

Supporting Statement Part A
Reconciliation of State Invoice (ROSI) (CMS-304)
and
Prior Quarter Adjustment Statement (PQAS) (CMS-304a)
OMB 0938-0676

Background

Section 1927 of the Social Security Act (the Act) requires drug manufacturers to enter into and have in effect a rebate agreement with the Federal government for States to receive funding for 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 national rebate agreements with the Federal Government. In turn, manufacturers are required to provide rebate payments for covered outpatient drugs as prescribed in section 1927(b) of the Act.

CMS is requesting a three-year approval of the manufacturer reporting requirements (forms CMS-304 and CMS-304a) under the drug rebate program.

The form CMS-304 (Reconciliation of State Invoice - ROSI) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. The form CMS-304a (Prior Quarter Adjustment Statement - PQAS) is required only in those instances where a change to the original rebate data submittal is necessary.

Effective July 1, 2021, the Medicaid Drug Rebate Program (MDRP) is 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 have also adjusted the number of CMS-304 respondents (manufacturer participation increased from 517 to 534) which resulted in an increase in our total time and total cost estimates. Our per response time estimate in unchanged.

We have also adjusted the number of CMS-304a respondents (manufacturer participation increased from 738 to 749) which resulted in an increase in our total time and total cost estimates. Our per response time estimate in unchanged.

See section 15 for more details regarding the changes.

A. Justification

1. Need and Legal Basis

Section 1927(a)(1) of the Act requires drug manufacturers to enter into and have in effect a rebate agreement with the Federal Government for States to receive funding for drugs dispensed to Medicaid recipients.

States are required to submit quarterly utilization data reports to CMS and drug manufacturers that have drug rebate agreements with CMS on behalf of the States. In turn, manufacturers are required to provide rebate payments for covered outpatient drugs as prescribed in section 1927(b) of the Act. Copies of these portions of the statute are attached.

2. Information Users

CMS develops the unit rebate amount (URA) from drug pricing information supplied by the drug manufacturers. Each quarter, CMS distributes the URA data to the States. States then report drug utilization data quarterly to the manufacturers (with a copy to CMS), and optionally may associate the URA to that data to establish a payment due amount. Manufacturers, in turn, must remit rebate payments in response to the State's invoice of utilization data.

In response to a need for improved data exchange between manufacturers and States, CMS, in conjunction with outside consultations (see item 8 below), developed the Reconciliation of State Invoice (ROSI), form CMS-304, and the Prior Quarter Adjustment Statement (PQAS), form CMS-304a. The ROSI is to be used by manufacturers to uniformly explain any adjusted rebate payments for the current quarter. It must be used when the manufacturer is not paying the full rebate amount due or the State invoice contains zeros in the unit rebate amount field. The PQAS is used by manufacturers to report adjusted rebate payments only on prior quarter actions/payments. Prior quarter activity includes changes to utilization data submitted by States, revisions to previously disputed units, and prior period adjustments (URA changes). Both forms assist in reducing disputes by standardizing data exchange and improving communication between manufacturers and States.

3. Use of Information Technology

The ROSI and the PQAS may be submitted by manufacturers to States either via paper or electronic media, depending on the needs and capabilities of the manufacturers. ROSI Electronic Format for CMS-304 and PQAS Electronic Format for CMS-304a show the electronic field size listing which must be used if manufacturers submit these forms to States electronically by either .CSV or .TXT.

4. Duplication of Efforts

The CMCS is the only CMS component requiring and collecting drug rebate data on the MDRP. Therefore, there are no existing data which duplicate these data and could be used in place of drug rebate program data.

5. Small Business

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

6. Less Frequent Collection

Section 1927 of the Act requires manufacturers to pay rebates, including the submittal of any applicable ROSI and/or PQAS forms, within 30 days of receiving State Medicaid drug utilization 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

FR Notices

The 60-day notice published in the Federal Register on November 30, 2020 (85 FR 76577). Comments were received and are 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.

Outside Consultations

In order to develop a uniform reporting format for current and prior quarter activity which meets the needs of both manufacturers and States, CMS convened an implementation workgroup from June through October of 1995. The workgroup consisted of representatives from the States, drug manufacturers, and CMS. There are no major issues unresolved as a result of this workgroup.

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

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)
Accountant / Auditor	13-2011	38.23	38.23	76.46
Business Operations Specialist	13-1000	36.31	36.31	72.62
Computer System Analyst	15-1211	46.23	46.23	92.46
Computer Programmer	15-1251	44.53	44.53	89.06
Computer Tester	15-1256	53.66	53.66	107.32
General & Operations Manager	11-1021	59.15	59.15	118.30
Office & Administrative Support Worker	43-9199	18.41	18.41	36.82

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.

Burden Estimates

CMS-304 – Reconciliation of State Invoice (ROSI)

There are approximately 749 drug manufacturers in the rebate program (derived from the MDR system), of which only about 70% (approximately 524 manufacturers) submit the ROSI to States on a quarterly basis as a result of unit adjustments or disputes. The quarterly burden associated with this package is the time and effort it takes to prepare and submit the Reconciliation of State Invoice (ROSI).

We estimate that it will take an Accountant/Auditor 4 hours at \$76.46/hr, a Business Operations Specialist 20 hours at \$72.62/hr, a Computer Systems Analyst 2 hours at \$92.46/hr, a General Operations Manager 4 hours at \$118.30/hr, and an Office & Administrative Support Worker 40 hours at \$36.82/hr (for a total of \$3,889.16 across all five positions) for each manufacturer to complete the quarterly collection/submission for the ROSI. This equates to a burden of 70 hours per manufacturer per response.

