PBM Fee Disclosure Regulation under 408(b)(2)
OMB Control Number 1210-NEW
Expiration Date:

SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT 1995: PBM FEE DISCLOSURE REGULATION UNDER 408(B)(2)

This ICR seeks approval for a new control number.

A. JUSTIFICATION

1. **Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.**

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.[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

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 S*ee 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.

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 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.

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6 It is well established that plan sponsors as defined in section 3(16)(B)(i) ERISA 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. 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.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The proposed regulation would require covered service providers to disclose information to responsible plan fiduciaries of group health plans regarding services and compensation in connection with the service contracts or arrangements with the plan. Covered service providers under the proposal are (i) providers of pharmacy benefit management services and (ii) providers of advice, recommendations, or referrals (*e.g.*, brokers and consultants) regarding pharmacy benefit management services who are themselves providers of pharmacy benefit management services or their affiliates.

The three main components of the proposed regulation are: (i) initial disclosure requirements; (ii) semiannual disclosure requirements; and (iii) requirements designed to preserve the group health plans' abilities to audit such disclosures. Additionally, the proposal includes a proposed prohibited transaction class exemption for responsible plan fiduciaries acting in good faith in the event the covered service provider fails to comply with the regulation.

The proposed regulation would require disclosures only to self-insured group health plans. The proposal reserves disclosure obligations with respect to fully insured group health plans for future action. This approach was taken 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 on an unbundled basis for pharmacy benefit management services.

1. <u>Initial Disclosures</u>

The proposal's initial disclosure requirements, which would be provided reasonably in advance of the contract or arrangement, would include disclosures of the services to be provided as well as a description of compensation reasonably expected to be received on a quarterly basis in connection with the service contract or arrangement. The proposal specifies that the compensation to be disclosed includes: (i) direct compensation paid by the plan; (ii) payments from drug manufacturers (*e.g.*, rebates PBMs receive from manufacturers); (iii) spread compensation; (iv) co-pay clawbacks; (v) price protection agreements; (vi) compensation for termination of the service contract or arrangement, as well as other compensation not specifically enumerated by name in the proposal (this is to function as a "catchall" category). The initial disclosure would also include a description of incentives and arrangements with drug manufacturers related to the placement of their drugs on the plan's formulary and of the drug pricing methodology that would be used to determine the drug prices paid by the plan. Additionally, this disclosure would also include a statement of fiduciary status if the covered service

provider, an affiliate, an agent, or a subcontractor will provide, or reasonably expects to provide, services as a fiduciary; and will also include a statement of audit right.

2. Semiannual Disclosures

The proposal's semiannual disclosures would describe compensation received in connection with the service contract or arrangement covering the preceding six-month period (actually received rather than expected to be received as in the initial disclosures). The compensation would be presented in the same categories of compensation as the initial disclosures, with the exception of compensation for termination of the service contract or arrangement (direct compensation, manufacturer payments, spread compensation, co-pay clawbacks, price protection agreements, and other compensation not otherwise disclosed). The semiannual disclosures would provide transparency into the actual compensation received in connection with the service contract or arrangement and a means for the responsible plan fiduciary to assess the estimates used by the covered service provider in its initial disclosure. Where any category of compensation, in aggregate, exceeds specified conditions, the covered service provider would be required to identify the amount and reason for the overage. This disclosure would also include a statement of audit rights.

3. Audit Rights

The regulation would also preserve the group health plans' ability to conduct an audit of the disclosures made pursuant to the regulation not less than once per year. In this regard, the proposal provides that the plan fiduciary may select an auditor without limitations imposed by the covered service provider, and the covered service provider would be required to make available within a commercially reasonable period all records, data, and other information that is reasonably necessary to confirm the accuracy of the disclosures. While the plan would have responsibility for the expenses related to the selection and retention of the auditor, the covered service provider would bear the cost of providing the information, data, and other materials needed to perform the audit. The covered service provider may not impose conditions that would restrict the covered plan's right to conduct an audit, 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 made pursuant to the regulation.

