2021.[281] Additionally, the U.S. Census Bureau reported there were 41,792 pharmacies and prescription drug stores in 2023, though a number had closed in the preceding years which makes estimating the current number challenging.[282] Other studies report a different number of pharmacies and different trends in industry growth depending on the methodology used.[283,284] One of these studies finds more turnover for independent pharmacies relative to chain pharmacies. Independent pharmacies were more than twice as likely to close as chain stores, though the overall decline was driven largely by chain pharmacy closures due to their market share. These trends correspond with reported increases in planned closures, mergers, and acquisitions, and the integration of PBMs with large pharmacy chains. The study noted that the closures might have been driven by lower

[280] U.S. Census Bureau, *2023 Economic Surveys Business Patterns, 325412: Pharmaceutical Preparation Manufacturing* (2023), available at https://data.census.gov/profile/325412_-_Pharmaceutical_Preparation_Manufacturing?n=325412&g=010XX00US.
[281] National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, 87 FR 6708 (Feb. 4, 2022https://www.federalregister.gov/documents/2022/02/04/2022-01929/national-standards-for-the-licensure-of-wholesale-drug-distributors-and-third-party-logistics).
[282] U.S. Census Bureau, *All Sectors: County Business Patterns, including ZIP Code Business Patterns, by Legal Form of Organization and Employment Size Class for the U.S., States, and Selected Geographies: 2023, Economic Surveys, ECNSVY Business Patterns County Business Patterns, Table CB2300CBP* (2025), available at
[283] Mattingly, T. Joseph, Maitreyi Sahu, & Kelly E. Anderson., Community *Pharmacy Turnover and Context of Openings and Closings by Ownership Type*, 6(8) In *JAMA Health Forum*, (2025) American Medical Association.https://jamanetwork.com/journals/jama-health-forum/fullarticle/2836775.
[284] Jenny S. Guadamuz, G. Caleb Alexander, Genevieve P. Kanter, & Dima Mazen Qato, *More US Pharmacies Closed Than Opened In 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk: Study Examines US Pharmacy Closures at the County Level, 2018–21*, Health Affairs (2024), available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2024.00192.

reimbursement rates for unaffiliated pharmacies rather than PBM affiliated counterparts and by the increased exclusion of independent pharmacies from pharmacy networks.[285]

Pharmacies can be subject to the final rule if they perform PBM-type functions or are affiliated with the covered service provider in a way that makes their compensation relevant and disclosable. The Department does not know how many pharmacies fall into this category.

7. Research Examining the Impact of PBMs on Prescription Drug Costs

Research shows mixed impact of PBMs on prescription drug costs. Some studies suggest that PBMs can lower costs by negotiating rebates and managing drug utilization, and that the absence of PBMs leads to greater inefficiencies and higher prescription drug prices. In contrast, other studies find that PBMs can inflate costs through spread pricing, formulary design, and requiring the use of mail-order or specialty pharmacies. These studies are discussed in greater detail below.

7.1. Research Finding that PBMs Generate Cost Savings and their Absence Increases Prescription Drug Costs

PBMs argue that they generate cost savings for employers, health plans, participants, beneficiaries, and taxpayers. For example, a 2025 study funded by the three largest PBMs — Caremark, Express Scripts, and OptumRx— found that PBMs reduce prescription drug costs for plan sponsors and their members. The authors estimate that PBM operating margins account for

[285] Jenny S. Guadamuz, G. Caleb Alexander, Genevieve P. Kanter, & Dima Mazen Qato, *More US Pharmacies Closed Than Opened In 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk: Study Examines US Pharmacy Closures at the County Level, 2018–21*, Health Affairs (2024), available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2024.00192.

less than five percent of overall prescription drug costs and that approximately 98 percent of manufacturer rebates in recent years have been passed through to plan sponsors.[286]

It is important to note that low profit margins in the PBM industry may be an artifact of discretionary accounting practices which allow PBMs to choose whether to count pass-through payments, such as rebates, as revenue. This, coupled with vertical integration which obfuscates where profits are generated, can make profit margins appear artificially low.[287] Moreover, the 2025 study does not account for significant variability across plan types and PBM contracts. For example, another 2025 paper suggests that larger employers were more likely to receive manufacturer rebates than small employers, with only 15 percent of small employers[288] reporting capturing rebates, compared to 49 percent of large employers in 2024.[289] Evidence from a 2015 paper finds that the average retail spread retained by PBMs is below two percent, though the Department notes that even a two percent spread represents a substantial amount when applied to prescription drug spending in billions of dollars. The study further shows that net prices for branded drugs with rebates have grown more slowly than those without rebates. According to the authors, plan sponsors rely on PBMs because they can negotiate larger discounts with manufacturers and pharmacies, develop formularies that encourage the use of lower-cost drugs, and manage pharmacy networks more efficiently than plan sponsors could on their own. The

[286] Dennis W. Carlton, Mary Coleman, Nauman Ilias, Theresa Sullivan, & Nathan Wilson, *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied against Pharmacy Benefit Managers* (Apr. 2025), available at https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.
[287] Karen Mulligan and Darius Lakdawalla, *Hidden Profits? How Accounting Conventions and Vertical Consolidation can Obscure PBM Profitability,* Schaeffer Center White Paper Series (Jan. 22, 2026), available at https://schaeffer.usc.edu/research/pbm-profitability/.
[288] The paper defines a small employer as an employer with fewer than with than 5,000 employees.
[289] Pharmaceutical Group Companies, *2025 Trends in Specialty Drug Benefits Report* (2025), https://www.psgconsults.com/blog/untapped-potential-medical-drug-rebate-strategies-for-payers/.

study concludes that PBMs create significant value by managing prescription drug spending, which can help reduce premiums and out-of-pocket costs for patients.[290]

Furthermore, a 2016 study, commissioned by a PBM trade association highlights the methods PBMs use to generate savings including negotiating rebates and discounts, encouraging the use of generics and alternatives, managing high-cost specialty medications, and expanding access via mail-service and specialty pharmacy channels. The study estimated that PBMs could generate $350 billion in savings for commercial plans and their members from 2016 to 2025 while promoting proper utilization and adherence to treatment. However, this analysis assumes that PBMs fully utilize their cost-saving tools: selective formularies with four or more tiers, pre-approval for step-therapy, strong incentives to use mail service, preferred pharmacy options with high performance networks, and high usage of specialty pharmacies.[291] It is also important to note that the study bases its estimates on several assumptions about prescription drug trends, including price inflation and specialty drug growth. The authors also do not control for any inflationary pressure that PBMs themselves may have on the list price of prescription drugs. Additionally, this study does not account for the varying efficacy of utilization management and adherence programs across heterogeneous patient populations, which poses limitations in accurately estimating cost savings. Finally, it is worth noting that the study does not discuss the impact of transparency on the ability of PBMs to continue to provide these services and generate savings.

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[290] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive*? International Journal of the Economics of Business (June 26, 2015), available at https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.

[291] Visante, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*, Prepared for Pharmaceutical Care Management Association (PCMA) (Feb. 2016), available at https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf.

A 2022 study, also funded by the same PBM trade association, estimates the societal value of PBM services using a quantitative model that reflects the structure of the U.S. prescription drug market. The paper compares current PBM operations with three hypothetical scenarios: the absence of PBM services, the use of government-enforced price controls, and in-house management of PBM functions by individual health plans.[292]

In the first scenario, PBM services are estimated to annually contribute an additional $145 billion more in societal value than would be experienced without PBM services, though more than one-third of the calculated value is attributed to manufacturer rebates. This estimate is based on $168 billion in quantified benefits, which include negotiated rebates, increased use of generic drugs, improved adherence, and reduced tax distortion, minus $22 billion in resource costs associated with providing PBM services.[293]

In the second scenario, PBM services are estimated to provide an additional $192 billion in societal value each year, compared to a healthcare system operating under government-enforced price controls. This estimate reflects the model's assumption that government-enforced price controls could lower drug utilization, weaken market-based price mechanisms, and significantly diminish incentives for pharmaceutical innovation.

Finally, in the third scenario, PBM services are estimated to provide between $64 to $81 billion more in societal value compared to a system in which self-insured group health plans perform all PBM functions internally, without relying on specialized PBM companies. This estimate reflects the model's assumption that self-insured group health plans would retain only a

[292] Casey B. Mulligan, *The Value of Pharmacy Benefit Management*, NBER Working Paper Series (July 2022), available at https://www.nber.org/system/files/working_papers/w30231/w30231.pdf.
[293] *Id.*

portion of PBM functions under this model, leading to decreased efficiency and increased operational costs.[294]

While these studies suggest the potential positive impact that PBMs may have in controlling costs, some studies have found that the absence of PBMs can result in higher costs for self-insured group health plans as well as State and federal government programs. For example, the Department of Labor's Inspector General conducted an audit of its Office of Workers' Compensation Programs (OWCP) in 2023 and concluded that the program lacked a "pharmacy benefit manager to help contain costs" between 2015 and 2020. Due to the absence of a PBM, OWCP could not capitalize on strategies typically facilitated by a PBM. For instance, OWCP did not have a process to identify other available pricing models or ensure its pricing was competitive with others in the industry. Specifically, OWCP did not compare its pricing to publicly available benchmarks, such as the MAC, NADAC, and the ACA Federal Upper Limit. Additionally, OWCP did not have a mechanism, or a contract, to incorporate rebates for pharmacy expenditures in its Federal Employees' Compensation Act (FECA) pharmaceutical program. The report noted that these rebates could have resulted in substantial savings for brand-name prescription drugs. As a result, the failure to incorporate these measures reportedly led up to $321.3 million in excess spending during the audit period.[295]

A 2021 study compared the experience of two State Medicaid programs managing their specialty pharmacy benefits with respect to Hepatitis C therapies: Michigan, which centralized purchasing Hepatitis C drugs from manufacturers, and Illinois which relied on PBMs to manage

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[294] https://www.nber.org/system/files/working_papers/w30231/w30231.pdf *Id.*

[295] U.S. Department of Labor, Office of Inspector General-Office of Audit, *Report to the Office of Workers' Compensation Programs*, *OWCP Did Not Ensure Best Prices and Allowed Inappropriate Potentially Lethal Prescriptions in The FECA Program* (Mar. 31, 2023), available at https://www.oig.dol.gov/public/reports/oa/2023/03-23-001-04-431.pdf.

purchasing and utilization of the drugs. Using CMS drug purchasing data from 2015 to 2019, the study found that Illinois's PBMs purchased cheaper generic alternatives when they became available in 2019. In contrast, Michigan continued to purchase more expensive brand-name prescription drugs. These findings suggest that Illinois, through their PBM, was able to quickly pivot to cheaper generic alternatives as soon as they were available, while Michigan continued to rely on more expensive brand drugs, resulting in a 55 percent gap in unit prices between the two States. This translated into additional costs for Michigan of $36 million in the latter part of 2019 alone.[296]

Following West Virginia's decision to carve prescription drugs out of their Medicaid managed care program in 2017, its Department of Health and Human Resources, Bureau for Medical Services commissioned a report to assess the potential savings they achieved from moving from a PBM-related managed care organization (MCO) to a fee-for-service approach. The report projected West Virginia would save $50 million in administrative costs under the change.[297]

However, later that year, America's Health Insurance Plans (AHIP) commissioned a review of that West Virginia study, which argued the projection was overstated, as the actual savings accounted for less than five percent of MCO administrative expenses, totaling approximately $9 million. The AHIP report found that, between April 2016 and June 2017, the use of generics declined by 0.6 percentage points (from 86.5 percent to 85.9 percent) resulting in

[296] Ike Brannon & Anthony L. Sasso, *The Myth That the State Can Do It Better: Hepatitis C Drug Centralized Pharmaceutical Purchasing Versus Pharmacy Benefit Managers* (May 25, 2021), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3852446.

[297] Navigant, *Pharmacy Savings Report: West Virginia Medicaid, Actuarial Assessment of the SFY18 Impact of Carving out Prescription Drugs from Managed Care for West Virginia's Medicaid Program* (Feb. 25, 2019), available at https://www.ncpa.co/pdf/state-advoc/west-virginia-report.pdf.

a 12.5 percent increase in the cost per prescription. It also argued that while some administrative costs would be eliminated under a pharmacy carve-out, such as the need for a Medicaid pharmacy director and fewer provider calls related to the prescription drug benefit, these savings were minimal, amounting to only two to three percent of overall administrative costs. The carve-out model also introduced new costs for West Virginia as the health plan would still need to obtain and manage prescription drug data for patient care coordination. Additionally, under the carve-out model, MCOs no longer receive this data in the format they use, but instead according to the State's required transmission format. Adapting to this format may require modifying the data system, which would add to the administrative costs. As a result, the AHIP report argued that cost increases associated with the carve-out model outweighed the savings, leading to an additional $18 million in annual Medicaid spending.[298]

7.2. Research Finding that PBM Business Practices Lead to Higher Prescription Drug Costs

Other sources suggest that PBM business practices may lead to higher prescription drug costs for employers, health plans, participants, and pharmacies. For instance, a 2024 investigation by the New York Times found that PBMs pushed patients toward higher out-of-pocket cost drugs, marked up low-cost prescription drugs excessively, and drove local pharmacies out of business. The investigation also found that PBMs restricted access to prescriptions by requiring patients to use their own mail-order or specialty pharmacies, even when a local pharmacy could have filled the prescription more quickly, resulting in a delay in treatment. The investigation provided an example of one PBM that overcharged the State

[298] Alex Cohn, Joel Menges, Amira Mouna, & Leigh Schreiber, *Assessment of Report on Impacts of West Virginia Medicaid Prescription Drug Carve-Out, Prepared for America's Health Insurance Plans*, The Menges Group (Apr. 2019), available at https://themengesgroup.com/wp-content/uploads/2022/06/assessment_of_study_of_wv_rx_carve-out_impacts_april_2019.pdf.

employee health plan in Oklahoma by more than $120,000 annually for a cancer drug, charging the plan $138,000 annually for a prescription drug that the patient could purchase online for $14,000.[299]

The 2024 investigation discussed several PBM practices which ultimately contribute to higher prescription drug costs. First, PBM's demand for increasing discounts or rebates from drug manufacturers for a drug's formulary placement may raise prescription drug list prices as drug manufacturers attempt to maintain their profit margins. This can result in higher out-of-pocket costs for patients, particularly if their cost sharing is a percentage of the list price. Additionally, this can lead to PBMs diverting patients toward brand-name prescription drugs, whose higher list prices result in greater rebates, rather than generic alternatives. However, higher list prices can also lead to increased out-of-pocket costs for patients. Furthermore, PBMs influence the prescription cost options available to employers, who often select plans based on perceived cost savings. The cost controls that PBMs market to employers to reduce premiums or plan expenditures, however, can result in higher out-of-pockets costs for employees due to less favorable copayments or coinsurance.[300]

The U.S. Senate Committee on Finance considered the role of PBM rebates in its 2021 investigation on the cost of insulin and the role of PBMs and manufacturers in influencing prices.[301] The Committee found insulin prices rose between 33 and 70 percent between 2014 and 2019, driven by both manufacturer pricing strategies and PBM practices. Manufacturers raised

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[299] Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, The New York Times (June 21, 2024), available at https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html.

[300] *Id.*

[301] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021), available at https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

their WAC or list prices, repeatedly, often in tandem with competitors, without improvement in drug efficacy. Meanwhile, the three largest PBMs accepted generous rebates that were tied to these higher list prices, leveraging formulary exclusions to pressure manufacturers into offering large rebates in exchange for formulary placement.

Manufacturers maintained or raised list prices to ensure PBM rebates and protect their products' formulary placement, resulting in dramatic increases in rebates for insulin prescriptions during that period. Examining the growth by specific manufacturers, the Committee reported that Sanofi's rebates increased by approximately 50 percent between 2013 and 2018, and Novo Nordisk's rebates increased by approximately 20 percent between 2014 and 2017. The Committee concluded that PBM contracting did little to control insulin pricing, and in many cases, made the problem worse.[302]

These findings were corroborated by a 2021 cross-sectional study which found that while average list prices for 32 insulin products increased by over 40 percent between 2014 and 2018, the average net prices received by manufacturers fell 31 percent. Moreover, while the share of insulin expenditures accruing to manufacturers and health plans fell respectively by one-third and one-quarter in that time period, the share of insulin expenditures retained by pharmacies increased by 229 percent, the share retained by PBMs increased 155 percent, and the share retained by wholesalers increased by 75 percent.[303]

Furthermore, a Delaware State auditor report examined the PBM Express Scripts' management of State employee prescription drug plans between 2018 and 2020 and found that

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[302] *Id.*

[303] Karen Van Nuys, Rocio Ribero, Martha Ryan, & Neeraj Sood, Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018, *JAMA Health Forum* (Nov. 5, 2021), available at https://pubmed.ncbi.nlm.nih.gov/35977268/

administrative fees, spread pricing, and direct pharmacy fees led to $24.5 million in excess costs. During this period, the average cost per prescription under the State plan increased by 14.3 percent, which was nearly triple the national drug inflation rate of 4.7 percent. Despite using a pass-through pricing model, Express Scripts charged the State over $104 million in administrative fees, averaging $21.05 per claim or nearly 13 percent of total claim costs. The report also highlighted that, in a sample from one independent pharmacy, Express Scripts paid nothing to the pharmacy for the 9,255 claims (39 percent of the sample), while still billing the State plan a total of $109,504 for those claims. In many of these instances, the employees' copayments appeared to cover the cost of the drug, raising concerns that the PBM retained 100 percent of the amount billed as profit.[304]

8. Research on How PBM Disclosures Impact Prescription Drug Costs

Prior to 2023, the FTC issued several advocacy letters and studies that opposed greater PBM transparency and disclosure requirements, arguing that such disclosures could undermine competitive processes. However, the FTC reversed this position in 2023, following compelling evidence and congressional pressure from Senator Grassley[305] and others, and withdrew those letters and studies, cautioning that horizontal and vertical integration in the industry along with other practices meant that their prior materials may not reflect current market dynamics.[306] This withdrawal underscores the need to assess how PBM disclosures affect the pharmaceutical

[304] State of Delaware, Office of Auditor of Accounts, *Lack of Transparency & Accountability in Drug Pricing Could be Costing Taxpayers Millions* (June 17, 2021), available at https://auditor.delaware.gov/wp-content/uploads/sites/40/2021/06/RPT_PBM_061721_FINAL.pdf.
[305] Press release, Senators Push FTC to Review Pharmacy Benefit Managers' Role in Insulin Prices (May 19, 2022), available at https://www.grassley.senate.gov/news/news-releases/senators-push-ftc-to-review-pharmacy-benefit-managers-role-in-insulin-prices.
[306] Federal Trade Commission, *Federal Trade Commission Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports That No Longer Reflect Current Market Realities* (July 18, 2023), available at https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf.

market. Some studies suggest that PBM disclosures can lower prescription drug costs by improving the negotiation leverage of responsible plan fiduciaries, whereas other studies find that they may inadvertently increase costs by reducing competition among PBMs, pharmacies, and manufacturers. In contrast, other studies find that the effects of PBM disclosures vary depending on market conditions. These studies are discussed in greater detail below.

8.1. Research Finding that PBM Disclosures Lowers Prescription Drug Cost

Some studies have found that PBM disclosures may help reduce prescription drug costs. For example, in October 2024, CBO analyzed various approaches to reducing prescription drug prices, including price transparency. CBO estimated that requiring PBMs to share their prescription drug price information with health issuers would reduce prescription drug prices by 0.1 percent to 1.0 percent. CBO noted that increased transparency would help some PBM clients, particularly smaller plans, negotiate better contract terms. These plan sponsors often have limited access to pricing information, and such disclosure requirements would improve their bargaining position. CBO predicted that the overall impact of these disclosures would be limited, as many existing contracts between PBMs and plan sponsors in the private health insurance market already include provisions for information sharing, suggesting a significant portion of the insured market would remain unaffected.[307] However, the self-insured plans covered in this final rule is not subject to state disclosure laws, thus the final rule could have a bigger impact than CBO's estimates.

Similarly, in December 2024, CBO estimated the budgetary effects of a bill, the *Pharmacy Benefit Manager Reform Act,* which would require PBMs to annually report detailed

[307] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), available at https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf.

information to plan sponsors about their services, though disclosures to plans sponsors for businesses with fewer than 50 employees would be more limited.[308] The bill would also ban spread pricing and require PBMs and their affiliates to pass 100 percent of the rebates, fees, discounts, or other remuneration received from pharmaceutical manufacturers, distributors, or other third parties related to use of prescription drugs by plan enrollees to plan sponsors.

CBO estimated that this bill could reduce net retail prescription drug costs by more than 0.5 percent in the first full year of implementation, which could lower average premiums for employment-based health insurance by less than 0.1 percent in the first year, compared to what they would be under current law. CBO estimated that the effect on premiums would diminish over time, reaching less than 0.01 percent by 2034 as PBMs employ new ways to generate revenue outside of the disclosure requirements. However, this does not imply that premiums would decline; rather, premiums are still expected to increase, but at a slower rate than they would have otherwise.[309] As the final rule does not prohibit spread pricing or require that PBMs pass on 100 percent of rebates, fees, or discounts that they receive from manufacturers, the Department believes that PBMs may not need to offset these revenue sources and that the impacts of the final rule would not diminish to the extent that CBO had estimated for the *Pharmacy Benefit Manager Reform Act*. The Department discusses the possibility of the final rule's impact diminishing over time in the Uncertainty Section of this regulatory analysis.

[308] *S. 1339 – Pharmacy Benefit Manager Reform Act*, 118th Congress (2023–2024), https://www.congress.gov/bill/118th-congress/senate-bill/1339.
[309] Congressional Budget Office, *Cost Estimate of S. 1339 Pharmacy Benefits Manager Reform Act* (Dec. 5, 2024), available at https://www.cbo.gov/system/files/2024-12/s1339.pdf.

