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: Proposed rule.

SUMMARY: The Department is proposing a regulation that would require providers of pharmacy benefit management services and affiliated providers of brokerage and consulting services to disclose information about their compensation to fiduciaries of self-insured group health plans subject to the Employee Retirement Income Security Act (ERISA). These disclosures are needed so that fiduciaries can assess the reasonableness of the contracts or arrangements with these service providers, including the reasonableness of the service providers' compensation. These disclosure requirements would apply for purposes of ERISA's statutory prohibited transaction exemption for services arrangements. This proposal implements section 12 of President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First,* which instructs the Department to propose regulations to improve employer health plan transparency into the direct and indirect compensation received by pharmacy benefit managers. If finalized, this regulation would affect sponsors and other fiduciaries of self-insured group health plans and certain service providers to such plans.

DATES: Comments are due on or before March 31, 2026.

ADDRESSES: You may submit comments, identified by RIN 1210–AB37, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail or personal delivery:* Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210.

Instructions: All submissions received must include the agency name and Regulation Identifier Number (RIN) for this rulemaking. Comments received, including any personal information provided, will be posted without change to *http://www.regulations.gov* and *http://www.dol.gov/ebsa,* and made available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue NW, Washington, DC 20210. Persons submitting comments electronically are encouraged not to submit paper copies.

We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist us in analyzing the comments.

Warning: Do not include any personally identifiable or confidential business information that you do not want publicly disclosed. Comments are public records posted on the internet as received and can be retrieved by most internet search engines.

Docket: Go to the Federal eRulemaking Portal at *https://www.regulations.gov* for access to the rulemaking docket, including the plain-language summary of the proposed rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023.

FOR FURTHER INFORMATION CONTACT: Stephen Sklenar or Saliha Moore, Office of Regulations and Interpretations, Employee Benefits Security Administration, Department of Labor, at 202–693–8513. This is not a toll-free number.

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 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 (hereinafter ''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 that lowers costs and ensures accountability across the health-care system.[2] This proposed rule responding to those directives is only one component of the Trump Administration's larger initiative to address rising health-care costs for Americans.[3]

PBMs are described as the ''middlemen'' in the pharmaceutical supply chain.[4] 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, establishing drug formularies,[5] and processing claims. In connection with these services, PBMs receive compensation from self-insured group health plans as well as other sources in the pharmaceutical supply chain. Self-insured group health plan sponsors and other fiduciaries who are responsible for prudently selecting and monitoring service providers (referred to herein as ''responsible plan fiduciaries'') also commonly rely on brokers or consultants to help them with advice, recommendations, and referrals regarding pharmacy benefit management services.[6] The brokers or

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

[2] See Fact Sheet: President Donald J. Trump Announces Actions to Lower Prescription Drug Prices (April 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 . . .''), *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, https://www.dol.gov/newsroom/releases/ebsa/ebsa20250522.*

[4] 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), *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[5] A formulary is a list of drugs covered by the plan.

[6] It is well established that plan sponsors as defined in ERISA section 3(16)(B)(i) often wear two hats—an employer or settlor hat and a fiduciary hat. 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.

consultants may, in some cases, be affiliated with a PBM, and they also may receive compensation from sources other than self-insured 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.[7] In addition, in 2020, Congress amended ERISA's statutory service provider exemption to add a provision addressing disclosure by brokers and consultants to group health plans' responsible plan fiduciaries.[8]

The Department's proposed regulation 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 ERISA-covered self-insured group health plans can better fulfill their statutorily mandated role to determine that the service contracts or arrangements are reasonable. Under the Department's proposed regulation, these service providers would be required to provide robust disclosures to responsible plan fiduciaries of self-insured group health plans regarding their compensation for such services, including the advance disclosure of compensation they reasonably expect to receive. The proposed regulation also includes audit provisions designed to ensure that the responsible plan fiduciaries of self-insured group health plans can verify the accuracy of the disclosures. The responsible plan fiduciaries would 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 also in analyzing the drivers of prescription drug costs.

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.[9] Group health plans provide healthcare benefits such as hospitalization, sickness, prescription drugs, vision, and dental. Group health plans provide these benefits by purchasing insurance or by self-funding benefits from the employer's general assets or using a funded trust.

Retail prescription drug spending in the U.S. is expected to have amounted to nearly $495 billion in 2024 and is projected to grow 7 percent in 2025, but grow more slowly from 2026 to 2033.[10] In 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) or a percentage of the drug's cost (coinsurance). The group health plan's drug formulary identifies the drugs that are covered and organizes the drugs into tiers with different cost-sharing requirements imposed on participants. The tiers often distinguish between generic drugs and brand-name drugs, and may have a separate tier for ''specialty drugs.'' [11]

Managing a group health plan's prescription drug coverage is exceedingly complex for a number of reasons, including, but not limited to, the vast number of drugs available on the market and the large number of drug manufacturers and pharmacies. 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.[12]

Due to the complexity of the pharmaceutical supply chain and the multitude of players involved, responsible plan fiduciaries of group health plans often outsource pharmacy benefit management services among other types of 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 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.[13]

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.

[7] See Advisory Council on Employee Welfare and Pension Benefit Plans (ERISA Advisory Council), *PBM Compensation and Fee Disclosure* at 20 (November 2014) (''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.''), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

[8] ERISA section 408(b)(2)(B), added by section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.

[9] 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 (August 30, 2024), *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf.*

[10] Centers for Medicare & Medicaid Services, *National Health Expenditure Projections 2024–2033, 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.'' Centers for Medicare & Medicaid Services, *National Health Expenditure Projections 2024–2033, https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf.*

[11] 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, *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), *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[12] 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) (''PBM business practices and their effects remain extraordinarily opaque.''), *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 65, *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, March 2024), *https://www.gao.gov/assets/gao-24-106898.pdf.*

[13] See National Association of Insurance Commissioners, *A Guide to Understanding*

Continued

2.1. Formulary Development and Design

PBMs develop a self-insured group health plan's prescription drug formulary,[14] which is a list of drugs that the self-insured group health plan will cover, typically sorted into tiers of cost-sharing requirements.[15] Formularies generally balance access to prescription drugs with managing costs, and their development is similar across PBMs in that they follow a multi-step process involving several distinct committees.[16] For example, the Pharmacy and Therapeutics (P&T) committee is often an external body of experts who ''evaluate clinical and medical literature to select the most appropriate medications for individual disease states and conditions.'' [17] These committees are staffed with health-care 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.[18] Notably, this is only one of several PBM committees with influence over formulary design.[19] There are also formulary review and value assessment committees which review P&T Committee recommendations to make formulary placement decisions and trade relations groups which negotiate and approve rebate agreements with drug manufacturers.[20]

In connection with formulary development, PBMs and their affiliates negotiate with drug manufacturers for rebates and fees on prescription drugs and other remuneration, in return for preferred formulary placement.[21] PBMs reportedly 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.[22] Rebates are paid to the PBM periodically after the prescriptions are filled and are passed through to the self-insured group health plan to the extent required by the services contract.[23]

More recently, 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, again pursuant to contractual terms.[24] Each of the three largest PBMs is part of a vertically integrated entity which owns and controls such GPO subsidiaries. These GPOs are affiliates of their respective PBMs and perform the roles of rebate aggregators, two of which are headquartered outside of the United States.[25]

2.2. Drug Utilization Management

PBMs also provide drug utilization management services, which help optimize medication use, improve clinical outcomes, and control drug costs.[26] For example, PBMs perform utilization management services by

Pharmacy Benefit Manager and Associated Stakeholder Regulation (2025), *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, March 2024), *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), *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 (April 2025), *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); *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* (November 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

[14] 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, *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), *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[15] Tasmina Hydery & Vimal Reddy, *A Primer on Formulary Structures and Strategies, Journal of Managed Care & Specialty Pharmacy* (February 3, 2024), *https://www.jmcp.org/doi/10.18553/jmcp.2024.30.2.206.*

[16] Tasmina Hydery & Vimal Reddy, *A Primer on Formulary Structures and Strategies, Journal of Managed Care & Specialty Pharmacy* (February 3, 2024), *https://www.jmcp.org/doi/10.18553/jmcp.2024.30.2.206.*

[17] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 18 (2025), *https://content.naic.org/sites/default/files/pmbwhitepap.pdf.*

[18] 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.*

[19] United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 36 (2021), *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.*

[20] United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 36, 38 (2021), *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.*

[21] 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), *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), *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), *https://content.naic.org/sites/default/files/pmbwhitepap.pdf.*

[22] 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), *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), *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.*

[23] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 19 (2025), *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), *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.*

[24] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 21 (July 2024), *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), *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.*

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

[26] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 12 (July 2024), *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), *https://www.gao.gov/assets/gao-24-106898.pdf.*

which they determine specific drugs that require prior authorization, under which prescribers must receive pre-approval from the PBM before a particular drug can be prescribed to the patient. Another utilization management technique is step therapy, under which a PBM determines that patients must first try and fail a particular drug or drugs, typically a lower cost or preferred drug, before moving to a different drug. Another is quantity limits on the doses provided to patients in a year. Other drug utilization management services PBMs provide include:

- Non-medical switching to move a patient from one drug to another for a non-clinical reason, such as lowering cost; [27]
- Patient compliance analysis, also known as medication adherence analysis, in which a PBM reviews various data elements related to a participant's prescription drug benefit claims to determine whether (or to the extent which) a participant is indicated as conforming to the usage of a drug as prescribed; [28]
- Therapeutic intervention, or therapeutic interchange intervention, is the substitution of a prescribed drug for another drug that is essentially equivalent in terms of efficacy, safety, and outcomes; [29] and,
- Generic substitution, which is the practice of substituting a prescribed brand name drug for a therapeutically equivalent generic alternative to reduce cost.[30]

2.3. *Pharmacy Networks*

PBMs also develop pharmacy networks for self-insured group health plans which can be divided into three categories: retail, mail-order, and specialty.[31] 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.[32] Mail order pharmacies dispense and deliver prescriptions directly to participants and are often utilized for prescription drugs that are taken regularly.[33] Specialty drugs that meet certain characteristics such as special handling needs or high cost may be provided through a separate pharmacy.[34] As noted by the Federal Trade Commission (FTC), Congress, and others, the largest PBMs are vertically integrated with retail, specialty, and mail-order pharmacies.[35]

In developing a pharmacy network, PBMs negotiate dispensing fees and reimburse pharmacies for the cost of a prescription drug.[36] PBMs will establish maximum allowable cost (MAC) lists that state the greatest amount that a self-insured group health plan will pay for generics and, in some cases, brand name drugs with generic equivalents.[37] As in their negotiations with drug manufacturers, PBMs negotiate with pharmacies based on volume expected from the participants of multiple plan sponsors.[38]

2.4. Claims Administration and Other Services

Finally, PBMs also perform prescription drug claims administration services, which like the others, is key 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.'' [39] PBMs have developed systems to transmit prescription information between themselves and pharmacies, permitting the rapid processing of claims as prescriptions are being filled.[40] Other services include adjudicating appeals, plan recordkeeping and regulatory compliance.[41]

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

[28] Taiwo Opeyemi Aremu, Oluwatosin Esther Oluwole, Kehinde Oluwatosin Adeyinka &, Jon C Schommer, *Medication Adherence and Compliance: Recipe for Improving Patient Outcomes,* MDPI (August 28, 2022), *https://pubmed.ncbi.nlm.nih.gov/36136839/.*

[29] 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 17 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

[30] William H Shrank, Michael E. Porter, Sachin H. Jain, & Niteesh K. Choudhry, *A Blueprint for Pharmacy Benefit Managers to Increase Value,* Am J Manag Care (February 2009), *https://pmc.ncbi.nlm.nih.gov/articles/PMC2737824/.*

[31] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 11 (July 2024), *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), *https://www.gao.gov/assets/gao-24-106898.pdf;.*

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

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

[34] 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), *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 15–18 (July 2024), *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 31 (2021), *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.*

[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), *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 26 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

[37] 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.*

[38] 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), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

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

[40] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 13 (July 2024), *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.*

[41] U.S. Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers* at 8 (GAO–24–106898, March 2024), *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 (November 2014) *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

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 third-party administrator (TPA) or other entity (examples discussed herein) that agrees to provide pharmacy benefit management services to the self-insured group health plan.[42] 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.[43]

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. Services can include requests for proposals (RFPs), PBM oversight, and PBM audit services.[44] In some cases, the consultants and brokers receive indirect compensation (*e.g.,* compensation from the PBMs or other sources other than the self-insured group health plan) that may create a conflict of interest with respect to their self-insured group health plan customers.[45] 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.[46] Consultants may have preferred relationships with certain PBMs which may impact their recommendations.[47]

In addition to the complexity of the negotiations, responsible plan fiduciaries often lack a clear understanding of the contractual terms, or knowledge of how PBMs operate and how they receive compensation.[48] 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.'' [49] 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.'' [50] The contracts also address the ability of the responsible plan fiduciary to audit the PBM's compliance with the contract.[51] 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 categories: pass through pricing and spread pricing.[52]

In a pass-through pricing model, self-insured group health plans may, for example, 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.[53] 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 a reduced administrative fee.[54] The PBM will instead retain the spread between the price reimbursed to the pharmacy, which might be based on

[42] See 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/.*

[43] 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 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

[44] Milliman, Pharmacy Benefits Consulting, *https://www.milliman.com/en/services/pharmacy-benefits-consulting.*

[45] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3 (November 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.;* AJ Ally, Patrick Cambel, Mark Gruenhaupt, & Kristin Niakan, *Report of Pharmacy Benefit Manager Practices* at 34 (2025), *https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1.*

[46] Bob Herman, 'It's beyond unethical': Opaque conflicts of interest permeate prescription drug benefits (June 2023), *https://www.statnews.com/2023/06/20/pbms-consulting-firms-investigation/.*

[47] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 21 (November 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

[48] While Congress has prohibited plans and issuers from entering into contracts with health care 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, 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.

[49] 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 (April 2025), *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 (September 2016), *https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/Articles/Best-practices-PBM-RFP-process.pdf.*

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

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

[52] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), *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), *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 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

[53] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), *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 (October 2024), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

[54] 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 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

maximum allowable costs (MAC) or a different formula, and the negotiated rate with self-insured group health plans.[55]

The spread pricing model presents challenges for responsible plan fiduciaries in evaluating costs because there is no agreed upon AWP for a given drug. Accessing AWP data may be costly, and AWP providers use proprietary, hard-to-verify data sources and methodologies.[56] Additionally, PBMs typically do not disclose to the responsible plan fiduciaries either the reimbursement amount paid to pharmacies or the pharmacies' acquisition costs.[57] 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.[58] 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.[59]

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.[60] 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.[61] 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.[62]

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.[63] PBMs sometimes operate affiliated pharmacies and require plan participants to use these affiliated pharmacies for certain prescriptions such as mail-order and/or specialty drugs. [64] In some ways, the vertically integrated structure can be efficient and cost-effective, but some believe it may affect price competition when participants are required to use a PBM-affiliated pharmacy for certain prescriptions.[65] 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.'' [66]

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, and price protection

[55] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 13 (2025), *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, March 2024), *https://www.gao.gov/assets/gao-24-106898.pdf.*

[56] AWP is described as ''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), *https://content.naic.org/sites/default/files/pmbwhitepap.pdf.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), *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.

[57] 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.''), *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 (September 2024), *https://aspe.hhs.gov/sites/default/files/documents/db1adf86053b1fda8ae9efd01c10ddc8/Pharma%20Supply%20Chains%20Margins%20Report_Final_2024.09.27_Clean_508.pdf.*

[58] Scott McEachern & Patrick Cambel, *PBM Contracts: Understand then Optimize;* Milliman White Paper (August 2020) (''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.''); *https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize.*

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

[60] 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 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

[61] House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 26 (2024), *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 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

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

[63] 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), *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[64] Federal Trade Commission, *Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 12 (July 2024), *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 (November 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

[65] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 23 (2025), *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 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

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

fees. These payments are often defined by reference to list price, which commenters allege incentivizes PBMs to choose high-list price, high-rebate drugs when creating a self-insured group health plan's formulary.

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.[67] 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 strategies.[68] 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.[69]

To the extent rebates, fees, and other sources of remuneration are passed through to the self-insured group health plan, this can help defray the cost of the health-care benefits being provided.[70] However, some sources indicate that responsible plan fiduciaries may benefit from more transparent disclosures to ensure that rebates, fees, and other sources of remuneration are passed through as agreed to under the contract with the PBM, in part due to evolving terminology used in the contracts.[71] Some have indicated that the role of rebate aggregators adds complexity to drug pricing and transparency for disclosure of rebates owed to group health plans.[72]

The rebate payment structure would also benefit from more transparent disclosure for other reasons. One commonly cited concern is that PBMs may 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.[73] In addition to providing PBMs with an incentive to select higher priced drugs for the formularies, some sources indicate that rebates may be offered by drug manufacturers to PBMs to exclude competing products from the formulary.[74] Disclosure of rebates and other payments from drug manufacturers will allow self-insured group health plan responsible plan fiduciaries to evaluate the impact of these payments on the plan's formulary.

Sources also indicate that rebates and related PBM formulary practices may be related to increases in the manufacturers' drug list prices.[75] Drug manufacturers may raise list prices to accommodate rebate demands to secure preferred formulary placement to protect its market share, profits, or to recoup the costs for research and development.[76] Increases in list prices do not directly impact self-insured group health plans, as they generally pay a lower price due to rebates and other discounts negotiated by the PBMs.[77] However, increases in list

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

[68] United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 8 (2021), *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 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

[69] United States Senate Finance Committee, *Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* at 9 (2021), *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 (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921.*

[70] 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, AJ Ally, Patrick Cambel, Mark Gruenhaupt, & Kristin Niakan, *Report of Pharmacy Benefit Manager Practices* at 40 (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.''), *https://portal.ct.gov/-/media/ohs/reports/ohs-report-of-pharmacy-benefit-manager-practices-pa-23-171-s7.pdf?rev=01a4809a4795421e890970d8cd5f2fc1.*

[71] Joanna Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs,* Yale Law & Policy Review at 382 (2020) (''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.''), *https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content;* Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 22 (November 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

[72] Percher, *Trends in Profitability and Compensation of PBMs & PBM Contracting Entities,* at 2 (Sep. 18, 2023).

[73] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 20 (2025) (''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.''), *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;* House Committee on Oversight and Accountability Staff, *The Role of Pharmacy Benefit Managers in Prescription Drug Markets* at 7 (2024), *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 Law & Policy Review at 360 (2020), *https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content;* T. Joseph Mattingly 2nd, David A Hyman, Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy, https://pubmed.ncbi.nlm.nih.gov/37921745/https://pubmed.ncbi.nlm.nih.gov/37921745/.*

[74] 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.''), *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), *https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.*

[75] Neeraj Sood, Rocio Ribero, Martha Ryan, & Karen Van Nuys, *The Association Between Drug Rebates and List Prices* at 3, U.S.C. Schaeffer (February 2020) *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.*

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

[77] 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 (November 2024) (''For 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 or rebates off the list price;'' noting that ''[a]s used throughout this report, the term 'rebates' includes rebates, fees, and other remuneration transferred to PBMs from drug manufacturers and pharmacies.''), *https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/2024-report-to-congress-prescription-drug-spending.pdf.*

prices may be a factor for a responsible plan fiduciary assessing the overall reasonableness of the contract or arrangement. Participants in self-insured group health plans that include a deductible not only often pay the full cost of the drug up to the amount of the annual deductible, but also a portion of prescription drug costs after the deductible is satisfied, typically in the form of a copayment or coinsurance. In many self-insured group health plans, cost sharing is often based off list price, resulting in higher out-of-pocket costs for participants.[78]

While participants can obtain assistance with the cost of prescription drugs from drug manufacturers in the form of copay cards and coupons, which can lower cost sharing for participants, some argue this effectively bypasses formulary designs, hindering generic drug substitution and increasing overall out-of-pocket costs to participants. Some self-insured group health plans have reacted to the use of copay cards and coupons by adopting programs that address how drug manufacturer assistance will interact with the self-insured group health plan's cost sharing structure, sometimes referred to as ''copay maximizer,'' ''copay accumulator,'' or ''alternative funding programs.'' For example, a PBM or their affiliated entity might develop a list of specialty medications as part of an alternative funding program for exclusion from coverage under a self-insured group health plan. This has the effect of allowing the plan sponsor to drop drug coverage for participants and beneficiaries in order to access assistance intended for uninsured patients. If a participant needs the medication, he or she is then redirected to another funding source, such as a patient assistance program, outside of the self-insured group health plan. These programs reportedly may be administered by PBMs and appear to be a source of additional PBM compensation.[79]

3.3. Payments From Pharmacies

PBMs receive payments from pharmacies in a number of 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.[80] 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).[81]

PBMs also reportedly recoup amounts paid to pharmacies for other reasons, including ''network participation fees, fees for non-compliance or lower performance with quality measures, and reimbursement reconciliation.'' [82] 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.[83] 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.[84] 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.[85]

C. Service Provider Arrangements Under ERISA

1. Prohibited Transaction Framework

Responsible plan fiduciaries of self-insured group health plans must determine that service provider relationships involving the self-insured group health plan meet certain conditions 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 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

[78] Neeraj Sood, Rocio Ribero, Martha Ryan, & Karen Van Nuys, *The Association Between Drug Rebates and List Prices* at 5, U.S.C. Schaeffer (February 2020) (''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.''), *https://schaeffer.usc.edu/wp-content/uploads/2024/10/SchaefferCenter_RebatesListPrices_WhitePaper-1.pdf;* Joanna Shepherd, *Pharmacy Benefit Mangers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs,* Yale Law & Policy Review at 362–63 (2020), *https://openyls.law.yale.edu/server/api/core/bitstreams/fc20e184-b2d6-4b02-a0f6-a495e3fb5cd2/content;* T. Joseph Mattingly 2nd, David A Hyman, & Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy, https://pubmed.ncbi.nlm.nih.gov/37921745/https://pubmed.ncbi.nlm.nih.gov/37921745/.*

[79] Michelle Long, Meghan Salaga, & Kaye Pestaina, *Copay Adjustment Programs: What Are They and What do They Mean for Consumers* (October 24, 2024), *https://www.kff.org/report-section/copay-adjustment-programs-what-are-they-and-what-do-they-mean-for-consumers-issue-brief/;* David Choi, Autumn D. Zuckerman, Svetlana Gerzenshtein, Katherine V. Katsivalis, Patrick J. Nichols, Marci C. Saknini, Megan P. Schneider, Paige Taylor, & Stacie B. Dusetzina, *A Primer on Copay Accumulators, Copay Maximizers, and Alternative Funding Programs* (August 1, 2024), *https://www.jmcp.org/doi/10.18553/jmcp.2024.30.8.883.*

[80] National Association of Insurance Commissioners, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation* at 21 (2025), *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 (November 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

[81] Some self-funded 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.

[82] AJ Ally, Patrick Cambel, Mark Gruenhaupt, & Kristin Niakan, *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.''), *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), *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

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

[84] 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), *https://www.finance.senate.gov/imo/media/doc/Jonathan%20Levitt%20Testimony%20US%20Senate%20Committee%20on%20Finance%20-%20Frier%20Levitt%20-%20March%202023_Redacted1.pdf.*

[85] 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?, *https://www.alliantrx.com/wp-content/uploads/2020/05/GER-Explainer-Document.pdf* (June 24, 2025).

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.[86] 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.[87]

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 arrangements to be reasonable.[88] 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 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 1 of ERISA. The amended regulation also carries over a provision from the initial regulation regarding termination of the contract or arrangement.[89]

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.[90] The Department's amended regulation is accompanied by an administrative class exemption for responsible plan fiduciaries, codified at paragraph (c)(1)(ix), 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.[91]

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.[92]

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.'' [93]

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 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.[94] Specifically, the Council recommended

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[86] 29 CFR 2550.408b–2(b), (c), (d).

[87] 29 CFR 2550.408b–2(e).

[88] Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure; Final Rule, 77 FR 5632 (Feb. 3, 2012).

[89] 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.'').

[90] 29 CFR 2550.408b–2(c)(1)(viii)(E).

[91] 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.'')

[92] 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.*

[93] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3–4 (November 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

[94] The council noted this audit should not be confused with the requirement under ERISA section 103(3)(A).

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.'' [95]

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.''
- ''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.[96] As part of the amendment, Congress designated the pre-existing text as ERISA section 408(b)(2)(A).[97] The requirements in ERISA section 408(b)(2)(B) apply 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.[98]

The new 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 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 new provision 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).[99] 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 ERISA section 408(b)(2)(B) to define a covered service provider, the Department noted that neither term was defined and the 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.'' [100]

D. Description of the Proposed Regulation

1. Scope of the Proposed Regulation

1.1. General—Proposed 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 the contracts or arrangements are reasonable, the services are necessary for the establishment or operation of the plan, and that no more than reasonable compensation is paid. Paragraph (a) of the proposed regulation provides that for purposes of the statutory exemption under ERISA section 408(b)(2), 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 the regulation are satisfied.[101]

[95] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 5 (November 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/2014-pbm-compensation-and-fee-disclosure.pdf.*

[96] Section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.