4. Innocent Fiduciary Exemption

The proposal also includes special relief – in the form of a proposed prohibited transaction exemption from the restrictions of ERISA section 406(a)(1)(C) and (D) – for a responsible plan fiduciary where the covered service provider fails to meet disclosure requirements set forth in the proposed regulation, if certain conditions are met. Otherwise, the proposal could inadvertently work harm on the entity the proposal is

intended to help. If the covered service provider does not correct disclosure failures as requested by the responsible plan fiduciary within specified time frames, the responsible plan fiduciary would notify the Secretary of the failure and further must assess whether to terminate or continue the contract or arrangement consistent with the duty of prudence under section 404 of ERISA.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration for using information technology to reduce burden.

Under 29 C.F.R. § 2520.104b-1(b) of ERISA, "where certain material, including reports, statements, and documents, is required under Part I of the Act and this part to be furnished either by direct operation of law or an individual request, the plan administrator shall use measures reasonably calculated to ensure actual receipt of the material by plan participants and beneficiaries." Section 2520.104b-1(c) sets forth conditions under which disclosures under Title I of ERISA made through electronic media will be deemed to satisfy the requirement of § 2520.104b-1(b). Section 2520-107-1 establishes standards concerning the use of electronic media for maintenance and retention of records. Under these rules, all pension and welfare plans covered under Title I of ERISA may use electronic media to satisfy disclosure and recordkeeping obligations, subject to specific safeguards.

The proposed rule and accompanying class exemption does not limit the ability of covered service providers to furnish information required by the regulation to responsible plan fiduciaries via electronic media. In addition, the proposed regulation 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.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

No duplication with other Federal statutes exists. In some circumstances, several states have adopted disclosures requirements for PBMs regarding elements included in this

proposed rule, including rebate payments, spread pricing and drug prices.[9] However, no duplication occurs because the same information disclosure may be used to satisfy duplicative or overlapping requirements.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The Department expects that the proposed rule would increase transparency in PBM compensation arrangements and enable small, 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).

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The purpose of the proposed regulation is to ensure that responsible plan fiduciaries have sufficient information to evaluate the quality and competitiveness of the fees received by their potential service providers. The enhanced disclosure will increase efficiency and competition in the service provider market, thereby generating benefits to self-insured group health plans and plan participants. These benefits will not be realized if the information is not collected or is collected less frequently.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**

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

- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

The proposal would require a covered service provider to confirm receipt of a request for an audit no later than 10 business days after the information is requested. The 10-day deadline is limited to confirmation of receipt of the request for an audit; the audit information requested is required to be provided within a commercially reasonable period.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

In addition to requesting public comment on the proposed regulation, the NPRM solicited public comment on the paperwork burden of the proposed regulation. The Office of Management and Budget has 60 days to review the information, but must allow at least 30 days for public comment. Therefore, the PRA section of the proposed rule requested the public to send comments within 30 days to ensure their consideration. (5 CFR 1320.11(c); 5 CFR 1320.11(e)). The ICR will incorporate public comments received on the proposal during a submission associated with the final rule.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

There are no payments or gifts in this information collection.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Under the audit provision, information necessary to confirm the accuracy of the disclosures must be provided to the self-insured group health plan. If requested, contracts with retail pharmacies and drug manufacturers must be provided subject to reasonable confidentiality agreements to prevent redisclosure of the information. If redisclosure to a third party by the self-insured group health plan is necessary, the covered contract or arrangement may also require the responsible plan fiduciary to establish reasonable confidentiality agreements with such third parties.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of sensitive nature in this information collection.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.**

- **The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.**

Affected Entities

Group Health Plans

The proposed rule apply only to a subset of ERISA-covered group health plans, which are self-insured group health plans. Fully insured ERISA plans are not subject to 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-funded plans packaged with extensive stoploss coverage that significantly reduces the risk retained by the plan sponsor.[10] Applying this percentage to the 2,454,996 small ERISA-covered group health plans,[11] the Department estimates there are approximately 1,031,098 level-funded plans.[12] The Department also estimates that there are 104,123 self-insured plans with 100 to 999 employees and 15,362 self-insured plans with 1,000 or more employees.[13] While all 1,150,583 of these plans are considered self-insured, the Department uses this distinction to categorize 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 health plans.[14,15] As such, the Department assumes that all of these self-insured and level-funded group health plans will be affected by the proposed rule.

