Supporting Statement for the
Medicaid Drug Rebate Program - Labelers
Reconciliation of State Invoice, CMS-304
and
Prior Quarter Adjustment Statement, CMS-304a
OMB-0938-0676

A. Background

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 03/31/2013. 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. We are requesting approval of a revision to both forms CMS-304 and CMS 304a to accommodate changes implemented by the Patient Protection and Affordable Care Act.

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.

States are required to submit quarterly utilization data reports to the Centers for Medicare & Medicaid Services (CMS) and drug manufacturers that have drug rebate agreements with CMS. In turn, manufacturers are required to provide rebate payments for covered outpatient drugs as prescribed in section 1927(b) of the Act.

Section 2501(c) of the Affordable Care Act amended section 1902 of the Act by specifying that covered outpatient drugs dispensed to Medicaid individuals enrolled with a Medicaid managed care organization (MCO) are subject to the same rebate agreement as other drugs authorized under section 1927 of the Act. It also amended section 1927(b) of the Act by requiring States to include information on drugs paid for by Medicaid MCOs under the State plan during the rebate period when requesting rebates from manufacturers and when reporting a copy of such information to CMS. Therefore, in accordance with these new requirements, and to keep the ROSI and the PQAS consistent with the information reported on the State invoice, forms CMS-304 and CMS-304a have been revised to include a new column titled, "FSS/MCO Record ID". This column will allow manufacturers to separately identify each drug record as representing either Fee-For-Service utilization or MCO utilization when the ROSI or PQAS is being submitted as part of a manufacturer's quarterly rebate payment to the State.

B. 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.

1. 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.

2. 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.

3. 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.

4. Small Business

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

5. 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. Outside Consultations

The 60-day Federal Register notice published on April 15, 2011 (76 FR 21370). 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 595 labelers in the rebate program, only about 70% of those labelers (approximately 416) 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 595 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
416 labelers X 70 hours per quarter X 4 quarters = 116,480

Quarterly Collection/Submittal of the PQAS
595 labelers X 28 hours per quarter X 4 quarters = 66,640

TOTAL ESTIMATED ANNUAL BURDEN HOURS = 183,120

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

183,120 annual burden hours X $15 per hour = $2,746,800

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

In accordance with the new reporting requirements established by the Patient Protection and Affordable Care Act, the State invoice is being revised to include a new column that will enable States to distinguish between fee-for service and managed care utilization. Consequently, form 304 and 304a are being revised to reflect a similar new field that will enable manufacturers to separately identify fee-for-service and managed care units. As a result, the burden estimate has been changed to reflect the increased time it will take manufacturers to complete the forms.

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.

C. Collections of Information Employing Statistical Methods

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