8.2. Research Finding that PBM Disclosures Increases Prescription Drug Cost

Other studies have found that PBM disclosures may increase prescription drug costs. For instance, a 2023 industry paper commissioned by a PBM trade association analyzed the impact of disclosure requirements, such as the *PBM Transparency Act of 2023*,[310] on competition among PBMs, manufacturers, and pharmacies. Although the proposed bill would have prohibited PBM pricing practices, including spread pricing, the paper specifically examined the effects of its disclosure requirements. The paper argues that disclosure requirements could increase prescription drug prices by reducing competition across these groups. By requiring manufacturers to disclose pricing details, the author contends that manufacturers may hesitate to offer significant discounts, fearing competitors will mimic their pricing strategies. This can lead to implicit price coordination, where manufacturers keep prices higher to avoid undercutting each other, resulting in a potential cost of up to $26.9 billion.[311]

This phenomenon is documented in the 2021 Senate Finance Committee Report, which found that PBMs' negotiations with insulin manufacturers, including the use of formulary exclusions, encouraged manufacturers to rapidly increase their list price in parallel with competitors. This practice, known as "shadow pricing," occurs when one manufacturer closely follows another's price increase to remain competitive for preferred formulary placement. This approach enables manufacturers to provide large rebates and maintain market access.[312] The

[310] *S.127 - Pharmacy Benefit Manager Transparency Act of* 2023, 118th Congress (2023–2024), https://www.congress.gov/bill/118th-congress/senate-bill/127.
[311] Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences*, National Bureau of Economic Research (Mar. 2023), available at https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.
[312] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021), available at https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

2023 industry paper further argues that disclosures could increase costs of pharmacies by $8.0 billion and by PBMs by as much as $48.0 billion if tax distortion from rebates or discounts applied at the point of sale are included. [313]

However, as mentioned above, while the FTC issued 11 advocacy letters and reports prior to 2015 which argued that certain State and Federal proposals to increase PBM transparency could undermine competitive processes, the FTC issued a statement withdrawing this stance in 2023. In the statement, the FTC cautioned against reliance on those letters as they may no longer reflect current market realities, raising "its concerns about how PBMs may be using market power to undermine competition from independent pharmacies, and its concerns about the role of PBMs in determining the prices consumers pay for prescription drugs, including the impact of PBM rebates." [314]

8.3. Research Finding that PBM Disclosures Have Mixed Impact on Prescription Drug Costs

In contrast, some research finds mixed results regarding PBM disclosures on prescription drug costs and other aspects of the market. For example, a 2025 study examining Medicare Part D data from 2016 to 2022 found that state laws requiring PBMs to disclose rebate information did not reduce prescription drug costs, including premiums, deductibles, or out-of-pocket spending. The study also found no meaningful differences in responses between PBM-affiliated and unaffiliated plans. However, the authors identified a spillover effect in multi-state plans, where states without transparency laws experienced roughly a seven percent increase in drug

[313] Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences*, National Bureau of Economic Research (Mar. 2023), available at https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.
[314] Federal Trade Commission, Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities, (July 20, 2023), available at https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf

costs compared to states with transparency requirements. These findings suggest that while disclosure mandates may improve transparency, their direct effects on consumer drug spending remain uncertain.[315]

Additionally, Scanlon (2024) used outpatient prescription drug claims data for chronic conditions of employer-sponsored health plans from 2014 to 2022 to examine two types of State-level PBM disclosures: inter-firm disclosures[316] and disclosures to regulators.[317] Focusing on disclosures related to rebate/pricing information, the paper found that the impact of inter-firm disclosures, those most like the ones contemplated in this rulemaking increased prescription drug costs for plans (the plan's share of the gross price for the prescription as negotiated between the health plan and PBM, after factoring in fee schedules and discounts) by 3.5 percent, but reduced out-of-pocket costs for participants (the sum of the copayment and coinsurance) by 1 percent.[318]

However, the impact of inter-firm disclosures varied by the competitiveness of the drug market. In competitive markets, the disclosures increased costs to plans while the impact on participants was insignificant. Alternatively, in monopoly drug markets, there was no significant impact on plans while patient costs significantly declined. The author argues this was because in competitive markets, disclosing price information reduces competition between drug manufacturers which increased gross prices and the plans' total costs; in a monopoly market, disclosures reduced information asymmetry and strengthened health plans' bargaining power,

[315] Nicola Maria Fiore, *Can Transparency Reduce Drug Costs* (as revised, Apr. 17, 2026), available at https://ssrn.com/abstract=5710162; http://dx.doi.org/10.2139/ssrn.5710162.
[316] "Inter-firm disclosures" are defined as disclosures where PBMs share pricing information with health plans, pharmacies, and drug manufacturers. As referred to in this paper, "health plans" include health insurance issuers.
[317] "Disclosures to regulators" are defined as disclosures where PBMs report pricing details to government authorities. These included state regulations related to auditing, pharmacy networks and fiduciary duties.
[318] Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market* (Dec. 20, 2024), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5021179.

resulting in a 9.4 percent decrease in out-of-pocket costs for these drugs. Additionally, States that required PBMs to disclose to pharmacies the sources used to determine MAC prices and update the information regularly, had 8.6 percent more pharmacies per capita and 10 percent more independent pharmacies overall than States that did not require those disclosures, improving patient access.[319]

The author concluded that inter-firm disclosures increase costs for plans but lower them for participants. This effect depended on the competitiveness of the drug market. For monopoly drugs, inter-firm disclosures resulted in more efficient contracting, which led to lower drug costs. When applied to more competitive markets, however, the disclosures discouraged competition among drug manufacturers. As a result, the author advocated for utilizing PBM disclosures in monopoly drug markets. The Department notes that the study was limited to actual amounts paid by plans and participants per prescription and did not account for rebates and other incentive payments to health plans that may have been applied later. As a result, the negative impact on plan costs of inter-firm disclosures may be overstated.[320]

9. Benefits and Transfers

The Department expects that the final rule would improve transparency in PBM operations, as directed by Executive Order 14273.[321] The final rule is expected to assist responsible plan fiduciaries in their selection and monitoring of service providers providing prescription drugs, and to foster a more efficient and competitive prescription drug market.

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[319] *Id.*

[320] The author utilizes the MarketScan prescription claim database for her analysis, which reports actual payment amounts paid by health plans and patients per prescription. The database does not include information on net costs to plans, meaning that rebates or other forms of incentive payments that may later offset costs to plans were not captured.

[321] *Lowering Drug Prices by Once Again Putting Americans First*, 90 FR 16441 (Apr. 15, 2025), available at .https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf

These improvements are anticipated to generate the following economic and societal effects experienced by participants, beneficiaries, enrollees, and the broader healthcare system:

- improved understanding of PBMs by self-insured group health plans' responsible plan fiduciaries,
- greater ability for responsible plan fiduciaries to compare offerings across PBMs, fostering competition and improving pricing,
- stronger negotiating positions for responsible plan fiduciaries, enabling better contractual terms with PBMs,
- reduced conflicts of interest that currently influence PBMs' key decisions regarding rebates, formulary design, and prescription drug pricing,
- reduced prescription costs for self-insured group health plans and participants,
- improved patient health outcomes due to increased treatment adherence from better access to more affordable prescription drugs,
- reduced costs to self-insured group plans and employers, allowing them to shift resources to other benefits or priorities.

This analysis provides both a qualitative discussion of the benefits and transfer impacts of the final rule as well as a quantitative analysis of the benefits. The Department's qualitative discussion focuses on how the final rule would enable self-insured group health plans, participants, and other stakeholders to better utilize the information provided by PBM disclosures.[322] The Department received multiple comments stating that increased transparency would reduce hidden fees, strengthen fiduciary oversight and negotiations, lower prescription

[322] If the various mechanisms and outcomes discussed above could be quantified and were then summed simplistically, the result would almost certainly include double counting.

drug costs, improve patient access to medications, and promote competition based on price and value rather than opaque financial arrangements. The Department agrees with the commenters regarding these anticipated benefits.

The Department also included in the proposed rule a quantitative analysis on the impact of lowered negotiating costs to self-insured group health plans and plan sponsors and reduced prescription drug costs for self-insured group health plans and participants. In the proposal, the Department utilized two alternative approaches, direct Willingness-to-Pay (WTP) and Quality Adjusted Life Years (QALY), to quantify the benefits from price decreases and requested comments on the appropriateness of each approach. Upon reviewing comments and further analysis, the Department has determined the WTP approach is more appropriate for this analysis. The Department has also included a QALY analysis in the uncertainty section.

WTP is defined as the maximum amount of money an individual would voluntarily exchange to obtain a benefit, given their budget constraints.[323, 324, 325] Because WTP is expressed in monetary terms, it is directly comparable to costs. In the context of reduced prescription drug prices, ideally WTP would measure, through consumer preferences, the total value patients place on improved medication adherence and the health improvements that follow—which would encompass reduced healthcare expenditures, extended life expectancy, and improved quality of life (possibly ***net*** quality changes including long-term improvements but also more immediate

[323] Office of Management and Budget, *Circular A-4* (Oct. 9, 2003), available at https://www.federalregister.gov/documents/2003/10/09/03-25606/circular-a-4-regulatory-analysis.
[324] Department of Health and Human Services, *Guidelines for Regulatory Impact Analysis* (2016), available at https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//171981/HHS_RIAGuidance.pdf.
[325] Environmental Protection Agency, *Guidelines for Preparing Economic Analyses* (Dec. 2024), available at https://www.epa.gov/system/files/documents/2024-12/guidelines-for-preparing-economic-analyses_final_508-compliant_compressed.pdf.

side effects). In this sense, a WTP-based consumer surplus measure would measure the direct welfare gained from the price reduction.

In contrast, QALYs indirectly measure welfare gains from improved health outcomes. Utilizing observed and reported patient health outcomes, QALYs quantify health gains in standardized units which allows them to be monetized using an indirect WTP value, such as the value of a statistical life (VSL), to compare health benefits to regulatory costs. QALYs are also a widely utilized measure in the health economics literature.[326] While they remain a comprehensive and accepted indirect measure of health outcome benefits, QALYs suffer from restrictive assumptions about how to value different health states, such as QALY gains being measured proportionally regardless of health state or age.[327]

Having weighed the attributes and limitations of both approaches, the Department has decided to pursue the WTP approach for the final rule. This decision is supported by other commenters, who advocated the use of WTP over QALY.[328] They argued that current regulatory guidance indicates direct WTP is the preferred measurement and that WTP more accurately captures the welfare impacts of all affected participants.[329]

Upon reviewing the comments, the Department has revised some of its underlying assumptions and application of the methodologies discussed to assess benefits of this final rule. These changes will be discussed in greater detail in the affected sections.

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[326] James Hammitt, *QALYs Versus WTP,* Risk Analysis, Vol. 22, No. 5, (2002).
[327] Matthew Adler, *QALYs and Policy Evaluation: A New Perspective,* Yale Journal of Health Policy, Law, and Ethics (2006).
[328] Comment ID: EBSA-2026-0001-0056.
[329] The most direct consumer impact of this final rule is reducing prescription drug prices, so analytically, it is feasible to use a direct-WTP approach to valuing morbidity effects, per HHS's Guidelines for Regulatory Impact Analysis: "Analysts should first… determine whether suitable WTP estimates of reasonable quality are available. If not, they should use monetized QALYs" (p. 18).

9.1. Benefits and Transfers to Self-insured Group Health Plans

9.1.1. Improved Understanding of PBMs by Plans

PBM disclosures would provide self-insured group health plans with greater insight into previously hidden fees, rebates, and discounts, as well as potential conflicts, which would lead to a better understanding of PBM costs and practices. For example, these disclosures would reveal to self-insured group health plans how much of the negotiated rebates are retained by PBMs and their agents, versus being passed through to self-insured group health plans, participants, and beneficiaries, enabling them to accurately assess the true costs of pharmacy benefits and if they are reasonable. Self-insured group health plans would be able to compare the prices they were charged for pharmacy claims to the reimbursement rates pharmacies received from PBMs through "spread pricing," and how much participants and beneficiaries paid at the point of sale through copays and coinsurance. This would allow self-insured group health plans to calculate how much the PBMs collected from each transaction. As a result, self-insured group health plans would more easily be able to monitor PBMs and the indirect fees they charge.

9.1.2. Increased PBM Market Place Competition and Self-insured Group Health Plans Negotiating Better Contractual Terms

Increased transparency into compensation arrangements would help self-insured group health plans better assess costs across different PBM providers, leading to more informed decision-making when selecting a PBM, increasing competition, and allowing self-insured group health plans to negotiate better contract terms.[330] Requiring PBMs to disclose pricing structures,

[330] Matthew Fiedler, Loren Adler, & Richard G. Frank, *A Brief Look at Current Debates About Pharmacy Benefit Managers*, The Brookings Institution (2023), https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers/.

discounts, and rebates reasonably in advance of entering into a contract or arrangement with a self-insured group health plan will help responsible plan fiduciaries determine the reasonableness of the proposed fees, including all direct and indirect compensation. Moreover, these disclosures could limit PBMs' ability to engage in spread pricing or accept undisclosed rebates, helping to ensure that formulary and reimbursement decisions better reflect clinical value and affordability.[331]

When evaluating the potential impact of a bill requiring additional transparency by PBMs related to utilization and direct and indirect compensation (as well as banning spread pricing and requiring pass-through rebates), CBO estimated only minimal cost savings, with premiums reduced by 0.1 percent in the first year of the rule with those savings eroding over time.[332] In their analysis, CBO stated that they also expected a portion of PBM clients, particularly sponsors of small- and medium-sized health plans, who had limited access to this information under current law, to obtain better terms in contract negotiations following these disclosures. The additional pressure from responsible plan fiduciaries coupled with more transparent pricing could lead to new entries in the PBM market, including pass-through and fee-based models, and could result in market-wide changes in pricing behavior. CBO did not, however, estimate these second-order effects.

While commenters couldn't provide market-share data on pass-through PBMs, they indicated it was growing as "employers become more aware of the pricing distortions in traditional PBM models." A 2024 survey aimed to gauge U.S. employers' perspectives on

[331] National Alliance of Healthcare Purchaser Coalitions, *A Playbook for Employers: Addressing Pharmacy Benefit Management Misalignment* (2023), available at https://www.nationalalliancehealth.org/wp-content/uploads/NationalAlliance_PBM_PB_2023_A.pdf.
[332] Congressional Budget Office, *S. 1339, Pharmacy Benefit Manager Reform Act* (2024), https://www.cbo.gov/system/files/2024-12/s1339.pdf

various factors, including PBM transparency and premiums, among private and public employers suggests these new entries were viewed favorably. The findings indicated that employers who used transparent PBMs were 1.6 times more likely to report lower premiums (42 percent compared to 27 percent) and 30 percent less likely to report higher premiums (29 percent compared to 41 percent) than those utilizing the three largest PBMs.[333]

Additionally, by requiring disclosures that clearly define contract terms, responsible plan fiduciaries can better assess potential cost levers when evaluating proposals. Currently, PBMs may provide their own definitions for brand, generic and specialty drugs. In doing so, PBMs can change a drug's classification to meet contracted guarantees or maximize their own fees. This can allow PBMs to classify certain prescription drugs as "specialty" drugs to justify higher markups or cost-sharing requirements.[334] By requiring PBMs to disclose spread pricing at the individual drug and pharmacy channel level, how formulary placement incentives and arrangements affect services, and reasons why reasonably available therapeutic equivalent alternative drugs (including biosimilar biological products) were omitted from the formulary, responsible plan fiduciaries can attain more appropriate formulary placement, more equitable patient cost-sharing, and broader access to prescription drugs that have been previously miscategorized, which could result in reduced prescription drug spending for large, self-insured group health plans and lower out-of-pocket costs for participants.

Similarly, definitions of rebates and discounts can be manipulated by PBMs to exclude "other" indirect payments to avoid contractual pass-through payments. This can be particularly

[333] National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchaser 2025 Survey Results* (Sept. 8, 2025), https://www.nationalalliancehealth.org/resources/pulse-of-the-purchaser-2025-survey-results/.
[334] Federal Trade Commission, *Interim Staff Report*, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

problematic when PBMs contract with an affiliated service provider that can in turn influence how acquisition costs or rebates are defined, allowing gaming of contracts.[335] By clarifying these terms prior to entering agreements, responsible plan fiduciaries can negotiate better contract terms. A 2024 survey found that 33 percent of employers had lower than average premiums following the adoption of more comprehensive definitions of the term "rebate" to include other revenue streams, such as access fees and credits in their contracts.[336]

The additional transparency and clarified terms can also reduce the complexity and scope of comparing proposals and contract negotiations, further reducing costs for self-insured group health plans. By removing the need for self-insured group health plans to independently verify price models, rebates, and fee structures, the required disclosures would limit search costs and reduce the resources needed to select a PBM and prepare for contract negotiations. Even a modest reduction in preparation costs, such as a one-hour reduction in the time for a legal professional to prepare for negotiations, could result in estimated cost savings of approximately $7.1 million across the 39,331 impacted self-insured group health plans that are expected to initiate new contracts, extend existing contracts, or renew contracts each year.[337]

By obtaining disclosures in advance of finalizing the contract, responsible plan fiduciaries can identify problematic provisions and negotiate modifications with the PBMs. For example, this allows responsible plan fiduciaries to negotiate the removal of certain contractual

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[335] National Alliance of Healthcare Purchaser Coalitions, *A Playbook for Employers: Addressing Pharmacy Benefit Management Misalignment* (2023), https://www.nationalalliancehealth.org/wp-content/uploads/NationalAlliance_PBM_PB_2023_A.pdf.

[336] National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchasers: 2024 Survey Reports,* (2024), https://www.nationalalliancehealth.org/wp-content/uploads/Pulse-of-the-Purchaser-Fall-2024.pdf. It is important to note that 9 percent of respondents reported high premiums following adoption of enhanced definitions of rebates.

[337] This estimate is calculated as: 131,102 self-insured group health plans × 1/3 of plans contracts with PBMs expiring annually = 39,331 self-insured group health plans negotiating contracts annually × $181.06 hourly wage of legal professional × 1 hour = $7,121,198.

terms that may limit the fiduciary from obtaining data related to prescription drugs, and negotiate for stronger audit rights in order to verify claim accuracy, monitor the PBMs' performance, and ensure contract compliance.[338] As a result, increased transparency could foster greater competition within the market, leading to more competition, lower prices and improved contract terms, as well as better value and lower health-care costs for self-insured group health plans and their participants and beneficiaries. The resulting savings could in turn allow self-insured group health plans, employers, and plan sponsors to invest those resources elsewhere.[339]

9.1.3. Reduced Conflicts of Interest in PBM Practices

Greater transparency in PBM operations could help reduce the conflicts of interest that influence PBMs' key decisions regarding rebates, formulary design, and reimbursement rates. Currently, PBMs often have significant existing relationships with consultants, manufacturers, rebate aggregators, and pharmacies which can circumvent claims of transparency in pricing. Even consultants advising plans on the selection of PBMs and the structure of their contracts may receive payments from PBMs based on the number of prescriptions or the number of covered employees, which may well influence their recommendations to plans.[340] Employers that receive confirmation that advisors do not receive direct or indirect compensation from PBMs or related third parties reported reduced annual premiums.[341]

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[338] Remy Samuels, *PLANSPONSOR Roadmap: A PBM Process* (Apr. 21, 2025) https://www.plansponsor.com/plansponsor-roadmap-a-pbm-process/.
[339] See discussion of the exclusive purpose rule in ERISA section 403(c), supra note 75.
[340] Advisory Council of Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure*, (Nov. 2014), available at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf.
[341] National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchasers: 2024 Survey Reports* (2024), available at https://www.nationalalliancehealth.org/wp-content/uploads/Pulse-of-the-Purchaser-Fall-2024.pdf.

Even with pass-through pricing enshrined in PBM contracts, without disclosures detailing existing relationships, these agreements can be compromised if PBMs subcontract with affiliated service providers. PBMs may structure preferred pharmacy networks so that patients are directed or are required to fill prescriptions at PBM-affiliated pharmacies, which are then reimbursed at a greater rate than independent pharmacies.[342] In contrast, requiring full disclosures of all revenue streams with affiliated pharmacy-related entities can result in reduced premiums.[343] PBMs may also utilize rebate aggregators to negotiate and collect rebates from drug manufacturers, whose extracted fees have been estimated to have doubled between 2018 and 2022. PBMs that use affiliated rebate aggregators can reduce the rebate that would be passed through to plans while retaining the rebate portion collected by the rebate aggregators if that relationship is not disclosed and addressed in the contract, resulting in higher plan costs.[344]

By requiring PBMs to disclose these relationships prior to entering into a formal agreement, the rule enables responsible plan fiduciaries to better evaluate whether there are sufficient mechanisms in place to ensure that those relationships do not adversely impact the self-insured group health plan and its participants and beneficiaries. Moreover, receiving updated information over the course of the contract will allow responsible plan fiduciaries to continue to monitor these relationships so that PBMs continue to perform their function without subordinating plan interests. As such, the final rule will help to reduce conflicts and mitigate the

[342] U.S. House Committee on Oversight and Accountability, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* (2024), available at https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf.
[343] National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchasers: 2024 Survey Reports* (2024), available at https://www.nationalalliancehealth.org/wp-content/uploads/Pulse-of-the-Purchaser-Fall-2024.pdf.
[344] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

risks that arise from them, resulting in more efficient and cost-effective pharmacy benefits for self-insured group health plans, including the replacement of more expensive drugs with cheaper, yet equally effective alternatives on the formularies.

9.2. Transfers and Benefits to Participants and Beneficiaries

9.2.1. Improved Health Benefits from Greater Drug Adherence

The disclosures required of PBMs in the final rule will help to reduce information asymmetry and aid self-insured group health plans' responsible plan fiduciaries in their selection of and negotiations with PBMs, helping to reduce costs for the self-insured group health plans and lower prescription drug prices.[345] By reducing prescription costs, the final rule could improve adherence to prescribed drugs, as patients are less likely to skip or reduce doses, delay refills, or forgo treatment due to financial concerns. Improved treatment adherence supports disease management and is associated with better overall health outcomes. Research corroborates that poor treatment adherence is associated with poorer health outcomes and significantly higher mortality rates.[346, 347] In the context of the final rule, the required disclosures could enable plan sponsors to design benefits and formularies that help reduce out-of-pocket costs and improve prescription adherence, particularly for patients at high risk of hospitalization which could

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[345] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), www.cbo.gov/publication/58793.

[346] Teresa B. Gibson, Xue Song, Berhanu Alemayehu, Sara S. Wang, Jessica L. Waddell, Jonathan R. Bouchard, & Felicia Forma, *Cost Sharing, Adherence, and Health Outcomes in Patients with Diabetes,* American Journal of Managed Care 16(7) (2010), https://pubmed.ncbi.nlm.nih.gov/20712392/;
Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality, British Medical Journal*, (2006), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf;Donald Pittman, William Chen, Steven Bowlin, and JoAnne Foody, *Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations,* American Journal of Cardiology 107(11) (2011), https://pubmed.ncbi.nlm.nih.gov/21439533/

[347] Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality, British Medical Journal* (2006), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf.

ultimately improve patient health outcomes over the long term. These outcomes are embedded in the value quantified in Section 9.2.3.

9.2.2. Reduced Prescription Payments for Participants and Beneficiaries

The Department believes that increased transparency from PBM disclosures will reduce prescription prices, resulting in a transfer, by correcting pricing distortions that currently inflate the prices that participants and beneficiaries face for prescription drugs. By highlighting preferential pricing for certain drugs and distribution channels, disclosures may result in self-insured group health plans retaining greater rebate shares, increasing the use of generics and biosimilars, and promoting less expensive pharmacy networks. This can result in cost savings for self-insured group health plans, which may share these cost savings with plan participants through reduced premium payments, as well as lower out-of-pocket costs that participants and beneficiaries face when filling their prescriptions.

Manufacturers factor rebates into their bottom line, which incentivizes them to increase list prices of covered drugs to protect their net prices. As a result, patients may pay cost-sharing based on the drug's list price, even though the net price after rebates is substantially lower.[348]

A 2023 U.S. Senate Finance Committee hearing further discussed that rebate-driven models reward manufacturers with greater volume and market share, making it difficult for lower-cost or new competitors to gain formulary access. Existing manufacturers can offer large rebates by leveraging their sales volume or by bundling multiple drugs into a single rebate agreement. These arrangements can effectively exclude competitors that cannot match the financial value of rebates, even if they offer lower-price alternatives. The Committee

[348] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (2021), available at https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

characterized this dynamic as the "rebate trap," in which rebates contribute to higher list prices, particularly for brand-name and specialty drugs. This dynamic reinforces market concentration and limits price competition, ultimately contributing to higher costs for self-insured group health plans and patients.[349]

As the prescription drug market becomes more transparent through the proposed disclosures, it may discourage PBM practices that favor high-rebate drugs over lower-cost drug alternatives. This shift could support more cost-effective and clinically driven formulary design. Moreover, PBMs may also pass through a greater share of the rebates to self-insured group health plans, ultimately helping to reduce prescription costs, particularly for specialty and brand-name drugs where rebate amounts tend to be the highest.[350] This, coupled with cost reductions stemming from improved contract negotiations related to spread pricing, copay claw-backs, and pharmacy reimbursement, may result in lower costs to participants and beneficiaries at the point of sale. Such reductions resulting from these disclosures would be particularly meaningful for individuals who heavily rely on prescription medication or who manage chronic health conditions, where even modest price differences can lead to substantial savings over time, and result in improved adherence to treatment plans.

