Supporting Statement
Medicaid Drug Rebate Program Forms
CMS-R-144 (Quarterly Report Data) and CMS-368 (Administrative Data)
OMB 0938-0582

A. Background

CMS is requesting a three year approval of the State reporting requirements (forms CMS-R-144 and CMS-368) under the drug rebate program. These State reporting requirements are currently approved under OMB no. 0938-0582 through April 30, 2012. The form CMS-R-144 is required from States quarterly to report utilization for any drugs paid for during that quarter. The form CMS-368 is required only in those instances where a change to the original data submittal is necessary. This form is a report of contact for the State to name the individuals involved in the drug rebate program. The ability to require the reporting of any changes to these data is necessary to the efficient operation of the rebate program. There have been no revisions to the form CMS-368; however, we are requesting approval of a revision to form CMS-R-144 to reflect 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 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 national rebate agreements 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.

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, form CMS-R-144 has been revised to include a new column titled, “Record ID”. This column will allow States to separately identify each drug utilization data record as either Fee-For-Service utilization or MCO utilization when the utilization data is being submitted as part of a a State’s quarterly rebate invoice to drug manufacturers, or as part of a State’s quarterly

drug utilization data submission to CMS. To reduce the number of pages necessary for data submittal, CMS does not display the disclosure statement on the form itself. Individual form instructions to the States (attached) contain the required disclosure statement under its own heading.

Listed below is a line-by-line description of the quarterly data (form CMS-R-144) required (electronic record layout and hard copy format attached).

Record ID: Constant "FFSU" or "MCOU". The FFSU Record ID indicates that the information for this NDC represents a Fee-for-Service Utilization record. The MCOU Record ID indicates that the information for this NDC represents a Managed Care Organization Utilization record. Valid Values: 4Q2009 and earlier = Constant record ID of FFSU. 1Q2010 and beyond = FFSU & MCOU.

NOTE: Per the Affordable Care Act, MCO utilization data cannot be reported for periods prior to first quarter 2010.

NOTE: Beginning with first quarter 2010, CMS will accept one utilization record per NDC per quarter/year combination per record ID type (FFSU vs. MCOU).

State Code: Two-character post office abbreviation for the state. Alphabetic, 2 digits.

Labeler Code: First segment of National Drug Code (NDC) that identifies the manufacturer, labeler, re-labeler, packager, re-packager or distributor of the drug. Numeric values only, 5-digit field, right justified and zero-filled for 4-digit labeler codes.

Product Code: Second segment of NDC. Alphanumeric values, 4-digit field, right justified, zero-filled for 3-digit product codes.

Package Size Code: Third segment of NDC. Alphanumeric values, 2-digit field, right justified, zero-filled for 1-digit package size codes.

Period Covered: The calendar quarter and year in which the 11-digit NDC was paid for by the State. Numeric, 5-digit field, QYYYY

Valid values for Q:
1 = January 1 – March 31
2 = April 1 – June 30
3 = July 1 – September 30
4 = October 1 – December 31

Valid values for YYYY: 4-digit calendar year covered.

Product FDA Reg. Name: (Abbreviated) – First 10 characters of product name as approved by and/or listed with the FDA. Alphanumeric values, 10 digits.

Unit Rebate Amount: The CMS calculated amount (per reported unit type) to be multiplied by Units Reimbursed by the state during the period covered. Numeric values, 12 digits: 5 whole numbers, 6 decimal places, and a decimal point.

Units Reimbursed: The number of FFS or MCO units (based on Unit Type and Record ID) of the drug (11-digit NDC level) reimbursed by the state during the period covered. Numeric values, 15 digits: 11 whole numbers, 3 decimal places and a decimal point.

Rebate Amount Claimed: The rebate amount that the State Agency claims it is owed by the labeler for the period covered for this (11-digit NDC) FFS or MCO drug. It is calculated by multiplying the FFS or MCO units reimbursed by the rebate amount per unit. Numeric values, 12 digits: 9 whole numbers, 2 decimal places and a decimal point.

Number of Prescriptions: The number of FFS or MCO prescriptions reimbursed (by the Medicaid Program ONLY) to pharmacies for the (11-digit NDC) drug during the period covered. Numeric values, 8 digits, whole numbers only.

