Supporting Statement – Part A
Medicaid Drug Rebate Program Labeler Reporting Format (CMS-367a-e)
Quarterly Pricing Data (CMS-367a)
Monthly Pricing Data (CMS-367b
Product Data (CMS-367c)
Manufacturer Contact Form (CMS-367d)
Quarterly VBP-MBP Data (CMS-367e)
OMB Control Number: 0938-0578

Background

Section 1927 of the Social Security Act (the Act) requires drug labelers to enter into and have in effect a National Drug Rebate Agreement (NDRA) with the Federal government for States to receive funding for drugs dispensed to Medicaid recipients. In order for payment to be made under Medicaid, drug labelers that have a signed an NDRA are required to report product and pricing data 30 days after every month and quarter. CMS forms 367a-e identify the product data fields that must be submitted to CMS, the pricing data fields that must be submitted on both a monthly and quarterly basis, the labeler contact information that must be submitted as needed, and to transmit quarterly pricing data (best prices associated with value-based purchasing (VBP) arrangements) for each of their covered outpatient drugs (CODs), on an as needed basis only.

Under the Medicaid program, states may provide coverage of prescribed drugs as an optional service under section 1905(a)(12) of the Act. Section 1903(a) of the Act provides for federal financial participation (FFP) in state expenditures for these drugs. Section 1927 of the Act governs the Medicaid Drug Rebate Program (MDRP) and payment for covered outpatient drugs (CODs), which are defined in section 1927(k)(2) of the Act.

In this January 2023 collection of information request, CMS is notifying users that it will also use data reported under 1927(b)(3)(A) to calculate inflation rebates under the Inflation Reduction Act of 2022. This additional use case will use existing data and will not require new data to be submitted.

We are not proposing changes to any of the following forms: CMS-367a (Quarterly Pricing), CMS-367b (Monthly Pricing), CMS-367c (Product Data), CMS-367d (Manufacturer Contact Form), or CMS-367e (Quarterly VBP-MBP Data.

Using current data, we have revised the number of respondents reporting drug information to CMS from 780 to 818; an increase of 38 participating labelers in the MDRP. Given that there are more respondents, the change has increased our total time and cost estimates. Our cost estimates have also increased by using more up to date wage figures. We are not proposing changes to any of our per response time estimates or to the frequency of reporting.

This Medicaid PRA OMB-0938-0578 is being submitted with the following two (2) Medicare PRAs, OMB-0938-0921 and OMB 0938-0982, in order for them to be published simultaneously in the Federal Register.

Overall, we estimate an increase of 26,648 hours (from 564,394 hrs to 591,042 hrs) and an increase of $3,274,686 (from $58,211,008 to $61,485,694).

A. Justification

1. Need and Legal Basis

The authority for requiring this data collection is section 1927 of the Act, and the February 1, 2016 Covered Outpatient Drug Final Rule with Comment (81 FR 5170).

Additionally, Section 11102 of the Inflation Reduction Act of 2022 establishes a Part D inflation rebate by manufacturers of certain single source drugs and biologicals with prices increasing at a rate faster than the rate of inflation. CMS will use data reported under section 1927(b)(3)(A) to determine if Part D drugs and biologicals have prices that exceed the rate of inflation.

2. Information Users

Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS uses the reported data to calculate the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each NDC and distributes that information to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report on the CMS-64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. Additionally, CMS information users will leverage data reported under section 1927(b)(3)(A) to determine if certain Part D drugs and biologicals will be subject to an inflation rebate.

3. Improved Information Technology

CMS uses a web-based application for all drug data collection. The MDP application is available at no charge to all participating labelers. Manufacturers have two data reporting options within MDP: first, they may key their data online on an individual NDC basis; second, they may upload a saved file to MDP.

For additional information regarding the online and file transfer data transmission methods in MDP, see the attached screen shots.

4. Duplication Information

CMCS is the only CMS component collecting drug data for purposes of the MDRP. Therefore, this information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Business

This collection of data may impact up to 100 small business entities that are currently in the voluntary program. MDP helps these entities more easily and accurately report their data than was possible under the previous data collection method. The MDP is free, and helps labelers detect and correct potential data errors for which they previously faced penalties and terminations from the program.

6. Less Frequent Collection

Section 1927 of the Act requires monthly and quarterly drug data reporting by labelers.

7. Special Circumstances

We require respondents to report information to the agency more often than quarterly. Section 1927 of the Act requires monthly and quarterly drug data reporting by labelers.

Otherwise, this information collection request does not include any other special circumstances. More specifically, this information collection does not do any of the following:

- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Includes a pledge of confidentiality that is not supported by authority established in statue 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
- Require 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.