[97] 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.''

[98] Specifically, see ERISA section 408(b)(2)(B)(ii)(I)(bb)(AA) (defining 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'') and ERISA sections 408(b)(2)(B)(ii)(I)(bb)(BB) defining 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.)''

[99] Field Assistance Bulletin No. 2021–03, *https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03.*

[100] *Id.* (emphasis added). In addition to the new 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 (January 13, 2025).

[101] Title I of ERISA sets forth various requirements for covered plans, which, subject to

Continued

1.2. Covered Plan—Proposed Paragraph (b)

Paragraph (b) of the proposed regulation provides that, for purposes of the regulation, a covered plan means a group health plan as defined in ERISA section 733(a), 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 insurance issuer as defined in § 2590.701–2.[102] ERISA section 733(a) defines a ''group health plan'' as ''an employee welfare benefit plan to the extent that the plan provides medical care . . . to employees or their dependents . . . directly or through insurance, reimbursement, or otherwise.'' The term ''group health plan'' includes both insured and self-insured group health plans, and includes grandfathered health plans, as defined in section 1251(e) of the Patient Protection and Affordable Care Act. Excepted benefits, such as limited scope dental and vision plans, are also group health plans for purposes of the definition of a covered plan in this proposal.[103] However, ERISA section 733(a)(1) expressly excludes qualified small employer health reimbursement arrangements from the definition of group health plan, and therefore such arrangements would not be covered plans under the regulation.

The definition of ''covered plan'' in the proposal excludes fully insured group health plans, and disclosure obligations with respect to these plans are reserved for future action. Accordingly, the requirements in the proposed regulation would apply only to contracts and arrangements involving self-insured group health plans. For clarity, this preamble description of the proposed regulation uses the term ''self-insured group health plan'' instead of the term ''covered plan.''

The Department has reserved 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-funding medical care and contracting for pharmacy benefit management services. Specifically, the Department questions whether responsible plan fiduciaries responsible for procuring fully insured health insurance policy would find the specific disclosures proposed in the regulation sufficiently useful when they are negotiating more comprehensive health insurance coverage 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). It is also the Department's 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.

However, the reservation of these disclosure obligations should not be interpreted as alleviating responsible plan fiduciaries of group health plans of any other obligations under ERISA. Responsible plan fiduciaries must continue to satisfy their general fiduciary obligations under ERISA with respect to the selection and monitoring of all service providers. Further, service contracts or arrangements with these service providers must be ''reasonable'' and otherwise satisfy the requirements of ERISA section 408(b)(2). For covered service providers as described in ERISA section 408(b)(2)(B), this includes providing the disclosures specified in that statutory provision.

The Department seeks comments on the relevance of the disclosures in this proposed regulation to responsible plan fiduciaries of fully insured group health plans. As indicated, the proposal would not apply to fully insured group health plans, in which the prescription drug coverage is integrated as a component of the insurance coverage and the insurance coverage is subject to State law. In these circumstances, in which services are fully bundled with insurance, the proposal assumes the responsible plan fiduciary discharges its 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 assumes 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.

The proposal could have required a disclosure from the insurance company in which each premium dollar is apportioned to the various elements comprising the insurance product, including insurance and services components. Moreover, the disclosure could have further required the prescription drug coverage portion to be divided between the insurance component and the services components, with an itemization of compensation received and expected to be received with respect to each of the service components. The Department has no basis, however, to determine whether the responsible plan fiduciaries of fully insured group health plans would benefit from these or similar disclosures. The Department welcomes comments on this conclusion in general, on the two specific disclosure regimes laid out above, and on whether (and, if so, how) the responsible plan fiduciary would benefit from such disclosures.

1.3. Covered Service Providers—Proposed Paragraph (c)

Paragraph (c) of the proposed regulation defines the entities that would be covered service providers under the regulation and therefore would have disclosure and related audit obligations. The proposal identifies two types of covered service providers: (i) providers of pharmacy benefit management services (as defined in paragraph (d) of the proposal) 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.[104] In each case, to be a covered service provider, the entity must reasonably expect to receive $1,000[105] or more in compensation,

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).

[102] 29 U.S.C. 1191b.

[103] See Field Assistance Bulletin No. 2021–03, Q&A 3 (''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).''), *https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03.*

[104] Non-affiliated brokers and consultants remain subject to the ERISA section 408(b)(2)(B) disclosures.

[105] This $1,000 threshold is consistent with the thresholds in the statute (29 U.S.C.

direct or indirect, in connection with providing the services.[106]

The proposal's focus on providers of pharmacy benefit management services is consistent with President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First,* which instructs 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 recognizes that self-funded group health plans have other service providers that are not covered by this proposal and that may not be considered providers of ''brokerage services'' or ''consulting'' for purposes of ERISA section 408(b)(2)(B). 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. Stakeholders have indicated that group health plan fiduciaries may not have access to all claims data, payments to providers, and fee and pricing data that could enable negotiation for cost savings to group health plans and participants.[107] The Department seeks comment on whether, and the extent to which it could and should expand the disclosures in this proposal to cover additional service providers and if so, which service providers should be covered. Additionally, the Department seeks comment on whether the disclosures proposed herein 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.

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

Paragraph (c)(1)(i) of the proposal defines, as covered service providers, service providers that enter into a contract or arrangement with a self-insured group health plan to provide pharmacy benefit management services. The proposal 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.[108] Thus, the proposed definition recognizes that the pharmacy benefit management services may be performed by the covered service provider, or they may be performed by an affiliate, agent, or subcontractor of the covered service provider. Likewise, the proposed definition recognizes that compensation in connection with the services may be received by the covered service provider or it may be received by an affiliate, agent, or subcontractor of the covered service provider.

Under this framework, paragraph (c)(1)(i) of the proposed rule focuses on the entity that has a contract or arrangement with the self-insured group health plan to provide any pharmacy benefit management services to that self-insured group health plan—that counterparty is the covered service provider. The Department believes that the service provider directly responsible to the self-insured group health 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 the Department's service provider regulation applicable to pension plans (29 CFR 2550.408b–2(c)(1)) as well as in the new statutory provision in ERISA section 408(b)(2)(B).[109]

In this regard, the Department understands that responsible plan fiduciaries to self-insured group health plans may take a number of different approaches in identifying and selecting a provider of pharmacy benefit management services. The self-insured group health 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 self-insured group health plan through an affiliate, agent, or 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 self-insured group health plan will enter into a contract directly with the PBM.

On the other hand, the Department understands that TPAs may contract directly with self-insured group health plans to provide a range of health-care related services, such as creating networks of health-care 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 self-insured group health 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 proposed rule and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

Self-insured group health 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 into level-funded arrangements that have excessive 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 self-insured group health plan to provide those services would be the covered service provider. As in the TPA example, if the entity contracting or arranging with the self-insured group health plan is not providing the services itself, it would be responsible for making the disclosures to the responsible plan fiduciary required under the proposal, 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

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)).

[106] 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 (29 U.S.C. 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)).

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

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

[109] 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.''); 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 . . .'').

fiduciary in the context of a multiple employer welfare arrangement (MEWA).[110] For MEWAs that are considered single ERISA plans, the responsible plan fiduciary for the self-insured group health plan would receive the disclosures from the party that contracts with the self-insured group health 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 self-insured group health 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 self-insured group health plans to provide pharmacy benefit management services. In that case, the MEWA operator would have the responsibility to make the disclosures required by the proposed 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),[111] and therefore must obtain the necessary information from the provider (*e.g.,* as a subcontractor) performing the pharmacy benefit management services.

Self-insured group health 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 self-insured group health 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 self-insured group health 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.[112] However, if the consortium or other employer group were to contract to provide the services to the self-insured group health plan, the consortium or other group would be the covered service provider.

Finally, a single self-insured group health plan may directly contract with more than one entity for pharmacy benefit management services as such services are defined in paragraph (d) of the proposal. In such circumstances, the self-insured group health 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 self-insured group health plan.

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

Paragraph (d) of the proposed regulation defines pharmacy benefit management services as services necessary for the management or administration of a self-insured group health plan's prescription drug benefits (including the self-insured group health 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 proposed 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;
- processing and payment of claims for prescription drugs;
- performing utilization review and management, including the processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic substitution programs;
- adjudicating appeals or grievances related to the self-insured group health plan's prescription drug benefits;
- recordkeeping related to the self-insured group health plan's prescription drug benefits; and
- in conjunction with any of these other services, performing regulatory compliance with respect to the self-insured group health 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 self-insured group health plans. The examples provided in the proposed definition are intended to describe the services expansively to ensure comprehensive disclosures are made. Consequently, the proposed 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 proposed definition.

The Department requests comments on its proposed definition of pharmacy benefit management services, including whether the description of any of the services should be altered and whether any services should be expressly added as examples.

1.4.2. Affiliates, Agents and Subcontractors—Proposed Paragraph (m)

The proposed terms ''affiliate,'' ''agent,'' and ''subcontractor,'' identify parties other than the covered service provider that may perform pharmacy benefit management services and also may receive compensation in connection with pharmacy benefit management services, and would be required to be disclosed under the regulation. As noted above, the regulation places the obligation on the covered service provider to make the disclosures and to seek any required information from these parties as needed for the disclosure. Proposed paragraph (c)(2) would clarify 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.[113]

[110] 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, https://www.dol.gov/sites/dolgov/files/ebsa/pdf_files/mewa-under-erisa-a-guide-to-federal-and-state-regulation.pdf.*

[111] See proposed paragraph (m)(4) defining ''responsible plan fiduciary.''

[112] Although the Department assumes these consortiums and employer groups are not affiliates of providers of pharmacy benefit management services (and therefore would not be affiliates providing advice, recommendations and referrals for purposes of paragraph (c)(2) of the proposal), depending on the facts, the consortium or other group may be considered to be a provider of ''brokerage services'' or ''consulting'' under ERISA section 408(b)(2)(B).

[113] This clarifying provision is also in the Department's service provider disclosure regulation

Under paragraph (m)(1) of the proposal, 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 proposed 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.[114]

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 self-insured group health plan. Accordingly, under the proposed definition, an affiliate of a subcontractor would also be considered a subcontractor for purposes of the regulation, including the disclosure requirements.

The proposed definitions of the terms ''affiliate'' and ''subcontractor'' are consistent with the definitions of these terms in the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)) as well as the new service provider disclosure obligations in ERISA section 408(b)(2)(B), and the Department believes they are well understood by stakeholders.[115]

The proposal 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. This additional proposed term is included based on the concern that, in the context of pharmacy benefit management services, entities that receive undisclosed compensation in connection with pharmacy benefit management services may not technically fall within the definition of an ''affiliate'' or a ''subcontractor.'' 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.[116] The Department intends that any compensation received by these entities in connection with pharmacy benefit management services to a self-insured group health plan would be disclosed under the regulation.

The Department requests comments on the proposed definitions of affiliate, agent, and subcontractor, including whether parties such as rebate aggregators or GPOs (or any other parties that fall within the proposed definition of agent) are likely to be covered by either of the other proposed definitions (*i.e.,* affiliate or subcontractor).

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

Concerns have been raised that brokers and consultants may receive payments from parties they are recommending, which may be undisclosed to their self-insured group health plan clients.[117] These arrangements have a high potential for conflicts of interest that warrant disclosure, as evidenced by Congress's amendment to ERISA section 408(b)(2) requiring disclosure of, among other things, indirect compensation reasonably expected to be received by providers of ''brokerage services'' and ''consulting'' with respect to pharmacy benefit management services.

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 has determined that special provisions under the proposal are needed. Paragraph (c)(1)(ii) of the proposed regulation therefore identifies as covered service providers those parties described in paragraph (c)(1)(i) of the proposal or their affiliates, that enter into a contract or arrangement with a self-insured group health plan to provide advice, recommendations, or referrals of pharmacy benefit management services. These covered service providers would have the obligation proposed in the regulation to disclose their compensation and to allow for an audit, as discussed below.

Although the terms ''brokerage services'' and ''consulting'' in ERISA section 408(b)(2)(B) are not defined, entities that would be covered service providers under paragraph (c)(1)(ii) of the regulation are also likely to be covered service providers under ERISA section 408(b)(2)(B). In the Department's view, the obligations under the proposal may be more specific than the statutory disclosure requirements but are not inconsistent with them. Moreover, because this proposed regulation provides specific descriptions of compensation streams and arrangements in the pharmaceutical supply chain that must be disclosed, the Department envisions that compliance with the requirements of the regulation, if adopted, would also satisfy the requirements of section 408(b)(2)(B) with respect to provision of brokerage services or consulting with respect to pharmacy benefit management services.

The Department believes that these brokers and consultants should be described as covered service providers under this regulation, rather than only under ERISA section 408(b)(2)(B), because of their affiliation with providers of pharmacy benefit management services. The conflicts associated with that affiliation should be disclosed to the self-insured group health plans' responsible plan fiduciaries. Further, if this regulation is adopted, it may be difficult as a practical matter for affiliated brokers and consultants to determine the extent of their obligations under the statutory provision given the lack of a definition of ''brokerage services'' and ''consulting'', and ambiguity surrounding the ''indirect compensation'' that must be disclosed. Additionally, the Department has tailored the requirements of this proposal to the practices of pharmacy benefit management service providers and therefore to the extent that their broker and consultant affiliates receive compensation that is specifically described in the regulation, responsible plan fiduciaries may receive higher

for pension plans (29 CFR 2550.408b–2(c)(1)(iii)(D) and is in ERISA section 408(b)(2)(B)(ii)(III).

[114] See *e.g.,* 29 CFR 2550.404c–1(e)(3).

[115] See 29 CFR 2550.408b–2(c)(1)(viii)(A) and (F); ERISA section 408(b)(2)(B)(ii)(I)(cc) and (ff).

[116] 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), *https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.*

[117] Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure* at 3 (November 2014) (''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.''), *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf.*

quality disclosures from these brokers and consultants than they would receive absent such tailoring. Brokers and consultants may benefit from greater confidence in satisfying their disclosure requirements under the prohibited transaction exemption. Therefore, including these entities in the regulation would serve a compliance assistance function. On the other hand, to the extent brokers and consultants that are covered service providers have very simple compensation arrangements—*e.g.,* they only receive direct payments from the self-insured group health plan—the obligations under the regulation would be relatively minor.

The Department intends that brokers and consultants that provide advice, recommendations, or referrals regarding pharmacy benefit management services, but are not affiliates of these providers, would be able to determine their disclosure obligations under ERISA section 408(b)(2)(B), which is self-effecting.[118] With respect to these entities, the Department does not envision that its enforcement policies announced in Field Assistance Bulletin 2021–03 would change in connection with this proposal. Thus, entities that are not affiliated with providers of pharmacy benefit management services would continue to use a good faith, reasonable interpretation of ERISA section 408(b)(2)(B), including with respect to determining their status as covered services providers. The Department continues to believe 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.'' [119]

2. Overview of Covered Service Provider Obligations Under This Proposed Regulation

Under this proposed regulation, covered service providers would be required to provide specified disclosures to a responsible plan fiduciary of the self-insured group health plan, and also to permit the responsible plan fiduciary to conduct an audit for accuracy of the disclosures. The disclosures would focus on the services provided, the compensation received, and the arrangements with other parties in the pharmaceutical supply chain.[120] The disclosures generally would be provided on an initial basis prior to the self-insured group health plan entering into the service contract or arrangement and then on a semiannual basis thereafter.

As discussed in greater detail below, the disclosure obligations of providers of pharmacy benefit management services (covered service providers under paragraph (c)(1)(i)) would ensure that both the service provider and the responsible plan fiduciary are clear as to the services to be provided. The disclosures would also ensure that responsible plan fiduciaries are aware of all compensation that the provider of pharmacy benefit management services (and its affiliates, agents, and subcontractors) will receive from other parties in the pharmaceutical supply chain in connection with their services to the plan as well as the arrangements (such as formulary incentives) and practices (such as claw-backs) that may impact the performance of the services or the reasonableness of the compensation received.

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 regulation would 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. The other compensation sources received by the brokers and consultants may be specifically described in the proposed regulation (*e.g.,* payments from drug manufacturers), but if not, they would be disclosed under the catch-all provisions in paragraphs (e)(8) (initial disclosure) and (g)(6) (semiannual disclosure).

Throughout the proposed regulatory text, the disclosure requirement is phrased in terms of compensation ''in connection with services under the service contract or arrangement.'' The Department intends that the proposed language ''in connection with'' would be construed broadly. This is consistent with the approach taken in the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2(c)(1)), where the Department stated in the preamble 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.'' [121] Therefore, for example, the required disclosures under the proposal of payments from drug manufacturers would extend to payments based on a structure of incentives not solely related to the contract or arrangement with the self-insured group health plan.[122] The Department seeks comment on whether the final rule should specify that such disclosures would be made on a pro-rata basis.

Paragraph (k) of the proposed regulation 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 contract or arrangement.'' For required descriptions of compensation amounts, paragraph (k) provides that these descriptions must be expressed as a monetary amount, may be estimated to the extent that the actual amount is not reasonably ascertainable, but in any event shall contain sufficient information and specificity to permit evaluation of the reasonableness of the compensation received by the covered service provider, affiliate, agent or subcontractor.

[118] See Field Assistance Bulletin No. 2021–03, (''The CAA does not require the Department to issue regulations under ERISA section 408(b)(2)(B) . . .''), *https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03*. Likewise, to the extent that PBMs were to provide ''brokerage services'' or ''consulting'' to group health plans with respect to any of the listed sub-services in ERISA section 408(b)(2)(B)(ii)(I)(bb) other than regarding the provision of pharmacy benefit management services as defined in paragraph (d) of the proposed regulation, such PBMs, in that capacity, would be subject to the disclosure requirements in ERISA section 408(b)(2)(B) and not the disclosure requirements in this proposed regulation.

[119] *Id* (emphasis added).

[120] 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.

[121] Reasonable Contract or Arrangement Under Section 408(b)(2)—Fee Disclosure 77 FR 5632, 5637 (February 3, 2012).

[122] See also ERISA section 408(b)(2)(B)(iii)(IV) (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'').

The specific elements of the disclosure and audit provisions are discussed in greater detail below. Paragraph (e) of the proposed regulation would establish initial disclosure requirements. Paragraph (f) is reserved for initial disclosure requirements for fully insured group health plans. Paragraph (g) would establish semiannual disclosure obligations. Paragraph (h) is reserved for semiannual disclosure obligations for fully insured group health plans. Paragraph (i) would establish a requirement for the covered service provider to provide certain information upon request of the responsible plan fiduciary of the self-insured group health plan. Paragraph (j) would establish the audit rights that must be provided to the self-insured group health plan under the service contract or arrangement. Paragraph (k) would address the manner of disclosure and paragraph (l) would address disclosure errors. Paragraph (m) provides definitions for certain terms used in the regulation.

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).

3. Initial Disclosure Requirements—Proposed Paragraph (e)

Paragraph (e) of the proposal sets forth the initial disclosure requirements. These disclosures would be required to be provided 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, the proposal specifies that 30 calendar days in advance is deemed to be a reasonable period of time absent an agreement by the parties to a longer timeframe. This timeframe is similar 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.[123] The Department is of the view that aligning the timing requirements with other disclosures that group health plans and issuers already comply with may provide clarity and minimize compliance burdens by streamlining the collection of similar data and disclosure for multiple purposes during the same cadence. The Department seeks comment on the proposed timing requirements for the initial disclosure including whether additional specificity is needed for the timing of the disclosure outside of the context of contract extensions and renewals. If commenters believe that additional specificity is needed, the Department requests that commenters identify the appropriate timing.

The required disclosures in some instances would require disclosure of amounts reasonably expected to be paid to the covered service provider or an affiliate, agent, or subcontractor. As noted above, paragraph (k) of the proposal would require descriptions of compensation to be expressed as a monetary amount, for example, $1,000. The amounts could be estimated to the extent that the actual amount is not reasonably ascertainable, but they 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, agent, or subcontractor.

In proposing paragraph (k), the Department intends that disclosures of a monetary amount (even if estimated) in this context would further the transparency goals of this rulemaking which are intended to make possible a responsible plan fiduciary's assessment of reasonableness of compensation and potential for or existence of conflicts of interest. This would also foster a fairer prescription drug market that lowers costs. Accordingly, on this point, the proposal offers less flexibility than the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2) and the statutory provision at ERISA section 408(b)(2)(B), each of which permit compensation disclosure to be expressed as an alternative to a monetary amount, such as a ''formula,'' ''per capita charge'' for each participant, or, if the compensation cannot reasonably be expressed in such terms, ''by any other reasonable method.'' [124] However, consistent with this proposal, the Department's service provider disclosure regulation for pension plans (29 CFR 2550.408b–2) and the statutory provision at ERISA section 408(b)(2)(B) also require that any description contain ''sufficient information to permit evaluation of the reasonableness of the compensation or cost.'' [125]

3.1. Description of Services

Under proposed 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 self-insured group health plan pursuant to the contract or arrangement. 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 particular pharmacy benefit services being provided, if they are not performed in accordance with parameters established with the plan, the provider may have assumed discretionary authority or control over the administration of the 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 proposal. 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.

[123] 29 CFR 2590.715–2715.

[124] 29 CFR 2550.408b–2(c)(1)(viii)(B)(3) (also permitting disclosure expressed as a percentage of the covered plan's assets); ERISA section 408(b)(2)(B)(ii)(II).

[125] 29 CFR 2550.408b–2(c)(1)(viii)(B)(3); ERISA section 408(b)(2)(B)(ii)(II).

3.2. Direct Compensation

Under proposed paragraph (e)(2), the initial disclosure must include a description of direct compensation 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. Specifically, the proposal requires 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. An example is an administrative fee calculated on a per-participant, per-month basis.

For purposes of paragraph (e)(2) of the proposal, 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. 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 proposal, because service providers to self-insured group health plans sometimes are paid, in whole or in part, directly from the general assets of the employer sponsoring the self-insured group health 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. An example of compensation covered by paragraph (e)(2) of the proposal is an administrative fee calculated on a per-participant, per-month basis, paid directly by the self-insured group health plan.

The Department requests comments as to whether the requirements under the proposed rule for disclosure of direct compensation as defined in paragraph (e)(2) ensure sufficient disclosure of information for bundled services. If not, should the description of direct compensation under paragraph (e)(2) for a bundled services option include additional information, such as the bundled discounted value along with a description of services provided in the bundle?

3.3. Payments From Drug Manufacturers

Under proposed paragraph (e)(3), the initial disclosure must include the amount, in dollars, of payments from drug manufacturers (or rebate aggregators) reasonably expected to be received by the covered service provider, affiliate, agent, or subcontractor in connection with the contract or arrangement. The disclosure must cover the amount of any payment, both in the aggregate and for each drug on the formulary, and it must be expressed as an amount reasonably expected to be paid on a quarterly basis. It also must specify both the amount that will be passed on to the self-insured group health 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 proposed paragraph (e)(6), the initial disclosure must include a description of any inflation protection or price protection agreements that the covered service provider, an affiliate, agent, or subcontractor has entered with any drug manufacturer or other party regarding each prescription drug dispensed under the service contract or arrangement. The disclosure must specify the quarterly amount reasonably expected to be retained by the covered service provider, affiliate, agent, or 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 self-insured group health plan and, if applicable, plan sponsor. The Department separated the disclosure required under this proposed paragraph (e)(6) from the disclosure required under proposed paragraph (e)(3) because of the contingent nature of inflation and price protection.

The disclosure required by these provisions would be intended to apply broadly to payments, including but not limited to rebates, fees, and other remuneration reasonably expected to be received from drug manufacturers by the covered service provider, affiliate, agent, or subcontractor in connection with their services to the self-insured group health plan, regardless of how they are characterized. The disclosure also would extend to payments received from rebate aggregators or other entities that negotiate rebates with drug manufacturers.

Disclosure of aggregate payments reasonably expected from drug manufacturers and rebate aggregators is important for responsible plan fiduciaries in their evaluation of the reasonableness of the compensation that the covered service provider, affiliate, agent, and subcontractor will receive. Additionally, disclosure of payments for each drug on the formulary may assist responsible plan fiduciaries in evaluating the covered service provider's incentives to select particular prescription drugs for the formulary.

The Department seeks comments on the proposed disclosure of payments from drug manufacturers and rebate aggregators. Do the provisions in proposed paragraph (e)(3) and proposed paragraph (e)(6) adequately describe the type of payments that may be received in this respect? Given the varied payment structures and definitional terms, is broad term ''payments'' sufficient to define the disclosure obligation or is more specificity needed to ensure full disclosure?