TPAs and Issuers

10 KFF, *2024 Employer Health Benefits Survey*, (Oct. 9, 2024), https://www.kff.org/report-section/ehbs-2024-section-10-plan-funding/#figure106.
11 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.
12 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.
13 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.
14 KFF reported this estimate for large firms only, as small firm respondents had a high percentage of "don't know" responses to these questions.
15 KFF, *2024 Employer Health Benefits Survey*, (Oct. 9, 2024), https://www.kff.org/report-section/ehbs-2024-section-9-prescription-drug-benefits/.

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[16] that provide services such as plan management to 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 less than 1,000 employees. TPAs and issuers are typically hired by group health plans to perform key administrative and compliance functions, including claims processing, formulary design, and oversight of pharmacy benefits. These service providers offer economies of scale in regulatory compliance by leveraging their expertise and infrastructure to implement the proposed rule's requirements on behalf of multiple plans. While plan fiduciaries remain ultimately responsible for ensuring compliance, they rely on TPAs and issuers to manage the day-to-day operations of the 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, though these sub-contracts are still covered by the requirements of these proposed regulations.

The following wage rates were used in this analysis: $181.06 (legal professional), $171.89 (IT professional), $129.14 (benefit specialist), $126.72 (project management specialists), $120.40 (business operations specialists), and $171.89 (software and web developers, programmers, and testers).[17]

1. IT Infrastructure Costs

The Department believes that most PBMs already have the required information needed to fulfill the disclosure requirements, as they manage complex healthcare operations and track the flow of pharmaceuticals and payments within the healthcare system as part of their regular business practices. Moreover, PBMs already provide this information, or elements of it, to self-insured group health plans and other entities, as required under the CAA and State laws.[18] 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.

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

16 Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data*, https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.
17 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.
18 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/.

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 1, 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,[19] ACA Medical Loss Ratio (MLR) Reporting,[20] Medicare Part D Reporting Requirements,[21] and the Hospital Price Transparency Requirements.[22] 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

19 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.
20 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.
21 CMS, *Part D Reporting Requirements*, https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/part-d-reporting-requirements.
22 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.

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.[23] In subsequent years, the estimated per-PBM average cost for maintaining and updating the IT system is $200,000.[24] 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

Please see Table 1 for calculations and burden.

TABLE 1. IT Infrastructure Costs

	Number of Notices	**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)**
PBMs design, develop, and implement needed IT systems changes (first year)					

23 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.

24 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.

Project Management Specialists	73	2,250	164,250	$126.72	$20,813,760
Business Operations Specialist	73	750	54,750	$120.40	$6,591,900
Software and Web Developers, Programmers, and Testers	73	3,500	255,500	$171.89	$43,917,895
PBMs design, develop, and implement needed IT systems changes (subsequent years)					
Project Management Specialists	73	500	36,500	$126.72	$4,625,280
Business Operations Specialist	73	50	3,650	$120.40	$439,460
Software and Web Developers, Programmers, and Testers	73	750	54,750	$171.89	$9,410,978
First Year Total	**73**	**-**	**474,500**	**-**	**$71,323,555**
Subsequent Year Total	**73**		**94,900**		**$14,475,718**
Three-Year Average	**73**		**221,433**		**$33,424,997**

3. Number of Notices from PBMs

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.[25] 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.

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.

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

25 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.

expected requests, the Department assumes that approximately ten percent of responsible plan fiduciaries will request covered information annually.

4. Number of Notices from Plans

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.[26] 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 section 2550.408b-2.

If the PBM or other covered service provider does not respond within 90 calendar days, the responsible plan fiduciary must notify the Department of the failure and further must assess whether to terminate or continue the service contract or arrangement consistent with the duty of prudence under section 404 of ERISA. 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 section 2550.408b-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 providers is borne by the self-insured group health plan itself, service providers are

26 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.

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 2 for calculations on the number of notices.

TABLE 2. 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 1,000 employees, send audit requests to PBMs	809	100%	100%	1	809
Total	**1,151,392**	**-**	**-**		**2,730,139**

5. Disclosure Costs

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,[27] 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 3 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.

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,

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

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 3 for the estimated costs of disclosures.

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 3 for the estimated costs of disclosures.

