Supporting Statement Part A
Medicaid Drug Rebate Program (MDRP) Forms – States
Quarterly State Invoice (CMS-R-144)
State Agency Contact Form (CMS-368)
OMB 0938-0582

Background

Section 1927 of the Social Security Act (the Act) requires drug manufacturers to enter into and have in effect a national rebate agreement with the Federal Government for States to receive funding for prescription drugs dispensed to Medicaid recipients. For purposes of this legislation, a drug manufacturer is defined as an entity holding legal title to the National Drug Code (NDC) number for a prescription drug, nonprescription drug or biological product.

To receive a rebate on the drugs dispensed to Medicaid recipients, States are required to submit quarterly utilization data reports to drug manufacturers that have a National Drug Rebate Agreement (NDRA) with the Federal Government. In addition, a copy of these reports must also be submitted to the Centers for Medicare & Medicaid Services (CMS). In turn, States are required to refund the Federal share of all Medicaid drug rebates they collect by reporting such rebates on a quarterly Medicaid expenditure report for the quarter in which the rebate was received.

Form CMS-R-144 is required from States quarterly to report utilization for any drugs paid for during that quarter.

There have been no updates to the CMS-R-144, however there were minor non-substantive verbiage updates to the corresponding CMR-R-144 Data Definitions, which have no impact on our currently approved burden estimates.

We are also removing a one-time requirement and burden of 1,344 hours (24 hr x 56 states) at a cost of $127,877 (56 responses x [(16 hr x $89.06/hr for a Computer Programmer) + (8 hr x $107.32/hr for a Computer Tester)]) for each manufacturer to make system updates to accommodate the updated field sizes and .CSV file formats for CMS-R-144. The one-time task has been met so we are removing the associated burden as a non-substantive change.

Form CMS 368 is a report of contact for the State to name the individuals involved in the Medicaid Drug Rebate Program (MDRP), and is 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.

Form CMS-368 has been revised to include a signature/date line for the submitter to confirm that the information provided is accurate. We have also updated the entire CMS-368 to a fillable format. Both of the changes are non-substantive and have no impact on our currently approved burden estimates.

A. Justification

1. Need and Legal Basis

The authority for requiring States to submit the quarterly data report is found in Section 1927 of the Act. Specifically, Section 1927(a)(1) describes the requirements for rebate agreements and section 1927(b)(2) describes the state's responsibilities with respect to the drug rebate program. Copies of these portions of the statute are attached, along with copies of the relevant statutory changes included in the Affordable Care Act.

2. Information Users

CMS develops the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the States. States then must report quarterly to the drug manufacturers and to CMS the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the State Medicaid agency during a calendar quarter.

3. Use of Information Technology

Currently, States are required to upload their quarterly reports to CMS via direct file upload within the Medicaid Drug Programs (MDP) system. However, States determine the vehicle by which they submit the same reports to the drug manufacturers, i.e., electronic media or hard copy. CMS developed a hard copy layout of the required reporting data which contains the same data as that developed for electronic record layout. This layout was agreed upon by the States and CMS for those instances where electronic media is not used for quarterly reporting to drug manufacturers.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This collection of information does not involve small businesses or other small entities.

6. Less Frequent Collection

Section 1927 of the Act requires the quarterly reporting by States of the drug identification and rebate data. Less frequent reporting of these documents would hamper the efficient administration and function of the MDRP.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted

in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include 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
- 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. FR Notice/Outside Consultations

Initially, we published a 60-day Federal Register notice on November 10, 2021 (86 FR 62543). While that notice characterized the collection of information request as a "revision," in hindsight we believe the proposed changes are "non-substantive." In that regard we are withdrawing the November 10 Federal Register notice and submitting this collection of information request to OMB under the non-substantive change process. As such, the collection of information request is not subject to public comment and does not require the publication of any Federal Register notices.

9. Payments/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. Burden Estimates

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 BLS' mean hourly wage along with 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)
Accountant/Auditor	13-2011	39.26	39.26	78.52
Chief Executive	11-1011	95.12	95.12	190.24
Computer System Analyst	15-1211	47.61	47.61	95.22
General & Operations Manager	11-1021	60.45	60.45	120.90
Office & Administrative Support Worker	43-9199	18.91	18.91	37.82

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 Collection of Information Requirements and Associated Burden Estimates

CMS-R-144 – Quarterly State Invoice

There are 56 states (including Washington, D.C. and the five U.S. Territories) in the rebate program. The majority of the State burden is associated with the quarterly drug utilization reports, in which all State agencies report drug utilization data to drug manufacturers and to CMS. Currently these reports are submitted to CMS via direct file upload via our MDP system; however, CMS has no control over the vehicle by which States report to the drug manufacturers. The States and the drug manufacturers agree on a method of data transmission. Some States opt for hard copy reports, while others use magnetic media or other forms of electronic transmission. States that opt to report via hard copy are required to use the format associated with the CMS-R-144. The quarterly burden associated with the CMS-R-144 is the total average of the time and effort it takes for both types of data transmissions.