8. Federal Register Notice/Outside Consultations

The 60-day notice published in the Federal Register on February 17, 2023 (88 FR 10340). Comments must be received by April 18, 2023.

9. Payments or Gifts

There is no provision for any payment or gift to respondents associated with this reporting requirement.

10. Confidentiality

Confidentiality has been assured in accordance with section 1927(b)(3)(D) of the Act.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimate of Burden and Costs to Respondents

The burden associated with our CMS-367(a-e) forms reflects the time used and cost incurred by labelers (respondents) when gathering and reporting Medicaid drug product and price information on a monthly,quarterly, and as needed basis.

The following provides a breakdown of the burden associated with this collection.

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

Hourly Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Computer System Analyst	15-1211	49.14	49.14	98.28
General & Operations Manager	11-1021	55.41	55.41	110.82
Operations Research Analyst	15-2031	46.07	46.07	92.14
Training & Development Manager	11-3131	61.92	61.92	123.84

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, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

12.2 Burden Estimates

Currently, there are approximately 818 respondents reporting drug information to CMS. Of the 818 total respondents reporting, 100% will report data via the MDP web-based application. Within MDP, there are two reporting options from which the respondents may choose (i.e., online and file transfer); however, there is no difference in the time burden associated with each option. File transfer submissions and online submissions are both performed on the same

reporting schedule (i.e., monthly and quarterly), and both require the submission of the same data fields with the exception of the Reactivation Date field which may only be entered online.

CMS-367a – Quarterly Pricing Data

Burden Due to Miscellaneous Quarterly Pricing Data Fields: On a quarterly basis, manufacturers are to report pricing data for each of their covered outpatient drugs to CMS. This data, which is reported on the CMS-367a, includes the following fields: "Record ID", "Labeler Code", "Product Code", "Period Covered", "Average Manufacturer Price", "Best Price", "Nominal Price", "Customary Prompt Pay Discount", "Initial Drug Available for Line Extension", and "Initial Drug".

We estimate that these requirements affect the approximately 818 drug manufacturers participating in the MDRP. The quarterly burden associated with the reporting of these miscelleanous data fields is the time and effort it takes to report these miscelleanous fields through direct file upload or manual data entry through the MDP system.

We estimate that it will take a Computer System Anaylst 13 hours at $98.28/hr, a General and Operations Manager 7 hours at $110.82/hr, a Training and Development Manager 6 hours at $123.84/hr, and an Operations Research Anaylst 8.8 hours at $92.14/hr (for a total of $3,591.55 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous data fields. This equates to an annual burden of 139.2 hours (34.8 hours per response x 4 responses a year) per manufacturer. In aggregate, we estimate 113,865.60 hours (818 drug manufacturers participating in the MDRP x 139.2 hr) at a cost of $11,773,474 ($3,598.25 per response x 4 responses/year x 818 manufacturers).

CMS-367a - Quarterly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses (frequency)	Time Per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Misc data fields	818	3,272 (4 quarterly responses/year)	34.8	113,866	Varies	11,773,474

CMS-367b – Monthly Pricing Data

Burden Due to Miscellaneous Monthly Pricing Data Fields: On a monthly basis manufacturers are to report pricing data for each of their covered outpatient drugs to CMS. This data, which is reported on CMS-367b, includes the following fields: "Record ID", "Labeler Code", "Product Code", "Month", "Year", "Average Manufacturer Price", "AMP Units", and "5i Threshold".

We estimate that these requirements affect the approximately 818 drug manufacturers participating in the MDRP. The monthly burden associated with the reporting of these miscelleanous data fields is the time and effort it takes to report these miscelleanous fields

through direct file upload or manual data entry through the MDP system.

We estimate that it will take a Computer System Anaylst 13 hours at $98.28/hr, a General and Operations Manager 7 hours at $110.82/hr, a Training and Development Manager 11 hours at $123.84/hr, and a Operations Research Anaylst 13.8 hours at $92.14/hr (for a total of $4,687.15 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous data fields. This equates to an annual burden of 537.6 hours (44.8 hours per response x 12 responses per year) per manufacturer. In aggregate, we estimate 439,756.8 hours (818 drug manufacturers participating in the MDRP x 537.6 hours) at a cost of $46,009,064.40 ($4,687.15 per response x 12 responses/year x 818 manufacturers).