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.[28] This

28 Based on a review of the 2022 Form 5500 Schedule C filings, approximately 0.3 percent of ERISA-covered group

assumption is based on the Department's experience that it is rare for pension plans to submit a notice under the requirement in 29 CFR 2550.408b-2. The Department also assumes that PBMs will rely on standardized templates and batch processing to prepare the notice. Therefore, the Department estimates that it will take 15 minutes of a benefit specialist's time to prepare and send the notice.

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 3 for the estimated costs of disclosures.

TABLE 3. 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	38,353	0.25	9,588	$129.14	$1,238,227

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.

send information					
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**

6. 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.[29] The Department does not anticipate level-funded group health plans

29 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.

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.[30] This includes the time to retrieve documents, gather data and put in place any necessary confidentiality agreements.

Please see Table 4 for calculations and burden.

TABLE 4. 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	1,403	0.25	351	$129.14	$45,296

30 The wage rate is calculated in the following manner: [($129.14 for a benefits specialist x (1/2)) + ($171.89 for an IT Professional) x (1/2))] = $150.52.

prepare and send audits request					
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**

7. Summary of Hour Burden

Table 5 provides a summary of the hour burden.

TABLE 5. Summary of Hour Burden

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

TABLE 6. Estimated Annualized Respondent Cost and Hour Burden

Activity	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden (Hours)	Total Burden (Hours)	Hourly Wage Rate	Equivalent Cost of Hour Burden
(1) IT Infrastructure **PBMs design, develop, and implement needed IT systems changes (first year)**							
Project Management Specialists	73	1	73	2,250	164,250	$126.72	$20,813,760
Business Operations Specialist	73	1	73	750	54,750	$120.40	$6,591,900
Software and Web	73	1	73	3,500	255,500	$171.89	$43,917,895

Developers, Programmers, and Testers							
(2) Disclosures							
PBMs design, develop, and implement needed IT systems changes (subsequent year)							
Project Management Specialists	73	1	73	500	36,500	$126.72	$4,625,280
Business Operations Specialist	73	1	73	50	3,650	$120.40	$439,460
Software and Web Developers, Programmers, and Testers	73	1	73	750	54,750	$171.89	$9,410,978
(A) 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	73	70.15	5,121	1	2,561	$155.10	$397,134
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	73	70.15	5,121	1	2,561	$155.10	$397,134
PBMs provide missing/other information requested by self-insured group health plans							
Benefits specialists prepare information	73	525.38	38,353	0	9,588	$129.14	$1,238,227

PBMs provide semiannual disclosures to self-insured group health plans							
Benefit specialists prepare disclosures	73	31,522.84	2,301,167	0	575,292	$129.14	$74,293,177
(B) Plan sends notice to PBMs and DOL							
Self-inured group health plans send request to PBMs to disclose missing information							
Benefits specialist prepares request	1,150,583	0.001	1,151	0	288	$129.14	$37,160
Self-insured group health plans sends notice to DOL after the PBM has not responded within 90 days							
Benefits specialist prepares notice	10	1	10	0	3	$129.14	$323
(3) Audit Costs							
Self-insured group health plans with 1,000 or more employees send audit request							
Benefit specialists prepare and send request	10	512.10	5,121	0.50	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 audit request	809	1.73	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	10	652.40	6,524	2	13,048	$150.52	$1,963,985
Three-Year Average Total	**1,151,392**	**-**	**2,730,806**		**919,725**		**$126,403,692**

Note:
* The number of respondents is calculated in the following manner: 1,031,098 level-funded group health plans + 119,485 self-insured plans + 809 issuers/state combinations = 1,151,392.
**The number of responses is calculated in the following manner: 2,724,209 disclosures + 6,524 audit requests + 73 PBMS updating and developing IT infrastructure = 2,730,806 requests.

13. Provide an estimate of the total annual cost burden to respondents or record-keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12.)

- **The cost estimate should be split into two components: (a) a total capital and start up cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of service component. The estimates should take into account costs associated with generating,**

maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.

- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

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 Question 12.

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

There are no costs to the Federal government associated with this information collection.

15. Explain the reasons for any program changes or adjustments.

There is a new collection of information.

16. For collections of information whose results will be published, outline plans for tabulation, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

There are no plans to publish the results of this collection of information.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

This information collection will display the expiration date for OMB approval.

18. Explain each exception to the certification statement identified in Item 19.

There are no exceptions to the certification statement identified in Item 19.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods used in this information collection.