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 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.

In this 2019 information collection request, we request a three year approval period for the labeler reporting requirements (Forms: CMS-367a - Quarterly Pricing Data; CMS-367b - Monthly Pricing Data; CMS-367c - Product Data; CMS-367d – Contact Information Sheet), under the MDRP.

In this iteration, two fields (ACA Base AMP and DRA Base AMP) are being removed from Form 367c because the fields are no longer collected. We also propose to remove two one-time requirements.

Additonally, 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 have also adjusted the number of respondents due to an increase in the number of participating labelers.

Overall, our total time estimate has decreased by -3,082,033 hours from our active estimate of 3,618,703 hours to our proposed estimate of 536,670 hours (see section 15 of this Supporting Statement for details).

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 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 Federal Register notice published on August 23, 2019 (84 FR 44316). A public comment was received but it was not germaine to this information collection request nor to CMS. Rather, it was intended for another agency. Consequently, the comment has not been attached to this package.

The 30-day Federal Register notice published on November 14, 2019 (84 FR 61910).

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
Computer System Analysts	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 Managers	11-3131	58.53	58.53	117.06

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 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 DDR system.

We estimate that it will take a computer system anaylst 13 hours at $90.02/hr, a general and operations manager 7 hours at $119.12/hr, a training and development manager 6 hours at $117.06/hr, and a operations research anaylst 8.8 hours at $84.96/hr (for a total of $3,454.11 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 103,426 hours (743 drug manufacturers participating in the MDR program x 139.2 hr) at a cost of $10,265,614.92 ($3,454.11 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)	34.8	103,426	Varies	10,265,615

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 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 DDR system.

We estimate that it will take a computer system anaylst 13 hours at $90.02/hr, a general and operations manager 7 hours at $119.12/hr, a training and development manager 11 hours at $117.06/hr, and a operations research anaylst 13.8 hours at $84.96/hr (for a total of $4,464.21 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous data fields. This equates to an annual burden of 537.60 hours (44.8 hours per response x 12 responses per year) per manufacturer. In aggregate, we estimate 399,437 hours (743 drug manufacturers participating in the MDR program x 537.60 hr) at a cost of $39,802,896.36 ($4,464.21 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)	44.8	399,437	Varies	39,802,896

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 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 DDR system.

We estimate that it will take a computer system anaylst 18 hours at $90.02/hr, a general and operations manager 6.5 hours at $119.12/hr, a training and development manager 2 hours at $117.06/hr, and a operations research anaylst 17 hours at $84.96/hr (for a total of $4073.08 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous product data fields. In aggregate, we estimate 32,321 hours (743 drug manufacturers participating in the MDR program x 43.5 hr) at a cost of $3,026,298.44 ($4,073.08 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)	43.5	32,321	Varies	3,026,298

CMS-367d – Contact Information Sheet

Burden Due to Contact Information Sheet submission: The Contact Information 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 Contact Information Sheet to CMS on average twice a year. The annual burden associated with the submission of the Contact Information 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 Contact Information 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 – Contact Information Sheet

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

12.3 Summary of Burden Estimates

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	34.8	103,426	10,265,615	0	10,265,615
CMS-367b	Monthly	743	8,916	44.8	399,437	39,802,596	0	39,802,596
CMS-367c	Occasionally	743	743	43.5	32,321	3,026,298	0	3,026,298
CMS-367d	Occasionally	743	1,486	1	1,486	133,770		133,770
TOTAL		**743**	**14,117**	**Varies**	**536,670**	**53,228,278**	**0**	**53,228,278**

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

Burden Changes: For the CMS-367c form, the per response time estimate has decreased by 10 hours due to the removal of the one-time burden resulting from the narrow exception application process that was included in the currently approved iteration of this package. When considering the increase in the number of participating labelers, the total time estimate (for the 367c form) is only slightly lower than what is currently approved by OMB.

Based on updated BLS wage info, we have also adjusted the cost estimates for each of the four forms.

Wage Adjustments

Occupation Title	Occupation Code	2016 Adjusted Hourly Wage ($/hr)	2019 Adjusted Hourly Wage ($/hr)	Difference ($/hr)
Business Operations Specialist	13-1199	70.66	74.00	+3.34
Computer System Analysts	15-1121	86.72	90.02	+3.30
General & Operations Managers	11-1021	114.88	119.12	+4.24
Lawyers	23-1011	131.02	138.68	+7.66
Operations Research Analysts	15-2031	80.94	84.96	+4.02
Training & Development Managers	11-3131	107.38	117.06	+9.68

Burden Adjustments

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 ($/hr)	Total Annual Cost ($)
Currently Approved Burden	610	2,440	34.8	84,912	Varies	8,022,891