3.4. Spread Compensation

Under proposed paragraph (e)(4), the initial disclosure must include the dollar amount of spread compensation 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. Spread compensation is defined under the proposal as the difference between the negotiated rate reasonably expected to be paid by the self-insured group health plan to the covered service provider, an affiliate, agent, or subcontractor and the negotiated rate reasonably expected to be paid by such entity to the pharmacy for dispensing drugs.

As discussed in greater detail elsewhere in this preamble, spread pricing is one of the primary sources of compensation in some PBM contracts or arrangements. Proposed paragraph (e)(4) would require a covered service provider to disclose two distinct amounts of spread compensation reasonably expected to be received each quarter. The covered service provider must disclose the amount of reasonably expected spread compensation for each drug on the formulary and in the aggregate (*i.e.,* the total spread on all drugs). These disclosures must be made for each pharmacy channel available under the contract or arrangement. Disclosure of spread compensation in these distinct amounts would serve multiple purposes in assisting a responsible plan fiduciary in evaluating the reasonableness of the contract or arrangement with the covered service provider.

Disclosure of the expected aggregate spread compensation, per pharmacy channel, would provide a high-level view of how much revenue the PBM earns from spread pricing across the entire self-insured group health plan. This would allow a responsible plan fiduciary to evaluate the reasonableness

of compensation, including whether any amounts of spread compensation appear to be excessive under the circumstances, and to compare the initial disclosures of expected aggregate compensation to semi-annual disclosures made pursuant to proposed paragraph (g)(3) of actual aggregate compensation received by the covered service provider.

Disclosure of spread at the level of each drug on the formulary would further transparency goals by affording a responsible plan fiduciary access to profit variations across specific drugs such as branded versus generic or biologics versus biosimilars, which can be used to evaluate whether selection of a particular drug by the covered service provider is driven by spread compensation rather than cost-effectiveness or clinical effectiveness.

Finally, disclosure of spread at the pharmacy channel level, separately for retail, mail order, and specialty pharmacies, would reveal whether the covered service provider earns disproportionate compensation based on which dispensing pharmacy is used.

The Department is seeking comments on the requirements under the proposed rule for disclosure of spread compensation as defined in proposed section (e)(4). Does the proposed provision require disclosure of information that is sufficient to assess reasonableness? Are arrangements with retail, mail order, and specialty pharmacies sufficiently similar to one another that dividing disclosures into these three channels is efficient? Would greater transparency incentivize the use of a pass-through pricing or a flat-fee compensation model? What challenges would arise from a covered service provider providing or a responsible plan fiduciary reviewing this level of disclosure?

3.5. Copay Claw-Backs

Under proposed paragraph (e)(5), the initial disclosure must include a description of amounts of copay claw-back compensation reasonably expected to be recouped from a pharmacy by a covered service provider, an affiliate, agent, or subcontractor in connection with prescription drugs dispensed under the contract or arrangement. The disclosure must be expressed as amounts per quarter and must specify the total number of transactions.

The proposed regulatory text specifies that a copay claw-back means the dollar amount of the difference between a copayment or coinsurance amount paid to the pharmacy by a self-insured group health plan participant or beneficiary and the reimbursement to the pharmacy by the covered service provider. There would be no claw-back compensation to disclose, however, if the pharmacy reimbursement amount exceeded the copayment amount.

Where a covered service provider, affiliate, agent, or 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 self-insured group health 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 self-insured group health 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, affiliate, agent, or subcontractor recouping such difference. The Department believes that additional disclosure of the total number of transactions reasonably expected to occur in the quarter 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 seeks comments on the requirements under the proposed rule for the disclosure of copay claw-back compensation as defined in proposed paragraph (e)(5). Is the proposed provision's scope of required disclosure of information for copay claw-back payments sufficient to assess reasonableness in this respect or should other types of recouped payments be included? If commenters believe the provision should require disclosure of information for recouped payments other than copay claw-backs, commenters are requested 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.

3.6. Compensation for Termination of Contract or Arrangement

Under proposed paragraph (e)(7), the initial disclosure must include a description of any compensation that the covered service provider, an affiliate, 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. A determination of reasonableness necessitates that a responsible plan fiduciary be aware of any termination costs or potential costs to a self-insured group health plan upfront. Without this information, a responsible plan fiduciary cannot sufficiently evaluate the economic consequences of such termination to the self-insured group health plan. Proposed paragraph (e)(7), for example, will 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 self-insured group health plan without penalty on reasonably short notice under the circumstances to prevent the self-insured group health plan from becoming locked into a contract or arrangement that has become disadvantageous.[126]

3.7. Other Compensation

Proposed paragraph (e)(8) provides a catch-all provision for any compensation not disclosed under proposed paragraphs (e)(1)–(7). The disclosure must include a description of all compensation that the covered service provider, affiliate(s), agent(s), or subcontractor(s) reasonably expects to receive on a quarterly basis in connection with the contract or arrangement along with 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, affiliate, agent, or subcontractor, as applicable, pursuant to which such compensation is paid.

This category of ''other'' compensation may be particularly relevant to covered service providers defined in proposed paragraph (c)(1)(ii) of the regulation (*i.e.,* affiliates of providers of pharmacy benefit management services that provide advice, recommendations and referrals regarding the pharmacy benefit management services). The compensation of these covered service providers may come from the providers of pharmacy benefit management services themselves, as opposed to the compensation described in the other

[126] 29 CFR 2550.408b–2(c)(3).

subparagraphs in paragraph (e). The Department requests comments on whether the final regulation should specify payments that these covered service providers may receive.

In connection with this category of ''other'' compensation, the Department also seeks 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 under paragraph (e)(8). For example, should there be specific disclosure requirements related to compensation received by entities providing pharmacy benefit management services in connection with copay maximizer, copay accumulator, or alternative funding programs? More generally, the Department seeks comments on the role of entities earning compensation in connection with these programs, including the mechanics of these programs and payment amounts related to these programs. The Department is also seeking comments on the extent to which self-insured group health plans use each of these types of programs.

3.8. Formulary Placement Incentives

Proposed paragraph (e)(9) would require the initial disclosures to include specified information regarding formulary placement incentives. The purpose of proposed paragraph (e)(9) would be 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 proposed paragraph (e)(3) would require 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, proposed paragraph (e)(9) would require *description of the arrangements* so that the responsible plan fiduciary would gain additional insight as to their impact. The proposed disclosures are set forth in three subparagraphs, described below, each of which addresses a different aspect of formulary design and maintenance.

3.8.1. Proposed Paragraph (e)(9)(i)

Under proposed paragraph (e)(9)(i), the initial disclosure would 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. The disclosure would also include an explanation of how the incentives and arrangements affect services to and are aligned with the interests of the self-insured group health 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 to include 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 a drug to be treated differently than therapeutically equivalent drugs 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 proposed paragraph (e)(9)(i).

Under proposed paragraph (e)(9)(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 self-insured group health plan and/or its participants and beneficiaries. The concept of alignment is inherently factual and depends 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 self-insured group health plan and/or its participants and beneficiaries, include incentives or arrangements to control prescription drug costs, provide clinically superior drugs, or both. In this regard, the Department notes that a particular formulary placement incentive or arrangement can be aligned with the interests of the self-insured group health 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 self-insured group health plan. Likewise, covered service providers would be required to determine that they could accurately disclose how the incentives and arrangements are aligned with the interests of the self-insured group health plan and/or its participants and beneficiaries, whether by contributing to controlling prescription drug costs, by providing clinically superior drugs, or both.

The Department requests comments on the proposed requirement to explain how formulary incentives and arrangements affect services to and are aligned with the interests of the self-insured group health plan and/or its participants and beneficiaries. Do commenters believe this requirement will contribute to the elimination of incentives and arrangements that are not aligned with the interests of the self-insured group health plan and/or its participants and beneficiaries? To ensure that the regulation appropriately protects the interests of the participants in self-insured group health plans, should any assertions of clinical superiority provided in the disclosure be required to be accompanied by evidence? Are there other examples of incentives or arrangements that align with the interests of the self-insured group health 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?

3.8.2. Proposed Paragraph (e)(9)(ii)

Under proposed paragraph (e)(9)(ii), the initial disclosure also must include an identification of reasonably available therapeutically equivalent alternatives for any drug on the formulary with respect to which the covered service provider, an affiliate, agent, or subcontractor reasonably expects to receive any payment by the manufacturer or rebate aggregator (and not passed through to the self-insured group health plan). This provision also requires the covered service provider to explain the reason for omitting such alternatives from the plan's formulary.

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 PBM will receive a payment from the drug manufacturer (and not pass the payment through to the self-insured group health plan), proposed paragraph (e)(9)(ii) requires the subject disclosure to identify reasonably available therapeutically equivalent alternatives that do not similarly compensate the PBM. This disclosure, thus, enables responsible plan fiduciaries to evaluate the way the PBM 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. Because the mere fact that alternatives without manufacturers' payments may exist in the marketplace is not dispositive of an unreasonable contract or arrangement, proposed paragraph (e)(9)(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.

Paragraph (e)(9)(ii) of the proposal does not define what is meant by ''identification'' with respect to the 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.[127] 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 requests comments on whether the final rule should contain an explicit standard on this topic versus allowing the contracting parties the leeway to establish parameters on their own.

3.8.3. Proposed Paragraph (e)(9)(iii)

Under proposed paragraph (e)(9)(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 provide 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 self-insured group health 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 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 self-insured group health plan and its participants. The responsible plan fiduciary could not properly carry out its administrative 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 self-insured group health plan if it unilaterally effected the modifications without the responsible plan fiduciary's consent.

With respect to this advance notice requirement, the proposed regulation does not specify a number of days ''in advance'' for the notice to be provided. 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. Comments are requested on whether the final regulation should provide more specificity regarding the timing of this advance notice. In this regard, for example, the Department currently is considering whether to require the notice to be furnished at least 75 days in advance of the change, to allow the self-insured group health plan to provide notice to plan participants at least 60 days prior to the date the upcoming material modification becomes effective, if required.[128]

This advance notice requirement would be 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 section 408(b)(2) of ERISA.

For this purpose, proposed paragraph (e)(9)(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 quarterly basis) disclosed pursuant to paragraph (e)(3) of the proposed regulation, adjusted for any increases previously disclosed under paragraph (e)(9). Thus, the base amount on which the materiality of the modification is judged would initially be the amount disclosed pursuant to paragraph (e)(3), but it would increase by the amount of any modifications disclosed under proposed paragraph (e)(9)(iii).

The following example illustrates how the base amount paragraph (e)(9)(iii) adjusts as material modifications are made to the formulary. Assume that in advance of entering a contract with a self-insured group health plan, a covered service provider discloses pursuant to paragraph (e)(3) reasonably expected payments on a quarterly basis of 100 dollars. After entering the contract, the drug formulary is not modified in the first quarter. In the second quarter, a contemplated modification 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 proposed paragraph (e)(9)(iii), unless the parties had agreed to a two percent threshold. No changes are made in the third quarter. Then, a contemplated modification in the fourth quarter would result in an increase in compensation above the initially-disclosed amount (100 dollars) by four percent. Because the aggregate of the fourth quarter modification (four percent increase to initially-disclosed amount) and the second quarter modification (two percent increase to initially-disclosed amount) collectively are expected to exceed five percent, advance notice of the fourth quarter modification would be required under proposed paragraph (e)(9)(iii). The disclosure would need to describe the aggregate (six percent) increase to the initially-disclosed amount. Going forward, the five percent threshold in proposed paragraph (e)(9)(iii) would apply to the initially disclosed amount (100 dollars) plus the amount disclosed under paragraph (e)(9) (six dollars, or six percent of 100 dollars).

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

[127] 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).

[128] See 29 CFR 2590.715–2715(b).

The proposed materiality standard has two components: it would include a ceiling of a five percent impact over the base amount, and it would also allow for the covered service provider and responsible plan fiduciary to negotiate a lower threshold (dollar or percentage).[129] The Department understands that in other contexts, materiality is determined based on the significance to the impacted parties.[130] However, the Department also believes that covered service providers and responsible plan fiduciaries may appreciate a bright line rule as an alternative. In another context, the Department has used a five percent standard to define materiality.[131]

The Department seeks comments on the approach in proposed paragraph (e)(9)(iii), including whether it is common for providers of pharmacy benefit management services to retain authority to modify the formulary during the term of the contract or arrangement—such as by adding or removing drugs, changing their tiering, or changing utilization management strategies. If it is common, how frequently do PBMs make formulary changes, and is advance notice of such modifications given to self-insured group health plans? Further, the Department seeks comments on the proposed definition of materiality. Do commenters believe the approach taken in the proposal is workable and identifies an appropriate test for materiality? For example, should the test for materiality in the proposal—which is based on a 5 percent increase over the estimated amount of expected rebates from manufacturers or aggregators—be broadened to include other compensation, such as spread? Are there alternative tests for materiality, such as the annual increase in the average cost of health care, that would be more appropriate? Alternatively, would it be better to trigger advance disclosure on ''any non-trivial changes in the formulary that could affect the covered service provider's own compensation?''

The Department also seeks comments on the proposed requirements in paragraph (e)(9) as a whole. Is the information required for disclosure under paragraph (e)(9) useful to a responsible plan fiduciary in assessing the reasonableness of compensation under the terms of the contract or arrangement, or potential conflicts on the part of the provider of services? Are there additional factors or considerations related to the use of formulary placement incentives that the Department should consider? What challenges are likely to arise in requiring a covered service provider to disclose this information? What challenges will a responsible plan fiduciary encounter in using the information disclosed to assess the reasonableness of compensation?

3.9. Drug Pricing Methodology

Under proposed paragraph (e)(10), the initial disclosure must include a description of the net cost to the self-insured group health plan of each drug on the formulary, 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 cost the self-insured group health plan will pay for each drug on the formulary, for each pharmacy channel, along with an objective means to verify the accuracy.

The proposed regulation would require the covered service provider to disclose the net cost to the self-insured group health plan of each drug on the formulary by pharmacy channel, including mail order pharmacy, retail pharmacy, and specialty pharmacy. The net cost refers to the total cost to the self-insured group health plan after all discounts, rebates, or other adjustments are applied by the covered service provider pursuant to the contract or arrangement. The covered service provider would disclose to the responsible plan fiduciary the cost 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 (e)(10) disclosure requirement may be satisfied if the covered service provider instead discloses the methodology that will be used to determine the cost to the self-insured group health 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 self-insured group health plan and PBM 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 self-insured group health plans and large PBMs.

The (e)(10) 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 self-insured group health plan. Additionally, the (e)(10) 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.

The Department requests comment on whether the language in paragraph (e)(10) provides sufficient clarity to covered service providers regarding their disclosure obligations or whether adjustments should be made. For example, should the provision specify how the term ''drug'' will be defined? If so, the Department requests that commenters please provide suggested language.

3.10. Statement of Fiduciary Status

Under proposed paragraph (e)(11), 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 self-insured group health plan as an ERISA fiduciary.

Along with this statement, such entity must disclose any activity or policy that may create a conflict of interest,

[129] 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 to memorialize in writing any such negotiated advance notice thresholds or triggers.

[130] See *e.g., Basic Inc.* v. *Levinson,* 485 U.S. 224, 240 (1988).

[131] See 29 CFR 2520.101–5(g)(3) (in the annual funding notice for defined benefit pension plans, providing that events having a material effect on liabilities or assets would be defined, in part, as events resulting in or projected to result in an increase or decrease of five percent or more in the value of assets or liabilities from the valuation date of the notice year); see also Annual Funding Notice for Defined Benefit Plans, 80 FR 5626 (February 2, 2015).

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.

As relevant to this proposal, 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 do so, or has any discretionary authority or discretionary responsibility in the administration of such plan.[132] In complying with proposed paragraph (e)(11), therefore, the covered service provider would carefully consider whether it, or an affiliate, agent, or subcontractor, will meet this definition in its services to the self-insured group health 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.[133] Thus, to avoid fiduciary status, a covered service provider would ensure that its services to the self-insured group health 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.[134]

3.11. Statement of Audit Right

Under proposed paragraph (e)(12), the initial disclosure must provide a statement of the self-insured group health plan's right to the audit described in paragraph (j) of this the proposed regulation and the procedures for requesting such an audit. Among other things, proposed paragraph (j) would ensure that the contract or arrangement does not contain terms that would impede the self-insured group health plan's ability to conduct an audit. As discussed in preamble section D.6., the right to audit the completeness and accuracy of the required disclosures is an essential part of the proposal's framework for establishing transparency in the marketplace for pharmacy benefit management services. Proposed paragraph (e)(12) would ensure that the responsible plan fiduciary is aware of the audit rights that are preserved in the regulation.

3.12. Initial Disclosure Requirements for Fully Insured Group Health Plans Reserved—Proposed Paragraph (f)

As discussed above, the initial disclosure requirements for fully insured group health plans are reserved.

4. Semiannual Disclosure Requirements—Proposed Paragraph (g)

Paragraph (g) of the proposed regulation would require semiannual disclosures of the actual compensation received by the covered service provider and its affiliates, agents, and subcontractors in connection with the contract or arrangement. This disclosure would serve an important purpose for the responsible plan fiduciary's monitoring obligations with respect to services to the self-insured group health plan. 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 is critical for ongoing oversight of the service arrangement.[135] The semiannual disclosures would be required to be provided no later than 30 calendar days after the end of each six-month period beginning on the date the contract or arrangement is entered, with respect to the preceding six-month period.

The content of semiannual disclosures would generally track the specific categories of compensation that were estimated in the initial disclosures. Thus, semiannual disclosures would address categorically direct compensation, manufacturer payments, spread compensation, copay claw-backs, and price protection agreements. Like the initial disclosures, the semiannual disclosures also would contain a catch-all category for any ''other compensation'' not covered by the specific compensation categories, and would include a disclosure of the audit rights. Unlike the initial disclosures, the semiannual disclosures would contain amounts of compensation actually received (rather than estimates) for each of these categories.[136]

Semiannual disclosures would contain an overage explanation, if applicable. Consistent with the purpose of the proposed semiannual disclosure to assist responsible plan fiduciaries in their ongoing monitoring of the contract or arrangement, proposed paragraph (g)(7) would require a disclosure if any category of compensation 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 proposed overage explanation provision would require an identification of the amount of the overage (in the aggregate) and the reason for the overage. For this purpose, the term ''materially'' would mean 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 proposed definition of materiality generally parallels the approach taken in proposed paragraph (e)(9)(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 arrangements. 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 in the proposal differs in some respects from the approach in the Department's service provider regulation for pension plans (29 CFR 2550.408b–2(c)(1)) and in ERISA section 408(b)(2)(B). While neither of these sources has a specific semiannual disclosure obligation, they each require disclosure of changes to the information provided in the initial

[132] ERISA section 3(21)(A)(i) and (iii); 29 U.S.C. 1002(3)(21)(A)(i) and (iii). ERISA section 3(21)(a)(ii) (29 U.S.C. 1002(3)(21)(A)(ii)) is not described in the text as it pertains to the provision of investment advice for a fee.

[133] Interpretive Bulletin 75–8, 29 CFR 2509.75–8 (Q&A D–2).

[134] 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.

[135] As discussed above, the semiannual disclosure requirements for fully insured group health plans are reserved.

[136] The Department intends these disclosures to be based on amounts actually received. Comments are solicited as to whether they, or any other disclosures required by this section, should reflect amounts earned even if not actually received.

disclosures.[137] 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.[138] The Department believes that in the pharmacy benefit management context, it may be more efficient to have a semiannual disclosure that would provide all the compensation received in the prior 6 month period, rather than a requirement to disclose changes on an ongoing basis.

As indicated above, the primary purpose of proposed paragraph (g) is to ensure that responsible plan fiduciaries have more than just the estimates provided in the initial disclosure (before the contract or arrangement was even entered) under paragraph (e) of the proposal when conducting their statutory duty to monitor the ongoing reasonableness of the self-insured group health plan's service relationship with the covered serve provider. In this way, the proposal responds to those instances of reported opacity in the pharmacy benefits management industry.

The Department has carefully attempted to mitigate regulatory burdens and welcomes ideas on ways to further simplify or streamline the semiannual disclosure without compromising the stated purpose of proposed paragraph (g). For example, the Department considered and rejected the idea of proposing annual disclosures of compensation actually received, rather than semiannual disclosures. The Department determined instead to propose a semiannual disclosure 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, when the ongoing duty to monitor the reasonableness of the relationship is most acute. The Department welcomes comments on proposed paragraph (g) generally and on its specific features, including the overage explanation and its related materiality trigger.

5. Reporting and Disclosure Information Upon Request—Proposed Paragraph (i)

Under proposed paragraph (i), certain information must be provided upon written request of the self-insured group health plan's responsible plan fiduciary. The required information is 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 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.

The information that might be requested by a responsible plan fiduciary may include information needed to complete the self-insured group health plan's Form 5500 filing.[139] 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.[140] 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.[141] While information to support these Schedule C items would likely be provided as part of the semiannual disclosure in proposed paragraph (g), 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 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).[142] 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 self-insured group health 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).

6. Right to Audit—Proposed Paragraph (j)

Paragraph (j) establishes a right for self-insured group health plans to audit their covered service providers at least once per year. The proposal leaves it to the parties to define ''year'' for this purpose, *e.g.,* contract year, calendar year, or plan year. Comments are invited on whether the final rule should be more prescriptive on this point.

The purpose of the audit is to enable the responsible plan fiduciary to verify the accuracy of the disclosures that would be required in the proposal, if adopted as a final regulation. In describing the scope of the audit provision, paragraph (j)(1) of the proposal narrowly reflects this purpose. Paragraph (j)(1), however, could be broader, *e.g.,* the scope of the audit could be extended more globally to ensure the covered service provider complied with the contract or arrangement, with all applicable law, or its scope could be left to the discretion of the responsible plan fiduciary.

[137] 29 CFR 2550.408b–2(c)(1)(v)(B)(*1*) (''A covered service provider must disclose a change to the information required by paragraph (c)(1)(iv)(A) through (D), and (G) of this section 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 must be disclosed as soon as practicable.''); 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.'')

[138] 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.

[139] 29 CFR 2520.103–1.

[140] Supplemental Frequently Asked Questions about the 2009 Schedule C, Q26, *https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/reporting-schedule-c-faq.pdf.*

[141] Id., at Q27.

[142] See *https://www.cms.gov/marketplace/about/oversight/other-insurance-protections/prescription-drug-data-collection-rxdc.*

Comments are invited on the scope of the audit provision considering the purpose of the proposal.

The parties would split the audit costs under the proposed regulation. The self-insured group health plan would be responsible for compensating the auditor. The covered service provider would 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 self-insured group health plans, and not unduly financially burdensome to covered service providers. The Department requests comment on this approach and 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 so, how should the regulation identify a level of disclosure inaccuracy that would trigger the obligation for the covered service provider to bear the audit cost?

Under the proposal, the self-insured group health 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 proposal 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 proposal, however, would allow the scope of the audit to be limited to the period covered by the disclosures under the regulation.

The Department considers these conditions 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 under the terms of the contract or arrangement 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 proposal'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 self-insured group health 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 in order 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 and is determined by a responsible plan fiduciary's assessment of the circumstances attendant to the terms of the contract or arrangement, information provided in the disclosures, and other factors related to the prudence and reasonableness of requesting such audit. The right to conduct an audit does not necessitate that it is exercised. For example, the responsible plan fiduciary of a small plan 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.

7. Manner of Disclosure—Proposed Paragraph (k)

Proposed paragraph (k) includes four separate provisions regarding the manner of disclosures under the regulation. Each is discussed below.

7.1. 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.

7.2. Description of Compensation

With respect to descriptions of compensation required under the regulation, proposed 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 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. As discussed above in section D.2. of the preamble, this aspect of the proposal offers less flexibility than 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), each of which permit compensation disclosure to be expressed—as an alternative to a monetary amount—as a ''formula,'' ''per capita charge'' for each participant, or, if the compensation cannot reasonably be expressed in such terms, ''by any other reasonable method.'' This difference in approach is based on the Department's tentative conclusion that disclosures of a monetary amount (even if estimated) in this context would further the transparency goals of this rulemaking which are intended to further a responsible plan fiduciary's assessment of reasonableness of compensation potential for conflicts of interest, and would also foster a fairer prescription drug market that lowers costs. The Department seeks comments on its tentative conclusion in support of this paragraph of the proposal.

7.3. Machine-Readability Format

Proposed paragraph (k)(3) provides that upon request of a responsible plan fiduciary of a self-insured group health plan, descriptions of compensation must also be provided, within a reasonable time after such request, in a machine-readable file. For this purpose, the proposal provides that ''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. This requirement of the proposal 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.

7.4. Confidentiality Agreements

Proposed paragraph (k)(4) addresses confidentiality agreements. The paragraph provides that, except as provided in paragraph (j)(3), the covered service provider and its affiliates, agents, and subcontractors may not impose restrictions on the self-insured group health 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 to execute reasonable confidentiality agreements preventing redisclosure by such parties.

