

Supporting Statement – Part A
Medicaid Drug Program
CMS-367a, 367b, 367c, and 367d
OMB 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 NDRA are required to report product and pricing data 30 days after every month and quarter. CMS forms 367a-c identifies 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 - Supplemental Data Sheet), under the MDRP. These labeler reporting requirements are currently approved under OMB no. 0938-0578 through December 31, 2019.

Two fields (ACA Base AMP and DRA Base AMP) are being removed from Form 367c because the fields are no longer collected. Additionally, several data definitions as well as verbiage have been updated on all the forms (367a-d) in order to provide better clarification for labelers. We do not anticipate that any of these changes will have an impact on either the hour or cost burden associated with these data collections.

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 application, Drug Data Reporting for Medicaid (DDR) is available at no charge to all participating labelers. Labelers have two data reporting options within DDR: first, they may key their data online on an individual NDC basis; second, they may transfer a saved file to DDR.

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

4. Duplication Information

CMCS is the only CMS component collecting drug data for purposes of the Medicaid program. 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. DDR helps these entities more easily and accurately report their data than was possible under the previous data collection method. The DDR 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 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

-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

N/A

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 2018 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Table 1 **Hourly Wage Estimates**

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business Operations Specialist	13-1199	37.00	37.00	74.00
ComputerSystemAnalysts	15-1121	45.01	45.01	90.02
General & Operations Managers	11-1021	59.56	59.56	119.12
Lawyers	23-1011	69.34	69.34	138.68
Operations Research Analysts	15-2031	42.48	42.48	84.96
Training & Development	11-3131	58.53	58.53	117.06

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Managers				

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.

12.2 Burden Estimates

Currently, there are approximately 743 respondents reporting drug information to CMS. Of the 743 total respondents reporting, 100% will report data via the DDR web-based application. Within DDR, 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 CMS 367a, includes the following fields: “Record ID”, “Labeler Code”, “Product Code”, “Package Size”, “Period Covered”, “Average Manufacturer Price (AMP)”, “Best Price (BP)”, “Nominal Price (NP)”, “Customary Prompt Pay (CPP) Discount”, “Initial Drug Available for Line Extension”, and “Initial Drug”.

We estimate that these requirements affect the approximately 743 drug manufacturers participating in the MDRP. The quarterly burden associated with the reporting of these miscellaneous data fields is the time and effort it takes to report these miscellaneous fields through the file transfer process or manual data entry through the DDR system.

We estimate that it will take a computer system analyst 10 hours at \$90.02/hr, a general and operations manager 1 hours at \$119.12/hr, a training and development manager 1 hour at \$117.06/hr, and a operations research analyst 5 hours at \$84.96/hr (for a total of \$1,561.18 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous data fields. This equates to an annual burden of 68 hours per manufacturer. In aggregate, we estimate 50,524 hours (743 drug manufacturers participating in the MDR program x 68 hr) at a cost of \$4,639,826.96 (\$1,561.18 per response x 4 responses/year x 743 manufacturers).

CMS-367a - Quarterly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
Misc data fields	743	2,972 (4 quarterly responses per year)	17.0	50,524	Varies	4,639,827
Currently	610	2,440	34.8	84,912	Varies	8,022,891

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
Approved Burden						

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”, “Package Size”, “Month”, “Year”, “Average Manufacturer Price (AMP)”, “AMP Units”, and “5i Threshold”.

We estimate that these requirements affect the approximately 743 drug manufacturers participating in the MDRP. The monthly burden associated with the reporting of these miscellaneous data fields is the time and effort it takes to report these miscellaneous fields through the file transfer process or manual data entry through the DDR system.