M'caid Amount Reimb: Medicaid Amount Reimbursed – The total amount reimbursed (by the Medicaid Program ONLY) FFS or MCO to pharmacies for the (11-digit NDC) drug in the period covered. Numeric values, 13 digits: 10 whole numbers, 2 decimal places and a decimal point.

Non-M'caid Amount Reimb: Non-Medicaid Amount Reimbursed – The amount reimbursed (by non-Medicaid entities) to pharmacies for the (11-digit NDC) FFS or MCO drug in the period covered. The Non-Medicaid Amount Reimbursed includes any reimbursement amount for which the state is not eligible for Federal Matching Funds. Numeric values, 13 digits: 10 whole numbers, 2 decimal places and a decimal point.

Total Amount Reimbursed: The FFS or MCO total amount reimbursed by both Medicaid and non-Medicaid entities to pharmacies for the (11-digit NDC) drug in the period covered (previous two fields added together). This total is not reduced or affected by Medicaid rebates paid to the state. This amount represents both the Federal and State Reimbursement and is inclusive of dispensing fees. Numeric values, 14 digits: 11 whole numbers, 2 decimal places and a decimal point.

Filler: 1 position filler. This field previously contained the Correction Flag Indictor which specified whether the record was the first submission (0=original record) or whether it is a correction (1 = correction) to an existing record. The CMS Medicaid Drug Rebate (MDR) system makes the determination: if the record does not exist within the MDR system, it processes as an original; if the record does exist within the MDR system, it processes as a correction.

B. 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

The States are required to submit their quarterly reports to CMS via magnetic media or Electronic File Transfer (EFT). However, States will 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.

7. Special Circumstances

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

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on April 15, 2011 (76 FR 21370). No comments were received.

9. Payments/Gifts to Respondents

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. Burden Estimates (Hours & Wages)

The majority of the State burden is associated with the quarterly drug utilization reports. All State agencies report drug utilization data to drug manufacturers and to CMS. These reports are submitted to CMS via magnetic media or via EFT. 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 which opt to report via hard copy are required to use the format associated with the CMS-R-144. The estimated quarterly report burden hours below are a total average for both types of data transmission and take into account the revisions that have been made to the CMS-R-144.

In addition, the State burden includes the reporting of 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.

The following is a calculation of the burden estimates:

Changes to Administrative Data Reports (Form CMS-368)
10 States x ½ hour each = 5 hours (annual)

Quarterly Utilization Reports (Form CMS-R-144)
56 States (including Washington, D.C and the U.S Territories) x 54 hours x 4 quarters = 12,096 hours (annual)

TOTAL ANNUAL HOURS: 12,101

Each State participating in the drug rebate program may use either manual or electronic

systems to report their data to the manufacturers and many use a combination of both transmission methods. All States must report to CMS via electronic media. An annual estimate of operating and maintenance costs for manual and electronic data reporting is as follows:

Manual and Electronic Data Submission (An Average Based on Reported Estimates from Three Randomly Selected States)
$5,900 / 3 States = $1,967 per quarter
56 States x $1,967 x 4 quarters = $440,608 Annual Cost Burden

13. Capital Costs

There are no 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

The estimate of annualized cost to the Federal Government is 87,500 which includes the cost to implement these changes in CMS's systems.

15. Changes to Burden

Section 1927 of the Social Security Act requires each State Medicaid agency to report quarterly prescription drug utilization information to drug manufacturers and to CMS via form CMS-R-144. As part of this information, the State Medicaid agencies are required to report the total Medicaid rebate amount they claim they are owed by each drug manufacturer for each covered prescription drug product each quarter. In accordance with new reporting requirements established by the Patient Protection and Affordable Care Act, form CMS-R-144 is being revised to include a new column that will enable States to distinguish between fee-for-service and managed care utilization.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS is seeking approval to not display the expiration date for OMB approval ONLY on the form CMS-R-144 and only by those States submitting data manually. States that submit their data in electronic format are asked to display the expiration date on the form because it is easily revised when necessary. Because States are responsible for their own supply of these forms and generally have them reproduced in large volumes to guard against depletion, an expiration date is impractical. Because States are required by law to submit these forms within a specific timeframe, they must keep a large supply of the forms on hand at all times.

Displaying the expiration date would require States to dispose of their stock of expired forms and reproduce forms with new expiration dates.

To assure that all parties are aware of OMB approval so that current form stock may be depleted, CMS notifies States that forms have been re-approved by OMB and are given the new expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.