Research from CBO on disclosures from PBMs to health plans estimated that requiring PBMs to share their drug price information with health issuers would lower the average net retail

[349] United States Senate Committee on Finance, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayer* (Mar. 30, 2023), available at https://www.finance.senate.gov/imo/media/doc/pharmacy_benefit_managers_and_the_prescription_drug_supply_chain_impact_on_patients_and_taxpayers.pdf.
[350] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (2021), available at https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

price of prescription drugs, approximately 0.1 percent to 1.0 percent.[351] Data from MEPS-HC indicates that average annual total prescription expenditures for individuals with private insurance aged 18 to 64 were approximately $1,548 for combined issuer and patient costs.[352] This translates into estimated, total prescription expenditures for self-insured participants and issuers of $81.8 billion annually.[353] Utilizing the CBO estimate of a one percent price reduction arising from PBM disclosures, the Department estimates that expenditures from patients and issuers will decline, producing an estimated $818.4 million transfer for the 52.9 million participants and beneficiaries[354] age 18 to 64 of large, self-insured group health plans covered by the final rule.[355] This estimate does not include the reduction in prescription costs for children in these plans, and therefore underestimates the full transfer effect. Because the policy estimated by CBO, however, is limited to only price disclosures and does not include information on conflicts of interest, audit rights and other additional elements of the final rule, this estimate may understate the impact of the final rule on prices.

The Department utilized the 1.0 percent price reduction estimated by CBO for the final rule in response to comments received. One commenter suggested that the CBO estimate likely underestimated the price reduction that would result from the rule, as the CBO estimate "was based on a narrower set of transparency requirements than [the proposed rule]."[356] The

[351] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (2024), available at https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf.
[352] Based on data reporting insurer and patient expenditures for privately insured patients aged 18–64. *See* Department of Health and Human Services, Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey* (2025).
[353] This estimate is calculated as: $1,547.67 × 52,882,418 participants age 18 to 64 in large, self-insured plans = $81,844,531,866.
[354] Estimate is based on the Department's tabulations of the March 2025 Current Population Survey (CPS) Auxiliary Data.
[355] These estimates are calculated as: $81,844,531,866 × 1.00 percent = $818,445,319.
[356] Comment ID: EBSA-2026-0001-0056.

Department agrees that the rulemaking is more robust than the transparency requirements analyzed by CBO. Given the mixed results in the literature reviewed above, however, the quantitative range may also overstate the impact (and may even inappropriately omit any quantification of transfers potentially flowing the opposite direction). In response to this uncertainty, the Department also considered alternative rates of price reductions stemming from the increased transparency, ranging from a 0.5 percent to a 2 percent reduction in price. This analysis can be found in the Uncertainty section.

9.2.3. Quantified Benefits

While the Department utilized two different approaches to quantify benefits in the proposal, WTP and QALY, as discussed above, in response to comments and additional data the Department is using only the WTP method for its final rule analysis. Estimates using the QALY approach can be found in the Uncertainty section. Similarly, while an estimated price reduction of one percent is utilized for the primary analysis in this section, a sensitivity analysis utilizing estimates of 0.5 percent and 2.0 percent is included in the Uncertainty section.

9.2.3.1 Benefits Measured by Direct Willingness-to-Pay

The high rates of non-adherence for reasons of cost indicate a price level for many drugs that exceeds participant willingness-to-pay. This suggests that lowering prices will provide additional consumer surplus to participants and other purchasers of prescription drugs as many will improve their welfare from increasing consumption of their prescribed medications at lower prices. As insurers also contribute toward the cost of the drug through cost-sharing for the net retail price, the Department anticipates that insurers will also benefit from the additional consumer surplus gained from the final rule.

Utilizing data from MEPS-HC on average annual out-of-pocket expenditures for prescription drugs of participants in private group health plans in 2023 ($146), as well as the average annual expenditures from insurers for such participants in private group health plans ($1,402), the Department finds that the average annual expenditures for prescription drugs total $1,548.[357] This data also reports an annual average of 7 prescription fills for all such participants, suggesting an average prescription cost of $218 for combined insurer and participant expenditures.[358] Given an estimate of 52.9 million participants and beneficiaries, age 18 to 64 in large, self-insured group health plans[359] and assuming a similar utilization and cost of prescription drugs, the Department estimates total prescription drug expenditures for this population at approximately $81.8 billion arising from an estimated 375.5 million prescription fills annually.[360]

Research on demand for prescription drugs among those with commercial insurance indicates a price elasticity of approximately -0.358 across all prescriptions.[361] Utilizing the stated price elasticity, estimated price decrease, and prescription demand, the Department estimates that approximately 1.34 million additional prescription drugs will be purchased as a result of lower prices.[362] Given an average WTP of $218 per prescription, the Department estimates that the

[357] Department of Health and Human Services, Agency for Healthcare Research and Quality*, 2023 Medical Expenditure Panel Survey* (2025).
[358] These estimates are calculated as $1,548 annual prescription expenditures ÷ 7.1 average annual prescriptions = $218 average cost of prescription for insurer and patient out-of-pocket expenses. Unrounded estimates are used in intermediate calculations, here and in subsequent analytic steps, and this practice explains any possible appearance of arithmetic discrepancies.
[359] Estimate is based on the Department's tabulations of the March 2025 Current Population Survey (CPS) Auxiliary Data.
[360] These estimates are calculated as: 52,882,418 participants in self-insured plans × 7.1 average prescription fills annually = 375,465,168 annual prescription fills for self-insured plan participants; $217.98 average cost × 375,465,168 prescriptions = $81.84 billion annual expenses for prescription drugs in large, self-insured plans.
[361] Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data,* Journal of Health Economics, Vol. 48 (2016).
[362] This estimate is calculated as: -1 percent price reduction × -0.358 price elasticity × 375,465,168 prescriptions = 1,344,165 prescriptions.

value of the gross willingness to pay would result in up to $293.0 million of benefits annually.[363] The $218 WTP includes not just consumers' but also insurers' portion of drug spending, reflecting an assumption that insurance markets capture pharmaceutical value, with such value taking various forms, including health improvements for consumers/patients and reduced non-adherence-related medical costs (with associated savings accruing to a combination of newly-adherent patients, premium-payers generally, and insurance companies).[364]

It is worth noting that this approach does not account for the marginal cost associated with the newly-filled prescriptions and therefore may overstate societal benefits of the final rule. The Department requested comments on refining the WTP approach and more generally on the preceding assumptions and calculations. The Department did receive several comments about the WTP approach.[365] Several comments provided general support for the WTP analysis, stating that it was more appropriate than QALY and would be the preferred approach as WTP more broadly captures the impact of the rule on all participants. One of the comments referenced OMB Circular A-4, suggesting that it indicates a clear preference for WTP over QALY-like measures. None of the comments offered data that might improve the WTP analysis from the proposal.

9.2.4. Transfers from Standard Traditional PBMs to Transparent PBMs

In response to the disclosure requirements, responsible plan fiduciaries may be increasingly inclined to utilize transparent PBMs like fully pass-through PBMs rather than PBMs using the standard business model. Under a fully pass-through pricing strategy, PBMs rely much

[363] This estimate is calculated as: $217.98 average prescription WTP × 1,344,165 prescriptions = $293,001,152.
[364] Insurance markets are likely to be characterized by distortions, so an alternative approach to quantifying benefits might take the form of adding the consumer portion of pharmaceutical WTP to separately estimated changes in medical spending (see Table 11, later in this regulatory impact analysis). However, this approach may yield underestimates.
[365] Comment ID: EBSA-2026-0001-0056; EBSA-2026-0001-0258; EBSA-2026-0001-0458; EBSA-2026-0001-0484.

more on administrative fees instead of other income streams, which can reduce hidden costs and conflicts of interest. This may be more attractive for responsible plan fiduciaries as it could potentially simplify auditing PBMs, lessening oversight and monitoring costs. One fully pass-through PBM testified before Congress that their first-year clients reported an average reduction in costs of 11 percent compared to other PBMs[366] while other fully pass-through PBMs have reported savings of as much as 30 percent.[367] As a result, in response to the final rule, responsible plan fiduciaries may engage fully pass-through PBMs in lieu of standard PBMs for their prescription drug services, resulting in a transfer of business across PBM type.[368]

One commenter stated that fully pass-through PBMs generally disclose more pricing information because their business model relies less on retained spread and manufacturer-side compensation. The commenter further indicated that the reported cost savings associated with fully pass-through PBMs are consistent with their experience in the market and emphasized that the price impact of opacity in traditional PBM pricing structures can be substantial. Additionally, the commenter noted that the fully pass-through PBM market remains small relative to the larger vertically integrated PBMs, estimating that approximately ten percent or less of the market is currently served by fully pass-through PBMs. The Department appreciates the commenter's insights regarding pricing transparency, market structure, and the potential cost impacts associated with fully pass-through PBM models.

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[366] Sharon Faust, *Prepared Testimony Before the United States Judiciary Committee* (May 11, 2025), available at https://www.judiciary.senate.gov/imo/media/doc/2025-05-13_testimony_faust.pdf.
[367] Alliance of Community Health Plans, *A Unique Approach: Transparent PBMs* (Apr. 2019), available at https://achp.org/wp-content/uploads/PBM-Infographic_4.5.19.pdf.
[368] Pharmaceutical Strategies Group, *2025 Trends in Drug Benefit Design Report* (June 2025), available at https://link.psgconsults.com/2025-trends-in-drug-benefit-design-report.

9.2.5. Transfers from PBM Affiliated Pharmacies to Unaffiliated Pharmacies

The final rule includes disclosures related to spread pricing, requiring information on the cost reimbursements for each drug on the self-insured group health plans' formulary for each pharmacy channel. Because PBMs often favor affiliated pharmacies, these disclosures may highlight price discrimination which has traditionally resulted in lower reimbursements and utilization rates for non-affiliated pharmacies. With the greater transparency required by the final rule, PBMs may choose to equalize treatment across all distribution channels which in turn may shift business from affiliated to non-affiliated pharmacies.

10. Costs

This final rule aims to enhance the responsible plan fiduciaries' ability to monitor costs and the administration of prescription drug benefits by PBMs, their agents, and affiliates, by requiring PBMs to provide disclosures regarding fees, pricing structures and potential conflicts of interest both prior to entering a service provider agreement, and semiannually during the agreement. In addition, PBMs must make available to responsible plan fiduciaries all information required to conduct audits to confirm the accuracy of any disclosure made to comply with the regulations.

Prior to this rulemaking, service providers that engage in consulting or provide brokerage services to self-insured group health plans for certain identified sub-services were already required under the CAA, 2021 to disclose to responsible plan fiduciaries a description of the service provided, direct and indirect compensation received, and the provider's fiduciary status with respect to the self-insured group health plan.[369] These disclosures are to be made not later

[369] 134 Stat. 1182 - Public Law No. 116-260.

than the date that is reasonably in advance of the date on which the contract or arrangement is entered into, extended or renewed. Moreover, while the Department did not issue specific rules governing these disclosures at the time, it provided guidance stating that the statute made unambiguous that covered service providers, as defined in the statute, must now disclose both direct and indirect fee compensation.[370]

When questioned by Congress in 2023 regarding PBMs' compliance with Section 408(b)(2), one PBM trade association responded that they believed their companies were in compliance and provided the appropriate disclosures related to direct and indirect compensation.[371] Additionally, several States have adopted disclosure requirements for PBMs regarding elements included in this final rule, including rebate payments, spread compensation and drug prices.[372]

This final rule provides a more detailed requirement of what information must be disclosed. It also requires initial disclosures and disclosures on a semiannual basis (or quarterly, at the plan's request) instead of just when the contract or arrangement is entered into, extended or renewed. As such, the Department assumes that PBMs already provide to various parties information like what is required under this final rule, though not necessarily at the same level of detail or frequency.

The Department acknowledges that PBMs, in revising their approach to documenting and disclosing their business practices to self-insured group health plans to be consistent with this

[370] Field Assistance Bulletin No. 2021-03, available at https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03.
[371] Committee on Education and the Workforce Subcommittee on Health, Employment, Labor and Pensions, *Competition and Transparency: The Pathway Forward for a Stronger Health Care Market*, (June 21, 2023).
[372] Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* (Mar. 2024), available at https://www.gao.gov/assets/d24106898.pdf.

final rulemaking, will incur additional costs. Moreover, by providing disclosures at a more granular level prior to entering into a formal agreement, the Department expects the self-insured group health plans may demand additional concessions, resulting in lower revenues for PBMs. This collection of costs would appropriately be included in any comparison with the benefits described, and in some cases illustratively quantified, elsewhere in this RIA.

10.1. Rule Familiarization and Compliance Costs

The Department anticipates that the costs related to this final rule will consist of both initial and annual costs. Initial costs include review of the regulation and identifying new requirements, developing templates for the new disclosures, and developing processes for capturing the necessary data (including automating systems). Ongoing costs will include the cost of producing the disclosures, transmitting them to responsible plan fiduciaries, and responding to audit requests.

Self-insured group health plans, issuers/State combinations, and TPAs are expected to review the final rule in order to familiarize themselves with the new requirements and how they will impact them. Self-insured group health plans with 1,000 or more participants and beneficiaries are expected to review the rule themselves. In contrast, self-insured group health plans with less than 1,000 participants and beneficiaries, are expected to utilize a TPA, issuer, or other service provider to review the final rule on the self-insured group health plan's behalf.

The Department assumes that it will take, on average, 5 hours for a legal professional for a large, self-insured group health plan to review the final rule, and 20 hours for a TPA or issuer

to review the rule on behalf of each self-insured group health plan.[373] The Department further assumes a wage rate of $187.58 per hour for the legal review[374] and that this burden would only be incurred in the first year.

PBMs would also need to review the final rule and evaluate whether their current disclosure practices comply with the requirements. Because the majority of the rule is focused on PBM policies and actions, the Department assumes that similar to TPAs or issuers, this initial review will take four times as long for PBMs to review and identify current practices that are not consistent with the final rule's requirements than responsible plan fiduciaries. As such, the Department assumes that it will take, on average, 20 hours for a legal professional to review the final rule on behalf of PBMs at a wage rate of $187.58 per hour. The Department assumes this burden would only be incurred in the first year. Please see Table 2 for calculations and burden totals.

The Department requested comments on these assumptions. One commenter stated that the 20-hour review burden is underestimated. The commenter asserted that reviewing the rule would require multiple days of review, consultation with outside counsel, and coordination with technical experts to evaluate operational and implementation measures. However, the Department continues to believe that the estimate is appropriate because it reflects the average

[373] On average, the reading rate is 250 words per minute (WPM), which also corresponds to the typical length of a page. Therefore, a regulation document that is approximately 300 pages long would take about 300 minutes to read, translating to 5 hours (300 pages x 250 words per page ÷ 250 words per minute ÷ 60 minutes = 5 hours). The Department notes that this estimate applies to the plans. In contrast, TPAs, issuers, and PBMs are anticipated to require more time for their review, as discussed in the following paragraph.

[374] Internal DOL calculation based on 2026 labor cost data. For a description of DOL's methodology for calculating wage rates, see https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.

expected burden across entities. The Department acknowledges that individual entities may require more or less time depending on their size, structure, and existing compliance systems.

TABLE 2. Rule Familiarization Costs

Entities	Number of Entities	Number of Hours per Entity	Total Hour Burden	Hourly Wage	Cost
	(A)	(B)	(C) = (A x B)	(D)	(E) = (C x D)
Self-insured group health plans with 1,000 or more participants and beneficiaries	17,876	5	89,380	$187.58	$16,765,900
TPAs on behalf of client self-insured group health plans with less than 1,000 participants and beneficiaries	205	20	4,100	$187.58	$769,078
Issuers on behalf of client self-insured group health plans with less than 1,000 participants and beneficiaries	809	20	16,180	$187.58	$3,035,044
PBMs	73	20	1,460	$187.58	$273,867
First-year Total	**18,963**	**-**	**111,120**	**-**	**$20,843,890**

As stated above, the Department believes that most PBMs already have the required information needed to fulfill the disclosure requirements, as they manage complex healthcare operations and track the flow of pharmaceuticals and payments within the healthcare system as part of their regular business practices. Moreover, PBMs already provide this information, or elements of it, to self-insured group health plans and other entities, as required under the CAA, 2021 and State laws.[375] Therefore, the Department does not expect that PBMs will need to devote significant resources to obtain or share information on the services provided under the agreement, direct and indirect compensation, rebates, drug prices and the pricing methodology,

[375] National Academy for State Health Policy, *State Pharmacy Benefit Manger Legislation* (last updated Mar. 10, 2026), available at https://nashp.org/state-tracker/state-pharmacy-benefit-manager-legislation/.

reimbursement rates, formulary placement incentives, and agreements with agents, affiliates and subcontractors.

Nonetheless, greater transparency could identify practices such as rebates and spread pricing that are often regarded as hidden revenue mechanisms. As a result, PBMs may explore alternative revenue strategies, including fee-based models, and renegotiate contracts with self-insured group health plans, manufacturers, and wholesalers. Moreover, the Department anticipates that PBMs will need to revise current disclosure documents to include: revised definitions of contract terms that are objectively determinable; a description of all arrangements and compensation received by the PBM and any agents, affiliates or subcontractors related to providing these benefits; pricing and reimbursement information for all drugs on the formulary by distribution channel; more detailed descriptions of the services provided including the development and ongoing management of the formulary; as well as projecting potential costs and extracting actual payments to the level stipulated in this final rule. The Department acknowledges that these updates and revisions may require substantial effort and coordination by PBMs and their agents, affiliates and subcontractors.

In Table 3, the Department estimates the costs associated with PBMs developing and maintaining the IT infrastructure system necessary to collect and report the required data. To develop these estimates, the Department reviewed IT infrastructure costs associated with reporting complex, sensitive, or high-frequency data for similar disclosure regulations, including Prescription Drug Data Collection,[376] ACA Medical Loss Ratio (MLR) Reporting,[377] Medicare

[376] *Prescription Drug and Health Care Spending*, 86 FR 66662 (Nov. 23, 2021), available at https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending.
[377] *Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care* Act, 77 FR 28790 (May 16, 2012), available at https://www.federalregister.gov/documents/2012/05/16/2012-11753/medical-loss-ratio-requirements-under-the-patient-protection-and-affordable-care-act.

Part D Reporting Requirements,[378] and the Hospital Price Transparency Requirements.[379] Of these rules, the IT costs associated with Prescription Drug Data Collection rule seemed most analogous to this final rule, as it specifically identified costs for PBMs to develop, implement, and maintain IT system changes to come into compliance with rulemaking related to prescription drug disclosures.

The Department used the Prescription Drug Data Collection rule as a benchmark but made a few notable adjustments. First, because the Department of Health and Human Services utilizes a different source for labor categories and wage rates than the Department, that information was mapped to the Department's source. Additionally, the hour burdens from the Prescription Drug Data Collection rule were adjusted downward by 50 percent to account for both the Prescription Drug Data Collection rule requiring additional information and calculations not found in this final rule, and the fact that the final rule relies on contract and pricing data that PBMs already track for commercial and compliance purposes, which should mitigate the associated costs. Finally, while data submission began in the second year for Prescription Drug Data Collection disclosures, the final rule requires reporting in the first year, and so the Department reallocated hour burdens from Prescription Drug Data Collection's second year into first and subsequent year categories for the final rule. Based on these considerations, the Department estimates the average, first-year per-PBM cost for designing, developing, and

[378] CMS, *Part D Reporting Requirements*, https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/part-d-reporting-requirements.
[379] *Price Transparency Requirements for Hospitals to Make Standard Charges Public*, 84 FR 65524 (Nov. 27, 2019), available at https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and#p-40.

implementing the IT system to be $1,100,000.[380] In subsequent years, the estimated per-PBM average cost for maintaining and updating the IT system is $300,000.[381] This includes providing quality assurance, conducting maintenance and making updates, and updating any needed security measures.

The Department acknowledges that these costs likely vary by the size of PBMs as well as their business model (i.e., fully pass-through PBMs and traditional PBMs may face very different costs to bring systems into compliance). Additionally, while the Department discounted the Prescription Drug Data Collection costs to reflect its impact on more of the overall market and requiring additional calculations and standardized submissions, the chosen discount rate may not have been appropriate.

The Department received several comments regarding its base-year cost assumptions. One commenter stated that the hour burden was underestimated, arguing that updating systems, generating required client reports, and maintaining the reporting infrastructure could require thousands of hours. Another commenter stated that rule review and compliance activities could exceed $1 million in annual expenditures. The Department acknowledges concerns regarding the

[380] The Department estimates that each PBM will incur a one-time first-year cost and burden to design, develop, and implement any necessary IT system changes to collect and report the required data. The Department estimates that for each PBM, on average, it will take outside legal counsel (at $659.15 per hour) 160 hours, project management specialists 2,250 hours (at $131.29 per hour), business operations specialists 750 hours (at $124.74 per hour), as well as software and web developers, programmers, and testers 3,500 hours (at $178.08 per hour) to complete this task. The Department estimates the total burden per PBM will be approximately 6,660 hours, with an equivalent cost of approximately $1,117,702, rounded to $1,100,000. For all 73 PBMs, the total one-time first-year implementation and reporting burden is estimated to be 486,180 hours with an equivalent total cost of approximately $81,592,210.

[381] In addition to the one-time first-year costs and burdens previously estimated, PBMs will incur ongoing annual costs related to maintaining and updating IT systems, providing ongoing quality assurance, and submitting the required data to the Department. The Department estimates that for each PBM it will take outside legal counsel (at $659.15 per hour) 100 hours, project management specialists 500 hours (at $131.29 per hour), business operations specialists 50 hours (at $124.74 per hour), as well as software and web developers, programmers, and testers 750 hours (at $178.08 per hour) to perform these tasks. The Department estimates the total annual burden for each PBM will be 1,400 hours, with an equivalent cost of approximately $271,3579, rounded to $300,000. For all 73 PBMs, the total annual maintenance and submission burden is estimated to be 102,200 hours with an equivalent total cost of approximately $19,809,061.

cost and complexity of implementing the IT system changes. In response to these comments, the Department has revised its burden estimates to include an additional 160 hours of outside legal counsel support in the first year and 100 hours in subsequent years for reviewing, advising on, and facilitating compliance with IT system changes.

TABLE 3. Implementation of IT Infrastructure Costs

Task	Number of PBMs	Average Costs	Total Cost
	(A)	(B)	(C)
PBMs design, develop, and implement needed IT systems changes (first year)	73	$1,100,000	$80,300,000
PBMs maintain and update the IT system (subsequent years)	73	$300,000	$21,900,000
Three-year Average Costs	**73**	**$566,667**	**$41,366,667**

10.2. Disclosure Costs

The following sections discuss the number of notices that PBMs would provide to self-insured group health plans and the associated costs. These notices apply to self-insured plans with 100 or more participants and beneficiaries.

10.2.1. Number of Notices from PBMs

10.2.1.1 Number of Initial Notices from PBMs

The final rule would require PBMs or other covered service providers to provide initial disclosures to responsible plan fiduciaries of self-insured group health plans, reasonably in advance of the date on which the contracts or arrangements are entered into, extended or renewed. Standard industry contracts appear to be for three-year periods, though it is unclear if

the agreements themselves are extended or renewed during that time.[382] The Department anticipates that approximately one-third of the self-insured group health plans will annually initiate new contracts, extend existing contracts, or renew contracts.