The primary purpose of paragraph (k)(4) of the proposal is to ensure that covered service providers are not able to undermine responsible plan fiduciaries' efforts to evaluate their compensation by limiting the self-insured group health 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 healthcare consultants or attorneys, for quality control and other purposes. At the same time, however, paragraph (k)(4) would also protect covered service providers by allowing them to make sure self-insured group health plans take steps to ensure that third parties to whom self-insured group health plans disclose the information do not themselves redisclose the information to fourth parties. The Department seeks comment on whether the proposal strikes the correct balance regarding the use of confidentiality agreements and the potential for re-disclosure of information disclosed under the regulation.

8. Disclosure Errors—Proposed Paragraph (l)

Proposed paragraph (l) provides a rule for disclosure errors. Under the proposed 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.

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

As directed by President Trump's Executive Order 14273, *Lowering Drug Prices by Once Again Putting Americans First,* this proposed regulation 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 self-insured group health plans would 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 also in analyzing the drivers of prescription drug costs.

In this regard, responsible plan fiduciaries of self-insured group health plans must determine that service provider relationships involving the self-insured group health 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 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.[143] The Department's enforcement will be aided by the requirement in the proposed administrative class exemption that plan fiduciaries report to the Department a service provider's non-compliance with the disclosure or audit provisions.

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 the regulation 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 the 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 is proposing 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 relief available in the Department's service provider regulation for pension plans (29 CFR 2550.408b–2(c)(1)(ix)) and ERISA section 408(b)(2)(B)(viii), 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.

Paragraph (n) of the proposed rule would provide a responsible plan fiduciary 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 regulation and ''reasonably believed'' that the regulatory requirements were satisfied. Upon discovery of a failure to comply, the responsible plan fiduciary must take certain specified steps within designated timeframes, as described in

[143] 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.

proposed paragraphs (n)(1) and (2), including notifying the Department of any failures that are not corrected within the designated timeframes. In this way, the proposed administrative class exemption would facilitate oversight by the Department of those covered service providers that fail to comply with the regulation. Proposed 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 the exemption would need to be able to demonstrate compliance with the conditions of the exemption.

Proposed paragraph (n)(5) 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 regulation. It provides that if the covered service provider fails to comply with the written request to correct the failure 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.

This provision is based on a similar provision in the Department's service provider regulation for pension plans and ERISA section 408(b)(2)(B)(viii)(IV), 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 the Department's service provider regulation for pension plans and ERISA section 408(b)(2)(B)(viii)(IV) 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. Comments are solicited on whether an approach that gives flexibility for a responsible plan fiduciary to continue a contract or arrangement is appropriate despite failure to comply with an obligation under the regulation with respect to future services, or whether paragraph (n)(5) should instead mirror the Department's service provider regulation for pension plans and ERISA section 408(b)(2)(B)(viii)(IV) and require termination of a contract or arrangement in such circumstances.

The Department is proposing 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 (January 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) before the proposed administrative class exemption may be granted under ERISA section 408(a), the Department must find that it 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) if granted, the proposed administrative class exemption is applicable only to transactions that satisfy the conditions specified in the exemption; and (4) the proposed administrative class exemption, if granted, 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.

10. Authority for and Placement of Proposed Regulation

10.1. 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)(i) of ERISA, in turn, clarifies that in the case of persons who provide ''brokerage services'' or ''consulting,'' no such contract or arrangement is ''reasonable'' unless the disclosure requirements in subparagraph (ii) of section ERISA 408(b)(2)(B) are satisfied.

While section 408(b)(2)(A) of ERISA comprehensively covers the full range of plans and service providers covered by ERISA, section 408(b)(2)(B) of ERISA deals only with a select type of plan (group health plans) and subset of service providers (brokers and consultants) to such plans. The existence of section 408(b)(2)(B) does not foreclose the Department from regulating arrangements not described in section 408(b)(2)(B) of ERISA but otherwise within the reach of section 408(b)(2)(A). Put differently, while Congress directly addressed brokers and consultants under ERISA section 408(b)(2)(B), this does not relieve other service providers of their obligations under ERISA section 408(b)(2)(A) to disclose information that would assist fiduciaries in determining the reasonableness of a contract or arrangement.

This proposed rule is under the authority of section 505 of ERISA, as well as both section 408(b)(2)(A) and section 408(b)(2)(B) of ERISA, as follows. The Department proposes to regulate entities providing pharmacy benefit management services, identified in paragraph (c)(1)(i) of the proposal, pursuant to the authority in sections 505 and 408(b)(2)(A) of ERISA. However, the Department notes that the terms ''brokerage services'' and ''consulting'' are undefined, and in connection with the list of sub-services in ERISA section 408(b)(2)(B)—these terms could be construed to describe services provided by PBMs. For example, pharmacy benefit management services related to establishment and maintenance of formularies could be considered to involve consulting related to the development and implementation of plan design.[144]

The Department is regulating entities providing advice, recommendations, or referrals regarding the provision of pharmacy benefit management services, identified in paragraph (c)(1)(ii) of the proposal and who are affiliated with entities described in paragraph (c)(1)(i) of the proposal, pursuant to the authority in sections 505, 408(b)(2)(A),

[144] See ERISA section 408(b)(2)(B)(ii)(I)(bb)(BB).

and 408(b)(2)(B) of ERISA. Paragraphs (c)(1)(i) and (c)(1)(ii) of the proposal admit that certain businesses are likely to perform services in both categories. Thus, the Department could structure the final regulation under either or both section 408(b)(2)(A) and section 408(b)(2)(B) along with section 505 of ERISA.

10.2. Placement

This proposed regulation, establishing disclosure requirements for covered service providers to group health plans, would appear at 29 CFR 2550.408b–22. In connection with this proposed regulation, the Department is also proposing to revise its existing service provider regulation (29 CFR 2550.408b–2(c)(2)) in the Code of Federal Regulations to cross-reference the proposed regulation.

11. Proposed Effective and Applicability Dates—Proposed Paragraph (p)

Proposed paragraph (p) provides both an effective date and an applicability date for the proposed rule. Under paragraph (p)(1), the proposed rule would be effective sixty calendar days after the date of the publication of the final rule. Once effective, however, paragraph (p)(2) of the proposal provides that the rule would be applicable to plan years beginning on or after July 1, 2026. 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 being given to the cost and burden associated with transitioning current and future contracts or arrangements to satisfy the requirements of the final rule.

E. Regulatory Impact Analysis

Summary

The Department has examined the impacts of this proposed rule as required by Executive Order 12866,[145] Executive Order 13563,[146] Executive Order 14192,[147] the Paperwork Reduction Act of 1995,[148] the Regulatory Flexibility Act,[149] section 202 of the Unfunded Mandates Reform Act of 1995,[150] and Executive Order 13132.[151]

[145] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[146] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 18, 2011).

[147] 90 FR 9065 (January 31, 2025).

[148] 44 U.S.C. 3506(c)(2)(A) (1995).

[149] 5 U.S.C. 601 *et seq.* (1980).

[150] 2 U.S.C. 1501 *et seq.* (1995).

[151] Federalism, 64 FR 153 (Aug. 4, 1999).

1. Executive Orders 12866 and 13563

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

(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 proposal 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. 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 proposed rule, and OMB has reviewed this proposed 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. This proposed rule, if finalized as proposed, is, therefore, expected to be an Executive Order 14192 regulatory action. When analyzing the rule for the purpose of Executive Order 14192, the Department considers the burden caused by the proposal alone. The proposed rule would require covered service providers, including PBMs, to provide fee and compensation structure disclosures to responsible plan fiduciaries of self-insured group health plans. As such, this proposal 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. health-care 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. 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. While the annual average rate of price increases was 20.1 percent for 2017 to 2018 compared to 15.2 percent for 2022 to 2023, the average increase was only $160 per prescription drug for 2017 to 2018 compared to $590 per prescription drug for 2022 to 2023. In other words, the average per prescription drug price increase between 2022 and 2023 was more than 3.5 times the average annual increase between 2017 and 2018. This suggests that recent price increases were concentrated in higher-cost prescription drug products.[152]

Despite this growth, the share of total health spending on prescription drugs has remained relatively stable over time (increasing from seven percent in 1970 to nine percent in 2022). However, an increasing share of these costs appears to have shifted from individuals directly

[152] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Changes in the List Prices of Prescription Drugs, 2017–2023,* (2023), *https://aspe.hhs.gov/sites/default/files/documents/0cdd88059165eef3bed1fc587a0fd68a/aspe-drug-price-tracking-brief.pdf.*

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 68 percent in 2000 and 86 percent in 2023, with out-of-pocket and other third-party payers and programs making up the balance.[153] Moreover, a survey of large employers reported that pharmacy costs are consuming an increasing share of their health-care budgets, with the median share rising from 21 percent in 2021 to 27 percent in 2023.[154]

Due to the complexity of the pharmaceutical supply chain and the multitude of players involved, 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 ensure that plan assets are used exclusively to provide benefits and pay plan expenses. While they may engage service providers to provide benefits for the plan, responsible plan fiduciaries are responsible for prudently negotiating terms when entering into 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 responsible 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 pharmacies to dispense drugs and with manufacturers for rebates to guarantee preferred placement on the self-insured group health plan's formulary among other entities. 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 fees related to these benefits are 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.[155] These cases highlight the plaintiffs' 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.[156] 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.'' [157] 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 health plan,[158] suggesting that many plans and their sponsors have little insight into PBM rebate practices.[159]

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.[160] Exacerbating matters

[153] Centers for Medicare & Medicaid Services (CMS), *National Health Expenditure Accounts,* National Health Expenditures by Type of Service and Source of Funds, 1960–2023, (2023), *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical.*

[154] Business Group on Health, *Executive Summary: 2025 Employer Health Care Strategy Survey,* (August 20, 2024), *https://www.businessgrouphealth.org/resources/2025-employer-health-care-strategy-survey-executive-summary.*

[155] See *Knudsen* v. *MetLife Group* (117 F.4th 570), *Navarro* v. *Well Fargo & Co* (24–cv–3043–LMP–DTS), and *Lewandowski* v. *Johnson and Johnson* (2025 WL 288230).

[156] Robin Feldman, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers Testimony,* (2023), at the U.S. Senate, Finance Committee, *https://www.finance.senate.gov/imo/media/doc/Feldman%20Written%20Testimony%20.pdf.*

[157] 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), *https://www.healthaffairs.org/content/forefront/policy-options-help-self-insured-employers-improve-pbm-contracting-efficiency.*

[158] KFF, *2024 Employer Health Benefits Survey,* (Oct. 9, 2024), *https://www.kff.org/report-section/ehbs-2024-section-13-employer-practices-provider-networks-coverage-for-glp-1s-abortion-and-family-building-benefits/.*

[159] Arthur Allen, *Employers Haven't a Clue How Their Drug Benefits Are Managed,* KFF Health News, (October 9, 2024), *https://kffhealthnews.org/news/article/employer-drug-benefits-pbms-survey-kff/.*

[160] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or*

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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.[161]

This creates conflicts of interest, where consultants may be incentivized to recommend PBMs offering the highest payouts to them, rather than those 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 proposed rule would help plan fiduciaries be aware of this conflict and consider its impact on decisions being made.

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, in order 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 in order to receive preferential placement on the formulary, the list of drugs covered by the self-insured group health plan.[162] Many contracts do not require PBMs to disclose the rebates that they receive and so self-insured group health plans often are unaware if monies are being refunded;[163] however, a frequently cited industry estimate is that ''PBMs achieve rebates of 30 percent off list price, accounting for all discounts and fees.'' [164] With respect to Medicare Part D, while Part D plan sponsors and their PBMs are required to disclose rebates retained by PBMs to the Centers for Medicare & Medicaid Services,[165] PBM contracts with issuers and self-insured group health plans often do not directly disclose the magnitude of rebates.[166] This in turn allows PBMs to retain rebates received from manufacturers, unless their service contracts explicitly require sharing of any rebates.[167] 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.[168]

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, 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.[169]

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) PBMs receive from manufacturers.'' [170] This can incentivize PBMs to prioritize drugs with higher rebates, such as brand-name prescription drugs, over lower-cost but equally effective alternatives. As a result, this can increase 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 impact of the change financially or its effect on the self-insured group health

Anti-Competitive? International Journal of the Economics of Business, (2015) *https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.*

[161] 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), *https://litigationtracker.law.georgetown.edu/wp-content/uploads/2024/02/lewandowski-v-johnson-and-johnson_2.5.24_Complaint.pdf.*

[162] Nicole Rapfogel, *5 Things to Know About Pharmacy Benefit Managers,* (202), Center for American Progress, *https://www.americanprogress.org/article/5-things-to-know-about-pharmacy-benefit-managers/#:~:text=Rebate:%20A%20price%20concession%20paid,in%20part%20or%20in%20full.*

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

[164] Health Affairs, *Health Policy Brief: Pharmacy Benefit Managers,* (2017), *https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf.*

[165] Social Security Act section 1150A.

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

[167] 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,* (2022) *https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf.*

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

[169] 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.*

[170] Rochelle Henderson & Julie Patterson, *Prescription Rebate Guarantees: Employer Insights,* The American Journal of Managed Care, Vol 30 (11), (November 2024), *https://www.ajmc.com/view/prescription-rebate-guarantees-employer-insights.*

plan participants.[171] This lack of transparency limits self-insured group health plans' ability to 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 health-care costs. Without transparent disclosures providing detailed descriptions of rebates, their impact on the formulary and how that will affect self-insured group health plan costs, 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.[172] 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.[173]

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 terms in the PBM contracts.[174] 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.[175] One source found that spread pricing accounted for an estimated 10 to 15 percent of a PBM's revenue.[176]

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 lawsuits that stem from allegations of deceptive practices resulting in financial losses.[177] 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.[178] Ohio brought a lawsuit against Centene, who ultimately agreed to pay $88.3 million to the State [179] and also switched to a pass-through pricing contract, which increased payments to pharmacists by 5.74 percent, though this was significantly less than the ''spread'' of 31.4 percent on generic drug claims from April 2017 to March 2019.[180] These findings suggest that overall group health plan costs may have declined as a result of eliminating spread pricing.[181]

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 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. [182] This means that nearly a quarter of the time, patients would find it cheaper to pay the out-of-pocket cost rather than 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.[183]

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.[184] Congress

[171] Linda Nilsen, *Written Testimony for the ERISA Advisory Council Hearing on PBM Compensation and Fee Disclosure,* (August 20, 2014), *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.*

[172] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,* (2021), *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[173] 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,* (2024), *https://www.cms.gov/files/document/medicare-prescription-drug-inflation-rebate-program-final-fact-sheet.pdf.*

[174] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,* (2021), *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[175] KFF, *Medicaid Pharmacy Benefits State Fact Sheets,* (2020), *https://www.kff.org/statedata/medicaid-pharmacy-benefits-state-fact-sheets/.*

[176] Colorado Health Institute, *Pharmacy Benefit Managers: As Drug Prices Soar, Policymakers Take Aim,* (2018), *https://www.coloradohealthinstitute.org/sites/default/files/file_attachments/Pharmacy%20Benefit%20Managers.pdf.*

[177] None of the discussed lawsuits have occurred in states that have banned spread pricing.

[178] Ohio's Office of Attorney General, *Ohio's Medicaid Managed Care Pharmacy Services,* (2018), Auditor of State Report, *https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.*

[179] Ohio's Office of Attorney General, *Centene Agrees to Pay a Record $88.3 Million to Settle Ohio PBM Case Brought by AG Yost,* (2021), *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.*

[180] Health Data Plan Solutions, *Ohio Department of Medicaid (ODM) Analysis of Pass-Through Pricing Implementation,* (September 2019), *https://medicaid.ohio.gov/wps/wcm/connect/gov/8c7214d2-2215-4b30-a03f-9df486ff1fe5/ODM-HDS-Qtr1-Analysis.pdf?MOD=AJPERES.*

[181] James Drew, *Centene PBM Settlement with South Carolina Raises Total Payout to $964.8M,* (2024), St. Louis Business Journal, *https://www.bizjournals.com/stlouis/news/2024/01/04/centene-pbm-settlement-south-carolina-raises-total.html.*

[182] This data includes self-insured group health plans. (*Source:* Karen Van Nuys, Geoffrey Joyce, Rocio Ribero, & Dana P. Goldman, *Overpaying for Prescription Drugs: The Copay Clawback,* (2018), *https://schaeffer.usc.edu/research/overpaying-for-prescription-drugs/.*)

[183] Megan Thompson (2018), W*hy a Patient Paid a $285 Copay for a $40 Drug, https://www.pbs.org/newshour/health/why-a-patient-paid-a-285-copay-for-a-40-drug.*

[184] Karen Van Nuys, Geoffrey Joyce, Rocio Ribero, & Dana P. Goldman, *Overpaying for Prescription*

Continued

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.[185] 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.

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.[186] 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.[187]

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 prescriptions filled by commercially insured patients increased from 3.0 to 11.8 percent.[188] 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.[189]

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.[190]

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.[191]

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 the Centers for Medicare & Medicaid Services (CMS).[192] While PBMs offer lower cost-sharing on generics, PBMs can still steer patients toward affiliated pharmacies and give those pharmacies 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.[193]

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 self-insured group health responsible plan fiduciaries to make informed decisions when selecting a PBM, as well as 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 self-insured group health responsible plan fiduciaries 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 decisions are crucial in ensuring patients have access to timely and affordable prescription drugs.[194]

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

Drugs: The Copay Clawback, (2018), *https://schaeffer.usc.edu/research/overpaying-for-prescription-drugs/.*

[185] 132 Stat. 3672—Public Law 115–263.

[186] Huseyin Naci & Aaron Kesselheim, *Specialty Drugs—A Distinctly American Phenomenon,* The New England Journal of Medicine, (2020), *https://eprints.lse.ac.uk/105102/4/nejmp1909513.pdf.*

[187] NAIC, *A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation, (*2023), *https://content.naic.org/sites/default/files/inline-files/PBM%20White%20Paper%20Draft%20Adopted%20B%20Committee%2011-2-23_0.pdf.*

[188] Stacie Dusetzina, *Share of Specialty Drugs in Commercial Plans Nearly Quadrupled, 2003–2014,* Health Affairs (2016), *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.*

[189] 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.*

[190] 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,* (2020), *https://pmc.ncbi.nlm.nih.gov/articles/PMC7351331/.*

[191] 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.*

[192] Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences,* (2023), No. w30998. National Bureau of Economic Research, *https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.*

[193] 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.*

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

arrangement. The Department proposed that this information was necessary in order 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.[195]

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 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.[196]

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.[197]

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.[198] 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.[199] However, the fees charged to plan participants had been declining both before and after the final rule took effect, making it difficult to isolate the specific benefits that resulted from this regulation.[200]

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.[201] As part of the amendment, Congress designated the pre-existing text as ERISA section 408(b)(2)(A).[202] The requirements in ERISA section 408(b)(2)(B) apply 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.[203]

The new 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 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 new provision 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.

Following the CAA, 2021, 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.[204]

3.2. Current Regulatory Action

Like the Department's 2012 final pension disclosure regulation, the proposed rule is intended to ensure transparency by requiring covered service providers to make adequate disclosures to the responsible plan fiduciary 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 section D of this preamble.

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),

[195] 72 FR 70988 (Dec. 13, 2007).

[196] 75 FR 41600 (July 16, 2010).

[197] 75 FR 41600 (July 16, 2010).

[198] 77 FR 5632 (Feb. 3, 2012).

[199] Based on internal analysis performed by EBSA.

[200] Investment Company Institute, *The Economics of Providing 401(k) Plans: Services, Fees, and Expenses,* (2024), page 11, *https://www.ici.org/system/files/2024-07/per30-06.pdf.*

[201] Section 202 of Title II of Division BB of the Consolidated Appropriations Act, 2021.

[202] 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.''

[203] Specifically, see ERISA section 408(b)(2)(B)(ii)(I)(bb)(AA) (defining 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'') and ERISA sections 408(b)(2)(B)(ii)(I)(bb)(BB) defining 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.)''

[204] Lowering Drug Prices by Once Again Putting Americans First, 90 FR 16441 (April 15, 2025).

as amended, and applicable provisions of the CAA, 2021. However, while the CAA, 2021 did effectively extend the disclosure requirements from the 2012 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 provisions do not explicitly apply to all pharmacy benefit management services. As a result, the baseline includes the disclosure requirements already in effect for covered service providers that provide brokerage or consulting services to group health plans, as required under the CAA, 2021. Benefits, costs, and transfers associated with the proposed rule are measured as changes relative to this baseline.

Accordingly, this regulatory impact analysis (RIA) does not account for the benefits or costs associated with the general requirements for service providers that provide brokerage or consulting services to group health plans to disclose direct and indirect compensation to fiduciaries, as these are already required by the provisions of the CAA, 2021 and are therefore included in the baseline. However, this analysis does take into account the expected impacts of the proposed rule, the new disclosure requirements for PBMs, as well as the additional granularity and frequency of disclosures required of covered service providers. These requirements are expected to impose costs for PBMs and may potentially impose new costs to other service providers already in compliance with the CAA, 2021, while providing meaningful benefits to self-insured group health plans, participants, and beneficiaries.

5. Summary of Impacts

Accordingly, the proposed 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. 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 proposed rule. However, the Department has determined that the benefits of the proposed 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 proposed rule, but have 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 proposed rule.

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TABLE 1. Accounting Statement

Benefits:	Estimate (QALY Approach)	Estimate (Direct WTP Approach)	Year Dollar	Discount Rate	Period Covered
Annualized Monetized ($million/year)	$74.5 to $746.2	$39.0 to $389.6	2025	7 percent	2026-2034
	$74.6 to $747.7	$39.0 to $389.6	2025	3 percent	2026-2034
Quantified Benefits using Quality Adjusted Life Years: • Improved health outcomes for patients due to increased treatment adherence from better access to lower cost prescription drugs (analysis limited to a subset of therapeutic classes) will result in undiscounted benefits of $71.7 to $717.1 million annually. • Reduced healthcare utilization arising from improved health outcomes (analysis limited to a subset of therapeutic classes) will result in undiscounted benefits of $3.2 million to $31.9 million annually.					
Alternative Method of Quantified Benefits directly using Consumer Willingness-to-Pay: • Increase in consumer surplus associated with increased consumption of prescribed medication resulting from lower prescription drug prices will generate undiscounted benefits of $39.0 to $389.6 million annually. • Annualized estimates are between $39.0 million and $389.6 million with a 7 percent discount rate and between $39.0 million and $389.6 million with a 3 percent discount rate.					
Non-Quantified Benefits and/or Mechanisms Yielding Quantified Benefits: • Improved understanding of PBMs by self-insured group health responsible plan fiduciaries. • Reduced administrative burden on self-insured group health plans due to lower search and preparation costs for PBM selection and contract negotiations. • Greater ability for self-insured group health responsible plan fiduciaries to compare offerings across PBMs, fostering competition, and improving drug pricing. • More favorably negotiated contracts for self-insured group health responsible plan fiduciaries with PBMs, resulting in lower costs and more appropriate coverage. • Reduced conflicts of interest that currently influence PBMs' key decisions regarding rebates, formulary design, and prescription drug pricing. • Non-quantified only in the QALY approach: o Improved health outcomes for patients due to increased treatment adherence from better access to lower cost prescription drugs (for those conditions not included in quantified analysis above). o Reduced healthcare utilization and future medical expenditures arising from improved health outcomes. • Reduced costs to self-insured group health plans and employers, allowing them to shift resources to other benefits or priorities.					
Costs:	Estimate	Year Dollar	Discount	Period Covered	
Annualized Monetized ($million/year)	$117.7	2025	7 percent	2026-2034	
	$116.3	2025	3 percent	2026-2034	
Quantified Costs: • For familiarization with the proposed rule, ERISA covered self-insured group health plans, TPAs, and PBMs will incur approximately $17.8 million in the first year. • For developing and maintaining the IT infrastructure systems, PBMs will incur $73.0 million in the first year and $14.6 million in subsequent years.					

- For preparing the required disclosures, PBMs and ERISA covered self-insured group health plans will annually incur approximately $90.6 million.
- For preparing the audit request, ERISA-covered self-insured group health plans will incur approximately $2.3 million.

Transfers:

	Estimate	Year Dollar	Discount	Period Covered
Annualized Monetized ($million/year)	$108.8 to $1,088.3	2025	7 percent	2026-2034
	$108.8 to $1,088.3	2025	3 percent	2026-2034

Quantified Transfers:

- Reduced prescription prices for self-insured group health plans and participants will result in undiscounted transfers to participants of between $108.8 million and $1.1 billion annually.

Non-Quantified:

- 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): $109.1 million.