In aggregate, we estimate 146,720 annual burden hours (524 manufacturers x 70 hr x 4 qtrs) at a cost of \$8,151,679.36 (\$3,889.16 per response x 4 responses/year x 524 manufacturers).

CMS-304 – Reconciliation of State Invoice (ROSI)

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 (\$)
Data Collection/Submission	524	2,096 (4 quarterly responses per year)	70	146,720	Varies	\$8,151,679

CMS-304a – Prior Quarter Adjustment Statement (PQAS)

The PQAS is submitted by the manufacturers on an as-needed basis; however, historically, prior quarter adjustment activity is constant and is typically reported on a quarterly basis by all 749 manufacturers. The quarterly burden associated with this package is the time and effort it takes to generate and submit the Prior Quarter Adjustment Statement (PQAS).

We estimate that it will take an Accountant/Auditor 2 hours at \$76.46/hr, a Business Operations Specialist 5 hours at \$72.62/hr, a Computer Systems Analyst 1 hour at \$92.46/hr, a General Operations Manager 2 hours at \$118.30/hr, and an Office & Administrative Support Worker 18 hours at \$36.82/hr (for a total of \$1,507.84 across all five positions) for each manufacturer to complete the quarterly collection/submission for the PQAS. This equates to a burden of 28 hours per manufacturer per response.

In aggregate, we estimate 83,888 annual burden hours (749 manufacturers x 28 hr x 4 qtrs) at a cost of \$4,517,488.64 (\$1,507.84 per response x 4 responses/year x 749 manufacturers).

CMS-304a – Prior Quarter Adjustment Statement (PQAS)

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 (\$)
Data Collection/Submission	749	2,996 (4 quarterly responses per year)	28	83,888	Varies	\$4,517,489

CMS-304 and CMS-304a – 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-304 and 304a (for a total of \$2,283.52 across both positions). This equates to a total one-time burden of 24 hours per manufacturer at a cost of \$1,710,356.48 (\$2,283.52 x 749 manufacturers).

Burden Summary

Summary of Annual Burden Estimates

Description / Form	Frequency	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Total Labor Cost (\$/hr)	Total Cost (\$)
CMS-304	Quarterly	524	2,096	70	146,720	8,151,679	8,151,679
CMS-304a	Quarterly	749	2,996	28	83,888	4,517,489	4,517,489
CMS-304 & 304a	One-Time	749	749	24	17,976	1,710,356	1,710,356
Total		749	5,841	Varies	248,584	14,379,524	14,379,524

Information Collection Instruments/Instruction/Guidance Documents

- CMS-304 - Reconciliation of State Invoice (ROSI) (Revised, see Crosswalk for details)

In the event that manufacturers disagree with or need to adjust the utilization data submitted by states on the current state invoice, manufacturers are required to complete and submit a ROSI along with their invoice payment.

- CMS-304 Instructions (Revised, see Crosswalk for details)
- CMS-304 Electronic Format (Revised, see Crosswalk for details)

Provides the electronic field size listing which must be used if manufacturers submit these forms to States electronically.

- CMS-304a – Prior Quarter Adjustment Statement (PQAS), with Disclosure Statement (Revised, see Crosswalk for details)

Once the current invoice cycle has passed, manufacturers may discover unit adjustments and/or disputes from a previous quarter. In these instances, manufacturers complete and submit a PQAS as official notification of the discrepancy.

- CMS-304a - Instructions (Revised, see Crosswalk for details)
- CMS-304a - PQAS Electronic Format (Revised, see Crosswalk for details)

Provides the electronic field size listing which must be used if manufacturers submit these forms to States electronically.

- Adjustment and Dispute Codes for CMS-304/-304a (No changes)

Provides the available adjustment and /or dispute codes for the ROSI and /or PQAS.

13. Capital Costs

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

14. Federal Costs

There is no annual cost to the Federal Government. The reported information is submitted by manufacturers to States.

15. Changes in Burden and/or Cost Estimates

In this 2020/2021 iteration we have adjusted the number of CMS-304 respondents (manufacturer participation increased from 517 to 534) which resulted in an increase in our total time and total cost estimates. Our per response time estimate is unchanged.

CMS-304 – Reconciliation of State Invoice (ROSI)

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 (\$)
Data Collection/Submission	524	2,096 (4 quarterly responses per year)	70	146,720	Varies	8,151,679
Currently Approved Burden	517	2,068	70	144,760	Varies	7,903,979
Change	+7	+28	No	+1,960	Varies	+247,700

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We have also adjusted the number of CMS-304a respondents (manufacturer participation increased from 738 to 749) which resulted in an increase in our total time and total cost estimates. Our per response time estimate in unchanged.

CMS-304a – Prior Quarter Adjustment Statement (PQAS)

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 (\$)
Data Collection/Submission	749	2,996 (4 quarterly responses per year)	28	83,888	Varies	4,517,489
Currently Approved Burden	738	2,952	28	82,656	Varies	4,380,000
Change	+11	+44	No Change	+1,232	Varies	+137,489

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 have added a one-time burden for manufacturers to update their systems which equates to an increase of 17,976 hours and \$1,710,356.

Summary of Changes

Form	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Total Labor Cost (\$/hr)	Total Cost (\$)
CMS-304	+7	+28	No Change	+1,960	Varies	+247,700
CMS-304a	+11	+44	No Change	+1,232	Varies	+137,489
CMS-304 & 304a	n/a	+749	+24	+17,976	Varies	+1,710,356
Total Change	+18	+821	Varies	+21,168	Varies	+2,095,545

16. Publication and Tabulation Data

There are no plans to publish this information collection.

17. Display of Expiration Date

CMS will display the expiration date for OMB approval on both the ROSI and the PQAS.

18. Exception to Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

There are no statistical survey methodologies employed with this data collection.