The Department requested comments on this assumption and received responses that generally supported this assumption. One commenter stated that PBM contracts are usually set up as one-to-three-year agreements, with three years being the typical standard. They further noted that these contracts often renew automatically at the end of the term unless one party gives advance notice to end the agreement. Please see Table 4 for the estimated number of disclosures.

10.2.1.2 Number of Follow-Up Notices from PBMs

The final rule also requires that PBMs or other covered service providers furnish disclosures on a semiannual basis (or at the request of the covered plan, quarterly) within 30 calendar days following the conclusion of each six-month period starting from the contract or arrangement initiation date. The Department estimates that PBMs or other covered service providers would submit these disclosures to each self-insured group health plan twice each year. The required semiannual disclosures cover two quarters each year, leaving two quarters in which no semiannual disclosure is provided. During those remaining quarters, the Department assumes that ten percent of plans will request quarterly disclosures. Please see Table 11 for the estimated number of disclosures.

10.2.2. Number of Notices Upon Requests from PBMs

The final rule also requires PBMs or other covered service providers to provide any other information related to the contract or arrangement that is required for the self-insured group

[382] Scott McEachern and Patrick Cambel, PBM Contracts: Understand then Optimize, Milliman White Paper (Aug. 2, 2020), available at https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize.

health plan to comply with the reporting and disclosure requirements of Title I of ERISA and the regulations, forms, and schedules issued, upon request of the responsible plan fiduciary. Without a strong data source for determining the number of expected requests, the Department assumes that approximately ten percent of responsible plan fiduciaries will request covered information annually. The Department requested, but did not receive comments on this assumption. Please see Table 4 for the estimated number of disclosures.

10.2.3. Number of Notices from Self-Insured Group Health Plans

10.2.3.1 Exemption for Responsible Plan Fiduciaries

The final rule also includes an administrative class exemption that would provide relief from ERISA section 406(a)(1)(C) and (D) for responsible plan fiduciaries who enter into a contract or arrangement, where the PBM or covered service provider fails to comply with its obligations under the regulation. To rely on the exemption, the responsible plan fiduciary must not have been aware that the PBM or covered service provider failed or would fail to meet these requirements and, upon discovering this omission, requests in writing that the PBM or other covered service provider furnish the required information or comply with the audit requirement. The Department does not have data on how often responsible plan fiduciaries do not receive all of the required disclosures from a covered service provider. In this analysis, the Department assumes that 0.3 percent of arrangements may experience an omission or error that will require the responsible plan fiduciary to send the request to the PBM.[383] This assumption is based on the

[383] Based on a review of the 2023 Form 5500 Schedule C filings, approximately 0.3 percent of ERISA-covered group health plans that filed Schedule C reported service providers who failed or refused to provide some of the information required to complete Part I. This estimate is used as a proxy for the percentage of self-insured group health plans that may need to request missing information from PBMs.

Department's experience that it is rare for pension plans to submit a notice under the requirement in 29 CFR section 2550.408b-2.

If the PBM or other covered service provider does not respond within 90 calendar days, the responsible plan fiduciary must notify the Department of the failure and further must assess whether to terminate or continue the service contract or arrangement consistent with the duty of prudence under section 404 of ERISA, including documenting the basis for that determination. The Department assumes that approximately 10 notices will be submitted, based on the experience that pension plans rarely submit these notices under the requirement in 29 CFR section 2550.408b-2. The Department requested, but did not receive, comments on this assumption. Please see Table 4 for the estimated number of disclosures.

10.2.3.2 Number of Notices from Self-Insured Group Health Plans Requesting Audits Information

As part of their oversight responsibilities, responsible plan fiduciaries must assess the quality of the PBM or other covered service provider's performance under the contract or arrangement (e.g., review and analyze claims data, network discounts, rebates, administrative fees), ensure that PBMs are meeting their contractual obligations, and ensure that self-insured group health plans are only paying reasonable and necessary costs. The final rule contains audit rights which are needed for fiduciaries to carry out these functions. While the cost of performing an audit of PBMs and other service providers is borne by the self-insured group health plan itself, service providers are required to provide the necessary information to the self-insured group health plan or its auditor. This final rule provides a self-insured group health plan's right to audit the PBM or other covered service provider not less than once per year. The PBM or

other covered service provider must confirm receipt of the audit request within 10 business days and must provide the information within a commercially reasonable period.

The Department estimates that one-third of self-insured group health plans will annually submit a request to their PBM or other covered service provider for all information necessary to perform an audit. The Department does not anticipate smaller, self-insured group health plans to submit a request themselves, but expects all issuers or TPAs that market to those self-insured group health plans to request audit materials. Please see Table 4 for calculations on the number of notices.

TABLE 4. Number of Notices

Notice	Number of Plans	Percent of Plans that will Initiate New Contracts, Extend Existing Contracts, or Renew Contracts	Percent of Plans Receiving or Sending Notices	Number of Notices Sent Each Year	Number of Notices
	(A)	**(B)**	**(C)**	**(D)**	**(E) = (A x C x D) or (A x B x C x D)**
Disclosures from PBMs to Self-insured Group Health Plans with 100 or more participants and beneficiaries					
PBMs provide initial disclosures to plans whose contract is entered, extended, or renewed for plans	131,102	33%	100%	1	43,701
PBMs provide missing/additional information requested by	131,102	33%	10%	1	4,370
PBM provides semiannual disclosures	131,102	100%	100%	2	262,204
PBM provides quarterly disclosures to plans upon request	131,102	100%	10%	2	26,220

Disclosures from Self-insured Group Health Plans with 100 or more participants and beneficiaries					
Plans send request to PBMs to disclose other/missing information	131,102	33%	0.3%	1	131
Plans document the basis for determination on whether to terminate or continue the service contract or arrangement, after PBMs has not responded in 90 days	10	-	100%	1	10
Plans send notice to DOL after PBMs has not responded in 90 days, and document basis for determination	10	-	100%	1	10
Self-insured Group Health Plans with 100 or more participants and beneficiaries send audit requests to PBM					
Plans send request for audits to PBMs	131,102	33%	100%	1	43,701
Total	**131,102**	**-**	**-**		**380,347**

10.2.4. Costs of Disclosures

10.2.4.1 Initial Disclosures

The Department acknowledges that the final rule will impose costs associated with producing initial disclosures before a service contract or arrangement is entered into, extended or renewed. While the Department expects that much of this information will have already been provided to the self-insured group health plan under the solicitation process and in response to a Request for Proposal, it acknowledges that the rule requires additional elements to be included or expanded upon in the required disclosures. Moreover, while it is expected that PBMs have the necessary underlying information readily available, PBMs will need to prepare plan-specific

disclosures such as detailed descriptions of projected compensation, payments, formulary placement incentives, and drug pricing.

The Department assumes that disclosures for large, self-insured group health plans with 100 or more participants and beneficiaries will need to be customized. Therefore, the Department estimates that it will take 30 minutes, due to the customization and review required. Please see Table 5 for calculations and burden.

Finally, paragraph (e)(9) of the proposal requires that the initial disclosure must provide that the responsible plan fiduciary will be notified in advance of any modifications to the formulary that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the contract or arrangement. The Department considers that this is a regular business activity and PBMs are providing this information prior to the proposed regulation. Therefore, PBMs will not incur any additional cost burden.

The Department requested comments on these assumptions. One commenter stated that much of the information required for the initial disclosures is already collected and analyzed by PBMs as part of their normal business operations, including activities related to negotiating with manufacturers, setting reimbursement rates, designing formularies, and reporting to regulators. The commenter further stated that the incremental costs associated with compiling the required disclosures should be considered in light of PBMs' existing business operations and revenues, suggesting that the burden associated with the required disclosures is small relative to the PBMs' revenues. The Department appreciates this insight and has considered this comment in estimating the burden associated with preparing the initial disclosure. Specifically, the Department's burden

estimates already reflect the assumption that PBMs collect and maintain the required information as part of their normal business operations.

10.2.4.2 Follow-Up Disclosures from PBMs

The final rule requires that PBMs or covered service providers furnish disclosures on a semiannual basis (or at the request of the covered plan, quarterly) within 30 calendar days following the conclusion of each six-month period starting from the contract or arrangement initiation date, disclosing the actual compensation that the PBM or other covered service provider received or reasonably expected to receive, under the specific categories that were estimated in the initial disclosures, as discussed earlier. This includes all direct compensation, rebate payments, spread pricing, copay claw-backs recouped from a pharmacy by the PBM or other covered service provider, price protection payments, and other compensation. If any category of compensation, in the aggregate, materially exceeds the corresponding estimate described in the initial disclosure, the PBM or other covered service provider must provide an identification of the amount and a reason for the overage. For this purpose, "materially" means five percent or more, or a lower dollar amount or percentage agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement.

It is anticipated that the PBM or other covered service provider will already possess the necessary information to fulfil this requirement, as these breakouts are already required in the initial disclosure and standard practice in PBM contracts is to regularly provide self-insured group health plans with invoices or statements that include claims payments, rebates, and administrative fees. The Department assumes these semiannual disclosures will require less time, as they often involve system-generated data, draw on similar information from initial disclosures, and rely on standardized templates. The Department assumes PBMs will rely on standardized

templates and batch processing to prepare the notice. Therefore, the Department estimates that requiring PBMs to compile and disclose this information will require 15 minutes of work from a benefits specialist for compilation and distribution of the information semiannually, resulting in 30 minutes of benefit specialist time each year.

The required semiannual disclosures cover two quarters each year, leaving two quarters in which no semiannual disclosure is provided. During those remaining quarters, the Department also estimates that it will take 15 minutes of a benefit specialist's time to prepare and distribute the requested information. Please see Table 5 for calculations and burden.

The Department requested and received comments on these assumptions. One commenter stated that because the three largest PBMs process nearly 80 percent of all U.S. prescriptions they would assume most reporting obligations. As these PBMs and their subsidiaries generate more than $800 billion in annual revenue, the semiannual disclosure requirements would represent only minimal compliance costs relative to the scale of compensation they handle. The Department notes that it has assigned a minimal hour burden for the follow-up disclosures, which aligns with the commenter's assumptions.

10.2.4.3 Information Upon Request

Paragraph (i) of the final rule provides that, upon the written request of the responsible plan fiduciary, the covered service provider must furnish any other information relating to the contract or arrangement that is required for the self-insured group health plan to comply with the reporting and disclosure requirements of Title I of the Act and the regulations, forms and schedules issued thereunder. Paragraph (i)(1) requires the covered service provider to disclose the information requested reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement,

unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information must be disclosed as soon as practicable. The Department assumes that PBMs will rely on automated IT systems to prepare the information. Therefore, the Department estimates that it would only require 15 minutes of a benefit specialist's time to prepare and distribute the covered information for each plan annually. Please see Table 5 for the estimated costs of disclosures.

10.2.4.4 Notice to PBMs and DOL

The exemption contained in paragraph (n) of the final rule provides relief from the restrictions of ERISA section 406(a)(1)(C) and (D) for plan fiduciaries who enter into a contract or arrangement where the PBM or other covered service provider fails to comply with its obligations under the regulation. Upon discovering that a PBM or other covered service provider failed to comply, the responsible plan fiduciary must request in writing that the PBM or other covered service provider furnish the information or comply with the audit requirement. As discussed earlier, the Department assumes that 0.3 percent of arrangements may experience an omission or error that will require the responsible plan fiduciary to send the request to the PBM or other covered service provider.[384] This assumption is based on the Department's experience that it is rare for pension plans to submit a notice under the requirement in 29 CFR 2550.408b-2. The Department also assumes that PBMs will rely on standardized templates and batch processing to prepare the notice. Therefore, the Department estimates that it will take 15 minutes of a benefit specialist's time to prepare and send the notice.

[384] Based on a review of the 2023 Form 5500 Schedule C filings, approximately 0.3 percent of ERISA-covered group health plans that filed Schedule C reported service providers who failed or refused to provide some of the information required to complete Part I. This estimate is used as a proxy for the percentage of self-insured group health plans that may need to request missing information from PBMs.

If the PBM or other covered service provider does not respond within 90 calendar days, the responsible plan fiduciary must notify the Department and further must assess whether to terminate or continue the service contract or arrangement consistent with the duty of prudence under section 404 of ERISA, including documenting the basis for that determination. As discussed earlier, the Department assumes that approximately 10 notices will be submitted. Similar to other notices, the Department assumes that PBMs will rely on standardized templates and batch processing to prepare the notice. Therefore, the Department estimates that it will take 15 minutes of a benefit specialist's time to document the basis for the determination, and 15 minutes of a benefit specialist's time to prepare and send the notice. Please see Table 5 for the estimated costs of disclosures.

TABLE 5. Annual Disclosure Costs

	Number of Notices	**Number of Hours Per Notice**	**Total Hour Burden**	**Hourly Wage Rate**	**Cost Equivalent of Hour Burden**
	(A)	**(B)**	**(C) = (A x B)**	**(D)**	**(E) = (C x D)**
PBMs send disclosures to self-insured group health plans with 100 or more participants and beneficiaries					
PBMs provide initial disclosures to self-insured group health plans					
Legal professionals and benefit specialists prepare disclosures for self-insured group health plans	43,701	0.50	21,851	$156.16	$3,412,174
PBMs provide missing/other information requested by self-insured group health plans					
Benefit specialists prepare and send information to plans	4,370	0.25	1,093	$124.74	$136,278
PBMs provide semiannual disclosures to self-insured group health plans					

Benefit specialists prepare and send disclosures to plans	262,204	0.25	65,551	$124.74	$8,176,832
PBM provides quarterly disclosures to plans					
Benefit specialists prepare and send disclosures to plans	26,220	0.25	6,555	$124.74	$817,671
Self-insured group health plans with 100 or more participants and beneficiaries send notice to PBMs and DOL					
Self-insured group health plans send request to PBMs to disclose missing/other information					
Benefits specialists prepare and send request	131	0.25	33	$124.74	$4,085
Self-insured group health plans document the basis for determination on whether to terminate or continue the service contract or arrangement, after PBMs has not responded in 90 days					
Benefit specialists document determination	10	0.25	3	$124.74	$312
Self-insured group health plans send notice to DOL after the PBM has not responded within 90 days					
Benefits specialists prepare and send notice, and document basis for determination	10	0.25	3	$124.74	$312
Total	**336,636**	-	**95,087**	**-**	**$12,547,664**

10.3. Audit Right Costs

A right to audit the veracity of any and all disclosures made by the PBM or other covered service provider to a responsible plan fiduciary under the terms of the contract or arrangement as required by this regulation is an essential part of the final rule's framework for establishing transparency in the marketplace for pharmacy benefit management services. This includes the responsibility of the PBM or other covered service provider to deliver all necessary information to conduct such an audit, subject to reasonable confidentiality agreements that prevent redisclosure of such information and limit its use to purposes related to compliance of the regulation. Though the final rule does not impose an obligation for responsible plan fiduciaries to

conduct an audit, it does require that the PBM or other covered service provider allow, not less than once per year, for the self-insured group health plan to conduct an audit for accuracy of any disclosures made to comply with the regulation.

The Department received comments expressing concerns regarding the audit provisions, including the adequacy of confidentiality protections, potential disclosure of sensitive commercial information, auditor conflicts of interest, and appropriate limitations on the scope of audits. The Department appreciates these comments and discusses its consideration of these issues in the preamble. However, several commenters support the audit provisions and stated that an audit right would improve transparency and address limitations on data access to information held by PBMs. One commenter evaluates audit rights as a means of ensuring transparency to verify disclosures, noting that without meaningful audit authority, fiduciaries would be forced to rely solely on representations from covered service providers, thereby limiting the ability to conduct an independent audit. The Department appreciates their support for the audit provisions and agrees that enhanced transparency is essential for effective fiduciary oversight.

Under the final rule, the cost of selecting an auditor and performing an audit of PBMs and other service providers is borne by the plan itself, while service providers are required to provide the necessary information to the self-insured group health plan or its auditor without conditions that would restrict the self-insured group health plan's right to conduct the audit. The PBM or other covered service provider must confirm receipt of the audit request within 10 business days and must provide the information within a commercially reasonable period.

The Department received comments concerning whether there were circumstances where the covered service provider should bear the entire cost of the audit. One specifically raised concerns that requiring PBMs to financially contribute to the audit could compromise audit

findings. Other commenters suggested the PBM should bear the full costs if the audit reveals material inaccuracies in the disclosures. The Department understands these concerns, and has determined that, consistent with the proposal, under the final rule plans that choose to conduct an audit bear the costs; PBMs and other service providers are only responsible for the cost of providing the underlying data to the auditor.

The Department estimates that only one-third of self-insured group health plans will annually submit a request to their PBM or other covered service provider for all information necessary to perform an audit. This assumption is based on PBM contracts being structured around a three-year master agreement and audits typically taking six to nine months to complete, making it challenging to conduct more than one audit in a given contract period.[385] As one commenter stated, PBM contracts are usually set up as one-to-three-year agreements, with three years being the typical standard. These contracts often renew automatically unless one party provides an advance notice to end the agreement.

To estimate the burden associated with responding to an audit request, the Department assumes that PBMs already have access to all information and data available, but may require time to compile the records, data and other necessary information, including contracts with retail pharmacies and drug manufacturers, for each self-insured group health plan. As one commenter stated, PBMs already collect and analyze the data underlying these disclosures as part of their normal business operations to negotiate with manufacturers, establish pharmacy reimbursement rates, design formularies, and report to State regulators and CMS (for Medicare Part D). Additionally, because this disclosure will also include contracts with agents, affiliates and

[385] Janus Desquitado & Francis Ayson, PBM Best Practice Series: Pharmacy Benefit Claims Auditing, Milliman White Paper (Sept. 21, 2023), available at https://www.milliman.com/en/insight/pbm-best-practices-pharmacy-benefits-claims-auditing.

service providers such as retail pharmacies and drug manufacturers, the Department also assumes that PBM may require additional legal assistance to put in place confidentiality agreements to prevent sharing of the disclosed information.

One commenter expressed concerns that these provisions could increase administrative burden and costs associated with responding to audit requests, particularly where proprietary information may be involved. However, as discussed above, the Department assumes that most PBMs maintain the underlying data needed for invoices, rebate reconciliation, and contractual compliance. Audit responses are often generated through standardized templates or automated reports, though custom data pulls may be required in some cases.

Therefore, the Department assumes that PBMs will rely on standardized templates and batch processing to prepare the audit request. The Department estimates it will take 30 minutes for a benefit specialist at a TPA or issuer to prepare and send the audit request on behalf of self-insured group health plans with 100 or more participants and beneficiaries. The Department also assumes it will take two hours of a PBM's benefit specialist and IT staff's time to prepare and disclose information needed for each requested audit, at a composite wage rate of $151.41.[386] This includes the time to retrieve documents, gather data and put in place any necessary confidentiality agreements. The Department requested, but did not receive, comments on these assumptions.

Please see Table 6 for calculations and burden.

[386] The wage rate is calculated in the following manner: [($124.74 for a benefits specialist x (1/2)) + ($178.08 for an IT Professional) x (1/2))] = $151.41.

TABLE 6. Annual Audit Cost

	Number of Requests	Number of Hours Per Requests	Total Hour Burden	Hourly Wage	Cost Equivalent of Hour Burden
	(A)	**(B)**	**(C) = (A x B)**	**(D)**	**(E) = (C x D)**
Self-*insured group health plans with* 100 or more participants and beneficiaries send audit request					
Benefit specialists prepare and send audit request	43,701	0.5	21,851	$124.74	$2,725,631
PBMs prepare and disclose the needed info for the audit					
Benefit specialists and IT staff prepare for requested audit	43,701	2	87,402	$151.41	$13,233,537
Total	**43,701**		**109,253**	**-**	**$15,959,168**

10.4. Disclosure Mailing Costs

The proposed regulation does not preclude distribution through the use of electronic technology. Consequently, the Department has assumed that interactions between parties will be carried out electronically. As a result, all costs associated with distributing the disclosures have already been included in Section 11.2.3. The Department requested, but did not receive, comments on this assumption.

10.5. Summary of Total Costs

The total costs associated with the final rule have been provided below in Table 7. In comparison, according to the SEC 10-k filings, CVS Caremark, Express Scripts, and Optum Rx

respectively 180.9 billion,[387] $216.7 billion,[388] and $154.7 billion[389] in revenue in 2025, resulting in a total of $552.3 billion. Therefore, the total three-year estimated average cost for this final rule represents 0.01 percent of total revenue of the three largest PBMs.

One commenter stated that the Department's comparison of implementation costs to PBM gross revenues does not fully reflect the financial structure of the PBM industry because a substantial portion of PBM revenue is paid out in pharmacy claims to pharmaceutical manufacturers. The commenter notes that, of the $481.1 billion in revenue cited by the Department for the three largest PBMs, approximately $469.9 billion was paid out in pharmacy claims. The commenter therefore suggests that comparing implementation costs to gross revenues understates the relative financial impact of the proposed requirements and states that the costs would represent a larger share of PBM gross profits.

The Department acknowledges the commenter's concern regarding the use of gross revenue to contextualize the estimated implementation costs. However, the commenter's concern appears to relate primarily to how the comparison is framed, rather than to the accuracy of the underlying revenue figures. The Department also notes that the commenter did not provide a source or methodology for the assertion that approximately $469.9 billion of the cited revenue was paid out in pharmacy claims. The Department continues to believe that revenue is an

[387] The Form 10-K does not directly report the revenue for CVS Caremark. However, it provides revenue for the pharmacy services within the Health Services segment, which includes the pharmacy network, mail order pharmacies, and specialty pharmacies, and these services are generally managed by the PBM. (*Source*: SEC, *Form 10-K*, *CVS Health Corporation*, Annual Report (2025), available at https://www.sec.gov/Archives/edgar/data/64803/000006480325000007/cvs-20241231.htm.

[388] The Form 10-K does not directly report the revenue for Express Scripts. However, it provides revenue for the pharmacy services, and these services are generally managed by the PBM. Securities and Exchange Commission, *Form 10-K, Cigna. Annual Report* (2025), available at https://d18rn0p25nwr6d.cloudfront.net/CIK-0001739940/64c4c39f-1b4e-4979-8b4a-bfc403377665.pdf.

[389] The Form 10-K directly reports revenue for Optum Rx. Securities and Exchange Commission, *Form 10-K, Cigna. Annual Report* (2025), available at https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2024/UNH-Q4-2024-Form-10-K.pdf.

appropriate measure for assessing the relative scale of compliance costs across affected entities because compliance costs are generally borne by the enterprise as a whole. Although a portion of PBM revenue may be associated with claims payments and other pass-through transactions, those amounts remain part of the overall business activity and scale of the entity. Accordingly, the Department believes the revenue-based comparison remains appropriate for purposes of the analysis.

TABLE 7. Summary of Total Costs

	First Year Cost	**Subsequent Year Cost**	**Ten-Year Average Cost**
Rule Familiarization	$20,843,890	$0	$2,084,389
IT Infrastructure	$80,300,000	$21,900,000	$27,740,000
Disclosure	$12,547,664	$12,547,664	$12,547,664
Audit	$15,959,168	$15,959,168	$15,959,168
Total Costs	**$129,650,722**	**$50,406,832**	**$58,331,221**

10.6. Sensitivity Analyses of Costs

Given the uncertainty surrounding these cost estimates, particularly due to variation in plan complexity and PBM system capabilities, the Department conducted a sensitivity analysis to examine how the estimated costs would change if there was a decrease or increase in the hour burden from the primary assumptions. Please see Table 8 for the results of this sensitivity analysis.