The quarterly burden is an average of the time and effort it takes for both types of data transmissions (hardy copy or electronic), for state data review and certification, and to account for any updates to state management CMS system access. We estimate a quarterly burden of 5 hours at $78.52/hr for an Accountant/Auditor, 1.0 hours at $190.24/hr for a Chief Executive, 5 hours at $95.22/hr for a Computer Systems Analyst, 4 hours at $120.90/hr for a General Operations Manager, and 40 hours at $37.82/hr for an Office & Administrative Support Worker to submit a quarterly drug utilization report to drug manufacturers and CMS.

This equates to a burden of 55 hours per state response at a cost of $3,055.34 [(5 hr x $78.52/hr)

+ (1.0 hr x $190.24/hr) + (5 hr x $95.22/hr) + (4 hr x $120.90/hr) + (40 hr x $37.82/hr)]. In aggregate we estimate an annual burden of 12,320 hours (56 states x 55 hr/response x 4 responses/yr) at a cost of $684,396.16 ($3,055.34 x 56 states x 4 responses/yr).

Our total annual burden estimate is 12,325 hours and $684,5856.26.

Information Collection Instruments and Instruction/Guidance Documents

- CMS Form R-144 – Quarterly State Invoice (No changes)

The established invoice format that states use to send rebate invoices (within 60 days of the end of the calendar quarter) to each manufacture Invoice Contact for any rebate- eligible drugs the states paid for during that quarter.

- CMS-R-144 – Record Format (No changes)

Provides the electronic field size listing which must be used if labelers submits the form electronically.

- CMS-R-144 – Data Definitions (Changes)

Provides the corresponding Data Field Definitions to the CMS-R-144 Record Layout.

- Invoice Process Instructions (No changes)

Provides an invoice process overview for states.

CMS-368 – State Agency Contact Form

Form CMS-368 is submitted by states on an as-needed basis in order to report changes to previously submitted administrative data (contact persons). We anticipate that only 10 States will need to revise their current administrative data on an as needed basis.

We estimate that it will take 0.5 hours at $37.82/hr for an Office & Administrative Support Worker to report any changes to previously submitted administrative data. This equates to a burden of 0.5 hours per state per response at cost of $18.91 (0.5 hr x $37.82/hr). In aggregate we estimate an annual burden of 5 hours (10 states x 0.5 hr/state) at a cost of $189.10 (5 hr x $37.82/hr).

Information Collection Instruments and Instruction/Guidance Documents

- CMS Form 368 – State Agency Contact Form (Changes)

Submitted by states on as as-needed basis in order to report changes to previously submitted administrative data (i.e., contact persons).

12.3 Summary of Burden Estimates

Form	Annual Frequency	No. Respondents	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost ($/hr)	Total Cost ($)
CMS-R-144	Quarterly	56	224	55	12,320	Varies*	684,396
CMS-368	As Needed	10	10	0.5	5	37.82	189
TOTAL		**56**	**234**	**Varies**	**12,325**	**Varies**	**684,585**

*See above for details.

13. Capital Costs

There are no capital or start-up costs associated with this information collection because the Medicaid Drug Rebate Program has been in existence since January 1, 1991. States have had their data systems in place for drug rebate data collection since that time.

14. Cost to Federal Government

Per the U.S. Office of Personnel Management (OPM), 2021 General Schedule (GS) Locality Pay Tables (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB_h.pdf), for the pay area of Washington, DC-Baltimore, MD-Arlington, VA. Quarterly, we estimate it will take a GS-11, Step 1, Health Insurance Specialist, 1 hour at $34.86/hr to update any state contact information, and a GS-13, Step 1, Health Insurance Specialist, 3 hours at $49.68/hr to review any issues with the state utilization data.

This equates to a burden of 4 hours per quarter at a cost of $183.90 [(1 hr x $34.86/hr) + (3 hr x $49.68/hr)]. In aggregate we estimate an annual burden of 16 hours (4 hr x 4 responses/yr) at a cost of $735.60 ($183.90 x 4 responses/yr).

Federal Burden Summary

Burden Category	Burden per Quarter (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting ($/hr)	Total Annual Cost ($)
Update State Contact Information	1	4	34.86	139.44
Review State Utilization Data	3	12	49.68	596.16
Total	**4**	**16**	**Varies**	**735.60**

15. Changes to Collection of Information Requirements and Burden

In this non-substantive collection of information request, we propose the following. Overall, we project a decrease of -56 responses (from 290 to 234), -1,344 hours (from 13,669 hr to 12,325 hr), and -$110,324 (from $794,909 to $684,585).

1-We are proposing minor non-substantive verbiage updates to the CMR-R-144 Data Definitions. Please see the attached Crosswalk for details.

The change has no impact on our currently approved burden estimates.

2-We propose to remove a one-time requirement and burden of 1,344 hours (24 hr x 56 states)

for each manufacturer to make system updates to accommodate the updated field sizes and .CSV file formats for CMS-R-144. The one-time task has been met so we are removing the associated burden as a non-substantive change.

3-We are proposing to revise the CMS-368 form to include a signature/date line for the submitter to confirm that the information provided is accurate. We have also updated the entire CMS-368 form to a fillable format.

Both of the changes are non-substantive and have no impact on our currently approved burden estimates.

4-We are adjusting our currently approved cost estimates which used May 2019 BLS wage data by using BLS' May 2020 wage data.

16. Publication/Tabulation Dates

There are no plans to publish the information for statistical use.

17. Expiration Date

Both the expiration date and PRA Disclosure Statement are set out on form CMS-368 and form CMS-R-144.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.