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6. Request for Comments

The Department invites comments addressing its estimates and underlying assumptions of the benefits, costs, and transfers associated with the proposed rulemaking, as well as any quantifiable data that would support or contradict any aspect of its analysis. Throughout the document, the Department has requested comments on specific assumptions in its analysis. In particular, the Department requests comments on the following questions:

1. How frequently are PBM contracts extended or renewed? Is this done once over the life of the contract or every year of the contract? Would initial disclosures only be required the first year of the contract or every year before an option is exercised?

2. Are there differences in how fully pass-through PBMs collect and disclose information and what are the impacts in prices associated with these differences?

3. What share of the PBM market is served by fully pass-through PBMs? Do these PBMs focus on specific segments of the market?

4. How many full-service PBMs provide services for the self-insured group health plans affected by this rulemaking?

5. Are there differences in extracting pricing, cost, rebate and utilization data for level-funded versus other self-insured group health plans? Are current disclosures for level-funded group health plans provided at the plan level? If not, how much additional effort would be required to provide this information at the plan level?

6. Do the existence of intermediaries like TPAs, coalition groups, rebate aggregators, etc. significantly impact the burden of collecting the information required in the disclosure? If so, to what degree?

7. How much of the information requested in the proposed rule for the initial disclosure is already included in responses to Requests for Proposals by self-insured group health plans seeking PBM services?

8. How much of the process of sending disclosures can be automated? What are the associated up-front costs to create templates and automate the disclosure process?

9. How much time does it take to prepare a disclosure for each self-insured group health plan? Are initial disclosures more time-consuming than semi-annual disclosures? What types of occupations are involved in preparing the actual disclosures?

10. How often and what share of self-insured group health plans request audit data? Do these requests vary by plan size? How often do insurers, serving as TPAs for self-insured plans, request this data?

11. If obtaining this data becomes easier, would plan sponsors be more likely to conduct audits? What are the main sources of costs for plans to conduct audits? Would this increase under the proposed regulation?

12. Quality Adjusted Life Years and Willingness-to-Pay are two possible ways to estimate the benefits of the proposed rule. Which approach is more appropriate for this analysis and the available data? How can the analysis presented be improved and are there other sources available for the needed data to perform the analysis?

7. 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 proposed rule. These estimates and their sources are discussed in greater detail later in Section 7 of the RIA.

TABLE 2. Affected Entities

	Total
Level-funded Group Health Plans	1,031,098
Large, self-insured Group Health Plans with 100 to 999 employees	104,123
Large, self-insured Group Health Plans with 1,000 or more employees	15,362
PBMs	73
Issuers	373
Issuers/State combinations in group market	809
TPAs	205
Pharmacies	43,879
Pharmaceutical Manufacturers	1,431
Pharmaceutical Wholesalers	1,427

7.1. Self-Insured and Level-funded Group Health Plans

The proposed rule applies only to a subset of ERISA-covered group health plans, which are self-insured and level-funded group health plans. Fully insured ERISA plans are not subject to these requirements and are therefore excluded from the estimates.

According to the 2024 KFF Employer Health Benefits Survey, 42 percent of small firms offering health benefits provide a level-funded plan, which are self-insured group health plans packaged with extensive stoploss coverage that significantly reduces the risk retained by the plan sponsor.[205] Applying this percentage to the 2,454,996 small, ERISA-covered group health plans,[206] the Department estimates there are approximately 1,031,098 level-funded group health plans.[207] The Department also estimates that there are 104,123 self-insured group health plans with 100 to 999 employees and 15,362 self-insured group health plans with 1,000 or more employees.[208] While all 1,150,583 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 2024 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.[209] [210] As such, the Department assumes that all self-insured and level-funded group health plans will be affected by the proposed rule.

7.2. TPAs and Issuers

The Department also estimates that the proposed rule will affect 205 TPAs and 373 issuers (*i.e.,* health insurance companies) in the group market with 809 issuers/State combinations [211] that provide services such as plan management to level-funded and self-insured group health plans. The Department assumes that these TPAs and issuers will provide their services to level-funded group health plans and self-insured group health plans with fewer than 1,000 employees. 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 proposed 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 proposed 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 required under the proposed rule and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

7.3. Participants and Beneficiaries

There are approximately 89.4 million participants and beneficiaries in ERISA-covered self-insured and level-funded group health plans.[212] According to the 2022 Center for Disease Control's (CDC) National Center for Health Statistics, United States, 64.1 percent of individuals under the age of 65 with

[205] KFF, *2024 Employer Health Benefits Survey,* (Oct. 9, 2024), *https://www.kff.org/report-section/ehbs-2024-section-10-plan-funding/#figure106.*

[206] The Department estimates that there 2,454,996 ERISA-covered group health plans with less than 100 employees using the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS–IC) and the 2021 County Business Patterns from the Census Bureau.

[207] Additionally, the Department estimates there are 1,031,098 small, level-funded ERISA-covered group health plans based on the 2024 KFF Employer Health Benefits Survey, the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS–IC) and the 2021 County Business Patterns from the Census Bureau. Large is defined as having 100 or more participants and beneficiaries in the plan.

[208] The Department estimates that there are 104,123 self-insured ERISA-covered group health plans with 100 to 999 employees and 15,362 self-insured ERISA-covered group health plans with 1,000 or more employees using the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS–IC) and the 2021 County Business Patterns from the Census Bureau.

[209] KFF reported this estimate for large firms only, as small firm respondents had a high percentage of ''don't know'' responses to these questions.

[210] KFF, *2024 Employer Health Benefits Survey,* (Oct. 9, 2024), *https://www.kff.org/report-section/ehbs-2024-section-9-prescription-drug-benefits/.*

[211] 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.*

[212] Employee Benefits Security Administration, *Health Insurance Coverage Bulletin and Abstract of Auxiliary Data for the March 2023 Annual Social and Economic Supplement to the Current Population Survey,* (August 30, 2024), *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf.*

private health insurance used a prescription medication in the past year or 57.3 million participants.[213]

7.4. PBMs

According to the Pharmaceutical Care Management Association (PCMA),[214] 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.[215] The Department requests comments on this assumption, including whether all PBMs service the self-insured group health plans affected by this rulemaking.

7.5. Brokers and Consultants

To the extent PBMs or their affiliates also act as brokers or consultants to level-funded and self-insured group health plans with respect to pharmacy benefit management services, they are covered service providers under the proposed regulation. The Department seeks comments on the number of brokers and consultants that are PBMs or affiliates of PBMs, and on their arrangements with level-funded and self-insured group health plans and PBMs, and costs, if any, that they will incur in complying with the requirements of the proposed regulation.

7.6. Drug Manufacturers, Wholesalers and Pharmacies

According to the U.S. Census Bureau, there were 1,436 drug manufacturers in 2023 [216] and 1,427 pharmaceutical drug wholesaler distributors in 2021.[217] 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.[218]

A 2024 study found that while the number of U.S. retail pharmacies increased from 2010 to 2017, there was a sharp decline beginning in 2018, resulting in the total number of retail pharmacies declining by 29 percent between 2010 and 2021. Moreover, 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 share of the market. 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 reimbursement rates for unaffiliated pharmacies rather than PBM affiliated counterparts and the increased exclusion of independent pharmacies from pharmacy networks.[219]

8. 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.

8.1. 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, 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 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.[220]

It is important to note that this paper 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 [221] reporting capturing rebates, compared to 49 percent of large employers in 2024.[222] Evidence from a 2015 paper also 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 the 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 study concludes that PBMs create significant value by managing prescription drug spending, which can help reduce premiums and out-of-pocket costs for patients.[223]

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[213] Centers for Disease Control and Prevention, National Center for Health Statistics, *Prescription Medication Use Among Adults,* United States (2023), *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*.

[214] The PCMA is a national trade association representing the PBM industry. (*Source:* PCMA, *About PCMA,* (2025), *https://www.pcmanet.org/about/*).

[215] 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. (*Source:* PCMA, *The PBM Marketplace is More Competitive, Not Less,* (May 8, 2023), *https://www.pcmanet.org/rx-research-corner/the-pbm-marketplace-is-more-competitive-not-less/05/08/2023/*).

[216] U.S. Census Bureau, *2023 Economic Surveys Business Patterns, 325412: Pharmaceutical Preparation Manufacturing,* (2023), *https://data.census.gov/profile/325412_-_Pharmaceutical_Preparation_Manufacturing?n=325412&g=010XX00US*.

[217] 87 FR 6708 (Feb. 4, 2022), *https://www.federalregister.gov/documents/2022/02/04/2022-01929/national-standards-for-the-licensure-of-wholesale-drug-distributors-and-third-party-logistics*.

[218] 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), *https://data.census.gov/table/CBP2023.CB2300CBP?q=44611:+Pharmacies+and+drug+stores*.

[219] 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), *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2024.00192*.

[220] 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* (April 2025), *https://compass-lexecon.files.svdcdn.com/production/files/documents/Carlton-PBM-Report-Sections-I-VII-2025.04.22.pdf?dm=1745347921*.

[221] The paper defines a small employer as an employer with fewer than with than 5,000 employees.

[222] Pharmaceutical Group Companies, *2025 Trends in Specialty Drug Benefits Report,* (2025), *https://www.psgconsults.com/blog/untapped-potential-medical-drug-rebate-strategies-for-payers/*.

[223] Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro or*

Furthermore, a 2016 study, commissioned by a PBM trade association, PCMA, 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.[224] 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.

A 2022 study, also funded by PCMA, 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.[225]

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.[226]

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 portion of PBM functions under this model, leading to decreased efficiency and increased operational costs.[227]

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 was not able to 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.[228]

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 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.[229]

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.[230]

Anti-Competitive? International Journal of the Economics of Business, (2015) *https://www.tandfonline.com/doi/full/10.1080/13571516.2015.1045741.*

[224] Visante, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers,* Prepared for Pharmaceutical Care Management Association (PCMA), (2016), *https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf.*

[225] Casey B. Mulligan, *The Value of Pharmacy Benefit Management,* NBER Working Paper Series, Working Paper 30231, (2022), *https://www.nber.org/system/files/working_papers/w30231/w30231.pdf.*

[226] Casey B. Mulligan, *The Value of Pharmacy Benefit Management,* NBER Working Paper Series, Working Paper 30231, (2022), *https://www.nber.org/system/files/working_papers/w30231/w30231.pdf.*

[227] Casey B. Mulligan, *The Value of Pharmacy Benefit Management,* NBER Working Paper Series, Working Paper 30231, (2022), *https://www.nber.org/system/files/working_papers/w30231/w30231.pdf.*

[228] 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,* (2023), *https://www.oig.dol.gov/public/reports/oa/2023/03-23-001-04-431.pdf.*

[229] Ike Brannon & Anthony L. Sasso, *The Myth That the State Can Do It Better: Hepatitis C Drug Centralized Pharmaceutical Purchasing Versus Pharmacy Benefit Managers,* (2021), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3852446.*

[230] 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,* (February 25, 2019), *https://dhhr.wv.gov/bms/News/Documents/WV%20BMS%20Rx%20Savings%20Final%20Report%202019-02-25.pdf.*

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 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.[231]

8.2. 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 costs, 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 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.[232]

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 copay 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, these 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.[233]

The U.S. Senate Committee on Finance considered the role of PBM rebates in its investigation on the cost of insulin and the role of PBMs and manufacturers in 2019. 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 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.[234]

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.[235]

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 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

[231] The Menges Group, *Assessment of Report on Impacts of West Virginia Medicaid Prescription Drug Carve-Out, Prepared for America's Health Insurance Plans,* (April 2019), *https://themengesgroup.com/wp-content/uploads/2022/06/assessment_of_study_of_wv_rx_carve-out_impacts_april_2019.pdf.*

[232] 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.*

[233] 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.*

[234] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,* (2021), *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[235] Van Nuys K, Ribero R, Ryan M, Sood N. 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.* 2021;2(11):e213409. Published 2021 Nov 5. doi:10.1001/jamahealthforum.2021.3409 *https://pubmed.ncbi.nlm.nih.gov/35977268/.*

concerns that the PBM retained 100 percent of the amount billed as profit.[236]

9. Research on How PBM Disclosures Impact Prescription Drug Costs

Prior to 2023, the FTC had issued several advocacy letters and studies that had opposed greater PBM transparency and disclosure requirements, arguing that such disclosures could undermine competitive processes. However, the FTC reversed this position in 2023 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.[237] This withdrawal underscores the need to assess how PBM disclosures affect the pharmaceutical 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.

9.1. 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. However, CBO indicated 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.[238] The self-insured and level-funded plans covered in these proposed rules are not subject to state disclosure laws and thus the proposed 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 information to plan sponsors about their services, though disclosures to plans sponsors for businesses with fewer than 50 employees would be more limited.[239] 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.[240] As the proposed 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 proposed 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 proposed rule's impact diminishing over time in the Uncertainty Section of this regulatory analysis.

9.2. 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 PCMA, analyzed the impact of disclosure requirements, such as the *PBM Transparency Act of 2023,*[241] on competition among PBMs, manufacturers, and pharmacies. 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.[242]

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.[243] The 2023 industry paper further argues that disclosures could increase costs of pharmacies by $8.0 billion and PBMs by as much as $48.0 billion if tax distortion

[236] State of Delaware, Office of Auditor of Accounts, *Lack of Transparency & Accountability in Drug Pricing Could be Costing Taxpayers Millions,* (2021), *https://auditor.delaware.gov/wp-content/uploads/sites/40/2021/06/RPT_PBM_061721_FINAL.pdf.*

[237] 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), *https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinalRevisionsnoon%29.pdf.*

[238] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices,* (2024), *https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf.*

[239] *S.1339—Pharmacy Benefit Manager Reform Act,* 118th Congress (2023–2024), *https://www.congress.gov/bill/118th-congress/senate-bill/1339.*

[240] Congressional Budget Office, *Cost Estimate of S. 1339 Pharmacy Benefits Manager Reform Act,* (2024), *https://www.cbo.gov/system/files/2024-12/s1339.pdf.*

[241] *S.127—Pharmacy Benefit Manager Transparency Act of* 2023, 118th Congress (2023–2024), *https://www.congress.gov/bill/118th-congress/senate-bill/127.*

[242] Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences,* (2023), No. w30998. National Bureau of Economic Research, *https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.*

[243] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,* (2021), *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

from rebates or discounts applied at the point of sale are included.[244]

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.'' [245]

9.3. 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. 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 [246] and disclosures to regulators.[247] 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.[248]

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, 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.[249]

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.[250]

10. Benefits and Transfers

The Department expects that the proposed rule, if finalized, would improve transparency in PBM operations, as directed by Executive Order 14273.[251] The proposed 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. 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 a mainly qualitative discussion of the benefits and transfer impacts of the proposed rule and discusses how the proposed rule would enable self-insured group health plans, participants, and other stakeholders to better utilize the information provided by PBM disclosures.[252] It also includes a quantitative analysis on 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. Finally, it includes two alternative approaches, Quality Adjusted Life Years (QALY) and Willingness-to-Pay (WTP) to quantify the benefits from decreasing prices. The

[244] Casey B. Mulligan, *Restrict the Middleman? Quantitative Models of PBM Regulations and Their Consequences,* (2023), No. w30998. National Bureau of Economic Research, *https://www.nber.org/system/files/working_papers/w30998/w30998.pdf.*

[245] Federal Trade Commission, Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports that No Longer Reflect Current Market Realities, (July 20, 2023), *https://www.ftc.gov/system/files/ftc_gov/pdf/CLEANPBMStatement7182023%28OPPFinal Revisionsnoon%29.pdf*

[246] ''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.

[247] ''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.

[248] Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market,* (December 20, 2024), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5021179.*

[249] Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market,* (December 20, 2024), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5021179.*

[250] 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.

[251] 90 FR 16441, *Lowering Drug Prices by Once Again Putting Americans First,* (April 15, 2025), *https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf.*

[252] If the various mechanisms and outcomes discussed above could be quantified and were then summed simplistically, the result would almost certainly include double-counting.

QALY approach is a quantitative analysis of the behavioral impacts of reduced out-of-pocket costs for three therapeutic classes resulting in improved adherence and health, and lowered utilization costs. While this quantitative analysis is only for a small subset of the prescription drug market impacted by this proposed rule, it is illustrative of the potential downstream benefits of this rulemaking on all therapeutic classes. The WTP approach more directly measures welfare improvements for patients from increasing consumption of their prescribed medications as prices decrease. The Department invites comments and data related to how it might quantify these benefits as part of the proposed rule, and which approach is more appropriate for this analysis and available data.

10.1. Benefits and Transfers to Self-Insured Group Health Plans

10.1.1. 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.

10.1.2. 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.[253] Requiring PBMs to disclose pricing structures, discounts, and rebates reasonably in advance of entering into a contract or arrangement with a self-insured or level-funded 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.[254]

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 its first year and those savings eroding over time.[255] 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.

Furthermore, a 2024 survey aimed to gauge U.S. employers' perspectives on various factors, including PBM transparency and premiums, among private and public employers. 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.[256]

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.[257] 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 any reasonably available therapeutic equivalent alternative drugs were omitted from the formulary, responsible plan fiduciaries can attain more appropriate formulary placement, more equitable patient cost-sharing, and broaden access to prescription drugs that have been previously miscategorized, which could result in reduced prescription drug spending for 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 in order to avoid contractual pass-through payments. This can be particularly 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.[258] 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

[253] 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/.*

[254] 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.*

[255] Congressional Budget Office, *S. 1339, Pharmacy Benefit Manager Reform Act,* (2024), *https://www.cbo.gov/system/files/2024-12/s1339.pdf.*

[256] National Alliance of Healthcare Purchaser Coalitions, *Pulse of the Purchaser 2025 Survey Results,* (September 8, 2025), *https://www.nationalalliancehealth.org/resources/pulse-of-the-purchaser-2025-survey-results/.*

[257] FTC, *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.*

[258] 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.*

streams, such as access fees and credits in their contracts.[259]

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 $69.4 million across the 383,528 impacted level-funded and self-insured group health plans that are expected to initiate new contracts, extend existing contracts, or renew contracts each year.[260]

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 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.[261] 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.[262] The Department requests comments on these assumptions.

10.1.3. 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.[263] Employers that receive confirmation that advisors do not receive direct or indirect compensation from PBMs or related third parties reported reduced annual premiums.[264]

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.[265] In contrast, requiring full disclosures of all revenue streams with affiliated pharmacy-related entities can result in reduced premiums.[266] 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.[267]

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 proposed rule will help to reduce conflicts and mitigate the 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.

10.2. Benefits and Transfers to Participants and Beneficiaries

10.2.1. 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 in order to protect their net prices. As a result, patients may pay cost-sharing based on the drug's list price, even

[259] 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.

[260] This estimate is calculated as: 1,150,583 level-funded and self-insured group health plans × 1/3 of plans contracts with PBMs expiring annually = 383,528 level-funded and self-insured group health plans negotiating contracts annually × $181.06 hourly wage of legal professional × 1 hour = $69,441,580.

[261] Remy Samuels, *PLANSPONSOR Roadmap: A PBM Process,* (April 21, 2025) *https://www.plansponsor.com/plansponsor-roadmap-a-pbm-process/.*

[262] See discussion of the exclusive purpose rule in ERISA section 403(c), supra note.

[263] Advisory Council of Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure,* (November 2014), *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf.*

[264] 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.*

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

[266] 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.*

[267] 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.*

though the net price after rebates is substantially lower.[268]

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 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.[269]

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.[270] 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 price of prescription drugs, approximately 0.1 percent to 1.0 percent.[271] Data from IQVIA indicates that expenditures for all prescription drugs from patients and issuers, less any rebates, totaled approximately $667.0 billion in 2022.[272] The Department estimates that level-funded and self-insured group health plans account for approximately 16 percent, or $108.8 billion, of these expenditures.[273] Utilizing the CBO estimates for price reductions arising from PBM disclosures, the Department estimates that expenditures from patients and issuers will decline, producing a transfer ranging from approximately $108.8 million and $1.1 billion annually for the 57.3 million participants with a prescription in the 1.1 million level-funded and self-insured group health plans covered by the proposed rule.[274] 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 proposed rule, this range of estimates may understate the impact of the proposed rule on prices. 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). The Department requests comments on these assumptions.

10.2.2. Quantified Benefits

The Department, in estimating the benefits under the proposed rule, considered two approaches: WTP and QALY. These approaches differ both in their approach and in what they measure. In simplistic terms, WTP measures the amount consumers are willing and able to pay to acquire a good or service based on the consumer's utility function; in the cases relevant to this analysis, most payment flows through issuers. QALY, alternatively, quantifies the value of a health intervention in terms of the duration of quality of life, which is estimated by multiplying the amount of time an individual spends in a health state by a standardized measure of their health-related quality of life associated with that state.

There are advantages and limitations to both approaches. WTP is thought to better capture the value of welfare changes when compared to QALY, since it values non-health utility (such as income and risk) in addition to health-related welfare changes.[275] WTP also benefits from having less restrictive assumptions.[276] For example, QALY's are assumed to be equally valued and a constant proportional tradeoff between health states and longevity is also assumed. However, morbidity risks are diverse, differing in duration and severity as well as in the attributes of health that are affected (*e.g.,* physical or cognitive functioning). Because high quality WTP estimates are not available for many morbidity risks, they often require the use of proxy measures, such as QALYs.[277]

While the WTP approach is attractive in that it considers the full universe of conditions that self-insured group health plan participants with prescriptions face, the Department is concerned that there is tremendous variability in the impact of drug use by condition, and that generalizing across the entire population fails to capture the significant health benefits of improved drug adherence for certain chronic conditions. The WTP approach could be implemented in a more tailored manner

[268] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,* (2021), *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[269] United States Senate Committee on Finance, *Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayer,* (March 30, 2023), *https://www.finance.senate.gov/imo/media/doc/pharmacy_benefit_managers_and_the_prescription_drug_supply_chain_impact_on_patients_and_taxpayers.pdf.*

[270] U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,* (2021), *https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.*

[271] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices,* (2024), *https://www.cbo.gov/system/files/2024-10/58793-rx-drug-prices.pdf.*

[272] IQVIA Institute, *Understanding the Use of Medicines in the U.S., 2025: Evolving Standards of Care, Patient Access, and Spending,* (2025), *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025.*

[273] This estimate is calculated as: 89,400,000 participants in level-funded and self-insured group plans x 6.72 average prescription fills annually = 600,768,000 prescriptions for participants in level-funded and self-insured group plans. 600,768,000 total prescriptions x $181.15 total average patient out-of-pocket and insurer expenditure per prescription = $108,831,984,000. This represents 16.3 percent of $667,000,000,000 total annual prescription expenditures. (*Source: 2022 Medical Expenditure Panel Survey,* Agency for Healthcare Research and Quality, Department of Health and Human Services, (2024).)

[274] These estimates are calculated as: $108,831,984,000 × 1.00 percent = $1,088,319,840. Additionally, $108,831,984,000 × 0.10 percent = $108,831,984.

[275] Mohan V. Bala, Lisa L. Wood, Gary A. Zarkin, Edward C. Norton, Amiram Gafni, and Bernie O'Brien, Valuing Outcomes in Health Care: A Comparison of Willingness to Pay and Quality-Adjusted Life-Years, J Clin Epidemiol Vol. 51, No. 8, pp. 667–676, 1998.

[276] Mohan Bala, Lisa Wood, Gary Zarkin, Edward Norton, Amiram Gafni, and Bernie O'Brien, *Valuing Outcomes in Health Care: A Comparison of Willingness to Pay and Quality-Adjusted Life Years,* Journal of Clinical Epidemiology, Vol. 51, No. 8, (1998).

[277] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171981/HHS_RIAGuidance.pdf.*

than what appears below if usable data is found in the future. For now, disaggregation by type of condition being treated is illustrated with the QALY approach. The Department has included estimates using both the WTP and QALY approaches in the Summary of Impact table.

It should be noted that, with both the QALY and WTP benefits approaches, the specific price change that is primarily relevant (due to its most-direct prompting of different behavior) is the change in price experienced by consumers. Scanlon (2024) finds that consumer price, including copayments and coinsurance, can change in a different direction or magnitude than price paid by health plans; however, her primary estimates of the effect of inter-firm disclosure on consumer price (entries in her columns 5 and 6 of Table 6 are used to calculate a weighted average) yield an estimate of a reduction in the net retail price of approximately one percent.[278] The preceding transfers-focused section discussed *overall* drug price reductions ranging from 0.1 percent up to this one percent, and the same range will be used in the benefits analyses appearing below, with most of the explanatory narrative highlighting the one-percent input.

The Department requests comments on this range of inputs and other details about the two benefits approaches.

10.2.2.1 Improved Health Outcomes Among Patients Utilizing Quality Adjusted Life Years

Table 1 presents estimates of annual benefits and transfers under a range of assumptions about reductions in average net retail prescription drug prices. The Department uses a range of estimates to reflect uncertainty regarding the magnitude of potential price reductions. The scenarios shown in this section's tables present calculations based on a one percent reduction in average net retail prescription drug prices. This is the high-end estimate as well as the preferred estimate of that range. The additional estimates in Table 3 are calculated in the same manner but utilizing a different estimate of price reduction. Total benefits are calculated as the sum of the monetized value of QALY's gained through improved medication adherence and reductions in insurer health care expenditures. Transfers associated with reduced prescription drug spending are reported separately. These estimates are intended to demonstrate a potential magnitude of benefits and transfers under plausible assumptions rather than to represent a single point estimate of expected effects.