TABLE 8. Sensitivity Analysis

	Ten-Year Average Annual Cost
25 Percent of Primary Scenario	$14,582,805
50 Percent of Primary Scenario	$29,165,611
Primary Scenario	**$58,331,221**

150 Percent of Primary Scenario	$87,496,832
200 Percent of Primary Scenario	$116,662,442

11. Uncertainty

11.1. Uncertainty over Rebates' Impact on Costs

The Department expects that the final rule will have a significant impact on rebates, as PBMs will be required to disclose not only how much of the rebate the self-insured group health plan will receive, but also how much will be retained by the PBM and other service providers. The Department expects that highlighting these payments will result in responsible plan fiduciaries negotiating a greater share of rebates, potentially leading PBMs to fully pass through all rebates to the self-insured group health plan, which could lower plan costs or cause changes in other forms of payment. Furthermore, increased transparency could enable responsible plan fiduciaries to compare offerings across PBMs, fostering competition and improving drug pricing.

However, their effects on the patients' out-of-pocket costs remain uncertain, as discussed in Sections 8.1 and 8.2. This is primarily because rebates are typically paid to issuers or plan administrators rather than directly to group health plan participants, and the portion of those rebates passed through to participants can vary depending on plan design.[390]

11.2. Uncertainty over other PBM Practices on Costs

The final rule may also impact other PBM pricing strategies, including reducing the use of copay claw-backs, exclusionary formularies, and pharmacy network restrictions. However, their effects on employer costs and patients' out-of-pocket costs remain uncertain. These

[390] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or Anti-Competitive?*, *International Journal of the Economics of Business* (June 26, 2015), available at https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.

mechanisms are opaque,[391] and the variability in how they are implemented across self-insured group health plans contributes to significant uncertainty about their financial impact on patients. For example, copay claw-backs are difficult to identify in the claims data, and patients are often unaware that they have paid more than the actual cost of the drug. This lack of visibility makes it challenging to measure how frequently claw-backs occur or to evaluate their overall impact on patient spending. Since there is limited publicly available data on how these practices affect patient costs, it is difficult to assess whether any particular PBM arrangement is delivering cost-savings for patients or merely shifting costs in ways that are not easily understood or tracked.

11.3. Uncertainty over the Impact of the Audit Rights on the Number of Audits Requested

The final rule intends to facilitate self-insured group health plan oversight of PBMs by enabling plans to request an audit so that they may have access to all information needed to assess the completeness and accuracy of the required disclosures. As discussed in the preamble of this regulation, PBMs often limit self-insured group health plans' audit rights by providing only a sample of records relating to contractual performance, requiring that the auditor be approved by the PBM, or requiring that the audit be conducted on-site at a facility chosen by the PBM. By removing these barriers, the audit requirement ensures that PBMs provide accurate and complete information to plans and their auditors, permitting plans to better determine if PBMs are complying with contract terms and to take corrective action as needed.

Currently, plans conduct audits, though often with less information and control over the audit process than the final rule ensures. Industry best practices suggest that "plan sponsors should have their pharmacy claims audited. If the plan sponsor suspects the PBM is not adhering

[391] Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, The New York Times (2024), https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html.

to the contract, or if the plan frequently changes benefits, then it is best to audit every year."[392] Because these audits can take up to nine months to perform, the Department has assumed that plans only conduct these audits once in a given three-year contract period.

By clarifying and standardizing audit rights, the final rule would provide plan fiduciaries with additional information relevant to oversight. However, it is uncertain whether the final rule would result in changes to the number of audits requested. In some cases, improved disclosures may reduce the need for additional audits by increasing transparency into PBM practices. In other cases, greater clarity regarding audit rights and available information may lead some plans to elect to make greater use of audits. To the extent that plans choose to increase their use of audits, any associated costs would be borne by the plan.

11.4. Uncertainty over the Impact of the Rule on the PBM Market

The PBM market has been facing significant market consolidation in recent years, with the three largest PBMs controlling roughly 80 percent of the market.[393] Since the final rule would require PBMs to provide disclosures at a more granular level, the Department expects that self-insured group health plans may demand additional concessions during the contract negotiation process, putting downward pressure on prices. CBO suggested in their 2019 analysis of S.1895, *Lower Health Care Costs Act,* that "smaller PBMs compete with larger PBMs by offering more transparent contracts. Removing that point of leverage may reduce the competitiveness of those

[392] Janus Desquitado & Francis Ayson, PBM Best Practice Series: Pharmacy Benefit Claims Auditing, Milliman White Paper (Sept. 21, 2023), available at https://www.milliman.com/en/insight/pbm-best-practices-pharmacy-benefits-claims-auditing.

[393] Federal Trade Commission, *Interim Staff Report: Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

smaller PBMs, which could reduce competition if larger PBMs garner greater market share as a result."[394]

The Department notes, however, that those PBMs that already leverage transparency in their contracts may not have their revenues significantly impacted by the final rule. While all PBMs would bear the costs of additional disclosures, more transparent PBMs would be less prone to contract revisions following those disclosures given that the required information has already been shared with the plan sponsor or issuer, and presumably priced into the contract. Less transparent PBMs, however, may need to make additional concessions and revisions in response to the disclosures, which would likely reduce their revenues. As such, the Department is unclear whether the final rule would impact market consolidation in the PBM space and if so, in what direction.

One commenter expressed concern that increased transparency is only an initial step toward addressing challenges in the PBM market, noting that future outcomes will determine whether the PBM market becomes more balanced or continues toward greater consolidation and fewer operating pharmacies. Another commenter similarly observed that transparency alone does not change the underlying incentives that influence stakeholder behavior within the system.

The Department acknowledges commenters' views that transparency, by itself, may not fully address the structural incentives affecting market participants. The purpose of this final rule is to provide plan sponsors with more complete and consistent information regarding prescription drug pricing and PBM practices. The information generated through the required disclosures may help group health plans identify inefficiencies, assess market dynamics, and evaluate

[394] Congressional Budget Office, *Cost Estimate: S. 1895, Lower Health Care Cost Act* (July 16, 2019), available at https://www.cbo.gov/publication/55457.

options to protect participants and beneficiaries. Overall, the Department believes that the final rule can strengthen accountability, support more informed decision-making, and facilitate oversight of PBM market practices.

11.5. Uncertainty over the Longevity of the Impact of Final Rule

The Department, when considering the impact of this final rule, relied heavily on analyses conducted by CBO for several prescription drug reform bills. In particular, CBO reviewed S. 1339 the *Pharmacy Benefit Manager Reform Act* which banned spread pricing, required PBMs to pass-through all rebates and required disclosures related to enrollees' use of prescription drugs, costs, rebates, fees, and cost-sharing amounts to plan sponsors.[395] CBO estimated that the reduction in plan premiums resulting from this bill would diminish significantly over time as "contract terms between parties are redefined and PBMs find more ways to generate revenue outside of the disclosure requirements." [396] While the Department's proposal includes similar disclosure requirements as that of the CBO bill described above, it does not include all the elements CBO analyzed. As a result, the Department is unclear on whether its impacts of the final rule would abate over time. The Department requested, but did not receive, comments on this assumption.

11.6. Uncertainty over the Benefit Estimates

The Department estimated in the proposed rule the benefits from improvements to health outcomes and reduced healthcare expenditures that will result from increased adherence due to lower prescription drug costs. Some commenters objected to this QALY approach and endorsed a WTP analysis, which was also calculated as part of the proposed rule. The Department

[395] Congressional Budget Office, *Cost Estimate: S. 1339, Pharmacy Benefit Manager Reform Act* (Dec. 5, 2024), available at https://www.cbo.gov/publication/61050.
[396] *Id.*

ultimately agreed and used WTP to quantify benefits for the final rule. However, the Department included alternative QALY estimates in the Uncertainty section.

In the proposed rule, the Department used QALYs to look at the impact of improved prescription drug adherence on health following a price decline due to the expanded disclosures. However, due to data limitations, the Department was only able to produce QALY estimates for three common health conditions – diabetes, high blood pressure and heart disease. The Department received several comments suggesting that due to the limited nature of the QALY analysis, the Department should instead utilize WTP, arguing that it would more fully capture the welfare effects on all participants, not just those with chronic diseases.[397] While one such commenter generally favored WTP, they claimed it would not accurately reflect health gains for improved adherence, and so proposed that the Department carve out those conditions impacted by improved adherence, to avoid double counting, and use QALY measures for them. That commenter additionally recommended adding mortality improvements to the benefits calculation, though the Department, upon review, is concerned that including both mortality and morbidity benefits would overstate the benefits and so is limiting its QALY-focused analysis to just health improvements. The Department was subsequently able to acquire additional information and data that allow it to conduct a QALY analysis over the entire population, rather than limiting it to three health conditions. For the final rule the Department has utilized the QALY analysis to provide an alternative estimate to reflect some of the uncertainty of the benefits.[398] The Department has also provided a sensitivity analysis of both methods to reflect

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[398] The QALY analysis illustrates how an analytic approach with many inputs drawn from outside directly-regulated market(s) has more opportunities for uncertainty to be introduced than an approach (such as the direct-WTP analysis) with inputs that are relatively few in number and minimally extrapolated across markets.

the uncertainty of the estimated range of price reductions that utilizes a low estimate of a 0.5 percent price reduction and a high estimate of a 2.0 percent price reduction in the sections that follow.

11.6.1.1 Improved Health Outcomes Among Patients Utilizing Quality Adjusted Life Years

As noted above in the Benefits sections, disclosures required of PBMs in the final rule will help to reduce information asymmetry and aid self-insured group health plans' responsible plan fiduciaries in their selection of and negotiations with PBMs, helping to reduce costs for the self-insured group health plans and lower prescription drug prices.[399] By reducing prescription costs, the final rule could improve adherence to prescribed drugs, as patients are less likely to skip or reduce doses, delay refills, or forgo treatment due to financial concerns. This will in turn improve disease management resulting in better overall health outcomes.

Price sensitivity towards drug adherence has been an increasing issue. A 2026 KFF health tracking poll reveals that concerns about drug affordability have grown over the past several years, from 44 percent in 2018 to 59 percent in early 2026.[400] The scale of this issue is reflected in the 2024 National Health Interview Survey, which found that approximately 8.0 percent of respondents aged 18 to 64 with private insurance reported not taking their medication as prescribed in order to save money.[401] Results from a meta-analysis of treatment adherence studies further indicated that nearly one-fourth (24.8 percent) of patients were non-adherent to

[399] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), www.cbo.gov/publication/58793.
[400] Kearney, Audrey, Julian Montalvo III, Ashley Kirzinger, & Liz Hamel, KFF (2026), https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/#caa040a6-6e54-4977-9b45-f0d168f535eb.
[401] National Center for Health Statistics, *Percentage of Adults aged 18-64 who did not Take Medication as Prescribed to Save Money in the Past 12 months, United States, 2019—2024*, National Health Interview Survey. Generated interactively: Jun 03 2026 from https://www.cdc.gov/nchs/data/databriefs/db470.pdf.

medication for various reasons.[402] Research on prescription drug price elasticity find increases in direct consumer costs reduce prescription fills, suggesting a price elasticity of demand between -0.1 and -0.4.[403] Moreover, consumers' sensitivity to prescription drug prices, as evidenced by claims data showing that more than half of high-cost prescriptions go unfilled, suggests that even small price decreases could increase access to prescription drugs for participants and beneficiaries.[404] Additionally, research corroborates that poor treatment adherence is associated with poorer health outcomes and significantly higher mortality rates.[405, 406]

To estimate the potential benefit to participants and beneficiaries of the final rule, the Department has provided an analysis that estimates the averted healthcare costs arising from increased prescription drug adherence. The final rule is expected to have a small but meaningful effect on the net retail price of prescription drugs, which the Department estimates will decrease

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[402] Robin DiMatteo, *Variations in Patients Adherence to Medical Recommendations: A Quantitative Review of 50 Years of Research, Medical Care* (2004), https://pubmed.ncbi.nlm.nih.gov/15076819/.

[403] Michael Chernew, Mayur Shah, Arnold Wegh, Stephen Rosenberg, Iver Juster, Allison Rosen, Michael Sokol, Kristina Yu-Isenberg, & A Mark Fendrick, *Impact of Decreasing Copayments on Medication Adherence within a Disease Management Environment,* Health Affairs (2008), https://pubmed.ncbi.nlm.nih.gov/18180484/;
Dana Goldman, Geoffrey Joyce, Jose Escarce, Jennifer Pace, Matthew Solomon, Marianne Laouri, Pamela Landsman, & Steven Teutsch, *Pharmacy Benefits and the Use of Drugs by the Chronically Ill*, Journal of the American Medical Association (2004), https://pubmed.ncbi.nlm.nih.gov/15150206/;
Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data,* Journal of Health Economics (2016), https://pubmed.ncbi.nlm.nih.gov/27107371/.

[404] IQVIA Institute, *Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines,* (Aug. 2020), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/medicine-spending-and-affordability-in-the-us.

[405] Teresa B. Gibson, Xue Song, Berhanu Alemayehu, Sara S. Wang, Jessica L. Waddell, Jonathan R. Bouchard, & Felicia Forma, *Cost Sharing, Adherence, and Health Outcomes in Patients with Diabetes,* American Journal of Managed Care 16(7) (2010), https://pubmed.ncbi.nlm.nih.gov/20712392/;
Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality, British Medical Journal*, (2006), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf;
Donald Pittman, William Chen, Steven Bowlin, and JoAnne Foody, *Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations,* American Journal of Cardiology 107(11) (2011), https://pubmed.ncbi.nlm.nih.gov/21439533/.

[406] Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality, British Medical Journal* (2006), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf.

by one percent. This estimate is consistent with the 2024 CBO analysis[407] and other research on the effect of disclosures to group health plans and other service providers on prescription drugs.[408] While these studies offer a comparable assessment of the potential impact of required rebate disclosures from PBMs to self-insured group health plans, the final rule is distinct as it contains more significant requirements that mandate the disclosure of all forms of direct and indirect compensation, including spread pricing, affiliate payments, as well as rebates. The final rule also includes enforceable rights, such as audit provisions and notification to the Department of incomplete disclosure, that will enhance compliance. These requirements may yield more substantial benefits, particularly to mid-sized self-insured group health plans, which are typically less informed and have fewer resources to monitor contracted services. As such, the Department believes that the final rule could reduce prices for prescription drugs more significantly, consistent with the effect of similar disclosures in other markets.[409]

The Department analyzes the impact arising from reduced prescription drug prices for the 52.9 million participants and beneficiaries aged 18 to 64 in large, self-insured plans.[410] Utilizing the National Health Interview Survey estimate of 8 percent cost-related non-adherence for prescription drugs among adults 18–64 with private health insurance, the Department estimates

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[407] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices* (Oct. 2024), www.cbo.gov/publication/58793. As noted earlier in this regulatory impact analysis, the price-reduction range suggested by this report is between 0.1 percent and 1.0 percent.

[408] Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market* (2024), available at https://ssrn.com/abstract=5021179.

[409] Christine Cuny, Omri Even-Tov, & Edward Watts, *From Implicit to Explicit: The Impact of Disclosure Requirements on Hidden Transaction Costs,* Journal of Accounting Research (2021), available at https://onlinelibrary.wiley.com/doi/10.1111/1475-679X.12340?msockid=18d7b391c5d560f015c7a5a9c4c7616c; Dominique Badoer, Charles Costello, & Christopher Jones, *I Can See Clearly Now: The Impact of Disclosure Requirements on 401(k) Fees,* Journal of Financial Economics 136(2), (2020), https://www.sciencedirect.com/science/article/abs/pii/S0304405X19302466.

[410] Estimate is based on the Department's tabulations of the March 2025 Current Population Survey (CPS) Auxiliary Data.

that approximately 2.9 million individuals in large, self-insured plans are non-adherent due to the cost of their medication.[411]

Data from MEPS-HC indicates that, for persons with a prescription medication reporting cost-related non-adherence, the average number of prescriptions each year (including refills) is approximately 21, resulting in an estimated 60.4 million prescriptions for individuals aged 18–64 in large, self-insured plans that are non-adherent to their medication due to cost.[412] Applying a one percent price reduction and an estimate price elasticity of demand of -0.358 for prescription drugs, [413] the Department estimates that an additional 216,131 prescriptions will be purchased by this group resulting in approximately 10,269 such participants improving their adherence to medication.[414] The Department believes that this calculation likely underestimates the number of participants that will improve their adherence to medication as a result of the rule.[415]

[411] This estimate is calculated as: 52,882,418 individuals aged 18-64 in large, self-insured plans × 67.8 percent reporting having a prescription medication × 8 percent cost-related non-adherence = 2,868,342 cost-related non-adherent individuals aged 18-64 in large, self-insured plans.

[412] https://pubmed.ncbi.nlm.nih.gov/18180484/ This estimate is calculated as: 2,868,342 × 21.05 prescriptions per prescribed adult 18-64 with private health insurance = 60,371,715 prescriptions for individuals aged 18-64 in large, self-insured plans that are non-adherent due to cost. Total may not sum due to rounding.

[413] Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data,* Journal of Health Economics, Vol 48, (2016).

[414] This estimate is calculated as: 60,371,715 prescriptions × -0.01 price change × -0.358 price elasticity of demand = 216,131 additional prescriptions for individuals aged 18–64 in large, self-insured plans that are non-adherent due to cost. Additionally, 216,131 additional prescriptions ÷ 21.05 prescriptions per prescribed non-adherent individual = 10,269 individuals aged 18-64 in large, self-insured plans improving their adherence. Total may not sum due to rounding.

[415] In the estimate provided here, the Department applies the price change and elasticity of demand to only the non-adherent population. This produces an estimate of 216,131 additional prescriptions that is utilized for the QALY analysis and the analysis of reductions in medical spending. In the primary analysis where direct WTP is utilized, the estimate results from applying the price change and elasticity of demand to the entire affected population, then attributing the change in demand for prescriptions entirely to non-adherent individuals, resulting in 1,344,165 additional prescriptions. As such, the QALY and medical spending estimates in the Uncertainty section likely have a tendency toward underestimating these impacts of the rule.

TABLE 9. Estimated Adherence Improvements

Price Reduction	Price Elasticity of Demand	Non-Adherent Population	Prescriptions for Non-Adherent Participants	Additional Prescriptions Arising from Rule	Estimated Population Experiencing Adherence Improvement
-1.0%	-0.358	2,868,342	60,371,715	216,131	10,269

Note: Some values in the table are rounded and may not result in precise calculations.
* Estimated population based on the self-insured participants aged 18 to 64 is 52,882,418.

Increased prescription adherence can reduce disease related medical costs due to improved health status and reduced utilization of medical care including hospitalizations, emergency room visits, and doctor appointments that would otherwise arise when medication for chronic diseases is not taken as prescribed.[416] Using data on medical events from the 2023 MEPS-HC, the Department estimates healthcare utilization for privately insured participants aged 18 to 64 with a prescription based on adherence status (see Table 10 below).[417] Observing the average number of distinct medical events, such as inpatient hospitalizations or office-based visits to physicians, the data suggests that across most categories of healthcare, cost-related non-adherence is associated with higher utilization of care. Adherent participants, for example, averaged 8.7 medical office visits in 2023, compared with an average of 14.5 office visits for non-adherent participants. This data supports other research suggesting medication adherence and compliance can reduce adverse health outcomes and healthcare utilization.

TABLE 10. Average Annual Healthcare Events Per Person, by Adherence Status

	Average Utilization, Adherent	Average Utilization, Non-Adherent
Emergency Room Visits	0.24	0.32

[416] Michael C. Sokol, Kimberly A. McGuigan, Robert R. Verbrugge, & Robert S. Epstein, *Medication Adherence on Hospitalization Risk and Healthcare Costs,* Medical Care Vol 43(6) (June 2008), available at https://pubmed.ncbi.nlm.nih.gov/15908846/.
[417] Based on self-reporting of delaying taking or being unable to afford their medication. Department of Health and Human Services, Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey* (2024).

Hospital, Inpatient Admissions	0.08	0.06
Hospital, Outpatient Admission	1.10	1.36
Office-Based Visits	8.72	14.45
Prescribed Medicines Filled	11.12	21.05

Note: The MEPS-HC data on healthcare utilization above represents the average number of distinct medical events in 2023 by facility type, based on the participants reported adherence status for those that have prescribed medication. The table above does not include all the healthcare utilization categories analyzed, such as telehealth or dental visits.

The Department further examined the cost savings of reduced utilization of medical services resulting from improved cost-related prescription adherence (see Table 11). Using 2023 MEPS-HC data on healthcare expenditures of privately insured patients aged 18 to 64 with a prescription medication, the Department estimated the impact of adherence on health expenditures for those costs paid by the issuer. The reduced utilization of medical services for these 10,269 participants could lower the reimbursement requirements of private issuers to healthcare providers by approximately $9.6 million annually.[418]

TABLE 11. Estimated Healthcare Expenditures and Savings, by Adherence Status

	Estimated Issuer Health Expenditures	
	Adherent	**Non-Adherent**
Emergency Room	$3,800,352	$4,692,132
Hospital, Inpatient	$20,082,785	$10,280,994
Hospital, Outpatient	$11,625,740	$7,832,828
Office-Based Visit	$17,924,314	$31,160,192
Prescription Medicine	$23,118,435	$31,446,902
All Medical Expenditures	$83,372,984	$93,022,353
Total Cost Savings	$9,649,369	

Note: These calculations utilize the average expenditure by payer for those indicating having a prescription medication based on reported adherence status. This average expenditure is then applied to the estimated number of participants improving adherence (10,269) in self-insured group health plans. The estimated cost-savings represent the expenditures for those improving adherence based on their adherence status (expenditures at non-adherence – expenditures at adherence = cost savings). Columns may not sum to total due to rounding. Not all sources of expenditure are listed.
Source: Agency for Healthcare Quality and Research, MEPS-HC, 2023.

[418] Based on data reporting insurer expenditures for privately insured patients aged 18-64 with a prescription medication. Department of Health and Human Services, Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey* (2024).

Increased prescription adherence is also associated with a decreased risk of adverse health outcomes.[419] For patients with chronic or severe diseases, the mortality risk associated with non-adherence to their medication can be considerable.[420,421] Additionally, health-related quality of life data from MEPS indicates that adherence is also associated with significantly higher health-related quality of life scores for both mental and physical health.[422]

To assess the value of these health benefits, the Department estimates the changes in health status through a single metric: quality-adjusted life-years (QALYs), which quantify the changes to morbidity for affected participants.[423] To calculate the QALY, the health utility metric, *Short Form Six-Dimension* (SF-6D),[424] is estimated for participants aged 18-64 with private health insurance. The average score for such participants that were adherent to their medication was approximately 0.82. An analysis of MEPS data by the Department indicated that non-adherence to medication for reasons of cost was associated with a 0.05 decrease in SF-6D

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[419] Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality,* BMJ (2006), https://pubmed.ncbi.nlm.nih.gov/16790458/; P. Michael Ho, John Rumsfeld, Frederick Masoudi, David McClure, Mary Plomondon, John F. Steiner, & David Magid, *Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus,* Archives of Internal Medicine, (2022), https://pubmed.ncbi.nlm.nih.gov/17000939/; Donald Pittman, William Chen, Steven Bowlin, & JoAnne Foody, *Adherence to Statins, Subsequent Healthcare Costs, and Cardiovascular Hospitalizations,* American Journal of Cardiology (2011).

[420] Sarah Van Alsten & Jenine Harris, *Cost-Related Nonadherence and Mortality in Patients with Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000–2014,* Preventing Chronic Disease, Center for Disease Control and Prevention (2020), https://pubmed.ncbi.nlm.nih.gov/33274701/.

