Supporting Statement – Part A
Medicaid Drug Rebate Program Labeler Reporting Format (CMS-367a-d)
OMB 0938-0578

Quarterly Pricing Data (CMS-367a)
Monthly Pricing Data (CMS-367b
Product Data (CMS-367c)
Manufacturer Contact Form (CMS-367d)

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-c 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, and the labeler contact information that must be submitted as needed.

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.

CMS is requesting a three year approval of the labeler reporting requirements (Forms: CMS-367a - Quarterly Pricing Data; CMS-367b - Monthly Pricing Data; CMS-367c - Product Data; CMS-367d – Manufacturer Contact Form), under the MDRP.

In this 2020/2021 iteration we have adjusted the number of respondents (manufacturer participation increased from 743 to 749) and adjusted our labor rates to more recent BLS data. The combination resulted in an increase in our total time and total cost estimates. Our per response time estimates are unchanged.

Effective July 1, 2021, we are updating to a new Medicaid Drug Programs (MDP) system which will now accept a delimited text file format, Comma Separated Values (.CSV), in addition to the current Text (.TXT) file format. We have also increased several file format data field sizes in order to accommodate the higher priced drugs that are entering the market. These changes in conjunction with numerous edits to verbiage are applicable to Forms CMS-304 and CMS-304a. This PRA package (0938-0676) is simultaneously being updated along with our two corresponding PRA packages (0938-0578 and 0938-0582), so that all the MDP file formats, field sizes, and verbiage will align across the MDRP. In this regard we added a one-time burden for each manufacturer to make any system updates to accommodate the updated field sizes and .CSV file formats for CMS-367a, CMS-367b, and CMS-367c.

See section 15 for more details regarding the changes.

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) .

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.

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 November 30, 2020 (85 FR 76577). One anonymous comment was received that simply stated “good.” The comment is included in this package along with our response.

The 30-day notice published in the Federal Register on February 23, 2021 (86 FR 10971). Comments are due by March 25, 2021.

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-d) forms reflects the time used and cost incurred by labelers (respondents) when gathering and reporting Medicaid drug product and price information on a monthly and quarterly 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 2019 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 the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Hourly Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)

Computer Programmer	15-1251	44.53	44.53	89.06
Computer System Analyst	15-1211	46.23	46.23	92.46
Computer Tester	15-1256	53.66	53.66	107.32
General & Operations Manager	11-1021	59.15	59.15	118.30
Operations Research Analyst	15-2031	43.56	43.56	87.12
Training & Development Manager	11-3131	59.36	59.36	118.72

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 749 respondents reporting drug information to CMS. Of the 749 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 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 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 749 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 the file transfer process or manual data entry through the MDP system.

To complete the reporting of these miscellaneous data fields, each drug manufacturer will take a Computer System Anaylst 13 hours at $92.46/hr, a General and Operations Manager 7 hours at $118.30/hr, a Training and Development Manager 6 hours at $118.72/hr, and an Operations Research Anaylst 8.8 hours at $87.12/hr.

In aggregate we estimate an annual burden of 104,261 hours (34.8 hr/response x 4 responses/yr x 749 drug manufacturers participating in the MDRP) at a cost of $10,513,144 [2,996 total responses/yr x {(13 hr x $92.46/hr for a Computer System Anaylst) + (7 hr x $118.30/hr for a General and Operations Manager) + (6 hr x $118.72/hr for a Training and Development Manager) + (8.8 hours x $87.12/hr for an Operations Research Anaylst)}].

CMS-367a - Quarterly Pricing Data

Burden Category	Annual Respondents	Annual Responses (frequency)	Time per response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)

Misc data fields	749 manufacturers	2,996 (4 quarterly responses per year)	34.8	104,261	Varies	10,513,144

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 749 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 the file transfer process or manual data entry through the MDP system.

In aggregate we estimate an annual burden of 402,662 hours (44.8 hr/response x 12 responses/yr x 749 drug manufacturers participating in the MDRP) at a cost of $40,789,881 [8,988 total responses/yr x {(13 hr x $92.46/hr for a Computer System Anaylst) + (7 hr x $118.30/hr for a General and Operations Manager) + (11 hr x $118.72/hr for a Training and Development Manager) + (13.8 hours x $87.12/hr for an Operations Research Anaylst)}].

CMS-367b – Monthly Pricing Data

Burden Category	Annual Respondents	Annual Responses (frequency)	Time per response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Misc data fields	749 manufacturers	8,988 (12 monthly responses per year)	44.8	402,662	Varies	40,789,881

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 749 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 the file transfer process or manual data entry through the MDP system.

We estimate that it will take a Computer System Anaylst 18 hours at $92.46/hr, a General and Operations Manager 6.5 hours at $118.30/hr, a Training and Development Manager 2 hours at $118.72/hr, and a Operations Research Anaylst 17 hours at $87.12/hr to complete the reporting of these miscellaneous product data fields.

In aggregate we estimate an annual burden of 32,582 hours (43.5 hr/response x 1 responses/yr x 749 drug manufacturers participating in the MDRP) at a cost of $3,109,631 [749 total responses/yr x {(18 hr x $92.46/hr for a Computer System Anaylst) + (6.5 hr x $118.30/hr for a General and Operations Manager) + (2 hr x $118.72/hr for a Training and Development Manager) + (17 hours x $87.12/hr for an Operations Research Anaylst)}].

CMS-367c – Product Data

Burden Category	Annual Respondents	Annual Responses (frequency)	Time per response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Misc data fields	749 manufacturers	749 (1 response per year)	43.5	32,582	Varies	3,109,631

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 749 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 and mail or email itto CMS.

