Supporting Statement Part A
Medicaid Drug Rebate Program - Labelers
Reconciliation of State Invoice (CMS-304)
and
Prior Quarter Adjustment Statement (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. These manufacturer reporting requirements are currently approved under OMB no. 0938-0676 through 10/31/2014 . The form CMS-304 (ROSI: Reconciliation of State Invoice) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. The form CMS-304a (PQAS: Prior Quarter Adjustment Statement) is required only in those instances where a change to the original rebate data submittal is necessary. There have been no revisions to either of the forms. .

A. Justification

1. Need and Legal Basis

Section 1927(a)(1) of the Act requires drug labelers 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 labelers that have drug rebate agreements with CMS on behalf of the States. In turn, labelers 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 labelers. Each quarter, CMS distributes the URA data to the States. States then report drug utilization data quarterly to the labelers (with a copy to CMS), and optionally

may associate the URA to that data to establish a payment due amount. Labelers, 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 labelers 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 labelers to uniformly explain any adjusted rebate payments for the current quarter. It must be used when the labeler 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 labelers 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 labelers and States.

3. Improved Information Technology

The ROSI and the PQAS may be submitted by labelers to States either via paper or electronic media, depending on the needs and capabilities of the labelers. Appendix A to forms CMS-304 and 304a is the electronic field size listing which must be used if labelers submit these forms to States electronically.

4. Duplicate Information

The CMCS is the only CMS component requiring and collecting drug rebate data on the Medicaid program. 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 labelers 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 Medicaid drug rebate program.

7. Special Circumstances

No special circumstances exist which require completion of this section of the supporting statement.

8. FR Notice/Outside Consultations

The 60-day Federal Register notice published on May 2, 2014 (79 FR 25132). No comments were received.

In order to develop a uniform reporting format for current and prior quarter activity which meets the needs of both labelers and States, CMS convened an implementation workgroup from June through October of 1995. The workgroup consisted of representatives from the States, drug labelers, 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 questions of a sensitive nature.

12. Estimate of Burden and Costs to Respondents

Although there are approximately 610 labelers in the rebate program, only about 70% of those labelers (approximately 427) are required to submit the ROSI to States on a quarterly basis as a result of unit adjustments or disputes. The PQAS is submitted by the labelers on an as-needed basis; however, historically, prior quarter adjustment activity is constant and will most likely be reported on a quarterly basis by all 610 labelers.

The quarterly burden hours listed below include a total number of hours associated with both the ROSI and the PQAS and an average cost associated with this reporting.

The total estimated annual burden hours for the ROSI and the PQAS are calculated as follows:

Quarterly Collection/Submittal of the ROSI
427 labelers X 70 hours per quarter X 4 quarters = 119,560

Quarterly Collection/Submittal of the PQAS
610 labelers X 28 hours per quarter X 4 quarters = 68,320

TOTAL ESTIMATED ANNUAL BURDEN HOURS = 187,880

The total annual cost to labelers associated with the estimated annual burden hours is as follows:

187,880 annual burden hours X $15 per hour = $ 2,818,200

13. Total Costs as a Result of Data Collection

There is no start-up cost associated with this information collection. The Medicaid drug rebate program has been in existence since January 1, 1991. Labelers 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.

15. Changes in Burden and/or Cost Estimates

For PQAS, the number of labelers has been adjusted from 595 to 610 due to the increase in labeler participation. Similarly, the number of labelers for ROSI has been adjusted to 427 or 70 percent of 610.

While the time per response remains unchanged, the total hours and cost have been adjusted to reflect the revised number of labelers.

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.