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Table 3. Benefits and Transfers under Different Assumptions about Reductions in Average Net Retail Prescription Drug Prices

Assumed Percent Decrease in Average Net Retail Rx Price	Participants Improving Adherence	Incremental QALYs	Monetized Value of QALYs ($ million)	Reduced Insurer Health Expenditures ($ million)	Total Benefits ($ million)	Transfers to Participants: Reduced Rx Spending ($ million)
(a)	(b)	(c)	(d) = (c x QALY of $35,160)	(e)	(f) = (d) + (e)	(g) = Baseline spending ($108.8 B) x (a)
0.1%	2,593	2,038	$71.7	$3.2	$74.8	$108.8
0.5%	12,963	10,202	$358.7	$15.9	$374.6	$544.2
1.0%	25,926	20,399	$717.1	$31.9	$749.0	$1,088.3

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The disclosures required of PBMs in the proposed 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.[279] By reducing prescription costs, the proposed 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. In the context of the proposed 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 ultimately improve patient health outcomes over the long term. Price sensitivity towards drug adherence is reflected in the 2023 National Health Interview Survey, which found that approximately 6.5 percent of respondents aged 18 to 64 with private insurance reported not taking their medication as prescribed in order to save money.[280] Results from a meta-analysis of treatment adherence studies further indicated that nearly one-fourth (24.8 percent) of patients were non-adherent to medication for various reasons.[281] This is consistent with research on prescription drug price elasticity, where increases in direct consumer costs reduce prescription fills for chronic diseases, suggesting a price elasticity of demand between –0.1 and

[278] Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market,* (December 20, 2024), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5021179.*

[279] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices,* (October 2024), *www.cbo.gov/publication/58793.*

[280] Laryssa Mykyta & Robin A. Cohen, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021,* NCHS Issue Brief No. 470, (2023) *https://www.cdc.gov/nchs/data/databriefs/db470.pdf.*

[281] 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/.*

–0.4.[282] 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.[283] Additionally, research corroborates that poor treatment adherence is associated with poorer health outcomes and significantly higher mortality rates.[284] [285] These findings suggest that by reducing prescription drug costs, PBM disclosures could improve treatment adherence and associated health outcomes.

To estimate the potential benefit to participants and beneficiaries of the proposed rule, the Department has provided an analysis that estimates the averted healthcare costs arising from increased prescription drug adherence for a subset of prescription drugs. The proposed rule is expected to have a small but meaningful effect on the net retail price of prescription drugs, which the Department estimates will decrease by one percent. This estimate is consistent with the 2024 CBO analysis [286] and other research on the effect of disclosures to group health plans and other service providers on prescription drugs.[287] While these studies offer a comparable assessment of the potential impact of required rebate disclosures from PBMs to self-insured group health plans, the proposed 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 proposed 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 the smaller level-funded and self-insured group health plans, which are typically less informed and with fewer resources. As such, the Department believes that the proposed rule could reduce prices for prescription drugs more significantly, consistent with the effect of similar disclosures in other markets.[288]

The Department is not able to analyze the impact of reduced prescription drug prices on patient health outcomes for all health conditions and therapeutic classes; however, the Department does provide an analysis which focuses on participants aged 18–64 with three of the most common chronic conditions in the United States: diabetes, heart disease, and hypertension. Using Medical Expenditure Panel Survey (MEPS) data from AHRQ on the self-reported prevalence of diabetes, heart disease, and hypertension, the Department estimates that there are approximately 22.0 million participants aged 18 to 64 with such conditions in level-funded or self-insured group health plans (see Table 4).[289] [290] Research on cost-related non-adherence suggests rates of prescription non-adherence for these conditions among privately insured individuals range from 33 to 37 percent, resulting in approximately 7.7 million participants in level-funded or self-insured group health plans with diabetes, heart disease, or hypertension that are non-adherent to prescription medication for reasons of cost.[291] [292]

A 2008 paper on the impact of reductions in copayments to drug adherence for privately insured adults aged 18 to 64 looked specifically at chronic conditions including diabetes, heart disease, hypertension, high cholesterol and found significant price elasticities in response to the copayment changes, ranging from –0.11 to –0.14 for these three conditions.[293] Applying these elasticities to the estimated number of self-insured and level-funded group health plan participants and beneficiaries prescribed these

[282] 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/.*

[283] IQVIA Institute, *Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines,* (August 2020), *https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/medicine-spending-and-affordability-in-the-us.*

[284] Teresa B. Gibson, Xue Song, Berhanu Alemayehu, Sara S. Wang, Jessica L. Waddell, Jonathan R. Bouchard, and 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), *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/.*

[285] 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), *https://pmc.ncbi.nlm.nih.gov/articles/PMC1488752/pdf/bmj33300015.pdf.*

[286] Congressional Budget Office, *Alternative Approaches to Reducing Prescription Drug Prices,* (October 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 one percent.

[287] Ginger Scanlon, *Prescription for Savings? Disclosure in the Drug Market,* (2024), *https://ssrn.com/abstract=5021179.*

[288] 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), *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.*

[289] The prevalence estimates for privately insured adults aged 18 to 64 with diabetes (6.55 percent), heart disease (7.52 percent), and hypertension (21.94 percent) were applied to the number of participants 18 to 64 in level-funded and self-funded plans (61,212,180), resulting in an estimated population of 4,009,398 participants with diabetes ($0.0655 \times 61,212,180 = 4,009,398$), 4,603,156 participants with heart disease ($0.0752 \times 61,212,180 = 4,603,156$, and 13,429,952 participants with hypertension ($0.2194 \times 61,212,180 = 13,429,952$). Finally, 13,429,952 + 4,603,156 + 4,009,398 = 22,042,506. (*Source:* Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality, (2022).)

[290] The Department has not adjusted this analysis to control for comorbid conditions, *e.g.* when a patient is diagnosed and receives treatment for both diabetes and heart disease. While this could potentially overstate the benefits of the proposed rule due to the inclusion of individuals accruing benefits from multiple health conditions, the Department believes that the following analysis continues to underestimate such benefits given the limited scope of the conditions observed and the potential health benefits to those with multiple chronic diseases.

[291] 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/.*

[292] The standard threshold to establish adherence to medication is 80% of medication taken in compliance with medical directives. This threshold was generally thought to be consistent with the minimal therapy administered for successful treatment outcomes, (Source: Sarah Chapman and Amy Chan, *Medication Non-Adherence: Definition, Measurement, Prevalence, and Causes,* Frontiers in Pharmacology, (2025), *https://pmc.ncbi.nlm.nih.gov/articles/PMC11925869/.*

[293] Michael E. Chernew, Mayur R. Shah, Arnold Wegh, Stephen N. Rosenberg, Iver A. Juster, Allison B. Rosen, Michael C. Sokol, Kristina, Yu-Isenberg, & A. Mark Fendrick, *Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment,* Health Affairs Vol. 27(1), (2008), *https://pubmed.ncbi.nlm.nih.gov/18180484/.*

medications and assuming a one percent decrease in average drug price resulting from improved disclosures leads to a 0.11 percent to 0.14 percent change in participants and beneficiaries improving their drug adherence. As a result, the Department estimates that 25,926 participants aged 18 to 64 in level-funded and self-insured group health plans with diabetes, heart disease, or hypertension will improve their drug adherence following improved disclosures under this proposed rule.

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TABLE 4. Disease Prevalence and Estimated Adherence Improvements

Condition	Prevalence	Estimated Population*	Percent Change Implied by Price Elasticity of Adherence	Estimated Population Experiencing Adherence Improvement**
Diabetes	6.6%	4,009,398	0.14%	5,453
Heart Disease	7.5%	4,603,156	0.12%	5,432
Hypertension	21.9%	13,429,952	0.11%	15,042
Total* **	-	**22,042,506**	-	**25,926**

Note: Some values in the table are rounded and may not result in precise calculations.
* Estimated population based on the level-funded and self-insured participants aged 18 to 64 is 61,212,180.
**Estimated adherence improvements based on 1 percent decrease in average drug price. Cells in Population columns would be 10% of the values presented if average drug price instead decreases by 0.1 percent.
***These totals may include individuals with more than one of the health conditions which could result in an overestimation of the affected population.

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.[294] Using data on medical events from the 2022 MEPS, the Department estimates healthcare utilization for privately insured participants aged 18 to 64 with diabetes, hypertension, or heart disease based on adherence status (see Table 5 below).[295] 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 with diabetes, for example, averaged 1.37 hospital outpatient admissions in 2022, compared with an average of 4.29 hospital outpatient admissions for non-adherent diabetic participants. This data supports other research suggesting medication adherence and compliance can reduce adverse health outcomes and healthcare utilization.

[294] 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), *https://pubmed.ncbi.nlm.nih.gov/15908846/.*

[295] Based on self-reporting of delaying taking or being unable to afford their medication. (*Source: 2022 Medical Expenditure Panel Survey,* Agency for Healthcare Research and Quality, Department of Health and Human Services, (2024).)

TABLE 5. Average Annual Healthcare Events Per Person, by Disease Condition and Adherence Status

	Average Utilization, Adherent			Average Utilization, Non-Adherent		
	Diabetes	Heart Disease	Hypertension	Diabetes	Heart Disease	Hypertension
Emergency Room Visits	0.18	0.24	0.17	0.49	0.48	0.38
Hospital, Inpatient Admissions	0.07	0.13	0.07	0.12	0.25	0.08
Hospital, Outpatient Admission	1.37	1.74	1.12	4.29	5.71	3.16
Office-Based Visits	8.84	9.20	7.98	10.62	13.96	10.04
Prescribed Medicines Filled	22.35	15.49	14.98	29.18	30.60	28.05

Note: The MEPS-HC data on healthcare utilization above represents the average number of distinct medical events in 2022 by facility type, based on the participants indicated disease condition and reported adherence status. 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 6). Using 2022 MEPS data on healthcare expenditures of privately insured patients aged 18 to 64 with diabetes, heart disease, or hypertension, 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 participants could lower the reimbursement requirements of private issuers to healthcare providers by approximately $31.9 million annually.[296]

TABLE 6. Estimated Healthcare Expenditures and Savings, by Disease Condition and Adherence Status

	Issuer Health Expenditures	
	Adherent	Non-Adherent
Diabetes	$49,860,374	$60,834,609
Heart Disease	$57,138,641	$64,826,269
Hypertension	$106,701,495	$119,907,341
Total Expenditures	$212,700,510	$245,568,219
Total Cost Savings	**$31,867,708**	

Note: These calculations utilize the average expenditure by payer for those indicating one of the three disease conditions based on reported adherence status. This average expenditure is then applied to the estimated number of participants improving adherence (5,453 participants with diabetes, 5,432 participants with heart disease, and 15,042 participants with hypertension) in level-funded and self-insured group health plans with the same conditions. 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).
Source: Agency for Healthcare Quality and Research, MEPS-HC, 2022

[296] Based on data reporting insurer expenditures for privately insured patients aged 18–64 diagnosed with Diabetes, Heart Disease, or Hypertension. (*Source: 2022 Medical Expenditure Panel Survey,* Agency for Healthcare Research and Quality, Department of Health and Human Services, (2024).)

Increased prescription adherence is also associated with a decreased risk of adverse health outcomes.[297] For patients with chronic or severe diseases, the mortality risk associated with non-adherence to their medication can be considerable. A 2020 CDC study found that the increased risk of all-cause mortality due to cost-related non-adherence to their medication for individuals with diabetes, hypertension, and heart disease, ranged from 15 to 22 percent.[298] While the population studied included higher-risk individuals (*e.g.,* those without insurance), these findings are consistent with other research indicating increased health risks from non-adherence.[299]

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.[300]

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.[301] To calculate the QALY for each condition, the number of participants improving adherence is first reduced by the estimated population mortality rate. Then the health utility metric, *Short Form Six-Dimension* (SF–6D),[302] is applied to all remaining participants in the group for that year, where their aggregate value is calculated as the annual QALYs.[303] [304] In subsequent years, these remaining participants are again subject to the same mortality risk, and their updated SF–6D scores are aggregated to calculate QALYs over time.

The post-rule, which captures the QALYs of participants in their adherent state, estimates an average SF–6D score of 0.81 for individuals aged 18 to 64 with private insurance, any of the three chronic diseases, and who indicated they are adherent to their treatment regimen. For the baseline, non-adherent state, the SF–6D score is approximately 0.08 less, or 0.73.[305]

The baseline and post-rule analysis both reflect an average mortality rate of 380.4 per 100,000 individuals aged 18 to 64, derived from mortality data from the National Center for Health Statistics.[306] The baseline calculations are provided in Table 7 below while the post-rule calculations are presented in Table 8.

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[297] 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).

[298] 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/.*

[299] 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/.*

[300] 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. (*Source: 2022 Medical Expenditure Panel Survey,* Agency for Healthcare Research and Quality, Department of Health and Human Services, (2024).)

[301] 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).

[302] 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 2022 MEPS.

[303] 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)).

[304] 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).

[305] Based on a regression analysis of calculated SF–6D values derived from 2022 MEPS data reflecting reported cost-related non-adherence and controlling for race, income, sex, marital status, and insurance status.

[306] Jiaquan Xu, Sherry Murphy, Kenneth Kochanek, & Elizabeth Arias, *Deaths: Final Data for 2022,* National Vital Statistics Reports 74(4), National Center for Health Statistics, (2025).

TABLE 7. Baseline QALY Estimates, by Condition

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Diabetes	N=	5,453	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	21	21	21	21	20	20	20	20	20	20
	Alive	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249
	QALYs	3,966	3,951	3,935	3,920	3,905	3,891	3,876	3,861	3,847	3,832
Heart Disease	N=	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	21	21	21	20	20	20	20	20	20	20
	Alive	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249	5,229
	QALYs	3,951	3,935	3,920	3,905	3,891	3,876	3,861	3,847	3,832	3,818
Hypertension	N=	15,042	14,984	14,927	14,870	14,813	14,757	14,701	14,645	14,589	14,534
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	57	57	57	57	56	56	56	56	55	55
	Alive	14,984	14,927	14,870	14,813	14,757	14,701	14,645	14,589	14,534	14,479
	QALYs	10,940	10,898	10,857	10,815	10,774	10,733	10,692	10,651	10,611	10,571

Note: The all-cause mortality rate is 380.36 per 100,000 for patients with diabetes, heart disease, or hypertension, respectively, based on data from Sarah Van Alsten and Jenine Harris, *Cost-Related Nonadherence and Mortality in Patients with Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000–2014,* Preventing Chronic Disease Vol. 17(151), Center for Disease Control and Prevention (2020). Baseline QALYs are estimated from the 2022 MEPS as 0.73 per participant based on an average of 0.81 for individuals aged 18 to 64 with private insurance and diabetes, heart disease, or hypertension that reported cost-related non-adherence, less the 0.08 associated with non-adherence.

TABLE 8. Post-Rule QALY Estimates, by Condition

		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Diabetes	N=	5,453	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	21	21	21	21	20	20	20	20	20	20
	Alive	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249
	QALYs	**4,402**	**4,385**	**4,368**	**4,351**	**4,335**	**4,319**	**4,303**	**4,286**	**4,270**	**4,254**
Heart Disease	N=	5,432	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	21	21	21	20	20	20	20	20	20	20
	Alive	5,411	5,390	5,369	5,349	5,329	5,309	5,289	5,269	5,249	5,229
	QALYs	**4,385**	**4,368**	**4,351**	**4,335**	**4,319**	**4,303**	**4,286**	**4,270**	**4,254**	**4,238**
Hypertension	N=	15,042	14,984	14,927	14,870	14,813	14,757	14,701	14,645	14,589	14,534
	Mortality Rate	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4	380.4
	Deaths	57	57	57	57	56	56	56	56	55	55
	Alive	14,984	14,927	14,870	14,813	14,757	14,701	14,645	14,589	14,534	14,479
	QALYs	**12,144**	**12,097**	**12,051**	**12,005**	**11,960**	**11,914**	**11,869**	**11,824**	**11,779**	**11,734**

Note: The all-cause mortality rate is estimated as 380.36 per 100,000 individuals, aged 15-64 based on data from *National Vital Statistics Report, Deaths: Final Data for 2022*, National Center for Health Statistics, Centers for Disease Control and Prevention (2025). QALYs is estimated from the 2022 MEPS as 0.81 per adherent participant based on an average for individuals aged 18 to 64 with private insurance and diabetes, heart disease, or hypertension that did not report cost-related non-adherence.

The difference between the baseline and post-rule estimates indicates that, each year, increased medication adherence among the 25,926 participants will result, on average, in 2,040 additional QALYs.[307] The Department uses an estimate for the value of a QALY (VQALY) of approximately $334,600,[308] [309] suggesting an average annual value of approximately $717.1 million from improvements to quality of life.[310] These calculations and estimates are provided in Table 9 below.

[307] This estimate is calculated as: 205,761 post-rule QALYs—185,362 baseline QALYs = 20,399 additional QALYs, averaging 2,040 additional QALYs across the first ten years of the rule.

[308] The estimate is calculated as the value of statistical life ÷ the present value of QALY remaining = Value of each QALY. The VSL estimate utilized here is a low estimate of $6.3 million. The QALYs remaining is discounted at 3 percent which estimates 18.9 remaining QALYs per participant and is derived from: *HHS, Standard Values for Regulatory Impact Analysis, 2025,* Office of Science and Data Policy, Department of Health and Human Services, (2025).

[309] The value of a QALY in year one is estimated as $334,612 and is adjusted upward 1.1 percent each year to account for projected earnings growth. This results in an average value of QALY of $351,671 over the 10 years observed.

[310] The undiscounted benefits related to QALY improvements result in an average annual value of approximately $421.7 million. The benefits related to QALY improvements, when discounted at 7 percent, result in an average annual value of approximately $1,175.6 million.

TABLE 9. 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
QALY Gain -- Diabetes	436	435	433	431	430	428	427	425	423	422
QALY Gain – Heart Disease	435	433	431	430	428	427	425	423	422	420
QALY Gain - Hypertension	1,204	1,199	1,195	1,190	1,186	1,181	1,177	1,172	1,168	1,163
Total QALY Gains	2,075	2,067	2,059	2,051	2,044	2,036	2,028	2,020	2,013	2,005
VQALY	$334,612	$338,293	$342,014	$345,776	$349,580	$353,425	$357,313	$361,243	$365,217	$369,235
Total Value (in $ millions)	$694.36	$699.30	$704.28	$709.30	$714.41	$719.54	$724.70	$729.88	$735.12	$740.39

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While the Department was able to quantify the impact of improved adherence to certain prescribed medications following reduced out-of-pocket costs in response to this proposed rule, these estimates were limited to a small subset of participants and beneficiaries being treated for diabetes, hypertension, and heart disease. The Department lacked data, however, on other therapeutic areas, including those for oncology drugs, autoimmune, and respiratory diseases, which are associated with some of the highest prescription drug spending in the United States. As a result, while the benefits quantified by the Department associated with improved health outcomes stemming from this proposed rule are significant, they likely are only a fraction of those actual benefits as the quantified benefits do not account for changes in morbidity or quality of life that would arise from increased adherence for these and other classes of drugs.

In total, the proposed rule is estimated to generate approximately $749.0 million in undiscounted benefits annually, accounting for averted medical costs, reduced prescription drug expenditures, and improved health outcomes from greater treatment adherence.[311] The Department requests comments on these assumptions and calculations.

10.2.2.2 Consumer Benefits Measured by Willingness-to-Pay

The high rates of non-adherence for reasons of cost (CRN) 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 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 proposed rule. Utilizing data from MEPS on average out-of-pocket expenditures for prescription drugs of participants in private group health plans in 2022 ($122), as well as the average expenditures from insurers for those in private group health plans ($1,096), the Department finds that the average annual expenditures for prescription drugs total $1,217.[312] This data also reports an annual average of 6.7 prescription fills for those participants, suggesting an average prescription cost of $181 for combined insurer and participant expenditures.[313] Given an estimate of 89.4 million participants in self and level-funded group health plans and assuming a similar utilization and cost of prescription drugs, the Department estimates total prescription drug expenditures for this population at approximately $108.8 billion arising from an estimated 600.8 million prescription fills annually.[314]

Research on demand for prescription drugs among those with commercial insurance indicates a price elasticity of approximately −0.36 across all prescriptions, slightly more elastic demand than those for chronic diseases discussed earlier.[315] Utilizing the stated price elasticity, estimated price decrease, and prescription demand, the Department estimates that approximately 2.2 million additional prescription drugs will be purchased as a result of lower prices.[316] Given an average price of $181 and an estimated price decrease of one percent, the Department estimates that the value of the gross consumer willingness to pay would result in up to $389.6 million of benefits annually.[317] Table 10 presents these estimates with a further range of assumptions about the reductions in average net retail prescription drug prices. 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 proposed rule. The Department requests comments on refining the approach to account for both consumer and producer surplus, and more generally on the preceding assumptions and calculations.

[311] This estimate is calculated as: $717,127,901 quality-adjusted life years + $31,867,708 in averted healthcare expenditures = $748,995,610 in total undiscounted benefits. Using a 3 percent discount rate, this results in annualized benefits of $637,845,854. Using a 7 percent discount rate, this results in annualized benefits of $524,073,852.

[312] Agency for Healthcare Research and Quality, *2022 Medical Expenditure Panel Survey,* Department of Health and Human Services, (2014).

[313] This estimate is calculated as: $1,217.36 annual prescription expenditures ÷ 6.72 average annual prescriptions = $181.15 average cost of prescription for patient out-of-pocket and insurer expenses.

[314] This estimate is calculated as: 89,400,000 participants in self and level-funded plans x 6.72 average prescription fills annually = 600,768,000 annual prescription fills for self and level-funded plan participants. $181.15 average cost × 600,768,000 = $108,831,984,000 annual expenses for prescription drugs in self and level-funded plans.

[315] 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).

[316] This estimate is calculated as: 1 percent price reduction × 0.36 price elasticity × 600,768,000 prescriptions = 2,150,749 prescriptions.

[317] This estimate is calculated as: $181.15 average prescription cost × 2,150,749 prescriptions = $389,618,503.

TABLE 10. Participant 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 ($108.8 B) x (a)
0.1%	600,768,000	-0.358	215,075	$181.15	$39.0	**$108.8**
0.5%	600,768,000	-0.358	1,075,375	$181.15	$194.8	**$544.2**
1.0%	600,768,000	-0.358	2,150,749	$181.15	$389.6	**$1,088.3**

10.2.3. 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 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 [318] while other fully pass-through PBMs have reported savings of as much as 30 percent.[319] As a result, in response to the proposed 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.[320]

10.2.4. Transfers From PBM Affiliated Pharmacies to Unaffiliated Pharmacies

The proposed 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 proposed rule, PBMs may choose to equalize treatment across all distribution channels which in turn may shift business from affiliated to non-affiliated pharmacies.

11. Costs

This proposed 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.[321] The statute, however, did not specifically name PBMs, generally, as covered service providers. 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.[322]

When questioned by Congress in 2023 regarding PBMs' compliance with Section 408(b)(2), PCMA responded that they believed their companies were in compliance and provided the appropriate disclosures related to direct and indirect compensation.[323] Additionally, several States have adopted disclosure requirements for PBMs regarding elements included in this proposed rule, including rebate payments, spread pricing and drug prices.[324] As such, the Department assumes that PBMs already compile and provide to various parties the information similar to what is required under this proposed 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 proposed rulemaking, will incur additional costs. Moreover, by providing disclosures at a more granular level prior to entering into a formal

[318] Sharon Faust, *Prepared Testimony Before the United States Judiciary Committee,* (May 11, 2025), *https://www.judiciary.senate.gov/imo/media/doc/2025-05-13_testimony_faust.pdf.*

[319] Alliance of Community Health Plans, *A Unique Approach: Transparent PBMs,* (April 2019), *https://achp.org/wp-content/uploads/PBM-Infographic_4.5.19.pdf.*

[320] Pharmaceutical Strategies Group, *2025 Trends in Drug Benefit Design Report,* (June 2025), *https://link.psgconsults.com/2025-trends-in-drug-benefit-design-report.*

[321] 134 Stat. 1182—Public Law 116–260.

[322] Field Assistance Bulletin No. 2021–03, *https://www.dol.gov/agencies/ebsa/employers-and-advisers/guidance/field-assistance-bulletins/2021-03.*

[323] 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).

[324] Government Accountability Office, *Prescription Drugs: Selected States' Regulation of Pharmacy Benefit Managers,* (March 2024), *https://www.gao.gov/assets/d24106898.pdf.*

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.

