

# **Supporting Statement for Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price**

## **A. Justification**

### **1. Circumstances Making the Collection of Information Necessary**

The Department of Health and Human Services proposes to amend the existing discount safe harbor so that it would explicitly exclude price reductions from manufacturers to plan sponsors under Medicare Part D or Medicaid managed care organizations (MCOs), either directly or through pharmacy benefit managers (PBMs) acting under contract with plan sponsors under Medicare Part D or Medicaid MCOs, in connection with the sale or purchase of prescription pharmaceutical products, unless the reduction in price is required by law. The Department is proposing a new safe harbor for certain point-of-sale price reductions from manufacturers to plan sponsors under Medicare Part D, Medicaid managed care organizations (MCOs), or PBMs acting under contract with either.

The Department is also proposing a new safe harbor (PBM Service Fees) that would protect fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers that meet specified criteria. The conditions of enjoying safe harbor protection would include that the PBM disclose, in writing, to each health plan with which it contracts at least annually, and to the Secretary upon request, the services it rendered to each pharmaceutical manufacturer that are related to the PBM's arrangements with that health plan and the associated costs for such services.

Accordingly, the proposed rule would condition protection under the new PBM Service Fees safe harbor on two disclosures: (1) one requiring the PBM disclose in writing to each health plan with which it contracts at least annually the services it rendered to each pharmaceutical manufacturer that are related to the PBM's arrangements with that health plan and the associated costs for such services; and (2) the other requiring the PBM to provide this information to the Secretary upon request.

The authorizing law for these collections is 42 U.S.C. Sec. 1320a-7b(b)(3)(E):

“any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w-104(e)(6) 1 of this title”

## **2. Purpose and Use of Information Collection**

As discussed above, this proposed rule would condition protection under the new PBM Service Fees safe harbor on the requirement that PBMs disclose in writing to each health plan with which it contracts at least annually, and to the Secretary upon request, the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan.

The purpose of this information is to increase transparency in the relationship between the PBM and the health plans. The Department believes that PBMs are agents of the health plans with which they contract and that this transparency requirement is important to ensure that the PBM's arrangements with pharmaceutical manufacturers are not in tension with the services that the PBM provides to the health plans for which it is acting as an agent. The health plans will use this information to ensure that the PBMs are working as their agent and to allow for clear information for negotiations.

An example of how this information would be used is that the health plans could review the services provided to certain pharmaceutical manufacturers, and decide to work with a different PBM because those services are in favor of the manufacturer or PBM, instead of the health plan.

The Secretary does not currently proactively monitor compliance with safe harbor conditions; however, this information could be requested and used for assessing compliance with the safe harbor if, for example, the safe harbor was being used as an affirmative defense in litigation.

## **3. Use of Improved Information Technology and Burden Reduction**

The regulation does not restrict PBMs from using electronic technology to provide either disclosure. The regulation is agnostic to the format or delivery technique. There was consideration of using technology to reduce burden, and HHS recommends the use of technology to reduce the disclosure burden. The ultimate format will be up to the PBMs, but 100% of the information could be transmitted electronically.

## **4. Efforts to Identify Duplication and Use of Similar Information**

The proposed rule would condition protection under the new PBM Service Fees safe harbor on a requirement to disclose new information that has not been previously disclosed. Whenever possible, existing information is used. In addition, the new information to be submitted to the Secretary upon request would be the same information that the PBMs submit to the health plans.

There will be no duplication of effort because the only disclosure requirement is for new information that will be submitted to the health plans and to HHS. No other departments require this information.

HHS has confirmed that this information does not already exist based on consultation with HHS agencies and with subject matter experts. The information is not currently captured because it has traditionally been considered proprietary on behalf of the PBMs.

**5. Impact on Small Businesses or Other Small Entities**

Not applicable.

**6. Consequences of Collecting the Information Less Frequent Collection**

The proposed rule conditions the protection of the new PBM Service Fees safe harbor on the requirement that the information be submitted to health plans annually, and to the Secretary upon request.