We estimate that it will take a Computer System Analyst 1 hour at $92.46/hr to complete the submission of the Manufacturer Contact Form.

In aggregate, we estimate an annual burden of 1,498 hours (749 drug manufacturers participating in the MDRP x 1 hr/response x 2 responses/yr) at a cost of $138,505 (1,498 hr x $92.46/hr).

CMS-367d – Manufacturer Contact Form

Burden Category	Annual Respondents	Annual Responses (frequency)	Time per response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
Currently Approved Burden	749 manufacturers	1,498 (2 responses per year)	1.0	1,498	92.46	138,505

CMS-367a, b, and c – One-Time System Updates

We also estimate a one-time burden of 16 hours at $89.06/hr for a Computer Programmer and 8 hours at $107.32/hr for a Computer Tester for each manufacturer to make any system updates to accommodate the updated field sizes and .CSV file formats for CMS-367a, CMS-367b, and CMS-367c (for a total of $2,284 across both positions). This equates to a total one-time burden of 17,976 hours (24 hr x 749 manufacturers) at a cost of $1,710,356 ($2,283 x 749 manufacturers).

12.3 Summary of Burden Estimates

Form	Frequency	Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Cost ($)
CMS-367a	Quarterly	749	2,996	34.8	104,261	Varies	10,513,144
CMS-367b	Monthly	749	8,988	44.8	402,662	Varies	40,789,881
CMS-367c	Occasionally	749	749	43.5	32,582	Varies	3,109,631
CMS-367d	Occasionally	749	1,498	1	1,498	92.46	138,505
CMS-367a, b, and c	One-Time	749	749	24	17,976	107.32	1,710,356
Total		749	14,980	Varies	558,979	Varies	56,261,517

12.4 Collection of Information Instruments and Instruction/Guidance Documents

CMS-367a - Quarterly Pricing Data Specifications (Revised, see crosswalk for details)

CMS-367b – Monthly Pricing Data Specifications (Revised, see crosswalk for details)

CMS-367c – Product Data Specifications (Revised, see crosswalk for details)

CMS-367d – Manufacturer Contact Form (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 2020/2021 iteration we have adjusted the number of CMS-367 respondents (manufacturer participation increased from 743 to 749) and adjusted our labor rates to more recent BLS data. The combination resulted in an increase in our total time and total cost estimates. As demonstrated below, our per response time estimates are unchanged.

CMS-367a - Quarterly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses	Time per response (hr)	Total Annual Time (hr)	Labor cost ($/hr)	Total Annual Cost ($)
Misc data fields	749	2,996	34.8	104,261	Varies	10,513,144
Currently Approved Burden	743	2,972	34.8	103,426	Varies	10,265,615
CHANGE	+6	+24	No Change	+835	Varies	+247,529

CMS-367b – Monthly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses	Time per response (hr)	Total Annual Time (hr)	Labor cost ($/hr)	Total Annual Cost ($)

Misc data fields	749	8,988	44.8	402,662	Varies	40,789,881
Currently Approved Burden	743	8,916	44.8	399,437	Varies	39,802,896
CHANGE	+6	+72	No Change	+3,225	Varies	+986,985

CMS-367c – Product Data

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses	Time per response (hr)	Total Annual Time (hr)	Labor cost ($/hr)	Total Annual Cost ($)
Misc data fields	749	749	43.5	32,582	Varies	3,109,631
Currently Approved Burden	743	743	43.5	32,321	Varies	3,026,298
CHANGE	+6	+6	No Change	+261	Varies	+83,333

CMS-367d – Manufacturer Contact Form

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses	Time per response (hr)	Total Annual Time (hr)	Labor cost ($/hr)	Total Annual Cost ($)
	749	1,498	1.0	1,498	92.46	138,505
Currently Approved Burden	743	1,486	1.0	1,486	90.02	133,770
CHANGE	+6	+12	No Change	+12	+2.44	+4,735

We have also added instructions to each instrument file. Previously, they were submitted as separate files.

Effective July 1, 2021, we are updating to a new Medicaid Drug Programs (MDP) system which will now accept a delimited text file format, Comma Separated Values (.CSV), in addition to the current Text (.TXT) file format. We have also increased several file format data field sizes in order to accommodate the higher priced drugs that are entering the market. These changes in conjunction with numerous edits to verbiage are applicable to Forms CMS-304 and CMS-304a. This PRA package (0938-0676) is simultaneously being updated along with our two corresponding PRA packages (0938-0578 and 0938-0582), so that all the MDP file formats, field sizes, and verbiage will align across the MDRP.

We also estimate a one-time burden of 16 hours at $89.06/hr for a Computer Programmer and 8 hours at $107.32/hr for a Computer Tester for each manufacturer to make any system updates to accommodate the updated field sizes and .CSV file formats for CMS-367a, CMS-367b, and CMS-367c (for a total of $2,284 across both positions). This equates to a total one-time burden of 17,976 hours (24 hr x 749 manufacturers) at a cost of $1,710,356 ($2,283 x 749 manufacturers).

Summary of Changes

Form	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
CMS-367a	+6	+24	No Change	+835	Varies	+247,529
CMS-367b	+6	+72	No Change	+3,225	Varies	+986,985
CMS-367c	+6	+6	No Change	+261	Varies	+83,333
CMS-367d	+6	+12	No Change	+12	+2.44	+4,735
CMS-367a, b, and c	n/a	+749	+24	+17,976	Varies	+1,710,356
Total Change	+6	+863	Varies	+22,309	Varies	+3,032,938

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.