[421] Scot Simpson, Dean Eurich, Sumit Majumdar, Rajdeep Padwal, Ross Tsuyuki, Janice Varney, & Jeffrey Johnson, *A Meta-Analysis of the Association Between Adherence to Drug Therapy and Mortality,* BMJ (2006), https://pubmed.ncbi.nlm.nih.gov/16790458/. See also, P. Michael Ho, John Rumsfeld, Frederick Masoudi, David McClure, Mary Plomondon, John F. Steiner, & David Magid, *Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus,* Archives of Internal Medicine (2022), https://pubmed.ncbi.nlm.nih.gov/17000939/.

[422] Physical Health Summary Scores (PCS) and Mental Health Summary Scores (MCS) showed significant variation between adherent and non-adherent respondents aged 18 to 64 with private health insurance. Department of Health and Human Services, Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey* (2024).

[423] A quality-adjusted life-year is standardized on a scale of 0 to 1, where 1 represents a perfect state of health and 0 represents the worst state of health (death).

[424] SF-6D is a value indicating the quality of a participant's life based on health determinants derived from physical health and mental health summary scores of the 2023 MEPS.

scores.[425] The Department estimates that QALY gains in each year will be equivalent to this 0.05 estimate for participants that improve their adherence.[426,427] The calculations are provided in Table 12 below.

TABLE 12. Annual QALY Estimates

Years →	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
N=	10,269	10,269	10,269	10,269	10,269	10,269	10,269	10,269	10,269	10,269
QALY Gains	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Total QALY Gains	531	531	531	531	531	531	531	531	531	531

Note: QALYs are estimated from the 2023 MEPS-HC as 0.05 per participant lower for participants that are non-adherent to their medication and aged 18 to 64 with private health insurance. Total may not sum due to rounding.

The difference between the baseline and post-rule estimates indicates that, each year, increased medication adherence among the 10,269 participants will result, on average, in 531 additional QALYs.[428] The Department uses an estimate for the central value of a QALY

[425] Based on a regression analysis of calculated SF-6D values derived from 2023 MEPS-HC data for participants reflecting reported cost-related non-adherence and controlling for mental and physical health status, race, income, sex, ethnicity, age, and insurance status.

[426] The MEPS Mental Health Score (MCS) and Physical Health Score (PCS) are standardized health-related quality of life scores from the VR-12 Assessment. The scores are adapted to a health utility metric, SF-6D using a peer-reviewed methodology. (*Source*: Hyun Song, Ji Haeng Heo, Debbie Wilson, Bui Shao, Haesuk Park, *National Catalog of Mapped Short-Form Six-Dimension Utility Scores for Chronic Conditions in the United States from 2010 to 2015,* Value in Health 25(8), (2022), (2003)).

[427] Hyun Jin Song, Ji Haeng Heo, Debbie L.Wilson, Hui Shao, & Haesuk Park, *A National Catalog of Mapped Short-Form Six-Dimension Utility Scores for Chronic Conditions in the United States From 2010 to 2015,* Value in Health, (2022).

[428] This estimate is calculated as: 10,269 participants improving adherence x 0.05 QALYs = 531 QALYs gained annually. Total may not sum due to rounding.

(VQALY) of approximately $763,000,[429, 430] suggesting an average total annual value of approximately $405.3 million from improvements to quality of life arising from a one percent reduction in prescription drug prices. These calculations and estimates are provided in Table 13 below.

TABLE 13. Estimated Value of QALY Improvements

	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**	**Year 10**
VQALY	$725,872	$733,980	$742,179	$750,469	$758,852	$767,328	$775,899	$784,566	$793,330	$802,191
QALY Gains (1.0%)	531	531	531	531	531	531	531	531	531	531
Total Value (1.0%)*	$385.4	$389.7	$394.0	$398.4	$402.9	$407.4	$411.9	$416.5	$421.2	$425.9

Note: *Value illustrated is reported in millions of dollars.

In total, the final rule is estimated to generate approximately $415.0 million in undiscounted benefits annually when considering QALYs. This total includes averted medical costs and improved health outcomes from greater treatment adherence.[431]

11.6.1.2 WTP Sensitivity Analysis

The Department has provided a sensitivity analysis of the WTP benefit estimates, utilizing the same approach as described in the benefits section. Table 14 presents the estimates of annual benefits and transfers under a 0.5 percent and 2.0 percent reduction in the average net

[429] The value of a quality-adjusted life-year (VQALY) utilizes the central estimate and is derived from *HHS, Standard Values for Regulatory Impact Analysis, 2026,* Office of Science and Data Policy, Department of Health and Human Services (2026).
[430] HHS values for a QALY, discounted at 3 percent, are utilized for this analysis. The value of a QALY in year one is estimated as $725,872 and is adjusted upward 1.1 percent each year to account for projected earnings growth. This results in an average value of QALY of $763,467 over the 10 years observed. Source: *HHS Standard Values for Regulatory Analysis 2025 – Supplemental Tables,* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. February 2025.
[431] This estimate is calculated as: $405,330,037 quality-adjusted life years + $9,649,359 in averted healthcare expenditures = $414,979,405 in total undiscounted benefits.

retail prescription drug price. The Department estimates that the annualized WTP benefits range from approximately $146.5 million to $586.0 million.

TABLE 14. Participant Annual Welfare Gains Measured by Willingness-to-Pay under Varying Assumptions about Reductions in Average Net Retail Prescription Drug Price

Decrease in Average Net Retail Prescription Price	Prescription Quantity in Baseline	Price Elasticity Estimate	Additional Prescriptions Filled	Average Price per Prescription ($)	Monetized Value of Willingness-to-Pay ($ million)	Transfers to Participants: Reduced Rx Spending ($ million)
(A)	(B)	(C)	(D)	(E)	(F) = (D × E)	(G) = Baseline spending ($81.8 B) x (A)
-0.5%	375,465,168	-0.358	672,083	$217.98	$146,500,576	$409.2
-1.0%	375,465,168	-0.358	1,344,165	$217.98	$293,001,152	$818.4
-2.0%	375,465,168	-0.358	2,688,331	$217.98	$586,002,305	$1,636.9

11.6.1.3 QALY Sensitivity Analysis

The Department analyzes the impact of health improvements arising from 0.5 and 2.0 percent reductions in the price of prescription drugs. Applying a one percent price reduction and an estimate price elasticity of demand of -0.358 for prescription drugs, [432] the Department estimates that between 108,065 and 432,261 additional prescriptions will be purchased by this

[432] Abe Dunn, *Health Insurance and the Demand for Medical Care: Instrumental Variable Estimates Using Health Insurer Claims Data,* Journal of Health Economics, Vol 48, (2016).

group resulting in approximately 5,134 to 20,537 additional such participants improving their adherence to medication.[433, 434]

Table 15. Estimated Adherence Improvements under Different Assumptions of Price Reduction in Average Net Retail Prescription Drug Price

Price Reduction	Price Elasticity of Demand	Non-Adherent Population	Prescriptions for Non-Adherent Participants	Additional Prescriptions Arising from Rule	Estimated Population Experiencing Adherence Improvement
-0.5%	-0.358	2,868,342	60,371,715	108,065	5,134
-1.0%	-0.358	2,868,342	60,371,715	216,131	10,269
-2.0%	-0.358	2,868,342	60,371,715	432,261	20,537

The calculations of the QALY estimates follow the same methodology as described earlier in the Uncertainty section, utilizing the estimated population experiencing adherence improvement from Table 15. The sensitivity analysis for 0.5 percent and 2.0 percent reductions in the average net retail price is stated in Table 16.

Table 16. Annualized QALY and Benefit Estimates under Different Assumptions of Price Reduction in Average Net Retail Prescription Drug Prices

Decrease in Average Net Retail Prescription Price	Prescription Quantity in Baseline	Price Elasticity Estimate	Additional Prescriptions Filled	Average Price per Prescription ($)	Monetized Value of Willingness-to-Pay ($ million)	Transfers to Participants: Reduced Rx Spending ($ million)
(A)	**(B)**	**(C)**	**(D)**	**(E)**	**(F) = (D × E)**	**(G) = Baseline spending**

[433] This estimate is calculated as: 60,371,715 prescriptions × -0.005 price change × -0.358 price elasticity of demand = 108,065 additional prescriptions for individuals aged 18-64 in large, self-insured plans that are non-adherent due to cost. Additionally, 108,065 additional prescriptions ÷ 21.05 prescriptions per prescribed individual = 5,134 individuals aged 18-64 in large, self-insured plans improving their adherence. Total may not sum due to rounding.
[434] This estimate is calculated as: 60,371,715 prescriptions × -0.02 price change × -0.358 price elasticity of demand = 432,262 additional prescriptions for individuals aged 18-64 in large, self-insured plans that are non-adherent due to cost. Additionally, 432,262 additional prescriptions ÷ 21.05 prescriptions per prescribed individual = 20,537 individuals aged 18-64 in large, self-insured plans improving their adherence. Total may not sum due to rounding.

						($81.8 B) x (A)
-0.50%	5,134	2,654	$202.70	$4.80	$207.50	$409.2
-1.00%	10,269	5,309	$405.30	$9.60	$415.00	$818.4
-2.00%	20,537	10,618	$810.60	$19.30	$829.90	$1,636.9

The value of the QALY benefits are estimated in the same manner as the benefit section and provided below in Table 17.

Table 17. Estimated Value of QALY Improvements under Different Assumptions of Price Reduction in Average Net Retail Prescription Drug Prices

	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**	**Year 10**
VQALY	$725,872	$733,980	$742,179	$750,469	$758,852	$767,328	$775,899	$784,566	$793,330	$802,191
Total Value (0.5%) *	$192.7	$194.8	$197.0	$199.2	$201.4	$203.7	$206.0	$208.3	$210.6	$212.9
Total Value (1.0%) *	$385.4	$389.7	$394.0	$398.4	$402.9	$407.4	$411.9	$416.5	$421.2	$425.9
Total Value (2.0%) *	$770.7	$779.3	$788.0	$796.8	$805.7	$814.7	$823.8	$833.0	$842.3	$851.7

*Values are stated in millions of dollars.

In total, the estimates of improved health outcomes for the final rule are estimated to generate approximately between $207.5 million and $829.9 million in undiscounted benefits annually under an estimated range of 0.5 percent and 2.0 percent price reductions for prescription

drugs. This total includes averted medical costs, reduced prescription drug expenditures, and improved health outcomes from greater treatment adherence.[435]

12. Alternatives

In addition to the regulatory approach outlined in the final rule, the Department considered an alternative approach during the development of the final rule. It is discussed in greater detail below.

12.1. Inclusion of Fully Insured Group Health Plans

The Department considered applying the proposed regulation to fully insured group health plans. In doing so, the full universe of ERISA -covered group health plans could benefit from these disclosures, which would aid responsible plan fiduciaries in fulfilling their fiduciary responsibilities, assist them in monitoring service providers to ensure that only reasonable costs are paid and that any conflicts of interest are disclosed and mitigated. This would in turn benefit plan participants and their beneficiaries.

Upon review, the Department found that fully insured group health plans generally do not enter into separate agreements for prescription drug benefits through carve-out arrangements but rather contract with issuers for comprehensive health insurance coverage with prescription drug benefits bundled into the larger package. A 2023 study on vertical integration in the Medicare Part D market finds that consolidation of PBMs and insurers can raise premiums for non-integrated insurers and lowers premiums for vertically integrated insurers. This research suggests that vertical integration may limit competition and increase costs even in markets, such as the

[435] This estimate is calculated as: $202,657,700 quality-adjusted life years + $4,824,510 in averted healthcare expenditures = $207,482,211 in total undiscounted benefits under a price reduction of 0.5 percent. Additionally, $810,632,677 quality-adjusted life years + $19,298,085 in averted healthcare expenditures = $829,930,762 in total undiscounted benefits under a price reduction of 2.0 percent.

fully insured group market, where prescription drugs benefits are bundled rather than separately carved out.[436] As such, it is not clear that responsible plan fiduciaries would find the disclosures required under this final rule helpful when negotiating or monitoring their benefit plan as to justify the costs associated with the disclosures (both to the covered service provider providing the disclosures and the responsible plan fiduciary reviewing and analyzing the disclosures). Therefore, the required disclosures under the final rule may not meaningfully reduce information asymmetry in the fully insured group health plan market, given that prescription drug benefits are bundled and negotiated at the issuer level rather than directly by plan fiduciaries. Based on these considerations, the Department has instead reserved obligations with respect to fully insured group health plans for future action.

12.2. Inclusion of Smaller Self-insured Group Health Plans

The Department considered including smaller self-insured group health plans, such as level-funded plans, within the scope of the final rule. Level-funded plans, in particular, tend to rely on TPAs and issuers to carry out their claims, administrative, and pharmacy benefit management functions. Requiring PBMs to furnish the required disclosures to these plans would impose additional administrative burdens associated with reviewing and analyzing these disclosures. The Department estimates there are approximately 953,420 level-funded group health plans, accounting for 90 percent of affected ERISA-covered group health plans.[437]

[436] Gray, Charles, Abby E. Alpert, & Neeraj Sood, *Disadvantaging Rivals: Vertical Integration in the Pharmaceutical Market*, National Bureau of Economic Research (2023), available at https://www.nber.org/system/files/working_papers/w31536/w31536.pdf.

[437] Additionally, the Department estimates there are 953,420 small, level-funded ERISA-covered group health plans based on the 20254 KFF Employer Health Benefits Survey, the 2024 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 20221 County Business Patterns from the Census Bureau. Large is defined as having 100 or more participants and beneficiaries in the plan.

The Department determined not to include small, self-insured group health plans for several reasons, including aligning the covered plan definition with ERISA section 726. ERISA section 726 also includes a requirement that small group health plans receive a summary document. Small, self-insured group health plans will also still receive the generalized compensation disclosures pursuant to ERISA section 408(b)(2)(B). In addition, the disclosures in the final rule will be most useful to responsible plan fiduciaries of large plans, who are more likely to have compliance staff and sufficient resources to analyze the disclosures and take appropriate action. Limiting the scope of the final rule is intended to avoid unintended negative consequences to smaller plans as described by some commenters. Accordingly, the Department determined not to include these small plans within the scope of the final rule.

12.3. Annual Disclosures from PBMs

The Department considered requiring annual disclosures from PBMs but determined that this information needed to be provided more frequently. Requiring disclosures only on an annual basis would delay actionable information for a substantial portion of the market, increasing the likelihood of inefficient pricing, foregone renegotiations opportunities, and higher plan costs. Semiannual disclosures reduce these market inefficiencies by improving the timeliness and useful of information available to plan fiduciaries. Therefore, under the final rule the Department requires that PBMs or covered service providers furnish disclosures on a semiannual basis within 30 calendar days following the conclusion of each six-month period starting from the contract or arrangement initiation date.

The Department requested comments on the proposed frequency of these disclosures. Some commenters expressed strong support for requiring semi-annual disclosures for the specific compensation categories estimated in the annual disclosures. One commenter supported

the proposed semi-annual timeframe because it aligns with the statutory reporting requirements under the CAA, 2026. The Department appreciates these comments for providing additional insight into the optimal frequency of disclosures.

12.4. Enhanced Disclosure for Bundled Services

The Department considered enhanced disclosures regarding direct compensation for bundled services. As proposed, the initial disclosure requirements would require a description of direct compensation that the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive in connection with the pharmacy benefit management services under the contract or arrangement. The term "direct compensation" means compensation received directly from the self-insured group health plan, or from the plan sponsor on behalf of the self-insured group health plan, regardless of whether such compensation is paid from plan assets. The proposal would require a description of the amount of all direct compensation, both in the aggregate and by service, that the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive on a quarterly basis in connection with pharmacy benefit management services under the contract or arrangement.

The Department considered whether to require the description of direct compensation for a bundled services option to include additional information, such as the bundled discounted value along with a description of services provided in the bundle. Greater additional disclosures could further reduce information asymmetries associated with bundled pricing by enabling fiduciaries to better compare compensation arrangements across providers. However, the Department was uncertain whether this level of detail would provide additional benefits to self-insured group health plan fiduciaries beyond the other disclosure requirements in the proposal, particularly

given potential increases in compliance and administrative costs. The Department requested comments on this alternative but did not receive any.

12.5. Other Alternatives Suggested by Commenters

One commenter suggested requiring standardized Application Programming Interface (APIs), such as Fast Healthcare Interoperability Resources (FHIR), to allow automated real-time compliance checks and make data easier to use. The Department considered this recommendation and recognizes that it could improve efficiency and reduce compliance checks over time. However, the Department also recognizes that creating and maintaining these systems could be costly and difficult.

Another commenter recommended that the Department provide standardized disclosure templates to improve consistency and make information easier to compare. The Department considered this recommendation and recognizes that standardized templates could reduce confusion and lessen the reporting burden for employers. However, the Department also notes that standardized templates may not work equally well for all entities and could create implementation challenges for organizations with different reporting systems.

Finally, one commenter suggested expanding disclosure requirements to include brokers and consultants who advise plan sponsors because of potential conflicts of interest. The Department considered this recommendation and acknowledges that greater transparency could help plan sponsors make more informed decisions. However, expanding disclosure requirements could also increase administrative and compliance costs for affected entities. Nevertheless, to the extent PBMs or their affiliates also act as brokers or consultants with respect to pharmacy benefit management services, they may be covered under the final rule as covered service providers.

12.6. Conclusion

The final rule is intended to allow responsible plan fiduciaries of self-insured group health plans to better fulfill their statutorily mandated role to determine that the service contracts or arrangements are reasonable under ERISA section 408(b)(2). The Department is of the view that increased transparency in PBM practices will empower responsible plan fiduciaries to increase market competition, negotiate more favorable contractual terms, reduce PBMs' conflicts of interest, and promote greater competition across the prescription drug supply chain. The final rule is expected to result in more accurate prescription drug classifications by PBMs, leading to more cost-effective and clinically appropriate formularies. Taken together, these outcomes will enhance market efficiency and ultimately improve access to affordable prescription drugs for consumers.

G. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), the Departments solicited comments concerning the information collection requests (ICRs) included in the proposed rules. At the same time, the Department also submitted ICRs to OMB, in accordance with 44 U.S.C. 3507(d). The Department received comments that specifically addressed the paperwork burden analysis of the ICRs contained in the proposed rules.

One commenter argued the proposed rule raised concerns under the PRA regarding duplication, burden, and practical utility. The commenter stated that the proposal overlaps with the existing CAA reporting requirements for rebates and fees, creating a risk of duplicative and inconsistent reporting. The Department acknowledges the concern regarding potential overlap with the CAA. However, to prevent unnecessary burden, the Department has harmonized the

disclosure requirements in this final rule with the existing CAA reporting framework. This harmonization avoids inconsistent reporting and minimizes additional compliance costs. Therefore, the Department concludes that the final rule provides necessary practical utility without creating an unwarranted duplicative burden.

Another commenter suggested updating Schedule C of Form 5500 to capture the compensation disclosures required under the final rule and the CAA 2026. The commenter noted that Schedule C currently does not reflect the expanded disclosure obligations for group health plan service providers. The Department believes that this rulemaking under ERISA section 408(b)(2) is properly focused on disclosures to responsible plan fiduciaries of covered plans. This rulemaking does not establish a new reporting framework for information to be submitted to the Department, other than the reporting provision in the administrative exemption in paragraph (n), which is discussed in greater detail in the preamble. Accordingly, changes to Schedule C of the Form 5500 are outside the scope of this rulemaking.

The changes made by this final rule affect the existing OMB control number, 1210-0173. A copy of the ICR for OMB Control Number 1210-0173 may be obtained by contacting the PRA addressee listed in the following sentence or at *www.RegInfo.gov.* For additional information contact, U.S. Department of Labor, Employee Benefits Security Administration, Office of Research and Analysis, Attention: PRA Officer, 200 Constitution Avenue NW, Room N-5718, Washington, DC 20210; or send to ebsa.opr@dol.gov.

The final rule is intended to help responsible plan fiduciaries better monitor prescription drug costs and benefit administration. The final rule requires PBMs and other covered service providers, and their affiliates, and agents, and subcontractors, to disclose pricing structures and potential conflicts of interest before entering, extending or renewing a service agreement and on

a semiannual basis afterward. PBMs and other covered service providers must also make available all the information needed for responsible plan fiduciaries to audit their disclosures provided under the regulation. Please see Table 18 for a summary of the hour and cost burden. For a description of how the estimates are obtained please see the Cost section of the RIA.

TABLE 18. Summary of Hour and Cost Burden

	Hour Burden	**Cost Equivalent of Hour Burden**	**Cost Burden**
IT Infrastructure (first year)	474,500	$80,300,000	$0
IT Infrastructure (subsequent years)	94,900	$21,900,000	$0
Disclosure (annual)	95,087	$12,547,664	$0
Audit (annual)	109,253	$15,959,168	$0
First Year Total	**678,839**	**$108,806,832**	**$0**
Subsequent Year Total	**299,239**	**$50,406,832**	**$0**
Three-Year Average Total	**425,773**	**$69,873,499**	**$0**

Below is a summary of the burden associated with the information collection.

Type of Review: New.

Agency: Employee Benefits Security Administration, U.S. Department of Labor.

Title: PBM Fee Disclosure Regulation under 408(b)(2).

OMB Control Number: 1210-0173.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 131,175 (3-year average).

Estimated Number of Annual Responses: 424,111 (3-year average).

Frequency of Response: Annual, Semi-annual.

Estimated Total Annual Burden Hours: 425,773 (3-year average).

Estimated Total Annual Burden Cost: $0.

H. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[438] imposes certain requirements with respect to Federal rules that are subject to the notice-and-comment requirements of section 553(b) of the Administrative Procedure Act and are likely to have a significant economic impact on a substantial number of small entities. Unless the head of an agency determines that a final rule is not likely to have a significant economic impact on a substantial number of small entities, section 604[439] of the RFA requires the agency to present a final regulatory flexibility analysis of the final rule.

The final rule only applies to self-insured plans of specified large employers and self-insured group health plans that are specified large plans. Small group health plans are not affected by the final rule. However, the final rule may still affect small, covered service providers, including PBMs and indirectly TPAs and issuers.

The Department has limited data to determine if this final rule would have a significant impact on a substantial number of small entities. As the Department is not able to certify that the final rule will not have a significant economic impact on a substantial number of small entities the Department has prepared this Final Regulatory Flexibility Analysis (FRFA) to evaluate the rule's potential effects on small entities.

1. Need for the Rule

Research suggests that PBMs contribute to high prescription drug prices in the United States by extracting economic rents in their role as intermediaries between self-insured group

[438] 5 U.S.C. 601 *et seq.* (1980).
[439] 5 U.S.C. 604 (1980).

health plans and prescription drug manufacturers. PBMs are often responsible for developing prescription drug formularies and benefit designs for self-insured group health plans, negotiating rebates with drug manufacturers for placement on those formularies, establishing preferred pharmacy networks, and processing prescription drug claims. In providing these services, PBMs often operate in ways that make it difficult for plans and plan sponsors to compare different PBM services, due to the non-transparent nature of the information.[440] These information asymmetries may also affect competition within the PBM market, including the ability of smaller PBMs to enter the market and compete with larger PBMs. Currently, the three largest PBMs – CVS Caremark, Express Scripts, and Optum Rx – account for 80 percent of the market.[441] As a result, reduced competition within the PBM market may contribute to higher prescription prices.

2. Objective of the Rule

The final rule aims to improve transparency in PBM arrangements by requiring covered service providers, including PBMs, to disclose detailed information to responsible plan fiduciaries. This will help them assess the reasonableness of compensation and fulfill their duties under ERISA.