11.1. Rule Familiarization and Compliance Costs

The Department anticipates that the costs related to this proposed 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). The Department does not intend to develop a template disclosure form, instead expecting regulated entities to develop their own templates that conform to regulatory requirements, but we welcome comments regarding the potential value and composition of such a Department-developed template. 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 proposed rule in order to familiarize themselves with the new requirements and how they will impact them.[325] Large, self-insured group health plans with 1,000 or more employees are expected to review the rule themselves. In contrast, small, self-insured group health plans, including level-funded group health plans, and self-insured group health plans with less than 1,000 employees, are expected to utilize a TPA, issuer, or other service provider to review the proposed 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 proposed rule, and 20 hours for a TPA or issuer to review the rule on behalf of each self-insured group health plan.[326] The Department further assumes a wage rate of $181.06 per hour for the legal review[327] and that this burden would only be incurred in the first year. The Department requests comments on these assumptions.

PBMs would also need to review the proposed 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 proposed 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 proposed rule on behalf of PBMs at a wage rate of $181.06 per hour. The Department assumes this burden would only be incurred in the first year. Please see Table 11 for calculations and burden totals.

TABLE 11. Rule Familiarization Costs

	Number of Entities	Number of Hours per Entity	Total Hour Burden	Hourly Wage	Cost
	(A)	(B)	(C) = (A x B)	(D)	(E) = (A x B x C)
Self-insured group health plans with 1,000 or more employees	15,362	5	76,810	$181.06	$13,907,219
TPAs on behalf of client level-funded plans and self-insured group health plans with less than 1,000 employees	205	20	4,100	$181.06	$742,346
Issuers on behalf of client level-funded plans and self-insured group health plans with less than 1,000 employees	809	20	16,180	$181.06	$2,929,551
PBMs	73	20	1,460	$181.06	$264,348
First-year Total	**16,449**	-	**98,550**	-	**$17,843,463**

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

[326] 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.

[327] Internal DOL calculation based on 2025 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.*

required under the CAA and State laws.[328] 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, reimbursement rates, formulary placement incentives, and agreements with agents, affiliates and subcontractors. The Department requests comments on this assumption.

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 proposed 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 12, 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,[329] ACA Medical Loss Ratio (MLR) Reporting,[330] Medicare Part D Reporting Requirements,[331] and the Hospital Price Transparency Requirements.[332] Of these rules, the IT costs associated with Prescription Drug Data Collection rule seemed most analogous to this proposed 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 proposed rule, and the fact that the proposed 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 proposed 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 proposed rule. Based on these considerations, the Department estimates the average, first-year per-PBM cost for designing, developing, and implementing the IT system to be $1,000,000.[333] In subsequent years, the estimated per-PBM average cost for maintaining and updating the IT system is $200,000.[334] 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 requests comments on these assumptions.

[328] National Academy for State Health Policy, *State Pharmacy Benefit Manger Legislation.* Last accessed on July 11, 2025, see *https://nashp.org/state-tracker/state-pharmacy-benefit-manager-legislation/.*

[329] 86 FR 66662, *Prescription Drug and Health Care Spending,* (November 23, 2021), *https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending.*

[330] 77 FR 28790, *Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care* Act, (May 16, 2012), *https://www.federalregister.gov/documents/2012/05/16/2012-11753/medical-loss-ratio-requirements-under-the-patient-protection-and-affordable-care-act.*

[331] CMS, *Part D Reporting Requirements, https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/part-d-reporting-requirements.*

[332] 84 FR 65524, *Price Transparency Requirements for Hospitals To Make Standard Charges Public,* (November 27, 2019), *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.*

[333] 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 project management specialists 2,250 hours (at $126.72 per hour), business operations specialists 750 hours (at $120.40 per hour), as well as software and web developers, programmers, and testers 3,500 hours (at $171.89 per hour) to complete this task. The Department estimates the total burden per PBM will be approximately 6,500 hours, with an equivalent cost of approximately $977,035, rounded to $1,000,000. For all 73 PBMs, the total one-time first-year implementation and reporting burden is estimated to be 474,500 hours with an equivalent total cost of approximately $71,323,555.

[334] 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 project management specialists 500 hours (at $126.72 per hour), business operations specialists 50 hours (at $120.40 per hour), as well as software and web developers, programmers, and testers 750 hours (at $171.89 per hour) to perform these tasks. The Department estimates the total annual burden for each PBM will be 1,300 hours, with an equivalent cost of approximately $198,298, rounded to $200,000. For all 73 PBMs, the total annual maintenance and submission burden is estimated to be 94,900 hours with an equivalent total cost of approximately $14,475,718.

TABLE 12. 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	$1,000,000	$73,000,000
PBMs maintain and update the IT system (subsequent years)	73	$200,000	$14,600,000
Three-year Average Costs	**73**	**$466,667**	**$34,066,667**

11.2. Disclosure Costs

11.2.1. Number of Notices From PBMs

11.2.1.1 Number of Initial Notices From PBMs

The proposed 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.[335] Currently, 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 requests comments on this assumption.

11.2.1.2 Number of Semi-Annual Notices From PBMs

The proposed rule also requires that PBMs or other 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 estimates that PBMs or other covered service providers would submit these disclosures to each self-insured group health plan twice each year. The Department requests comments on these assumptions.

11.2.2. Number of Notices Upon Requests From PBMs

The proposed 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 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 requests comments on this assumption.

11.2.3. Number of Notices From Self-Insured Group Health Plans

11.2.3.1 Exemption for Responsible Plan Fiduciaries

The proposed rule also includes a proposed 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 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.[336] 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.

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. The Department assumes that approximately 10 notices will be submitted, based on the same experience that pension plans rarely submit these notices under the requirement in 29 CFR 2550.408b–2. The Department requests comments on this assumption. Please see Table 12 for the estimated number of disclosures.

11.2.3.2 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 proposal 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

[335] Scott McEachern and Patrick Cambel. ''PBM Contracts: Understand then Optimize. Milliman White Paper, August 2, 2020. *https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize.*

[336] Based on a review of the 2022 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.

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 proposed regulation 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 level-funded group health plans or 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 13 for calculations on the number of notices.

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TABLE 13. 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				
PBMs provide initial disclosures to plans whose contract is entered, extended, or renewed	1,150,583	33%	100%	1	383,528
PBMs provide missing/additional information requested by plans	1,150,583	33%	10%	1	38,353
PBM provides semiannual disclosures to plans	1,150,583	100%	100%	2	2,301,167
	Disclosures from Self-insured Group Health Plans				
Plans send request to PBMs to disclose other/missing information	1,150,583	33%	0.3%	1	1,151
Plan send notice to DOL after PBMs has not responded in 90 days	10	-	100%	1	10
	Self-insured Group Health Plans send audit requests to PBM				
Self-insured plans with 1,000 or more employees send requests for audits to PBMs	15,362	33%	100%	1	5,121
Issuers, on behalf of client level-funded plans and self-insured plans with less than	809	100%	100%		809

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11.2.4. Costs of Disclosures

11.2.4.1 Initial Disclosures

The Department acknowledges that the proposed 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 1,000 or more employees will generally require more time as these disclosures will need to be customized. In contrast, the Department assumes that disclosures for small plans, including level-funded group health plans and self-insured group health plans with less than 1,000 employees, will require less time as PBMs managing hundreds of small, self-insured group health plans often rely on standardized templates and batch processing. Therefore, for those small, self-insured group health plans whose contracts are initiated, extended, or renewed in a given year, the Department estimates it will take 15 minutes for a legal professional and a benefit specialist, at a composite wage rate of $155.10,[337] to prepare and send the disclosures. For large, self-insured group health plans, the Department estimates that it will take 30 minutes, due to the greater customization and review required. Please see Table 13 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 requests comments on these assumptions.

11.2.4.2 Semiannual Disclosures From PBMs

The proposed rule 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, disclosing the actual compensation that the PBM or other covered service provider received, under the specific categories that were estimated in the initial disclosures, as discussed earlier. This includes all direct compensation, rebate payments, spread compensation, 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 5 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. Please see Table 13 for calculations and burden.

11.2.4.3 Information Upon Request

Paragraph (i) of the proposal 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) of the proposal would require 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 13 for the estimated costs of disclosures.

11.2.4.4 Notice to PBMs and DOL

The exemption contained in paragraph (n) of the proposed 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.[338] This assumption is based on the Department's experience that it is rare for pension plans to submit a notice under the requirement

[337] The wage rate is calculated in the following manner: [[($181.06 for a legal professional × 0.5)) + ($129.14 for a benefits specialist × 0.5)] = $155.10.

[338] Based on a review of the 2022 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.

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.

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. 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 prepare and send the notice. Please see Table 14 for the estimated costs of disclosures.

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TABLE 14. Annual Disclosure Costs

	Number of Notices (first year)	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					
PBMs provide initial disclosures to self-insured group health plans					
Legal professionals and benefit specialists prepare disclosures for level-funded group health plans and self-insured group health plans with less than 1,000 employees	378,407	0.25	94,602	$155.10	$14,672,731
Legal professionals and benefit specialists prepare disclosures for level-funded group health plans and self-insured group health plans with 1,000 or more employees	5,121	0.50	2,561	$155.10	$397,134
PBMs provide missing/other information requested by self-insured group health plans					
Benefit specialists prepare and send information	38,353	0.25	9,588	$129.14	$1,238,227
PBMs provide semiannual disclosures to self-insured group health plans					
Benefit specialists prepare and send disclosures	2,301,167	0.25	575,292	$129.14	$74,293,177
Self-insured group health plans 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	1,151	0.25	288	$129.14	$37,160
Self-insured group health plans send notice to DOL after the PBM has not responded within 90 days					
Benefits specialists prepare and send notice	10	0.25	3	$129.14	$323
Total	**2,724,209**	**-**	**682,333**	**-**	**$90,638,751**

11.3. 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, including the responsibility of the PBM or other covered service provider to deliver all necessary information to conduct such an audit, is an essential part of the proposal's framework for establishing transparency in the marketplace for pharmacy benefit management services. The proposed regulation requires that the PBM or other covered service provider allow, not less than once per year, for the self-insured group health

plan to request such an audit for accuracy of any disclosures made to comply with the regulation.

While the cost of selecting an auditor and performing an audit of PBMs and other service providers is borne by the plan itself, 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 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.[339] The Department does not anticipate level-funded group health plans submitting a request themselves but expects all issuers or TPAs that market to those plans to request audit materials. The Department requests comments on these assumptions.

Given that self-insured group health plans are requesting the data required to assess the services provided and fees charged for their prescription drug benefits, the Department assumes that PBMs already have or have access to all information and data readily 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. Additionally, because this disclosure will also include contracts with agents, affiliates and service providers such as retail pharmacies and drug manufacturers, the PBM may also require additional legal assistance to put in place confidentiality agreements to prevent sharing of the disclosed information.

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. The Department also assumes that PBMs will rely on standardized templates and batch processing to prepare the audit request. Therefore, the Department estimates it will take 15 minutes for a benefit specialist at a TPA or issuer to prepare and send the audit request on the behalf of level-funded group health plans and self-insured group health plans with less than 1,000 employees. The Department also assumes it will take 2 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 $150.52.[340] This includes the time to retrieve documents, gather data and put in place any necessary confidentiality agreements. The Department requests comments on these assumptions.

Please see Table 15 for calculations and burden.

TABLE 15. Annual Audit Cost

	Number of Notices (first year)	Number of Hours Per Notice	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 1,000 or more employees send audit request					
Benefit specialists prepare and send audit request	5,121	0.5	2,561	$129.14	$330,663
Issuers send audit request on behalf of level-funded group health plans and self-insured group health plans with less than 1,000 employees					
Benefit specialists prepare and send audits request	1,403	0.25	351	$129.14	$45,296
PBMs prepare and disclose the needed info for the audit					
Benefit specialists and IT staff prepare for requested audit	6,524	2	13,048	$150.52	$1,963,985
Total	**6,524**		**15,959**	**-**	**$2,339,944**

11.4. 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 requests comments on this assumption.

[339] Janus Desquitado and Francis Ayson, PBM Best Practice Series: Pharmacy Benefit Claims Auditing, Milliman White Paper, September 21, 2023, *https://www.milliman.com/en/insight/pbm-best-practices-pharmacy-benefits-claims-auditing.*

[340] The wage rate is calculated in the following manner: [($129.14 for a benefits specialist × (½)) + ($171.89 for an IT Professional) × (½))] = $150.52.

11.5. Summary of Total Costs

The total costs associated with the proposed rule have been provided below in Table 16. In comparison, according to the SEC 10–k filings, CVS Caremark, Express Scripts, and Optum Rx respectively reported $162.5 billion,[341] $185.4 billion,[342] and $133.2 billion [343] in revenue in 2024, resulting in a total of $481.1 billion. Therefore, the total three-year estimated average cost for this proposed rule represents 0.03 percent of total revenue of the three largest PBMs.

TABLE 16. Summary of Total Costs

	First Year	Subsequent Year	Three-Year Average
Rule Familiarization	$17,843,463	$0	$5,947,821
IT Infrastructure	$73,000,000	$14,600,000	$34,066,667
Disclosure	$90,638,751	$90,638,751	$90,638,751
Audit	$2,339,944	$2,339,944	$2,339,944
Total Costs	**$183,822,158**	**$107,578,695**	**$132,993,183**

11.6. 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 baseline assumptions of 10 or 25 percent Please see Tables 17, 18, and 19 for the results of this sensitivity analysis.

[341] 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, (2024), *https://www.sec.gov/Archives/edgar/data/64803/000006480325000007/cvs-20241231.htm.*

[342] 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,* (2024), *https://d18rn0p25nwr6d.cloudfront.net/CIK-0001739940/64c4c39f-1b4e-4979-8b4a-bfc403377665.pdf.*).

[343] The Form 10–K directly reports revenue for Optum Rx. (*Source:* SEC, *Form 10–K, UnitedHealth Group. Annual Report,* (2024) *https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2024/UNH-Q4-2024-Form-10-K.pdf.*).

TABLE 17. Sensitivity Analysis of IT Infrastructure Costs

Adjustment	Number of PBMs	Average Costs	Total Cost	Change in Cost
	(A)	(B)	(C) = A x B	(D) = (C) – Baseline Cost
Total costs in first year: Design, develop, and implement necessary IT system changes to collect and report the required data				
Lower estimate (25%)	73	$750,000	$54,750,000	-$18,250,000
Lower estimate (10%)	73	$900,000	$65,700,000	-$7,300,000
Baseline assumption	***73***	***$1,000,000***	***$73,000,000***	***$0***
Higher estimate (10%)	73	$1,100,000	$80,300,000	$7,300,000
Higher estimate (25%)	73	$1,250,000	$91,250,000	$18,250,000
Total costs in second year: Maintain and update IT systems, provide ongoing quality assurance, and report the required data				
Lower estimate (25%)	73	$150,000	$10,950,000	-$3,650,000
Lower estimate (10%)	73	$180,000	$13,140,000	-$1,460,000
Baseline assumption	***73***	***$200,000***	***$14,600,000***	***$0***
Higher estimate (10%)	73	$220,000	$16,060,000	$1,460,000
Higher estimate (25%)	73	$250,000	$18,250,000	$3,650,000
Three-year average costs				
Lower estimate (25%)	73	$350,000	$25,550,000	-$8,516,667
Lower estimate (10%)	73	$420,000	$30,660,000	-$3,406,667
Baseline assumption	***73***	***$466,667***	***$34,066,667***	***$0***
Higher estimate (10%)	73	$513,333	$37,473,333	$3,406,667
Higher estimate (25%)	73	$583,333	$42,583,333	$8,516,667

TABLE 18. Sensitivity Analysis of Sending Disclosure Notices

Activity	Notices	Hour per entity	Hourly Wage Rate	Equivalent Cost	Change in Cost
Cost for PBMs to prepare initial disclosure notices to send to level-funded group health plans and self-insured health plans with less than 1,000 employees					
	378,407	0.08	$155.10	$4,890,910	-$9,781,821
	378,407	0.17	$155.10	$9,781,821	-$4,890,910
Baseline assumption	***378,407***	***0.25***	***$155.10***	***$14,672,731***	***$0***
	378,407	0.33	$155.10	$19,563,642	$4,890,910
	378,407	0.50	$155.10	$29,345,463	$14,672,731
	378,407	1.00	$155.10	$58,690,926	$44,018,194
Cost for PBMs to prepare initial disclosure notices by PBMs to send to self-insured group health plans with more than 1,000 employees					
	5,121	0.08	$155.10	$66,189	-$330,945
	5,121	0.17	$155.10	$132,378	-$264,756
	5,121	0.25	$155.10	$198,567	-$198,567
Baseline assumption	***5,121***	***0.50***	***$155.10***	***$397,134***	***$0***
	5,121	0.75	$155.10	$595,700	$198,567
	5,121	1	$155.10	$794,267	$397,134
Cost for self-insured group health plans to request to disclose missing/other information					
	38,353	0.08	$129.14	$412,742	-$825,484
	38,353	0.17	$129.14	$825,484	-$412,742
Baseline assumption	***38,353***	***0.25***	***$129.14***	***$1,238,227***	***$0***
	38,353	0.50	$129.14	$2,476,453	$1,238,227
	38,353	0.75	$129.14	$3,714,680	$2,476,453
	38,353	1	$129.14	$4,952,906	$3,714,680
Cost for PBMs to send semiannual disclosure notices by PBMs					
	2,301,167	0.08	$129.14	$24,764,392	-$49,528,784
	2,301,167	0.17	$129.14	$49,528,784	-$24,764,392
Baseline assumption	***2,301,167***	***0.25***	***$129.14***	***$74,293,177***	***$0***
	2,301,167	0.50	$129.14	$148,586,353	$74,293,177
	2,301,167	0.75	$129.14	$222,879,530	$148,586,353
	2,301,167	1	$129.14	$297,172,706	$222,879,530
Costs for self-insured group health plans to send request to PBM to disclose missing/other information					
	1,151	0.08	$129.14	$12,387	-$24,773
	1,151	0.17	$129.14	$24,773	-$12,387
Baseline assumption	***1,151***	***0.25***	***$129.14***	***$37,160***	***$0***
	1,151	0.50	$129.14	$74,320	$37,160
	1,151	0.75	$129.14	$111,480	$74,320
	1,151	1.00	$129.14	$148,640	$111,480
Cost for self-insured group health plans to send notice to DOL after the PBM has not responded within 90 days					

	10	0.08	$129.14	$108	-$215
	10	0.17	$129.14	$215	-$108
Baseline assumption	***10***	***0.25***	***$129.14***	***$323***	***$0***
	10	0.50	$129.14	$646	$323
	10	0.75	$129.14	$969	$646
	10	1	$129.14	$1,291	$969
Lower Bound Cost	-	-	-	**$30,146,728**	**-$60,492,023**
Baseline Assumption Cost	-	-	-	**$90,638,751**	**$0**
Upper Bound Cost	-	-	-	**$361,760,737**	**$271,121,986**

TABLE 19. Sensitivity Analysis of Audit Costs

Activity	Notices	Hour per entity	Hourly Wage rate	Equivalent Cost	Change in Cost
	(A)	(B)	(C)	(D) = (A x B x C)	(E) = (D) – Baseline Cost
Cost for self-insured group health plans to send audit requests to PBMs					
	5,121	0.08	$129.14	$55,110	-$275,552
	5,121	0.17	$129.14	$110,221	-$220,442
Baseline assumption	***5,121***	***0.50***	***$129.14***	***$330,663***	***$0***
	5,121	0.75	$129.14	$495,994	$165,331
	5,121	1.00	$129.14	$661,326	$330,663
Cost for issuers to send audit requests to PBMs					
	1,403	0.08	$129.14	$15,099	-$30,197
	1,403	0.17	$129.14	$30,197	-$15,099
Baseline assumption	***1,403***	***0.25***	***$129.14***	***$45,296***	***$0***
	1,403	0.50	$129.14	$90,592	$45,296
	1,403	0.75	$129.14	$135,888	$90,592
	1,403	1.00	$129.14	$181,183	$135,888
Cost for PBMs to prepare requested information for audits					
	6,524	0.5	$150.52	$490,996	-$1,472,989
	6,524	1	$150.52	$981,992	-$981,992
Baseline assumption	***6,524***	***2***	***$150.52***	***$1,963,985***	***$0***
	6,524	3	$150.52	$2,945,977	$981,992
	6,524	4	$150.52	$3,927,970	$1,963,985
Lower Bound Cost	-	-	-	**$561,205**	**-$1,778,738**
Baseline Assumption Cost	-	-	-	**$2,339,944**	**$0**
Upper Bound Cost	-	-	-	**$4,770,479**	**$2,430,535**

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12. Uncertainty

12.1. Uncertainty Related to Level-Funded Group Health Plans

The Department has generally treated the service provider arrangements for level-funded group health plans as similar to those of self-insured group health plans. The form of the arrangements would affect the costs associated with providing disclosure. Level-funded group health plans tend to be significantly smaller than purely self-insured group health plans, therefore, while it is likely that larger, self-insured group health plans may contract directly with PBMs, smaller level-funded group health plans may contract with a TPA for provision of their health benefits, including administering payment of hospital charges, medical/surgical claims and prescription coverage, as well as procuring reinsurance. In this case, PBMs would be a subcontractor to the TPA for level-funded group health plans rather than a contractor with the plan itself.

While under this scenario, PBMs would still be responsible for providing disclosure information regarding their compensation to the TPA as the covered service provider, it is less clear whether it would impact the manner and cost of providing this information. PBMs may instead provide more aggregated data to issuers who would in turn provide more granular disclosures to the level-funded group health plans. It is unclear whether this would result in additional costs or cost savings to level-funded group health plans, compared to the Department's current assumptions.

12.2. Uncertainty Over Rebates' Impact on Costs

The Department expects that the proposed 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.[344]

12.3. Uncertainty Over Other PBM Practices on Costs

The proposed 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 mechanisms are opaque,[345] 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 clawbacks 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.

12.4. Uncertainty Over the Impact of the Audit Rights on the Number of Audits Requested

The proposed 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 proposed 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 to the contract, or if the plan frequently changes benefits, then it is best to audit every year.'' [346] 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 proposed rule would provide plan fiduciaries with additional information relevant to oversight. However, it is uncertain whether the proposed 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.

12.5. 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.[347] Since the proposed 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 smaller PBMs,

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

[345] 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.*

[346] Janus Desquitado and Francis Ayson, PBM Best Practice Series: Pharmacy Benefit Claims Auditing, Milliman White Paper, September 21, 2023, *https://www.milliman.com/en/insight/pbm-best-practices-pharmacy-benefits-claims-auditing.*

[347] 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.*

which could reduce competition if larger PBMs garner greater market share as a result.'' [348]

The Department notes, however, that those PBMs that already leverage transparency in their contracts may not have their revenues significantly impacted by the proposed 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 proposed rule would impact market consolidation in the PBM space and if so, in what direction.

12.6. Uncertainty Over the Longevity of the Impact of Proposed Rule

The Department, when considering the impact of this proposed 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.[349] 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.'' [350] 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 proposed rule would abate over time. The Department seeks comments on this assumption.

13. Alternatives

In addition to the regulatory approach outlined in the proposed rule, the Department considered an alternative approach during the development of the proposed rule. It is discussed in greater detail below.

13.1. 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 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 fully-insured group market, where prescription drugs benefits are bundled rather than separately carved out.[351] As such, it is not clear that responsible plan fiduciaries would find the disclosures required under this proposed 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 proposal 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.

13.2. Exempting Smaller Entities

The Department considered exempting smaller entities, such as level-funded group health plans which are self-funded arrangements that utilize rich stop-loss policies to emulate characteristics of fully insured arrangements, such as predictable spending. Smaller level-funded plans, in particular, tend to rely on TPAs and issuers to carry out their claims, administrative, and pharmacy benefit management functions. In such a case, while the entity contracting or arranging with the group health plan is not providing the services itself, it would be responsible for making the disclosures to the responsible plan fiduciary required under the proposal, and therefore must be able to obtain information from the provider performing the pharmacy benefit management services necessary for those disclosures.

The Department believes that providing an exemption for these smaller entities would risk reducing transparency in a segment of market where disclosures are most needed. The Department estimates there are 1,031,098 level-funded group health plans, accounting for 90 percent of affected ERISA-covered group health plans. For these reasons, the Department determined that a small entity exemption would not achieve the intended goals of the proposed rules.