Proposed Burden	743	2,972 (4 quarterly responses per year)	34.8	103,426	Varies	10,265,615
Difference	**+133**	**+532**	**No Change**	**+18,514**	**Varies**	**+2,242,724**

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 ($/hr)	Total Annual Cost ($)
Currently Approved Burden	610	7,320	44.8	327,936	Varies	30,961,184
Proposed Burden	743	8,916 (12 monthly responses per year)	44.8	399,437	Varies	39,802,896
Difference	**+133**	**+1,596**	**No Change**	**+71,501**	**Varies**	**+8,841,712**

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 ($/hr)	Total Annual Cost ($)
Currently Approved Burden	610	610	53.5	32,635	Varies	2,965,307
Proposed Burden	743	743 (1 response per year)	43.5	32,321	Varies	3,026,298
Difference	**+133**	**+133**	**-10**	**-314**	**Varies**	**+60,991**

CMS-367d – Contact Information 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	610	1,220	1.0	1,220	86.72	105,798
Proposed Burden	743	1,486 (2 responses per year)	1.0	1,486	90.02	133,770
Difference	**+133**	**+266**	**No Change**	**+266**	**+3.30**	**+27,972**

Summary of Burden Adjustments

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

CMS-367a (Quarterly Pricing Data)	+133	+532	No Change	+18,514	Varies	+2,242,724
CMS-367b (Monthly Pricing Data)	+133	+1,596	No Change	+71,501	Varies	+8,841,712
CMS-367c (Product Data)	+133	+133	-10	-314	Varies	+60,991
CMS-367d (Contact Information Sheet)	+133	+266	No Change	+266	+3.30	+27,972
TOTAL	+133	+2,527	-10	+89,967	+32.24	+11,173,399

Program Changes: There have been no substantial program changes since the last iteration of this PRA packages; however, the 367a, b, c and d forms all contain significant wording changes in order to bring the verbiage into alignment with other Medicaid Drug Rebate Program-related documentation. In addition, two fields (ACA Base AMP and DRA Base AMP) are being removed from Form 367c because the fields are no longer collected. 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.

The following requirements and burden do not appear in any of the CMS-367 form data fields and are one-time requirements that are currently approved. Since the requirements have been met, we are removing the burden.

One-Time Reconfiguration of Labeler Drug Pricing Systems: The February 1, 2016 (81 FR 5170) final rule significantly revised the definitions of AMP and best price, which are both part of the pricing information submitted by manufacturers on a monthly and/or quarterly basis. Consequently, drug manufacturers must reconfigure their pricing systems to correctly calculate AMP and best price. Specifically, the burden associated with these new requirements is the time and effort it takes a drug manufacturer to reconfigure its pricing systems to correctly calculate AMP and best price, before it can submit the required data to CMS.

We had estimated that these requirements affect the approximately 610 drug manufacturers in the MDR program. We estimated it will take a computer system analyst 400 hours, a general and operations manager 180 hours, a training and development manager 180 hours, a lawyer 40 hours, and an operations research analyst 400 hours to update a manufacturer's pricing system to incorporate the requirements related to the changes to AMP and best price definitions. The one-time total burden for the 610 drug manufacturers participating in the MDR program is estimated to be 732,000 hours (610 drug manufacturers x 1,200 hr/ drug manufacturer).

This information is not located on the CMS-367 forms. As indicated above this burden requirement is to update a manufacturer's pricing system to incorporate the requirements related to the changes to AMP and best price definition so that AMP and best price data can be reported on the CMS-367 forms.

One-Time Cost of Training Drug Manufacturer Staff: In addition to the one-time burden of reconfiguring pricing systems, we are also estimating a one-time cost to train drug manufacturer staff on the new, reconfigured pricing systems. To perform this training, we believe it will take a general and operations manager 600 hours, a training and development manager 1,700 hours, and an operations research analyst 1,700 hours. The one-time total burden associated with this training is estimated to be 2,440,000 hours (610 drug manufacturers x 4,000 hr/ drug manufacturer).

Regulation Section(s)	Description / Form	Respondents	Total Responses	Burden per Response	Total Time (hours)	Total Labor Cost of	Total Capital/Maintenance Costs ($)

in Title 42 of the				**(hours)**		**Reporting ($)**	
447.510	One-Time Reconfiguration of Labeler Drug Pricing Systems	610	610	1,200	732,000	68,510,076	0
447.510	One-Time Cost of Training Drug Manufacturer Staff s	610	610	4,000	2,440,000	237,333,920	0
TOTAL		**610**	**1,220**	**Varies**	**3,172,000**	**305,843,996**	**0**

Reconciliation of Active and Proposed Burden Estimates

*See the TOTAL in section 12.3 of this Supporting Statement.

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.