PBMs and other covered service providers would be required to disclose, both before entering into an agreement and throughout the term of the contract, the full range of services provided, including those delivered through affiliates, agents, and subcontractors. They must also report all compensation, including manufacturer payments, spread pricing, copay claw-backs,

[440] Véronique C. Raimond, William B. Feldman, Benjamin N. Rome, & Aaron S. Kesselheim, *Why France Spends Less than the United States on Drugs: A Comparative Study of Drug Pricing and Pricing Regulation*, The MilBank Quarterly (Mar. 22, 2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984670/.
[441] Federal Trade Commission, *Interim Staff Report*: *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

and incentives related to formulary placement or price protection agreements. Disclosures must include enough information to allow responsible plan fiduciaries to independently estimate the cost of each drug by pharmacy channel. On a semiannual basis, PBMs and other covered service providers must provide updated disclosures summarizing the actual amounts received in manufacturer payments, spread pricing, copay claw-backs, and any other compensation received or reasonably expected to be received. They must also provide additional information upon request from the responsible plan fiduciary.

The final rule also specifies the responsible plan fiduciary's right to audit PBM and other covered service providers compliance once per year. Although the self-insured group health plan is responsible for audit costs, PBMs and other covered service providers must provide access to all necessary records, including contracts with pharmacies, drug manufacturers, and affiliates. The covered service provider must confirm receipt of the audit request within 10 business days and must provide the information within a commercially reasonable period.

The Department expects that the final rule would increase transparency in PBM compensation arrangements and enable self-insured group health plans to better understand these practices. This increased transparency would allow responsible plan fiduciaries to compare offerings across PBMs more effectively, helping them enter into the most appropriate PBM contracts for their needs. The final rule is intended to allow fiduciaries of self-insured group health plans to fulfill their statutorily mandated role to determine that the service contracts or arrangements are reasonable under ERISA section 408(b)(2).

Some commenters stated that small and mid-sized employers are particularly disadvantaged in contract negotiations because they lack the market power, expertise, and resources to negotiate effectively with large, vertically integrated PBMs. The Department agrees

that greater transparency from PBMs is needed to address these concerns and has therefore issued this final rule.

3. Affected Small Entities

The final rule will affect small, covered service providers, including PBMs and indirectly TPAs and issuers. These entities are discussed in greater detail in this FRFA.

3.1. Group Health Plans

For the purposes of the FRFA, the Department considers employee benefit plans with fewer than 100 participants to be small entities.[442] The basis of this definition is found in ERISA Section 104(a)(2), which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under ERISA Section 104(a)(3), the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of Section 104(a)(3), the Department has previously issued (see 29 C.F.R. § 2520.104–20, § 2520.104–21, § 2520.104–41, § 2520.104–46, and § 2520.104b–10) simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans, that and satisfy certain requirements.

For purposes of this analysis, small group health plans would not be affected by the final rule. The final rule requires PBMs to provide disclosures only to large, self-insured group health plans with 100 or more participants and beneficiaries.

[442] The Department consulted with the Small Business Administration in making this determination, as required by 5 U.S.C. § 601(3) and 13 C.F.R. § 121.903(c). Memorandum received from the U.S. Small Business Administration, Office of Advocacy on July 10, 2020.

3.2. TPAs and Issuers

The Department also estimates that the final rule will indirectly affect 205 TPAs and 373 issuers in the group market with 809 issuers/State combinations.[443] These are service providers acting on behalf of level-funded group health plans and self-insured group health plans, who typically provide plan management, regulatory compliance, and administrative services.

3.3. PBMs

In 2023, there were 73 full-service PBMs in the marketplace.[444] These PBMs may also provide brokerage services to self-insured group health plans with respect to pharmacy benefit management services. PBMs fall under the NACIS Code 524292, or "Pharmacy Benefit Management and Other Third-Party Administration of Insurance and Pension Funds," and the SBA considers businesses with up to $45.5 million in annual receipts to be small.[445] Notably, 92 percent of businesses within this industry are small businesses according to the SBA size standards. However, the Department believes that the distribution of revenue for this entire category does not reflect the distribution of PBM revenues. This is because the size distribution for TPAs is different than the size distribution for PBMs – PBMs are larger than TPAs and the annual receipts of most PBMs exceed this threshold. In particular, the three largest PBMs which account for 80 percent of the market, CVS Caremark, Express Scripts, and Optum Rx

[443] An "issuer/state combination" refers to a health insurance issuer and the state in which it offers coverage, such that the same issuer operating in multiple states is treated as separate issuer/state combinations. Data source: Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data*, https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.

[444] The PCMA article estimated the total number of PBMs in 2023 in the following manner: 70 full-service PBMs + 6 new full-service PBMs – 8 acquired PBMs + 5 PBMs that expanded services = 73 full-service PBMs.

[445] SBA, *Table of Size Standards* (last updated Mar. 2023), available at https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf.

respectively reported $180.9 billion,[446] $216.7 billion,[447] and $154.7 billion[448] in revenue in 2025, according to the SEC 10-K filings. Even for "small" PBMs, the Department expects that annual receipts would not be significantly below the SBA threshold. The Department requested, but did not receive, comments on this assumption.

4. Cost of Final Rule

The Department expects small PBMs to review the final rule, evaluate their current disclosure practices, and make any necessary changes to ensure compliance. Increased transparency may reveal concern with revenue strategies, causing some PBMs to shift toward fee-based compensation models and renegotiate contracts with manufacturers, and wholesalers. The Department notes that these second-order effects are not reflected in the cost estimates presented in this analysis.

Under the final rule, PBMs must provide fee disclosures to self-insured group health plans and permit self-insured group health plans to audit the covered service provider at least once per year. The Department estimates that only one-third of self-insured group health plans will submit an annual request for all information necessary to conduct such an audit. While self-insured plans are not expected to make these requests directly, the Department anticipates that

[446] The Form 10-K does not directly report the revenue for CVS Caremark. However, it provides revenue for the pharmacy services within the Health Services segment, which includes the pharmacy network, mail order pharmacies, and specialty pharmacies, and these services are generally managed by the PBM. Securities and Exchange Commission, *Form 10-K*, *CVS Health Corporation*, *Annual Report* (Fe. 10, 2026), available at https://www.sec.gov/Archives/edgar/data/64803/000006480325000007/cvs-20241231.htm.

[447] The Form 10-K does not directly report the revenue for Express Scripts. However, it provides revenue for the pharmacy services, and these services are generally managed by the PBM. (*Source*: SEC, *Form 10-K*, *Cigna. Annual Report* (Feb. 26, 2026), available at https://d18rn0p25nwr6d.cloudfront.net/CIK-0001739940/64c4c39f-1b4e-4979-8b4a-bfc403377665.pdf.

[448] The Form 10-K directly reports revenue for Optum Rx. Securities and Exchange Commission, *Form 10-K*, *UnitedHealth Group, Annual Report* (Mar. 2, 2026), available at https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2024/UNH-Q4-2024-Form-10-K.pdf.

issuers or TPAs providing services to self-insured group health plans will submit audit requests on their behalf.

4.1. Responses to Comments

One commenter stated the Department underestimated the burden on small group health plans, since the reporting requirements are complex and that many contractual agreements will have to be reviewed and revised at a high cost. The Department acknowledges the commenter's concern that the complexity of the reporting requirements and the need to review and revise contractual agreements could impose significant costs on small entities. However, the Department notes that the final rule does not affect small group health plans. Therefore, small group health plans are not expected to incur any burden. The Department has received comments regarding the impact on smaller PBMs. Some commenters contend that the disclosure requirements in the NPRM are duplicative and would require PBMs to divert substantial resources toward compliance activities rather than innovation or competition. They argue that these demands could disproportionately burden smaller PBMs and diminish their ability to compete with larger entities. One commenter further asserts that smaller PBMs lack the economies of scale necessary to distribute these costs across large enrollee populations or to absorb them while remaining competitive on an administrative-cost basis. According to this commenter, the requirements could create new barriers to market entry and expansion, discouraging innovation and reducing competition. Another commenter states that the machine-readable format requirement would impose substantial infrastructure costs, which would have a particularly pronounced impact on smaller PBMs serving regional and community employer markets.

The Department acknowledges these concerns, but believes that the benefits of the disclosure requirements justify the associated costs. The Department notes that transparency is essential for enabling plans, plan sponsors, and other stakeholders to better assess PBM practices and negotiate more effectively. Additionally, the Department believes that increased transparency may enhance rather than diminish market competition by reducing information asymmetries and enabling smaller PBMs to compete on clearer and more consistent negotiation terms.

4.2. Illustration of Costs for Small PBMs

Tables 19 and 20 illustrate how the estimated costs for PBMs compare to revenue in the first year and subsequent years, respectively. Table 19 specifically presents a range of potential cost impacts at different revenue levels. The Department does not have data on the revenue distribution of PBMs or on how many self-insured group health plans a small PBM typically provides services for. Since both the disclosure and audit costs depend on the number of self-insured group health plans, these tables present a range of per-entity costs as a percentage of revenue, varying both the average number of self-insured group health plans serviced by a PBM and the revenue relative to the SBA small business threshold.

As previously discussed, while the Department uses the SBA threshold for NACIS Code 524292, or "Pharmacy Benefit Management and Other Third-Party Administration of Insurance and Pension Funds" in this analysis, the Department expects that the size distribution for TPAs to be different than the size distribution for PBMs. Based on these assumptions, the Department estimates that the final rule's costs for small PBMs would represent at least 2.5 percent of revenues in the first year and at least 1 percent of revenues in subsequent years. The Department requested comments on the parameters used in this illustration, particularly any data on the

revenues of small PBMs and how many self-insured group health plans a small PBM typically provides services self-insured plans. No comments were received that addressed these topics.

TABLE 19. PBM Per Entity Costs as a Percentage of Revenue, First Year

	Per-Entity Cost	Cost as a Percent of 100% of SBA Threshold	Cost as a Percent of 75% of SBA Threshold	Cost as a Percent of 50% of SBA Threshold	Cost as a Percent of 25% of SBA Threshold	Cost as a Percent of 10% of SBA Threshold
PBMs						
Dollar Amount of Percent of SBA Small Business Threshold ($ millions)		$45.5 million	$34.1 million	$22.8 million	$11.4 million	$4.6 million
Rule Familiarization	$3,752 [a]	0.008%	0.011%	0.016%	0.033%	0.082%
IT Infrastructure	$1,100,000 [b]	2.418%	3.223%	4.835%	9.670%	24.176%
Disclosure [c]						
Servicing 50 Plans	$3,969	0.009%	0.012%	0.017%	0.035%	0.087%
Servicing 100 Plans	$7,938	0.017%	0.023%	0.035%	0.070%	0.174%
Servicing 150 Plans	$11,907	0.026%	0.035%	0.052%	0.105%	0.262%
Servicing 200 Plans	$15,876	0.035%	0.047%	0.070%	0.140%	0.349%
Audit [d]						
Servicing 50 Plans	$15,141	0.033%	0.044%	0.067%	0.133%	0.333%
Servicing 100 Plans	$30,282	0.067%	0.089%	0.133%	0.266%	0.666%
Servicing 150 Plans	$45,423	0.100%	0.133%	0.200%	0.399%	0.998%
Servicing 200 Plans	$60,564	0.133%	0.177%	0.266%	0.532%	1.331%
Total						
Servicing 50 Plans	**$1,122,862**	**2.468%**	**3.290%**	**4.936%**	**9.871%**	**24.678%**
Servicing 100 Plans	**$1,141,972**	**2.510%**	**3.346%**	**5.020%**	**10.039%**	**25.098%**
Servicing 150 Plans	**$1,161,082**	**2.552%**	**3.402%**	**5.104%**	**10.207%**	**25.518%**
Servicing 200 Plans	**$1,180,192**	**2.594%**	**3.458%**	**5.188%**	**10.375%**	**25.938%**

Note:

[a] Calculated as 20 hours per PBM x an hourly labor cost of $187.58.

[b] Calculated as an hourly labor cost of $131.29 for project management specialists x 2,250 hours + $659.15 for outside legal counsel x 160 hours + an hourly labor cost of $124.74 business operations specialists x 750 hours + an hourly labor cost of $178.08 for software developers, programmers, and testers x 3,500 hours.

[c] The costs associated with the initial disclosure are calculated as: 0.5 hour per PBM x an hourly labor cost of $156.16 for legal professionals and benefit specialists x 1/3 x the number of self-insured group health plans serviced by the PBM. The costs associated with the semiannual disclosure are calculated as: 0.25 hour x an hourly labor cost of $124.74 for benefit specialist x 2 x the number of self-insured group health plans serviced by the PBM. The costs associated with the quarterly disclosures upon request are calculated as: 0.25 hour x an hourly labor cost of $124.74 for benefit specialist x 2 x the number of self-insured group health plans serviced by the PBM, The costs associated with providing missing information are calculated as:

0.25 hour x an hourly wage rate of $124.74 for benefit specialist x 3.3 percent x the number of self-insured group health plans serviced by the PBM.

[d] Calculated as: 2 hours x an hourly labor cost of $151.41 for benefit specialist and IT professional x 1/3 x the number of self-insured group health plans serviced by the PBM.

TABLE 20. PBM Per Entity Costs as a Percentage of Revenue, Subsequent Years

	Per-Entity Cost	SBA Small Business Threshold ($ millions)	Cost as a Percent of Threshold (100%)	Cost as a Percent of 75% of Threshold	Cost as a Percent of 50% of Threshold	Cost as a Percent of 25% of Threshold	Cost as a Percent of 10% of Threshold
PBMs		$45.5					
IT Infrastructure	$300,000 [a]		0.659%	0.879%	1.319%	2.637%	6.593%
Disclosure Cost [b]							
Servicing 50 Plans	$3,969		0.009%	0.012%	0.017%	0.035%	0.087%
Servicing 100 Plans	$7,938		0.017%	0.023%	0.035%	0.070%	0.174%
Servicing 150 Plans	$11,907		0.026%	0.035%	0.052%	0.105%	0.262%
Servicing 200 Plans	$15,876		0.035%	0.047%	0.070%	0.140%	0.349%
Audit [c]							
Servicing 50 Plans	$15,141		0.033%	0.044%	0.067%	0.133%	0.333%
Servicing 100 Plans	$30,282		0.067%	0.089%	0.133%	0.266%	0.666%
Servicing 150 Plans	$45,423		0.100%	0.133%	0.200%	0.399%	0.998%
Servicing 200 Plans	$60,564		0.133%	0.177%	0.266%	0.532%	1.331%
Total							
Servicing 50 Plans	**$319,110**		**0.701%**	**0.935%**	**1.403%**	**2.805%**	**7.013%**
Servicing 100 Plans	**$338,220**		**0.743%**	**0.991%**	**1.487%**	**2.973%**	**7.433%**
Servicing 150 Plans	**$357,330**		**0.785%**	**1.047%**	**1.571%**	**3.141%**	**7.853%**
Servicing 200 Plans	**$376,440**		**0.827%**	**1.103%**	**1.655%**	**3.309%**	**8.273%**

Note:

[a] Calculated as 73 PBMs x an hourly labor cost of $131.29 for project management specialist x 500 hours + an hourly labor rate of $659.15 for outside legal counsel x 100 hours + an hourly labor cost of $124.74 business operations specialists x 50 hours + an hourly labor cost of $178.08 for software developers, programmers, and testers x 750 hours.

[b] The costs associated with the initial disclosure are calculated as: 0.5 hours per PBM x an hourly labor cost of $156.16 for legal professionals and benefit specialists x 1/3 x the number of self-insured group health plans serviced by the PBM. The costs associated with the semiannual disclosure are calculated as: 0.25 hours x an hourly labor cost of $124.74 for benefit specialist x 2 x the number of self-insured group health plans serviced by the PBM. The costs associated with the quarterly disclosures upon request are calculated as: 0.25 hours x an hourly labor cost of $124.74 for benefit specialist x 2 x the number of self-insured group health plans serviced by the PBM. The costs associated with providing missing information are calculated as: 0.25 hours x an hourly wage rate of $124.74 for benefit specialist x 3.3 percent x the number of self-insured group health plans serviced by the PBM.

[c] Calculated as: 2 hours x an hourly labor cost of $151.41 for benefit specialist and IT professional x 1/3 x the number of self-insured group health plans serviced by the PBM.

5. Steps Taken to Minimize Compliance Costs to Small Entities

The Department considered including smaller self-insured group health plans, such as level-funded plans, within the scope of the final rule. However, the Department determined not to include small, self-insured group health plans for several reasons, including aligning the covered plan definition with ERISA section 726. ERISA section 726 also includes a requirement that small group health plans receive a summary document. Small, self-insured group health plans will also still receive the generalized compensation disclosures pursuant to ERISA section 408(b)(2)(B). In addition, the disclosures in the final rule will be most useful to responsible plan fiduciaries of large plans, who are more likely to have compliance staff and sufficient resources to analyze the disclosures and take appropriate action. Limiting the scope of the final rule is intended to avoid compliance costs and unintended negative consequences to smaller plans as described by some commenters.

The final rule applies only to self-insured group health plans offered by "specified large employers" and self-insured group health plans that are "specified large plans." The exclusion of small plans from the final rule will likely help small PBMs. While the Department lacks explicit information on the clients of small PBMs, small PBMs likely have small plans for which they will not have to provide required disclosures or other items covered by the final rule.[449]

Comments and the Department's rationale for limiting to large self-insure plans is discussed in more detail in the section of the preamble titled, "Limitation to Large, Self-insured Group Health Plans."

[449] Drug Channels, *Plan Sponsors Like More Transparent PBMs—Yet Not All Choose Transparency*, (December 2016), https://www.drugchannels.net/2016/12/plan-sponsors-like-more-transparent.html.

6. Duplicate, Overlapping, or Relevant Federal Rules

There are no duplicate, overlapping, or relevant Federal rules.

I. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector.[450] For purposes of the UMRA, this rulemaking is expected to have such an impact on the private sector. For the purposes of this rulemaking, the RIA shall meet the UMRA obligations.

J. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on the States, the relationship between the Federal Government and States, or on the distribution of power and responsibilities among the various levels of government.[451] Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the final rule. Federal agencies must also ensure that "National action limiting the policymaking discretion of the States shall be taken only where there is constitutional and statutory authority

[450] 2 U.S.C. 1501 *et seq*. (1995).
[451] Federalism, 64 FR 43255 (Aug. 4, 1999).

for the action and the national activity is appropriate in light of the presence of a problem of national significance."[452]

Although this final rule is not intended to have any substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, this rule may have federalism implications. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA. Whether ERISA preempts any particular State law is decided on a facts-and-circumstances basis by Federal courts and remains governed by relevant case law and Supreme Court precedent.

In the proposed rule, the Department stated that the rule may have some implications for States, particularly if the rule is found to preempt State laws affecting PBMs providing services to self-insured group health plans. The Department requested input from affected States regarding this assessment. The Department received a comment letter from the National Association of Attorneys General, joined by attorneys general from 43 States, Washington D.C. and American Samoa, in support of the rulemaking, calling it an important step towards transparency. This comment offered feedback on, and a proposed clarification of, the Department's assessment of the rule's federalism implications. Specifically, this comment requested that it be clarified that neither does the Department intend that this rule preempts State law, nor does this rule in fact preempt State law. The commenters also urged the Department to

[452] Id. at section 3(b), 64 FR at 43256.

reiterate its ongoing commitment to continued coordination and information sharing with State regulators and attorneys general.

The Department acknowledges these concerns and recognizes that State attorneys general play an important role in overseeing PBM practices under applicable State laws. Nothing in this rule precludes the Department from consulting, coordinating, sharing information as permitted by law, or referring matters to State attorneys general where the Department determines that State laws may be violated or that such cooperation would promote effective oversight and enforcement. Furthermore, this final rule does not alter, expand, or modify the scope of ERISA preemption.

K. Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801–808), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Therefore, this rule shall be submitted to each House of the Congress and to the Comptroller General as part of a report containing a copy of the rule along with other information specified in 5 U.S.C. 801(a)(1).

List of Subjects in 29 CFR Part 2550

- Employee benefit plans
- Individual retirement accounts
- Pensions
- Plans

For the reasons set forth in the preamble, the Department amends part 2550 of subchapter F of chapter XXV of title 29 of the Code of Federal Regulations as follows:

Subchapter F—Fiduciary Responsibility Under the Employee Retirement Income Security Act of 1974

PART 2550—RULES AND REGULATIONS FOR FIDUCIARY RESPONSIBILITY

1. The authority citation for part 2550 continues to read as follows:

Authority: 29 U.S.C. 1135, sec. 102, Reorganization Plan No. 4 of 1978, 5 U.S.C. App. at 727 (2012) and Secretary of Labor's Order No. 1-2011, 77 FR 1088 (Jan. 9, 2012). Section 2550.401c-1 also issued under 29 U.S.C. 1101. Sections 2550.404a-2 and 2550.404a-3 also issued under sec. 657, Pub. L. 107-16, 115 Stat. 38. Sections 2550.404a-5, 2550.404c-1 and 2550.404c-5 also issued under 29 U.S.C. 1104. Sec. 2550.408b-1 also issued under 29 U.S.C. 1108(b)(1). Sec. 2550.408b-19 also issued under sec. 611, Pub. L. 109-280, 120 Stat. 780, 972. Sec. 2550.412-1 also issued under 29 U.S.C. 1112.

2. Amend § 2550.408b-2 by revising paragraph (c)(2) to read as follows:

§ 2550.408b-2 General statutory exemption for services or office space.

* * * * *

(c) * * *

(2) *Welfare plan disclosure*. See § 2550.408b-22.

* * * * *

3. Add § 2550.408b-22 to read as follows:

§2550.408b-22 Compensation transparency; pharmacy benefit management services.

(a) *General*. Section 408(b)(2) of the Employee Retirement Income Security Act of 1974 (the Act) exempts from the prohibitions of section 406(a) of the Act payment by a plan to a party

in interest, including a fiduciary, for office space or any service (or a combination of services) if such office space or service is furnished under a contract or arrangement which is reasonable. No contract or arrangement for services between a covered plan and a covered service provider, nor any extension or renewal, is reasonable within the meaning of section 408(b)(2) of the Act unless, in addition to meeting the general requirements in § 2550.408b-2, the requirements of section 408(b)(2)(B) of the Act are met. This regulation implements ERISA section 408(b)(2)(B) with respect to the covered service providers defined herein. A contract or arrangement between a covered plan and a covered service provider as defined herein that satisfies the requirements of this regulation also satisfies the requirements of section 408(b)(2)(B) of the Act.

(b) *Covered plan*. For purposes of this section, a "covered plan" means a group health plan as defined in section 733(a) of the Act that is offered by a specified large employer or that is a specified large plan, each as defined in paragraph (m), other than (1) a group health plan in which all of the benefits are provided exclusively through a contract or policy of insurance issued by a health insurance issuer as defined in § 2590.701-2 of this chapter and (2) a group health plan established by a plan sponsor that is, or that is affiliated with, a drug manufacturer, distributor, wholesaler, pharmacy benefit manager, rebate aggregator (or other purchasing entity designed to aggregate rebates).

(c) *Covered service provider*. (1) For purposes of this section, a "covered service provider" means a service provider that enters a contract or arrangement with the covered plan and reasonably expects $1,000 or more in compensation, direct or indirect, to be received in connection with:

(i) Providing any pharmacy benefit management services, as defined in paragraph (d) of this section, pursuant to the service contract or arrangement, regardless of whether such services

will be performed, or such compensation received, by the covered service provider, an affiliate, an agent, or a subcontractor; or

(ii) Providing advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, as defined in paragraph (d) of this section, pursuant to the service contract or arrangement, and is the entity described in paragraph (c)(1)(i) of this section or an affiliate of such entity.

(2) No person or entity is a "covered service provider" solely on the basis of providing services as an affiliate, an agent, or a subcontractor of the covered service provider, with respect to performing one or more of the services described in paragraph (c)(1)(i) or (ii) of this section under the contract or arrangement with the covered plan.