13.3. Annual Disclosures From PBMs

The Department did consider requiring annual disclosures from PBMs but determined that this information needed to be provided more frequently. Given that level-funded group health plans account for approximately 90 percent of affected ERISA-covered group health plans, the timing of the required disclosures has market-level effects. 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, the Department is requiring 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

[348] Congressional Budget Office, *Cost Estimate: S. 1895, Lower Health Care Cost Act,* July 16, 2019, *https://www.cbo.gov/system/files/2019-07/s1895_0.pdf.*

[349] Congressional Budget Office, *Cost Estimate: S. 1339, Pharmacy Benefit Manager Reform Act,* December 5, 2024, *https://www.cbo.gov/system/files/2024-12/s1339.pdf.*

[350] Congressional Budget Office, *Cost Estimate: S. 1339, Pharmacy Benefit Manager Reform Act,* December 5, 2024, *https://www.cbo.gov/system/files/2024-12/s1339.pdf.*

[351] Gray, Charles, Abby E. Alpert, and Neeraj Sood, *Disadvantaging Rivals: Vertical Integration in the Pharmaceutical Market,* (2023), No. w31536. National Bureau of Economic Research, *https://www.nber.org/system/files/working_papers/w31536/w31536.pdf.*

contract or arrangement initiation date. The Department is seeking comments on the proposed timing requirements.

13.4. 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. Instead of an affirmative requirement, the Department determined to request public comment on that option.

13.5. Conclusion

The proposed rule is intended to allow responsible plan fiduciaries of level-funded and 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 proposed 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.

F. Paperwork Reduction Act

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to allow the general public and Federal agencies to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA).[352] This helps to ensure that the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

Currently, the Department is soliciting comments concerning the proposed information collection request (ICR) included in the *PBM Fee Disclosure Regulation under 408(b)(2).* To obtain a copy of the ICR, contact the PRA addressee shown below or go to *https://www.RegInfo.gov.*

The Department has submitted a copy of the proposed rule to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Department and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden for the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (for example, permitting electronically delivered responses).

Commenters may send their views on the Department's PRA analysis in the same way they send comments in response to the proposed rule (for example, through the *www.regulations.gov* website), including as part of a comment responding to the broader NPRM.

PRA Addressee: Address requests for copies of the ICR to PRA Clearance Officer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210; *ebsa.opr@dol.gov* (*https://www.reginfo.gov/public/do/PRAMain*).

For a full discussion of burden related to this information collection please see the supporting statement which is part of the ICR available at *https://www.reginfo.gov/public/do/PRAMain*.

The proposed rule is intended to help responsible plan fiduciaries better monitor prescription drug costs and benefit administration. The proposed 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 20 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.

[352] 44 U.S.C. 3506(c)(2)(A) (1995).

TABLE 20. Summary of Hour and Cost Burden

	Hour Burden	Cost Equivalent of Hour Burden	Cost Burden
IT Infrastructure (first year)	474,500	$73,000,000	$0
IT Infrastructure (subsequent years)	94,900	$14,600,000	$0
Disclosure (annual)	682,333	$90,638,751	$0
Audit (annual)	15,959	$2,339,944	$0
First Year Total	**1,172,792**	**$165,978,695**	**$0**
Subsequent Year Total	**793,192**	**$107,578,695**	**$0**
Three-Year Average Total	**919,725**	**$127,045,362**	**$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–New.

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 1,151,392.

Estimated Number of Annual Responses: 2,730,806.

Frequency of Response: Annual, Semi-annual.

Estimated Total Annual Burden Hours: 919,725.

Estimated Total Annual Burden Cost: $0.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) [353] 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 603 [354] of the RFA requires the agency to present an initial regulatory flexibility analysis of the proposed rule.

The Department has limited data to determine if this proposed rule would have a significant impact on a substantial number of small entities. The Department has prepared this initial regulatory flexibility analysis (IRFA) and requests data or other information it would need to make a final determination.

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 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 small, self-insured group health plans to compare different PBM services, due to the non-transparent nature of the information.[355]

Employers that sponsor health plans and other responsible plan fiduciaries have expressed concerns about PBM practices, especially regarding rebates, transparency, and the complexity of contracts. Many plan sponsors believe that PBMs' goals are not aligned with the plans they service, and they often do not fully understand their self-insured group health plans' contracts with PBMs.[356] A 2024 survey found that for firms offering health benefits with 500 or more employees, 37 percent had no idea how much of PBM negotiated rebates they received.[357] Responsible plan fiduciaries of small self-insured group health plans, in particular, often have limited access to pricing information compared to larger self-insured group health plans, which receive higher retail discounts on brand and generic prescription drugs, pay lower dispensing fees, and are more likely to receive manufacturer rebates than small self-insured group health plans.[358]

2. Objective of the Rule

The proposed rule aims to improve transparency in PBM arrangements by requiring disclosures similar to those in the Department's 2012 pension disclosure regulation. Covered service providers, including PBMs, must disclose detailed information to responsible plan fiduciaries to 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,

[353] 5 U.S.C. 601 *et seq.* (1980).

[354] 5 U.S.C. 603 (1980).

[355] 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, (2021), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984670/.*

[356] National Pharmaceutical Council, *Toward Better Value: Employer Perspectives on What's Wrong with the Management of Prescription Drug Benefits and How to Fix it,* (2017), *https://www.npcnow.org/sites/default/files/media/npc-employer-pbm-survey-final.pdf.*

[357] KFF, *2024 Employer Health Benefits Survey,* (Oct. 9, 2024), *https://www.kff.org/report-section/ehbs-2024-section-13-employer-practices-provider-networks-coverage-for-glp-1s-abortion-and-family-building-benefits/.*

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

including manufacturer payments, spread pricing, copay claw-backs, 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. They must also provide additional information upon request from the responsible plan fiduciary.

The proposed 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 proposed rule would increase transparency in PBM compensation arrangements and enable self-insured group health plans to better understand these practices. This increased transparency would help responsible plan fiduciaries to compare offerings across PBMs more effectively, helping them enter into the most appropriate PBM contracts for their needs. The proposal is intended to allow fiduciaries of level-funded and 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).

3. Affected Small Entities

The number of small, affected entities are discussed in greater detail later in this IRFA.

3.1. Group Health Plans

For the purposes of the IRFA, the Department considers employee benefit plans with fewer than 100 participants to be small entities.[359] 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 CFR 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.

As discussed in subsection 7.1 of the RIA, the proposed rule would affect all self-insured ERISA-covered group health plans. The Department estimates that the proposed rule would affect approximately 1,031,098 level-funded group health plans.[360] The number of affected level-funded group health plans by participant count has been provided below in Table 21.[361]

TABLE 21. Number of Affected Level-Funded Group Health Plans by Participant Count

Participant Count	Less than 10 participants	10 to 24 participants	25 to 99 participants	Total
Level-Funded Group Health Plans	544,035	260,432	226,631	1,031,098

3.2. TPAs and Issuers

The Department also estimates that the proposed rule will indirectly affect 205 TPAs and 373 issuers in the group market with 809 issuers/State combinations.[362] 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.

Health insurance companies are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $47 million or less are considered small entities for this NAICS code.[363] The Department believes that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from the CMS Medical Loss Ratio (MLR) annual report submissions for the 2023 reporting year, approximately 65 [364] out of 373 health insurance companies had total premium revenue of $47 million or less.[365] The Department estimates that approximately 80 percent of these small issuers belong to larger holding groups

[359] The Department consulted with the Small Business Administration in making this determination, as required by 5 U.S.C. 603(c) and 13 CFR 121.903(c). Memorandum received from the U.S. Small Business Administration, Office of Advocacy on July 10, 2020.

[360] The Department estimates that 42 percent of ERISA-covered group health plans with less than 100 participants are level-funded, based on the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS–IC), the 2021 County Business Patterns from the Census Bureau and the 2024 KFF Employer Health Benefits Survey. Therefore, 2,454,996 ERISA-covered group health plans × 42 percent = 1,031,098 level-funded group health plans.

[361] Plan assets are not an appropriate measure for health plans, as many self-insured plans pay benefits directly from the employer's general assets. Therefore, this analysis uses participant count as a proxy for plan size.

[362] 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.*

[363] SBA, *Table of Size Standards, https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf,* as of March 2023.

[364] Projection using 2023 MLR Data.

[365] Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data, https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.*

based on the MLR data, and many, if not all, of these small companies are likely to have non-health lines of business that result in their revenues exceeding $47 million. Therefore, the Department assumes approximately 20 percent, or 13, of the 65 potential small issuers are in fact small issuers for purposes of this analysis. The Department believes this is an overestimate, as many if not all of these small issuers are likely to have non-health lines of business that result in their revenues exceeding $47 million, but the Department uses 13 small issuers for purposes of this analysis. The Department seeks comments on these estimates.

3.3. Participants, Beneficiaries, and Enrollees

There are approximately 14.8 million participants and beneficiaries in small self-insured and level-funded ERISA-covered group health plans.[366] According to the 2022 Center for Disease Control's (CDC) National Center for Health Statistics, United States, 64.1 percent of individuals under the age of 65 with private health insurance used a prescription medication in the past year.[367] Therefore, the Department estimates that approximately 9.5 million participants and beneficiaries in these self-insured group health plans will be affected by the proposed rule.

3.4. PBMs

In 2023, there were 73 full-service PBMs in the marketplace.[368] 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.[369] 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, CVS Caremark, Express Scripts, and Optum Rx respectively reported $162.5 billion,[370] $185.4 billion,[371] and $133.2 billion [372] in revenue in 2024, 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 and that few PBMs have annual receipts levels below 25 percent of the SBA threshold. The Department requests comments on this assumption and would appreciate any data to inform the Department on the size distribution of PBMs by revenue and clients served.

4. Cost of Proposed Rule

The Department expects small PBMs to review the proposed rule, evaluate their current disclosure practices, and make any necessary changes to ensure compliance. Increased transparency may reveal revenue strategies such as rebates and spread pricing, causing some PBMs to shift toward fee-based compensation models and renegotiate contracts with level-funded group health plans, manufacturers, and wholesalers. Small issuers, TPAs, and level-funded group health plans are also expected to review the proposed requirements for compliance.

Under the proposed 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 level-funded plans are not expected to make these requests directly, the Department anticipates that issuers or TPAs providing services to self-insured group health plans will submit audit requests on their behalf.

4.1. Illustration of Costs for Small PBMs

Tables 22 and 23 illustrate how the estimated costs for PBMs compare to revenue in the first year and subsequent years, respectively. Table 22 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.

It is important to note that this illustration is not intended to reflect current market conditions. 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 proposed rule's costs for most PBMs are likely less than three percent of revenues in the first year and two percent in subsequent years. The Department requests 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 for.

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[366] Employee Benefits Security Administration, Health Insurance Coverage Bulletin and Abstract of Auxiliary Data for the March 2023 Annual Social and Economic Supplement to the Current Population Survey, (August 30, 2024), *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf.*

[367] Centers for Disease Control and Prevention, National Center for Health Statistics, *Prescription Medication Use Among Adults,* United States (2023), *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.*

[368] 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.

[369] SBA, *Table of Size Standards, https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf,* as of March 2023.

[370] 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,* (2024), *https://www.sec.gov/Archives/edgar/data/64803/000006480325000007/cvs-20241231.htm.*

[371] 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,* (2024), *https://d18rn0p25nwr6d.cloudfront.net/CIK-0001739940/64c4c39f-1b4e-4979-8b4a-bfc403377665.pdf.*)

[372] The Form 10–K directly reports revenue for Optum Rx. (*Source:* SEC, *Form 10–K, UnitedHealth Group, Annual Report,* (2024) *https://www.unitedhealthgroup.com/content/dam/UHG/PDF/investors/2024/UNH-Q4-2024-Form-10-K.pdf.*

TABLE 22. 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	$3,621 [a]	0.008%	0.011%	0.016%	0.032%	0.080%
IT Infrastructure	$1,000,000 [b]	2.198%	2.930%	4.396%	8.791%	21.978%
Disclosure [c]						
Servicing 50 Plans	$4,586	0.010%	0.013%	0.020%	0.040%	0.101%
Servicing 100 Plans	$9,171	0.020%	0.027%	0.040%	0.081%	0.202%
Servicing 150 Plans	$13,757	0.030%	0.040%	0.060%	0.121%	0.302%
Servicing 200 Plans	$18,342	0.040%	0.054%	0.081%	0.161%	0.403%
Audit [d]						
Servicing 50 Plans	$15,052	0.033%	0.044%	0.066%	0.132%	0.331%
Servicing 100 Plans	$30,104	0.066%	0.088%	0.132%	0.265%	0.662%
Servicing 150 Plans	$45,156	0.099%	0.132%	0.198%	0.397%	0.992%
Servicing 200 Plans	$60,208	0.132%	0.176%	0.265%	0.529%	1.323%
Total						
Servicing 50 Plans	**$1,023,259**	**2.249%**	**2.999%**	**4.498%**	**8.996%**	**22.489%**
Servicing 100 Plans	**$1,042,896**	**2.292%**	**3.056%**	**4.584%**	**9.168%**	**22.921%**
Servicing 150 Plans	**$1,062,534**	**2.335%**	**3.114%**	**4.670%**	**9.341%**	**23.352%**
Servicing 200 Plans	**$1,082,172**	**2.378%**	**3.171%**	**4.757%**	**9.514%**	**23.784%**

Note:

[a] Calculated as 20 hours per PBM x an hourly labor cost of $181.06.

[b] Calculated as an hourly labor cost of $126.72 x 2,250 hours + an hourly labor cost of $120.40 business operations specialists x 750 hours + an hourly labor cost of $171.89 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 $155.10 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 $129.14 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 $129.14 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 $150.52 x 1/3 x the number of self-insured group health plans serviced by the PBM.

TABLE 23. 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	$200,000 [a]		0.440%	0.586%	0.879%	1.758%	4.396%
Disclosure Cost [b]							
Servicing 50 Plans	$4,586		0.010%	0.013%	0.020%	0.040%	0.101%
Servicing 100 Plans	$9,171		0.020%	0.027%	0.040%	0.081%	0.202%
Servicing 150 Plans	$13,757		0.030%	0.040%	0.060%	0.121%	0.302%
Servicing 200 Plans	$18,342		0.040%	0.054%	0.081%	0.161%	0.403%
Audit [c]							
Servicing 50 Plans	$15,052		0.033%	0.044%	0.066%	0.132%	0.331%
Servicing 100 Plans	$30,104		0.066%	0.088%	0.132%	0.265%	0.662%
Servicing 150 Plans	$45,156		0.099%	0.132%	0.198%	0.397%	0.992%
Servicing 200 Plans	$60,208		0.132%	0.176%	0.265%	0.529%	1.323%
Total							
Servicing 50 Plans	**$219,638**		**0.483%**	**0.644%**	**0.965%**	**1.931%**	**4.827%**
Servicing 100 Plans	**$239,275**		**0.526%**	**0.701%**	**1.052%**	**2.104%**	**5.259%**
Servicing 150 Plans	**$258,913**		**0.569%**	**0.759%**	**1.138%**	**2.276%**	**5.690%**
Servicing 200 Plans	**$278,550**		**0.612%**	**0.816%**	**1.224%**	**2.449%**	**6.122%**

Note:

[a] Calculated as 73 PBMs x an hourly labor cost of $126.72 x 500 hours + an hourly labor cost of $120.40 business operations specialists x 50 hours + an hourly labor cost of S171.89 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 $155.10 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 $129.14 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 $129.14 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 $150.52 x 1/3 x the number of self-insured group health plans serviced by the PBM.

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4.2. Illustration of Costs for Small Self-Insured Group Health Plans

Similarly, Table 24 illustrates how the estimated costs for self-insured group health plans compare to plan premiums in each year by the number of participants. This illustration assumes that a self-insured group health plan's premiums are equal to the number of participants multiplied by the weighted average of annual health insurance premiums for family and single coverage. In this analysis, the Department estimates average annual premiums to be $14,104.[373]

[373] According to the 2023 Medical Expenditure Panel Survey Insurance Component (MEPS–IC), the average annual health insurance premiums in 2023 for self-insured plans were $8,363 for single coverage (represents 55 percent of enrollees), $16,495 for employees-plus-one coverage (represents 19 percent of enrollees), and $24,596 for family coverage (represents 26 of enrollees). Based on these shares, the weighted average annual self-insured premiums is $14,104.

Under the proposed rule, small, self-insured group health plans would incur costs (1) if they send a request to the PBM for missing information, (2) if they send a request to the Department notifying that the aforementioned information has not been disclosed within 90 calendar days, or (3) if they request an audit of the PBM or other covered service provider.

It is important to note that as explained in Section 11.2 of the RIA, these costs will not necessarily be incurred by all self-insured group health plans every year. In the RIA, the Department assumed that only ten percent of arrangements may experience an omission or error that will require the responsible plan fiduciary to send the request to the PBM and other covered service providers, only 10 notices will be submitted the Department, and 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. The Department requests comments on how this may differ for small, self-insured group health plans.

The Department expects that small, self-insured group health plans would rely on TPAs to review the proposed rule and that some small, self-insured group health plans may also rely on TPAs to send audit requests. Some of these TPAs may be considered small entities. However, the Department expects that these TPAs would pass along these costs to self-insured group health plans. The Department requests comments on what functions small, self-insured group health plans would perform in-house versus relying on a TPA, how large any costs passed along to small, self-insured group health plans would be, and how many of these TPAs would be small entities.

As such, this illustration likely overestimates the average costs to self-

insured group health plans as a percentage of premiums. Nevertheless, even as an overestimate, the costs borne by self-insured group health plans are expected to account for a small proportion of annual premiums.

TABLE 24. Per Plan Costs as a Percentage of Premiums

	Per-Entity Cost	Cost as Average Assets for Plans with 100 Participants	Cost as Average Assets for Plans with 75 Participants	Cost as Average Assets for Plans with 50 Participants	Cost as Average Assets for Plans with 25 Participants	Cost as Average Assets for Plans with 10 Participants
Average Premiums by Plan Size		$1,410,400	$1,057,800	$705,200	$352,600	$141,040
Disclosure	$64.57	0.005%	0.006%	0.009%	0.018%	0.046%
Audit	$64.57	0.005%	0.006%	0.009%	0.018%	0.046%
Total	**$129.14**	**0.009%**	**0.012%**	**0.018%**	**0.037%**	**0.092%**

5. Alternatives

The Department considered whether smaller entities, such as level-funded group health plans, should be exempted. Since smaller level-funded plans often depend on TPAs and insurers to handle claims, administrative, and pharmacy benefit management. The Department acknowledges that entity contracting or arranging with the group health plan is not performing these functions themselves. However, the contracting entity would still be responsible for making disclosures to the responsible plan fiduciary required under the proposal and obtaining information from the provider performing the pharmacy benefit management services necessary for those disclosures.

The Department believes that providing an exemption for these smaller entities would risk reducing transparency in a segment of market where disclosures are most needed. The Department estimates there are 1,031,098 level-funded group health plans, accounting for 90 percent of affected ERISA-covered group health plans. As a result, the Department determined that a small entity exemption would not achieve the intended goals of the proposed rules.

6. Duplicate, Overlapping, or Relevant Federal Rules

There are no duplicate, overlapping, or relevant Federal rules.

H. 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.[374] 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.

I. 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.[375] 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 proposed rule.

The proposed rule does not have federalism implications because it has no 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. 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. The Department acknowledges that the proposed rule may have some implications for States, particularly if the proposed rule is found to preempt State laws affecting PBMs providing services to self-insured group health plans. The Department welcomes input from affected States regarding this assessment.

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 is proposing to amend part 2550 of subchapter F of chapter XXV of title 29 of the Code of Federal Regulations as follows:

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 and Secretary of Labor's Order No. 1–2011, 77 FR 1088 (January 9, 2012). Sec. 102, Reorganization Plan No. 4 of 1978, 5 U.S.C. App. at 727 (2012). Sec. 2550.401c–1 also issued under 29 U.S.C. 1101. Sec. 2550.404a–1 also issued under sec. 657, Pub. L. 107–16, 115 Stat 38. Sec. 2550.404a–2 also issued under sec. 657 of Pub. L. 107–16, 115 Stat. 38. Sections 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:

[374] 2 U.S.C. 1501 *et seq.* (1995).

[375] *Federalism,* 64 FR 153 (Aug. 4, 1999).

§ 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 disclosure requirements of this section are satisfied.

(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, 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 insurance issuer as defined in § 2590.701–2 of this chapter.

(c) *Covered service provider.* (1) For purposes of this section, a ''covered service provider'' means a service provider that enters into 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, agent, or 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.

(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) Processing and payment of claims for prescription drugs.

(v) Performing utilization review and management, including the processing of prior authorization requests for drugs, step therapy protocols, patient compliance analyses, conducting therapeutic intervention, and administering generic substitution programs.

(vi) Adjudicating appeals or grievances related to the covered plan's prescription drug benefits.

(vii) Recordkeeping related to the covered plan's prescription drug benefits; and

(viii) In conjunction with any of these other services, 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 (12) 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, 30 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 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.

(3) *Manufacturer payments.* A description of the amount of any payment, both in the aggregate and for each drug on the formulary, reasonably expected to be paid on a quarterly basis by the manufacturer or an aggregator to the covered service provider, an affiliate, an agent, or subcontractor in connection with the service contract or arrangement, specifying both the amount that will be passed on to the 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.

(4) *Spread compensation.* A description of the quarterly amount of spread compensation reasonably expected to be received by the covered service provider, an affiliate, an agent, or subcontractor in connection with the service contract or arrangement. For purposes of this paragraph (e)(4), spread compensation is defined as the difference between the negotiated rate reasonably expected to be paid by the covered plan to the covered service provider, an affiliate, an agent, or subcontractor and the negotiated rate reasonably expected to be paid by such entity to the pharmacy for dispensing drugs, both in the aggregate and for each drug on the formulary, and for each pharmacy channel (*i.e.,* retail, mail order, and specialty pharmacy).

(5) *Copay claw-backs.* A description of the quarterly amount of copay claw-back compensation reasonably expected to be recouped from a pharmacy by a covered service provider, an affiliate, an agent, or subcontractor in connection with prescription drugs dispensed under the service contract or

arrangement, specifying the anticipated total number of transactions resulting in recoupment. For purpose of this paragraph (e)(5), 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.

(6) *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 or other party in connection with prescription drugs dispensed under the service contract or arrangement, specifying the quarterly 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 and the amount that will be passed on to the plan and, if applicable, plan sponsor.

(7) *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.

(8) *Description of other compensation.* To the extent not already disclosed under paragraphs (e)(1) through (7) of this section—

(i) A description of all compensation that the covered service provider, an affiliate, an agent, or a subcontractor reasonably expects to receive on a quarterly basis in connection with the service contract or arrangement;

(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.

(9) *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, 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)(9)(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 quarterly basis) disclosed pursuant to paragraph (e)(3) of this section, adjusted for any increases previously disclosed under this paragraph (e).

(10) *Drug pricing methodology.* A description of the net cost to the covered plan of each drug on the formulary, 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 cost the covered plan will pay for each drug on the formulary, for each pharmacy channel, along with an objective means to verify the accuracy.

(11) *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). Along with this statement, such entity must disclose any activity or policy 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.

(12) *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 no later than 30 calendar days after the end of each six-month period beginning on the date the service contract or arrangement is entered, the following information with respect to the preceding six-month period:

(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 on a quarterly basis in connection with the service contract or arrangement.

(2) *Manufacturer payments.* A description of all payments, both in the aggregate and for each drug on the formulary, paid on a quarterly basis by a manufacturer or aggregator to the covered service provider, an affiliate, an agent, or a subcontractor in connection with 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) *Spread compensation.* A description of all spread compensation (within the meaning of paragraph (e)(4) of this section) received on a quarterly basis by a covered service provider, an affiliate, an agent, or subcontractor in connection with the service contract or arrangement, both in the aggregate and for each drug on the formulary, and for

each pharmacy channel (*i.e.,* retail, mail order, and specialty pharmacy).

(4) *Copay claw-backs.* A description of all amounts of copay claw-back compensation (as described in paragraph (e)(5) of this section) recouped on a quarterly basis from a pharmacy by a covered service provider, an affiliate, an agent, or subcontractor in connection with prescription drugs dispensed under the service contract or arrangement, specifying the total number of transactions.

(5) *Price protection agreements.* A description of all amounts received on a quarterly basis by the covered service provider, an affiliate, an agent, or subcontractor pursuant to any inflation protection or price protection agreements that the covered service provider, an affiliate, an agent, or subcontractor entered with any drug manufacturer or other party 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.

(6) *Other compensation.* To the extent not already disclosed under paragraphs (g)(1) through (5) of this section—

(i) All compensation that the covered service provider, an affiliate, an agent, or subcontractor received in connection with the service contract or arrangement;

(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.

(7) *Overage explanation.* If any category of compensation described in this paragraph (g), in the aggregate, materially exceeds the corresponding 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)(7), 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.

(8) *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, 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, subject to reasonable confidentiality agreements to prevent redisclosure of such information.

(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.

(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 may be 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.

(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.* 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 to execute reasonable confidentiality agreements preventing redisclosure by such parties.

(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 into, or 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.

(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.

(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 [60 days after date of publication of final rule].

(2) This section shall apply to plan years beginning on or after July 1, 2026.

Signed at Washington, DC.

Daniel Aronowitz,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

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