CMS-367b – Monthly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses (frequency)	Time Per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Misc data fields	818	9,816 (12 monthly responses per year)	44.8	439,757	Varies	46,009,064

CMS-367c – Product Data

Burden Due to Miscellaneous Product Data Fields: When a manufacturer reports a new drug to CMS or makes a change to the product data of an existing drug, the manufacturer is responsible for reporting these product data. This data, which is reported on form CMS-367c, may include the following fields: “Record ID”, “Labeler Code”, “Product Code”, “Package Size”, “Drug Category”, “Unit Type”, “FDA Approval Date”, “Therapeutic Equivalence Code”, “Market Date”, “Termination Date”, “Drug Type”, “OBRA ’90 Baseline AMP”, “Units Per Package Size”, “FDA Product Name”, “Package Size Intro Date”, “Purchased Product Date”, “5i Drug Indicator”, “5i Route of Administration”, “Covered Outpatient Drug Status”, “FDA Application Number/OTC Monograph Number”, “Line Extension Drug Indicator”, and “Reactivation Date”.

We estimate that these requirements affect the approximately 818 drug manufacturers participating in the MDRP. The annual burden associated with the reporting of these miscelleanous product data fields is the time and effort it takes to report these miscelleanous fields through direct file upload or manual data entry through the MDP system.

We estimate that it will take a Computer System Anaylst 18 hours at $98.28/hr, a General and Operations Manager 6.5 hours at $110.82/hr, a Training and Development Manager 2 hours at $123.84/hr, and a Operations Research Anaylst 17 hours at $92.14/hr (for a total of $4,303.43 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous product data fields. In aggregate, we estimate 35,583 hours (818 drug manufacturers participating in the MDRP x 43.5 hr) at a cost of $3,520,205.74 ($4,303.43 per response x 1 response/year x 818 manufacturers).

CMS-367c – Product Data

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses (frequency)	Time Per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Misc data fields	818	818 (1 response per year)	43.5	35,583	Varies	3,520,206

CMS-367d – Manufacturer Contact Form

Burden Due to Contact Information Sheet submission: The Manufacturer Contact Form is submitted to CMS when manufacturers have a need to update CMS on contact information such as email address, phone number, or address, of their legal, invoice or technical contact for the MDP system.

We estimate that this requirement affects the approximately 818 drug manufacturers participating in the MDRP. Furthermore, we estimate that drug manufacturers need to submit the Manufacturer Contact Form to CMS on average twice a year. The annual burden associated with the submission of the Manufacturer Contact Form is the time and effort it takes to complete the form andemail it to CMS.

We estimate that it will take a Computer System Analyst 1 hour at $98.28/hour to complete the submission of the Manufacturer Contact Form. This equates to an annual burden of 2 hours (1 hr/response x 2 responses/year) per drug manufacturer. In aggregate, we estimate 1,636 hours (818 drug manufacturers participating in the MDRP x 2 hrs) at a cost of $160,786.08 ($98.28 per response x 2 response/year x 818 manufacturers).

CMS-367d – Manufacturer Contact Form

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses (frequency)	Time Per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Misc data fields	818	1,636	1.0	1,636	98.28	160,786

CMS-367e – Quarterly VBP-MBP Data

Burden Due to Miscellaneous Quarterly VBP-MBP Data Fields: On an as neededquarterly basis, for manufacturers to report pricing data (best prices associated with value-based purchasing (VBP) arrangements) for each of their covered outpatient drugs. These data, which are reported on form CMS-367e, may include the following fields: “Labeler Code”, “Product Code”, “FDA Product Name”, “Arrangement Identifier”, “Tier”, and “VBP GNUP”.

We estimate that these requirements would affect about 50 of the approximately 818 drug manufacturers participating in the MDRP. There are 21 gene therapy manufacturers (https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products) as well as a small percentage of high cost drug manufacturers (~30), which equates to a total of ~50 manufacturers that may opt to report multiple best prices as well as a a single best price for a covered outpatient drug. The quarterly burden associated with the reporting of these miscellaneous product data fields is the time and effort it takes to report these miscellaneous fields through direct file upload or manual data entry through the MDP system.