(3) Nothing in this section requires disclosure of the compensation of an individual who is an officer, director, employee, or partner of a covered service provider, an affiliate, an agent or a subcontractor, received for their duties performed as set forth in their job description or as expected in their role in connection with the provision of pharmacy benefit management services described in paragraph (d).

(d) *Pharmacy benefit management services—*

(1) *General*. For purposes of this section, the term "pharmacy benefit management services" means services necessary for the management or administration of a covered plan's prescription drug benefits (including the covered plan's provision of prescription drugs through the plan's medical benefit), regardless of whether the person, business, or entity performing the service identifies itself as a "pharmacy benefit manager."

(2) *Examples*. Pharmacy benefit management services include but are not limited to:

(i) Acting as a negotiator or aggregator of rebates, fees, discounts, and other price concessions for prescription drugs.

(ii) Establishing or maintaining prescription drug formularies.

(iii) Establishing or maintaining pharmacy networks, through contract or otherwise, including a mail order pharmacy, a specialty pharmacy, a retail pharmacy, a nursing home pharmacy, a long-term care pharmacy, and an infusion or other outpatient pharmacy, to provide prescription drugs.

(iv) Performing utilization review and management, including the instituting or processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic and biosimilar substitution programs.

(v) In conjunction with any of these other services, processing and payment of claims for prescription drugs; adjudicating appeals or grievances related to the covered plan's prescription drug benefits; recordkeeping related to the covered plan's prescription drug benefits; or performing regulatory compliance with respect to the covered plan's prescription drug benefits under the service contract or arrangement.

(e) *Initial disclosure requirements*. A covered service provider shall disclose to a responsible plan fiduciary, in writing, the following information in paragraphs (e)(1) through (9) of this section, not later than the date that is reasonably in advance of the date on which the service contract or arrangement is entered, and extended or renewed (for extensions and renewals, 90 calendar days in advance is deemed to be a reasonable period of time):

(1) *Description of services*. A description of each pharmacy benefit management service, or of the advice, recommendations, or referrals regarding the provision of pharmacy benefit

management services, to be provided to the covered plan pursuant to the service contract or arrangement.

(2) *Direct compensation*. A description of the amount of all direct compensation, both in the aggregate and by service, that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive on a semiannual (or at the request of the covered plan, quarterly) basis in connection with services under the service contract or arrangement. For purposes of this paragraph (e)(2), the term "direct compensation" means compensation received directly from a covered plan or from the plan sponsor on behalf of the plan (regardless of whether such compensation is paid from plan assets). An example is an administrative fee calculated on a per-participant, per-month basis. In the case of a bundled service or aggregated compensation arrangement, the description must include a reasonable and good faith allocation of the compensation associated with each service in the bundle.

(3) *Indirect compensation*. A description of the following, which shall include compensation based on a structure of incentives not solely related to the contract or arrangement with the covered plan:

(i) *Manufacturer payments*. A description of the amount of any rebate, fee, alternative discount or other remuneration, both in the aggregate and for each drug on the formulary, reasonably expected to be received from any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), by the covered service provider, an affiliate, an agent, or a subcontractor in connection with the service contract or arrangement, for the semiannual period (or quarter) (A) for claims incurred during the period and (B) related to utilization of such drug or spending on such drug during the period, specifying both the amount that is reasonably expected to be passed on to the covered plan and, if

applicable, plan sponsor and the amount that will be retained by the covered service provider, an affiliate, an agent, or a subcontractor.

(ii) *Spread compensation*.

(A) A list of drugs on the formulary and with respect to each such drug on such list:

(*1*) the contracted compensation to be paid by the covered plan for each drug (identified by the National Drug Code) to the covered service provider, an affiliate, an agent, or a subcontractor on behalf of the covered plan;

(*2*) the contracted compensation to be paid to the pharmacy by the covered service provider, an affiliate, an agent, or a subcontractor on behalf of the covered plan for each drug (identified by the National Drug Code);

(*3*) for each drug, the difference between the amount to be paid under subparagraph (*1*) and the amount paid under subparagraph (*2*) (spread compensation);

(B) A description of the amount of spread compensation reasonably expected to be received by the covered service provider, an affiliate, an agent, or a subcontractor in connection with the service contract or arrangement, for claims filed during each semiannual period (or quarter) both in the aggregate and for each drug on the formulary, and for each pharmacy channel (i.e*.,* retail, mail order, and specialty pharmacy); and

(C) A description of arrangements, incentives, contractual provisions, and policies that will be implemented under the service contract or arrangement that direct patients to pharmacies that are affiliates of the covered service provider.

(iii) *Pharmacy Recoupment*. A description of the amount of copay claw-back compensation and any other retroactive adjustment to pharmacy reimbursement reasonably expected to be recouped from a pharmacy by a covered service provider, an affiliate, an agent, or

a subcontractor in connection with prescription drugs dispensed under the service contract or arrangement for each semiannual period (or quarter), specifying the anticipated total number of transactions resulting in recoupment. For purpose of this paragraph (e)(3)(iii), copay claw-back compensation means the dollar amount of the difference between a copayment or coinsurance amount paid to the pharmacy by a plan participant or beneficiary and the reimbursement to the pharmacy.

(iv) *Price protection agreements*. A description of any inflation protection or price protection agreements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), in connection with prescription drugs dispensed under the service contract or arrangement, specifying the amount reasonably expected to be retained by the covered service provider, an affiliate, an agent, or a subcontractor in connection with each such inflation protection or price protection contract or arrangement for each semiannual period (or quarter) (A) for claims incurred during the period and (B) that is related to utilization of such drug or spending on such drug during the period, and the amount that will be passed on to the plan and, if applicable, plan sponsor.

(4) *Compensation for termination of service contract or arrangement*. A description of any compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with termination of the service contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination.

(5) *Description of other compensation*. To the extent not already disclosed under paragraphs (e)(1) through (4) of this section—

(i) A description of any compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive in connection with the service contract or arrangement for the semiannual period (or quarter), regardless of whether such compensation is paid regularly or irregularly or from plan assets or is subject to any contingency or other condition;

(ii) The identification of the payer of such compensation;

(iii) An identification of the services for which such compensation will be received; and

(iv) A description of the arrangement between the payer and the covered service provider, an affiliate, an agent, or a subcontractor, as applicable, pursuant to which such compensation is paid.

(6) *Description of formulary placement incentives*.

(i) A description of any formulary placement incentives and arrangements that the covered service provider, an affiliate, an agent, or a subcontractor has entered with any drug manufacturer in connection with the service contract or arrangement, along with an explanation of how the incentives and arrangements affect services to and are aligned with the interests of the plan and/or its participants and beneficiaries (*e.g.*, incentives or arrangements are to control prescription drug costs, provide clinically superior drugs, or both).

(ii) For any drug on the formulary with respect to which the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive any payment by the manufacturer or aggregator in connection with the service contract or arrangement (and that is not passed through to the plan), an identification of any reasonably available therapeutically equivalent alternatives (including biosimilar biological products), and the reason for omitting the alternatives from the formulary.

(iii) If the covered service provider, an affiliate, an agent, or a subcontractor retains authority to modify the formulary during the term of the service contract or arrangement, such as by adding or deleting drugs or changing their tiering, an explanation of the reasons for retaining such authority, the expected frequency of such changes, and that the responsible plan fiduciary will be notified reasonably in advance of any modifications that, individually or in the aggregate, are reasonably expected to have a material impact on the reasonableness of compensation under the service contract or arrangement, as well as the covered plan's right to terminate the service contract or arrangement on reasonably short notice under the circumstances. For purposes of this paragraph (e)(6)(iii), the term "material" means an amount that is 5 percent or more, or such lower percentage or dollar amount as may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement, of the aggregate compensation (on a semiannual basis, or at the request of the covered plan, quarterly basis) disclosed pursuant to paragraph (e)(3)(i) of this section, adjusted for any increases previously disclosed under this paragraph (e)(6).

(7) *Drug pricing methodology*. A description of the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, to the covered plan of each drug on the formulary, as defined by National Drug Code, after rebates, fees, alternative discounts, or other remuneration received from drug manufacturers, distributors, wholesalers, or rebate aggregators (or other purchasing entities designed to aggregate rebates), for each pharmacy channel, expressed as a monetary amount. If a monetary amount is not ascertainable, the covered service provider must disclose the methodology used by the covered service provider, an affiliate, an agent, or a subcontractor, under the service contract or arrangement, to determine the net price

per course of treatment or single fill, the covered plan will pay for each drug on the formulary, for each pharmacy channel, along with an objective means to verify the accuracy.

(8) *Statement of fiduciary status*. If applicable, a statement that the covered service provider, an affiliate, an agent, or a subcontractor will provide, or reasonably expects to provide, services pursuant to the service contract or arrangement directly to the covered plan as a fiduciary (within the meaning of section 3(21) of the Act).

(9) *Statement of audit right*. A statement of the covered plan's right to the audit described in paragraph (j) of this section and the procedures for requesting such an audit.

(f) [Reserved]

(g) *Semiannual disclosure requirements*. A covered service provider shall disclose to a responsible plan fiduciary, in writing, on a semiannual basis (or at the request of the covered plan, quarterly) no later than 30 calendar days after the end of each six-month period or quarter beginning on the date the service contract or arrangement is entered, the following information with respect to the preceding six-month period (or quarter):

(1) *Direct compensation*. A description of all direct compensation (within the meaning of paragraph (e)(2) of this section), both in the aggregate and by service, that the covered service provider, an affiliate, an agent, or a subcontractor received or reasonably expects to receive for the semiannual period (or quarter) in connection with services under the service contract or arrangement. In the case of a bundled service or aggregated compensation arrangement, the description must include a reasonable and good faith allocation of the compensation associated with each service in the bundle.

(2) *Indirect compensation.* A description of the following, which shall include compensation based on a structure of incentives not solely related to the contract or arrangement with the covered plan:

(i) *Manufacturer payments*. A description of all rebates, fees, alternative discounts or other remuneration, both in the aggregate and for each drug on the formulary, received or reasonably expected to be received from any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), by the covered service provider, an affiliate, an agent, or a subcontractor in connection with the service contract arrangement for the semiannual period (or quarter) (A) for claims incurred during the period and (B) that are related to utilization of such drug or spending on such drug during such period, specifying both the amount passed on to the plan and, if applicable, plan sponsor and the amount retained by the covered service provider, an affiliate, and agent, or a subcontractor.

(ii) *Spread compensation*.

(A) A list of drugs for which a claim was filed during the semiannual period or quarter, and with respect to each drug on the list-

(*1*) the contracted compensation paid by the covered plan for each drug (identified by the National Drug Code) to the covered service provider, an affiliate, an agent, or a subcontractor on behalf of the covered plan;

(*2*) the contracted compensation paid to the pharmacy by the covered service provider, an affiliate, an agent, or a subcontractor on behalf of the covered plan for each drug (identified by the National Drug Code);

(*3*) for each such claim, the difference between the amount paid under subparagraph (*1*) and the amount paid under subparagraph (*2*) (spread compensation); and

(B) A description of the amount of all spread compensation (within the meaning of paragraph (e)(3)(ii) of this section) received for the semiannual period (or quarter) by the covered service provider, an affiliate, an agent, or a subcontractor in connection with the service contract or arrangement, both in the aggregate and for each drug, and for each pharmacy channel (i.e., retail, mail order, and specialty pharmacy).

(iii) *Pharmacy Recoupment*. A description of all amounts of copay claw-back compensation (as described in paragraph (e)(3)(iii) of this section) and any other retroactive adjustment to pharmacy reimbursement recouped for the semiannual period (or quarter) from a pharmacy by a covered service provider, an affiliate, an agent, or a subcontractor in connection with prescription drugs dispensed under the service contract or arrangement, specifying the total number of transactions resulting in recoupment.

(iv) *Price protection agreements*. A description of all amounts received or reasonably expected to be received from a drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), by the covered service provider, an affiliate, an agent, or a subcontractor for the semiannual period (or quarter) (A) for claims incurred during the period and (B) that is related to the utilization of such drug or spending on such drug during the period pursuant to any inflation protection or price protection agreements that the covered service provider, an affiliate, an agent, or a subcontractor entered with any drug manufacturer, distributor, wholesaler, or rebate aggregator (or other purchasing entity designed to aggregate rebates), in connection with prescription drugs dispensed under the service contract or arrangement, specifying both the amount passed on to the plan and, if applicable, plan sponsor and the amount retained by the covered service provider, an affiliate, and agent, or a subcontractor.

(3) *Other compensation*. To the extent not already disclosed under paragraphs (g)(1) or (2) of this section—

(i) A description of any compensation that the covered service provider, an affiliate, an agent, or a subcontractor received or reasonably expects to receive in connection with services under the service contract or arrangement for the semiannual period (or quarter), regardless of whether such compensation is paid regularly or irregularly or from plan assets or is subject to any contingency or other condition;

(ii) The identification of the payer of indirect compensation;

(iii) An identification of the services for which indirect compensation was received; and

(iv) A description of the arrangement between the payer and the covered service provider, an affiliate, an agent, or a subcontractor, as applicable, pursuant to which such compensation was paid.

(4) *Overage explanation*. If any category of compensation to the covered service provider, an affiliate, an agent, or a subcontractor described in this paragraph (g), in the aggregate, materially exceeds the corresponding semiannual (or quarterly) estimate described in paragraph (e) of this section, an identification of the amount of the overage (in the aggregate) and the reason for the overage. For purposes of this paragraph (g)(4), the term "materially" means 5 percent or more, or such lower percentage or dollar amount as may be agreed to by the responsible plan fiduciary and set forth in writing in the contract or arrangement.

(5) *Statement of fiduciary status*. To the extent not previously disclosed under paragraph (e), if applicable, a statement that the covered service provider, an affiliate, an agent, or a subcontractor will provide, or reasonably expects to provide, services pursuant to the service

contract or arrangement directly to the covered plan as a fiduciary (within the meaning of section 3(21) of the Act).

(6) *Statement of audit right*. A statement of the covered plan's right to the audit described in paragraph (j) of this section and the procedures for requesting such an audit.

(h) [Reserved]

(i) *Information on request*. (1) Upon the written request of the responsible plan fiduciary, the covered service provider must furnish any other information relating to the contract or arrangement that is required for the covered plan to comply with the reporting and disclosure requirements of Title I of the Act, the regulations in this chapter, and forms and schedules issued under Title I.

(2) The covered service provider must disclose the information required by paragraph (i)(1) of this section reasonably in advance of the date upon which such responsible plan fiduciary states that it must comply with the applicable reporting or disclosure requirement, unless such disclosure is precluded due to extraordinary circumstances beyond the covered service provider's control, in which case the information must be disclosed as soon as practicable.

(j) *Right to audit.* (1) *Frequency and scope*. Not less than once per year, at the written request of the covered plan, the covered service provider shall allow for an audit of the covered service provider for accuracy of any disclosure made to comply with this section.

(2) *Auditor*. A responsible plan fiduciary of the covered plan shall have the right to select an auditor. The covered service provider shall not impose any limitations on the selection of such auditor.

(3) *Provision of information*. The covered service provider shall make available to the auditor all records, claims and transaction-level data, and other information reasonably necessary to confirm the accuracy of any disclosure made to comply with this section, including contracts with retail pharmacies, drug manufacturers, and rebate aggregators, subject to reasonable confidentiality agreements to prevent redisclosure of such information and to limit use of such information for purposes related to the covered plan's contract or arrangement.

(4) *Fees*. The covered plan shall bear responsibility for all expenses related to the selection and retention of the auditor. The covered service provider shall bear the cost of providing the requested information.

(5) *Timing*. The covered service provider shall confirm receipt of a request for an audit under this section no later than ten (10) business days after the information is requested. The covered service provider shall provide the information required under paragraph (j)(3) of this section within a commercially reasonable period but in no event later than 60 calendar days absent extraordinary circumstances beyond their control.

(6) *Restrictions*. The covered service provider may not impose conditions that would restrict the covered plan's right to conduct an audit under this section, including restrictions on the period of the audit, the location of the audit, or the number of records to be provided, except that the scope of the audit is limited to the period covered by the disclosures under this section.

(7) *Information from affiliates and subcontractors*. The covered service provider shall be responsible for providing such auditor with the information required under paragraph (j)(3) of this section that is owned or held by an affiliate, an agent, or a subcontractor of the covered service provider.

(k) *Manner of disclosure.*

(1) *General*. All disclosures under this section must be clear and concise, free of misrepresentations, and contain sufficient specificity to permit evaluation of the reasonableness of the service contract or arrangement. For example, the Department will consider the use of generic industry terms, jargon, or legalese, without definition, to lack the sufficient specificity required under the preceding sentence unless the language in question specifically refers to objectively determinable definitions, standards, or other similar guidelines, that are publicly available or will be provided by the covered service provider to the responsible plan fiduciary free of charge and within a reasonable period of time following the request.

(2) *Descriptions of compensation*. Descriptions of compensation or amounts required under this section must be expressed as a monetary amount (e.g., $1,000) and may be estimated to the extent that the actual amount is not reasonably ascertainable but shall contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, an affiliate, an agent, or a subcontractor. Estimates shall be grounded in good faith assumptions based on contractually defined methodologies, historical utilization and rebate experience, or other information reasonably available at the time of disclosure.

(3) *Machine-readability format*. Upon request of a responsible plan fiduciary of a covered plan, descriptions of compensation required under this section must also be provided, within a reasonable time after such request, in a standard machine-readable file. For purposes of this paragraph (k)(3), "machine-readable file" means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost. Drugs must be referred

to using an industry standard name and include a useful, non-proprietary identifier such as the National Drug Code, promulgated by the U.S. Food and Drug Administration.

(4) *Confidentiality agreements*.

(i) Except as provided in paragraph (j)(3) of this section, the covered service provider and its affiliates, agents, and subcontractors may not impose restrictions on the covered plan's use of disclosures required under this section, or the contract or arrangement described in paragraph (c)(1) of this section, except that the covered contract or arrangement may require the responsible plan fiduciary to require third parties to whom it rediscloses such information and any subcontractors of those third parties to execute reasonable confidentiality agreements preventing redisclosure by such parties and limiting use of such information to purposes related to the covered plan's contract or arrangement.

(ii) Neither this paragraph (k)(4) nor paragraph (j)(3) of this section restrict a covered plan, auditor, or a third party hired by the plan, or their subcontractors, from sharing information with State or Federal Government regulators or with legal counsel, even if the activities of those entities are unrelated to the purpose of a covered plan's contract or arrangement.

(l) *Disclosure errors*. No service contract or arrangement will fail to be reasonable under this section solely because the covered service provider, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the information required pursuant to paragraph (e), (g), or (j) of this section, provided that the covered service provider discloses the correct information to the responsible plan fiduciary as soon as practicable, but not later than 30 calendar days from the date on which the covered service provider knows of such error or omission.

(m) *Definitions.*

(1) *Affiliate*. A person's or entity's "affiliate" directly or indirectly (through one or more intermediaries) controls, is controlled by, or is under common control with such person or entity; or is an officer, director, or employee of, or partner in, such person or entity. Unless otherwise specified, an "affiliate" in this section refers to an affiliate of the covered service provider.

(2) *Agent*. An "agent" is any person or entity authorized (whether that authorization is expressed or implied) to represent or act on behalf of another person or entity. Unless otherwise specified, an "agent" in this section refers to an agent of the covered service provider.

(3) *Compensation*. The term "compensation" means anything of monetary value but does not include any item or service valued at $250 or less, in the aggregate, during the term of the service contract or arrangement.

(4) *Responsible plan fiduciary*. A "responsible plan fiduciary" is a fiduciary with authority to cause the covered plan to enter, extend, or renew the service contract or arrangement.

(5) *Subcontractor*. A "subcontractor" is any person or entity (or an affiliate of such person or entity) that is not an affiliate of the covered service provider and that, pursuant to a contract or arrangement with the covered service provider or an affiliate, reasonably expects to receive $1,000 or more in compensation for performing one or more services described pursuant to paragraph (d) of this section provided for by the service contract or arrangement with the covered plan.

(6) *Specified large employer*. The term "specified large employer" means, in connection with a group health plan established or maintained by a single employer, with respect to a calendar year, an employer who employed an average of at least 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the

calendar year. Whether an employer is a specified large employer shall be determined in accordance with the rules for counting employees and employer aggregation under section 4980H of the Internal Revenue Code and its implementing regulations at 26 CFR 54.4980H.

(7) *Specified large plan*. The term "specified large plan" means a group health plan established or maintained by a plan sponsor described in clause (ii) or (iii) of section 1002(16)(B) of this title that had an average of at least 100 participants on business days during the preceding plan year. Whether a group health plan is a specified large plan is determined by taking the sum of the total number of participants (not including beneficiaries) for each calendar month in the preceding plan year, and dividing by 12. The result, if not a whole number, is then rounded to the next lowest whole number.

(n) *Exemption for responsible plan fiduciary.*

(1) *General*. Pursuant to section 408(a) of the Act, the restrictions of section 406(a)(1)(C) and (D) of the Act shall not apply to a responsible plan fiduciary, notwithstanding any failure by a covered service provider to meet the requirements in paragraphs (e) through (l) of this section, if the following conditions are met:

(i) The responsible plan fiduciary did not know that the covered service provider failed or would fail to meet the requirements in paragraphs (e) through (l) of this section and reasonably believed that such requirements had been met.

(ii) The responsible plan fiduciary, upon discovering that the covered service provider failed to meet any requirement in paragraphs (e) through (l) of this section, requests in writing that the covered service provider correct the failure, e.g., to furnish required information or comply with the audit requirement.

(iii) If the covered service provider fails to comply with the written request described in paragraph (n)(1)(ii) of this section within 90 calendar days of the request, the responsible plan fiduciary notifies the Secretary of the covered service provider's failure, in accordance with paragraphs (n)(2) and (3) of this section.

(2) *Notice content*. The notice to the Secretary shall contain-

(i) The name of the covered plan;

(ii) The plan number used for the annual report on the covered plan;

(iii) The plan sponsor's name, address, and employer identification number;

(iv) The name, address, and telephone number of the responsible plan fiduciary;

(v) The name, address, phone number, and, if known, employer identification number of the covered service provider;

(vi) A description of the services provided to the covered plan;

(vii) A description of the covered service provider's failure;

(viii) The date on which the corrective action described in paragraph (n)(1)(ii) of this section was requested in writing from the covered service provider; and

(ix) A statement as to whether the covered service provider continues to provide services to the plan.

(3) *Notice timing*. The notice described in paragraph (n)(2) of this section shall be filed with the Department not later than 30 calendar days following the earlier of:

(i) The covered service provider's refusal to correct the failure identified in the written request described in paragraph (n)(1)(ii) of this section; or

(ii) 90 calendar days after the written request described paragraph (n)(1)(ii) of this section is made.

(4) *Where to file notice*. The notice described in paragraph (n)(2) of this section shall be furnished to the U.S. Department of Labor electronically in accordance with instructions published by the Department; or may be sent to the following address: U.S. Department of Labor, Employee Benefits Security Administration, Office of Enforcement, P.O. Box 75296, Washington, DC 20013.

(5) *Termination of service contract or arrangement*. If the covered service provider fails to comply with the written request under paragraph (n)(1)(ii) of this section within 90 calendar days of such request, the responsible plan fiduciary shall determine whether to terminate or continue the service contract or arrangement consistent with its duty of prudence under section 404 of the Act and shall document the basis for that determination.

(o) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof.

(p) *Effective and applicability dates*. (1) This section is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

(2) This section shall apply to plan years beginning on or after July 1, 2027.