We estimate that it will take a computer system analyst 10 hours at \$90.02/hr, a general and operations manager 1 hours at \$119.12/hr, a training and development manager 1 hour at \$117.06/hr, and a operations research analyst 5 hours at \$84.96/hr (for a total of \$1,561.18 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous data fields. This equates to an annual burden of 204 hours per manufacturer. In aggregate, we estimate 151,572 hours (743 drug manufacturers participating in the MDR program x 204 hr) at a cost of \$13,919,480.90 (\$1,561.18 per response x 12 responses/year x 743 manufacturers).

CMS-367b – Monthly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
Misc data fields	743	8,916 (12 monthly responses per year)	17	151,572	Varies	13,919,481
Currently Approved Burden	610	7,320	44.8	327,936	Varies	30,961,184

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 (TEC)”, “Market Date”, “Termination Date”, “Drug Type”, “OBRA ’90 Baseline AMP”, “Units Per Package Size (UPPS)”, “FDA Product Name”, “Package Size Intro Date (PSID)”, “Purchased Product Date (PPD)”, “5i Drug Indicator”, “5i Route of Administration”, “Covered Outpatient Drug (COD)”

Status”, “FDA Application Number/OTC Monograph Number”, “Line Extension Drug Indicator”, and “Reactivation Date”.

We estimate that these requirements affect the approximately 743 drug manufacturers participating in the MDRP. The annual burden associated with the reporting of these miscellaneous product data fields is the time and effort it takes to report these miscellaneous fields through the file transfer process or manual data entry through the DDR system.

We estimate that it will take a computer system analyst 10 hours at \$90.02/hr, a general and operations manager 1 hours at \$119.12/hr, a training and development manager 1 hour at \$117.06/hr, and a operations research analyst 9 hours at \$84.96/hr (for a total of \$1,901.02 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous product data fields. In aggregate, we estimate 15,603 hours (743 drug manufacturers participating in the MDR program x 21 hr) at a cost of \$1,412,457.86 (\$1,901.02 per response x 1 response/year x 743 manufacturers).

CMS-367c – Product Data

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
Misc data fields	743	743 (1 response per year)	21	15,603	Varies	1,412,458
Currently Approved Burden	610	610	53.5	32,635	Varies	2,965,307

CMS-367d – Supplemental Data Sheet

Burden Due to Supplemental Data Sheet submission: The Supplemental Data Sheet 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 MDR system.

We estimate that this requirement affects the approximately 743 drug manufacturers participating in the MDRP. Furthermore, we estimate that drug manufacturers need to submit the Supplemental Data Sheet to CMS on average twice a year. The annual burden associated with the submission of the Supplemental Data Sheet is the time and effort it takes to complete the form and fax, mail or email the form to CMS.

We estimate that it will take a computer system analyst 1 hour at \$90.02/hour to complete the submission of the supplemental data sheet. This equates to an annual burden of 2 hours (1 hr/response x 2 responses/year) per drug manufacturer. In aggregate, we estimate 1,486 hours (743 drug manufacturers participating in the MDR program x 2 hrs) at a cost of \$133,770 (\$90.02 per response x 2 response/year x 743 manufacturers).

CMS-367d – Supplemental Data Sheet

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
Currently Approved Burden	743	1,486 (2 responses per year)	1.0	1,486	90.02	133,770

12.3 Summary of Burden Estimates

Regulation Section(s) in Title 42 of the CFR	Description/ Form	Frequency	Respondents	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
	CMS-367a	Quarterly	743	2,972	17	50,524	4,639,827	0	4,639,827
	CMS-367b	Monthly	743	8,916	17	151,572	13,919,481	0	13,919,481
	CMS-367c	Occasionally	743	743	21	15,603	1,412,458	0	1,412,458
	CMS-367d	Occasionally	743	1,486	1	1,486	133,770		133,770
Total	--	--	743	14,117	--	219,185	20,105,536	0	20,105,536

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 Drug Data Reporting for Medicaid (DDR) and Medicaid Drug Rebate (MDR) systems 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

There has been a decrease in the overall hour and cost burden estimates from the previous iteration of this PRA package, due to the removal of the one-time burden calculations that no longer apply.

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.