We estimate that it will take a General and Operations Manager 1 hour at $110.82/hr to report these miscellaneous VBP-MBP data fields. This equates to an annual burden of 200 hours (50 affected drug manufactures x 4 quarters) at a cost of $22,164 ($110.82 per response x 4 responses/year x 50 affected manufacturers)

CMS-367e – Quarterly VBP-MBP Data

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses (frequency)	Time Per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Misc data fields	50	200 (4 quarterly responses per year)	1.0	200	$110.82	$22,164

12.3 Summary of Burden Estimates

Description / Form	Frequency	Respondents	Total Responses	Time Per Response (hours)	Total Annual Time (hours)	Total Capital/Maintenance Costs ($)	Total Cost ($)
CMS-367a	Quarterly	818	3,272	34.8	113,866	0	11,773,474
CMS-367b	Monthly	818	9,816	44.8	439,757	0	46,009,064
CMS-367c	Occasionally	818	818	43.5	35,583	0	3,520,206
CMS-367d	Occasionally	818	1,636	1	1,636	0	160,786
CMS-367e	Occasionally	50	200	1	200	0	22,164
Total		818	15,742	Varies	591,042	0	61,485,694

12.4 Collection of Information Instruments and Instruction/Guidance Documents

CMS-367a - Quarterly Pricing Data Specifications (No changes)

CMS-367b – Monthly Pricing Data Specifications (No changes)

CMS-367c – Product Data Specifications (No changes)

CMS-367d – Manufacturer Contact Form (No changes)

CMS-367e – Quarterly VBP-MBP Data (No changes)

13. Capital Costs

There are no capital costs.

14. Federal Costs

The estimated annual federal cost for our contractor to maintain the operation of the Medicaid Drug Programs (MDP) system is roughly $2,000,000. Please note that this is not a new cost to the Federal government. During the review process for this submission we realized that past PRA packages incorrectly included a cost estimate that only reflected the change being requested in the package rather than the change plus the existing burden. Therefore, in this package we are correcting this error and reporting the annual cost for the contract.

15. Changes in Burden/Program

In this December 2022 collection of information request, we are not proposing any changes to any of the following forms: CMS-367a (Quarterly Pricing), CMS-367b (Monthly Pricing), CMS-367c (Product Data), CMS-367d (Manufacturer Contact Form), or CMS-367e (Quarterly VBP-MBP Data.

Using current data, we have revised the number of respondents reporting drug information to CMS from 780 to 818; an increase of 38 participating labelers in the MDRP. Given that there are more respondents, the change has increased our total time and cost estimates. Our cost estimates have also increased by using more up to date wage figures. We are not proposing changes to any of our per response time estimates or to the frequency of reporting.

CMS-367a - Quarterly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses	Time Per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved Burden	780	3,120	34.8	108,576	Varies	11,205,636
Proposed Burden	818	3,272	34.8	113,866	Varies	11,773,474
Change	+38	+152	No Change	+5,290	Varies	+567,838

CMS-367b – Monthly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses	Time Per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved Burden	780	9,360	44.8	419,328	Varies	43,436,484
Proposed Burden	818	9,816	44.8	439,757	Varies	46,009,064
Change	+38	+456	No Change	+20,429	Varies	+2,572,580

CMS-367c – Product Data

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses	Burden per response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved Burden	780	780	43.5	33,930	Varies	3,315,429
Proposed Burden	818	818	43.5	35,583	Varies	3,520,206
Change	+38	+38	No Change	+1,653	Varies	+204,777

CMS-367d – Manufacturer Contact Form

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses	Time Per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved Burden	780	1,560	1.0	1,560	95.22	148,543
Proposed Burden	818	1,636	1.0	1,636	98.28	160,786
Change	+38	+76	No Change	+76	+3.06	+12,243

CMS-367e – Quarterly VBP-MBP Data

Burden Category	Annual Respondents (#of manufacturers)	Total Annual Responses	Time Per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved Burden	50	200	1.0	200	120.90	24,180
Proposed Burden	50	200	1.0	200	110.82	22,164
Change	No Change	No Change	No Change	No Change	-10.08	-2,016

Overall, we estimate an increase of 26,648 hours (from 564,394 hrs to 591,042 hrs) and an increase of $3,274,686 (from $58,211,008 to $61,485,694).

Form	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Total Cost ($)
CMS-367a	+38	+152	No Change	+5,290	+567,838
CMS-367b	+38	+456	No Change	+20,429	+2,572,580
CMS-367c	+38	+38	No Change	+1,653	+204,777
CMS-367d	+38	+76	No Change	+76	+12,243
CMS-367e	n/a	50	Varies	-800	+104,916
CMS-367a, b, and c	n/a	-749	-24	-17,976	-1,710,356
Total Change	+31	+90	Varies	+5,414	+1,949,491

16. Publication and Tabulation Data

There are no plans to publish the collected information.

17. Display of Expiration Date

CMS will display this collection of information's expiration date.

18. Exception to Certification Statement

We certify that this information collection complies with 5 CFR 1320.9. We do not seek any exemptions.

B. Collections of Information Employing Statistical Methods

CMS does not intend to employ statistical methods to the collected information.