

Supporting Statement – Part A
OMB 0938-0578

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)

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.

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; and CMS-367e – Quarterly VBP-MBP Data), under the MDRP. These labeler reporting requirements are currently approved under OMB no. 0938-0578 through May 31, 2024.

Form CMS-367d is a report of contact for the Manufacturer to name the individuals involved in the MDRP, upon initial entrance into the MDRP, and then required only in those instances where a change to the originally submitted data is necessary. The ability to require the reporting of any changes to these data is necessary to the efficient operation of these programs. The CMS-367d is being updated to include a signature/date line for the submitter to confirm that the information provided is accurate, and we have additionally updated the entire 367d to a fillable format, per multiple labeler requests. We do not anticipate that any of these changes will have an impact on either the hour or cost burden associated with this data collection.

Form CMS-367e is a new form to be used by manufacturers as needed, on a quarterly basis, to transmit pricing data (best prices associated with value-based purchasing (VBP) arrangements) for each of their covered outpatient drugs (CODs) to CMS either via direct file upload to the MDP System or manual on-line entry. The use of Form CMS-367e is considered optional under the authority of Section 1927 of the Social Security Act, 42 CFR 447.510, and the National Drug Rebate Agreement.

We are not proposing any changes to the CMS-367a (Quarterly Pricing), CMS-367b (Monthly Pricing), or CMS-367c (Product Data) forms.

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) . On December 31, 2020, the Centers for Medicare & Medicaid Services (CMS) published the final rule entitled: *Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and TPL Requirements*'' (hereinafter referred to as the final rule) (85 FR 87000). This new regulation amended the definition of best price at 42 CFR 447.505(a) to allow manufacturers to report multiple best prices (instead of just one best price) for a drug based on a VBP arrangement's guaranteed net unit price (GNUP,) and the patient's performance on the relevant evidence-based or outcome-based measure when a manufacturer chooses to offer these VBP arrangements to states. This action allows the manufacturer to report the VBP multiple best prices as permitted under 42 CFR 447.505(a), and allows the state to participate in a VBP agreement. Otherwise, the Medicaid drug rebate will reflect a Best Price that is not related to the VBP arrangement.

The effective date is January 1, 2022. However, CMS has proposed a delay to the effective date under *Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements: Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States* due to the current public health emergency. The proposed effective date for the reporting of multiple best prices is July 1, 2022.

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 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

Not applicable

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 2020 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 (calculated at 100 percent of salary), and the adjusted hourly wage.

Hourly Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
General & Operations Manager	11-1021	60.45	60.45	120.90
Training & Development Manager	11-3131	60.54	60.54	121.08
Computer System Analyst	15-1211	47.61	47.61	95.22
Computer Programmer	15-1251	45.98	45.98	91.96
Computer Tester	15-1256	54.94	54.94	109.88
Operations Research Analyst	15-2031	44.37	44.37	88.74

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 780 respondents reporting drug information to CMS. Of the 780 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 780 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 direct file upload or manual data entry through the MDP system.

We estimate that it will take a Computer System Analyst 13 hours at \$95.22/hr, a General and Operations Manager 7 hours at \$120.90/hr, a Training and Development Manager 6 hours at \$121.08/hr, and an Operations Research Analyst 8.8 hours at \$88.74/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 108,576 hours (780 drug manufacturers participating in the MDRP x 139.2 hr) at a cost of \$11,205,636 (\$3,591.55 per response x 4 responses/year x 780 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	780	3,120 (4 quarterly responses/year)	34.8	108,576	Varies	11,205,636
Currently Approved Burden	749	2,996	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 “Si Threshold”.

We estimate that these requirements affect the approximately 780 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 direct file upload or manual data entry through the MDP system.

We estimate that it will take a Computer System Analyst 13 hours at \$95.22/hr, a General and Operations Manager 7 hours at \$120.90/hr, a Training and Development Manager 11 hours at \$121.08/hr, and a Operations Research Analyst 13.8 hours at \$88.74/hr (for a total of \$4,640.65 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

419,328 hours (780 drug manufacturers participating in the MDRP x 537.6 hours) at a cost of \$43,436,484 (\$4,640.65 per response x 12 responses/year x 780 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	780	9,360 (12 monthly responses per year)	44.8	419,328	Varies	43,436,484
Currently Approved Burden	749	8,988	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 780 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 direct file upload or manual data entry through the MDP system.

We estimate that it will take a Computer System Analyst 18 hours at \$95.22/hr, a General and Operations Manager 6.5 hours at \$120.90/hr, a Training and Development Manager 2 hours at \$121.08/hr, and a Operations Research Analyst 17 hours at \$88.74/hr (for a total of \$4,250.55 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous product data fields. In aggregate, we estimate 33,930 hours (780 drug manufacturers participating in the MDRP x 43.5 hr) at a cost of \$3,315,429 (\$4,250.55 per response x 1 response/year x 780 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	780	780 (1 response per year)	43.5	33,930	Varies	3,315,429
Currently						

Approved Burden	749	749	43.5	32,582	Varies	3,109,631
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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 780 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 email it to CMS.

We estimate that it will take a Computer System Analyst 1 hour at \$95.22/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 1,560 hours (780 drug manufacturers participating in the MDRP x 2 hrs) at a cost of \$148,543 (\$95.22 per response x 2 response/year x 780 manufacturers).

CMS-367d – Manufacturer Contact Form

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	780	1,560	1.0	1,560	95.22	148,543
Currently Approved Burden	749	1,498 (2 responses per year)	1.0	1,498	92.46	138,505

CMS-367e – Quarterly VBP-MBP Data

Burden Due to Miscellaneous Quarterly VBP-MBP Data Fields: On an as needed quarterly 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 780 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 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 \$120.90/hr to report these miscellaneous VBP-MBP data fields. This equates to an annual burden of 200 hours (50 affected drug manufacturers x 4 quarters) at a cost of \$24,180 (\$120.90 per response x 4 responses/year x 50 affected manufacturers)

CMS-367e – Quarterly VBP-MBP 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	50	200 (4 quarterly responses per year)	1.0	200	\$120.90	\$24,180
Currently Approved Burden	N/A	N/A	N/A	N/A	N/A	N/A

We also estimate a one-time burden of 8 hours at \$91.96/hr for a Computer Programmer and 8 hours at \$109.88/hr for a Computer Tester for each manufacturer to make any system updates to accommodate the reporting of the new fields for the CMS-367e (for a total of \$1,614.72 across both positions). This equates to a total one-time burden of 16 hours per 50 manufacturers at a cost of \$80,736 (\$1,614.72 x 50 manufacturers).

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	780	3,120	34.8	108,576	11,205,636	0	11,205,636
CMS-367b	Monthly	780	9,360	44.8	419,328	43,436,484	0	43,436,484
CMS-367c	Occasionally	780	780	43.5	33,930	3,315,429	0	3,315,429
CMS-367d	Occasionally	780	1,560	1	1,560	148,543	0	148,543
CMS-367e	Occasionally	50	200	1	200	24,180	0	24,180
CMS-367e	One-Time	50	50	16	800	80,736	0	80,736
Total		--	15,020	--	564,394	58,211,008	0	58,211,008

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

Burden Changes: Although the hourly burden associated with the 367a, 367b and 367d forms has remained the same since the previous iteration of this PRA package, the total annual burden hours for all three of those forms did increase because the number of participating labelers in the MDRP has increased. In addition, the hourly wage estimates cited in this package have all increased, which has consequently increased the total annual cost of all four forms.

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. 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.

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.