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

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.

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 on behalf on the States. 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 an extension of the manufacturers' reporting requirements under the drug rebate program (forms CMS-304 and 304a). These forms are currently approved under the Office of Management and Budget No. 0938-0676 through January 31, 2010.

A. Justification

1. Need and Legal Basis

Section 1927 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.

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 consultants (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 CMSO 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 and submit the ROSI and/or PQAS 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

A 60-day Federal Register notice was published on June 15, 2009.

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 570 labelers in the rebate program, only about 385 are required to submit the ROSI to States on a quarterly basis. The PQAS is submitted by the labelers on an as-needed basis; however, historically, prior quarter activity is constant and will most likely be reported on a quarterly basis by all labelers.

The quarterly burden hours listed below include a total number of hours associated with current and prior quarter reporting, and an average burden for record keeping.

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

Quarterly Collection/Submittal of the ROSI
385 labelers X 62 hours per quarter X 4 quarters = 95,480

Quarterly Collection/Submittal of the PQAS
570 labelers X 20 hours per quarter X 4 quarters = 45,600

TOTAL ESTIMATED ANNUAL BURDEN HOURS 141,080

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

141,080 annual burden hours X $10 per hour = $1,410,800

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

The change in Burden Estimate results from the fact that there are a few more prescription drug labelers currently participating in the Medicaid Drug Rebate Program then there were the last time this package was prepared; therefore, that estimate was adjusted accordingly to reflect the approximately 570 labelers currently participating.

16. Publication and Tabulation Data

There are no plans to publish this information collection.

17. Display of Expiration Date

CMS is not seeking approval to not display the expiration date for OMB approval.

18. Exception to Certification Statement

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

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.