Health plans must have access to the information annually to use it for its intended purpose of providing transparency and for allowing the health plans to develop contracts with PBMs.

Disclosure to Secretary will be upon request in order to allow for these disclosures to occur less frequently than the annual disclosures to health plans while still affording the Secretary the ability to obtain the information as needed.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

None.

**8. Comments in Response to the Federal Register Notice/Outside Consultation**

The proposed rule went on display at the Office of the Federal Register on January 31, 2019. The rule published in the *Federal Register* on February 6, 2019 (84 FR 2340).

**9. Explanation of any Payment/Gift to Respondents**

There are no payments or gifts to the respondents of this information collection request. However, the PBMs that elect to comply with the PBM Service Fees safe harbor, including the information collection requirements, would have that arrangement protected under the anti-kickback statute.

**10. Assurance of Confidentiality Provided to Respondents**

Data will be kept private to the extent allowed by law.

**11. Justification for Sensitive Questions**

Not applicable.

**12. Estimates of Annualized Hour and Cost Burden**

A. Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates ([https://www.bls.gov/oes/2016/may/oes\\_nat.htm](https://www.bls.gov/oes/2016/may/oes_nat.htm)). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Medical and Health Services Managers	11-9111	\$52.58	\$52.58	\$105.16
Lawyers	23.1011	\$67.25	\$67.25	\$134.50
Network and Computer Systems Administrators	15-1142	\$40.63	\$40.63	\$81.26

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

**12A. Estimated Annualized Burden Hours**

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
PBM	PBM Services Form	60	50	4	12,000
<b>Total</b>		60	50	4	<b>12,000</b>

**B. Burden Estimates**

Proposed §1001.952(dd)(3) would require PBMs that elect to pursue protection under the PBM Service Fees safe harbor to disclose in writing to each health plan with which it contracts at least annually, and to the Secretary upon request, the services rendered to each pharmaceutical manufacturer related to the PBM’s arrangements to furnish pharmacy benefit management services to the health plan. As stated in the Regulatory Impact Analysis of the related notice of proposed rulemaking (RIN: 0936-AA08), we estimate the total number of PBMs operating in the U.S. to be approximately 60. We estimate that each PBM will provide these information disclosures approximately 50 times each year and that these disclosures will require an average of 4 hours to develop, with 50% of time spent by managers, 25% of time spent by attorneys, and 25% of time spent by IT staff. The estimated annual burden is 12,000 hours. As a result, using wage information provided in the table in section 12.A, the Department estimates costs of \$1.28 million in each year following publication of the final rule after adjusting for overhead and benefits.

$(60 \text{ PBMs}) \times (50 \text{ responses/PBM}) \times (4 \text{ hours/response}) = 12,000 \text{ hours}$

**C. Cost Estimates**

**Total Hourly Wages**

Medical and Health Services Managers:	\$105.16 x 50% = \$52.58
Lawyers:	\$134.50 x 25% = \$33.63
Network and Computer Systems Administrators	<u>\$81.26 x 25% = \$20.32</u>
<b>Total</b>	<b><u>\$106.53</u></b>

$(60 \text{ PBMs}) \times (50 \text{ responses/PBM}) \times (4 \text{ hours/response}) \times (\$106.53/\text{hour}) = \$1,278,360 \text{ or } \$1.28 \text{ million}$

**12B. Estimated Annualized Burden Costs**

<b>Type of Respondent</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Costs</b>
PBM	12,000	\$106.53	\$1,278,360
Total	12,000		\$1,278,360

**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

There are no capital costs associated with this information collection request.

**14. Annualized Cost to Federal Government**

The cost to the government is estimated to be \$1,630. This assumes that there will be 50 hours of a GS-11 analyst reviewing the program.

**15. Explanation for Program Changes or Adjustments**

This is a new information collection request.

**16. Plans for Tabulation and Publication and Project Time Schedule**

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

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The expiration date will be listed on the disclosure documents.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.