Supporting Statement Part A
Medicaid Drug Program
CMS-367a, 367b, 367c, and 367d (OCN 0938-0578)

Background

We are requesting a revision of this collection.

Section 1927 of the Social Security Act (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. In order for payment to be made under Medicaid, the drug labeler must complete and sign a drug rebate agreement and fill in the information on the related documents. The drug manufacturer must also supply information within 30 days after the end of each calendar quarter and month on the average manufacturer price of the drugs.

To reduce the number of pages necessary for data submittal, CMS does not display the disclosure statement on the form itself. Instructions to the labelers (attached) contain the required disclosure statement under its own heading.

A. Justification

1. Need and Legal Basis

The authority for requiring this data collection is section 1927 of the Act as modified by the Education Jobs and Medicaid Assistance Act, and the Patient Protection and Affordable Care Act.

2. Information Users

Labelers transmit drug data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) for each NDC and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology.

3. Improved Information Technology

CMS has developed a web-based application for all drug data collection. The application, Drug Data Reporting for Medicaid (DDR) is available at no charge to all participating labelers. Labelers have two data reporting options within DDR: first, they may key their data online on an NDC basis; second, they may transfer a saved file to DDR. For additional information regarding the online and file transfer data transmission methods in DDR, see the attached screen shots,

4. Duplication Information

CMCS is the only CMS component collecting drug data for purposes of the Medicaid program. Therefore, this information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Business

This collection of data may impact up to 100 small business entities that are currently in the voluntary program. DDR helps these entities more easily and accurately report their data than was possible under the previous data collection method. The DDR is free, and helps labelers detect and correct potential data errors for which they previously faced penalties and terminations from the program.

6. Less Frequent Collection

Section 1927 of the Act requires monthly and quarterly drug data reporting by labelers.

7. Special Circumstances

Section 1927 of the Act and Federal regulations (CMS-2238-FC) require labelers to submit drug data on both a monthly and quarterly basis to CMS. Record retention of drug price-related data is addressed in Federal regulations (CMS-2175-F), which require labelers to retain such data for ten years.

8. Federal Register Notice/Outside Consultations

The 60-day Federal Register notice published on February 2, 2012 (77 FR 5318), under NPRM CMS-2345-P (RIN 0938-AQ41). No comments were received regarding the reporting requirements from that 60-day Federal Register posting.

The manufacturer collection items in this stand-alone package have been removed from the Feb 2012 proposed rule since the associated final rule is still in the clearance process and we would like to begin collecting these items in July 2014. Importantly, we have the authority to collect these items in Section 2503 of the Patient Protection and Affordable Care Act, Section 1927(k)(2) of the Social Security Act, and Section 202 of the Education Jobs and Medicaid Assistance Act.

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

The burden associated with the 367(a-d) forms reflects the time used and cost incurred by labelers (respondents) when gathering and reporting Medicaid drug product and price information on a monthly and quarterly basis.

Currently, there are approximately 610 respondents reporting drug information to CMS. Of the 610 total respondents reporting, 100% will report data via the DDR web-based application. Within DDR, there are two reporting options from which the respondents may choose (i.e., online and file transfer); however, there is no difference in the time burden associated with each option. File transfer submissions and online submissions are both performed on the same reporting schedule (i.e., monthly and quarterly), and both require the submission of the same data fields with the exception of the Reactivation Date field which may only be entered online.

The following tables represent both the total existing manufacturer burden and the total new burden requirements established by this PRA package, which together represent a calculation of the annual burden estimates for electronic data reporting. This burden is based on a total of 610 manufacturers reporting data on both a quarterly and monthly basis at an hourly rate of $60/hour. (The previously approved PRA package included 590 manufacturers. We have since added an additional 20 manufacturers to the Medicaid Drug Rebate Program.)

Changes to Currently Approved Annual Burden due to adding 20 Annual Respondents:

Manufacturers	Annual Respondents	Annual Responses	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting	Total Annual Cost
Currently Approved Existing Burden	590	9,440	14.8	139,712	$60	$8,382,720
Changes to the Existing Burden (due to increase in the number of annual	+20	+320	14.8 (no change)	+4,736	$60 (no change)	+$284,160

respondents)						
Revised Existing	**610**	**9,760**	**14.8** (no change)	**144,448**	$60 (no change)	**$8,666,880**

Changes Due to Statute:

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting	Total Annual Cost
Revised Existing On-going reporting	610	9,760 (4 quarterly and 12 monthly responses per year)	14.8	144,448	$60	$8,666,880
New On-going reporting	610	7,320 (12 monthly responses per year)	1	7,320	$60	$439,200
Subtotal for On-going Burden	610	9,760 (4 quarterly and 12 monthly responses per year)	15.8	151,768	$60	9,252,480
New one-time Burden	610	610 (1 response)	7.5	4,575	$60	274,500
Total Burden for the next 3 years (On-going + One-time)	610	**10,370**		**156,343**	$60	**9,526,980**

The following provides a breakdown of the cost and hour burden amounts associated with each new field being added to the 367 forms:

Additional Burden Due to One-Time Reporting of COD Status and FDA Application Number/OTC Monograph Number Fields: Section 1927(k)(2) of the Social Security Act defines the term "Covered Outpatient Drug" (COD) for purposes of the Medicaid Drug Rebate Program (MDRP). If a product does not meet this statutory definition, it is generally ineligible for coverage under the MDRP. Therefore, in order to assist manufacturers in making determinations as to whether or not a product meets the COD definition, CMS is adding both a COD Status and FDA Application Number/OTC Monograph number field to the 367c form. Manufacturers will be required to submit the FDA application number issued by FDA when the product is approved, and will be required to submit an OTC Monograph Number if the product is marketed as an over-the-counter drug. This information should be easily obtainable for manufacturers, since the FDA assigns an application number when a new or generic drug receives approval to be marketed in the U.S. If a product does not have FDA approval, a manufacturer should be able to identify the reason it qualifies as a COD because the terms of the National Rebate Agreement between CMS and the manufacturer require that the labeler report only those products that meet the COD definition to CMS. We

estimate that these requirements would affect approximately 610 drug manufacturers that participate in the MDRP. The burden associated with the reporting of the COD Status and FDA Application Number/OTC Monograph Number fields is the time and the effort it would take for each drug manufacturer to retrieve this information from their records, update record layouts accordingly, and submit it to CMS. Therefore, we believe that the new requirement to report the COD Status and FDA Application Number/OTC Monograph Number fields will require a one-time total of 3,050 hours and a one-time total estimated burden cost of $183,000.

Additional Burden Due to One-Time Reporting of 5i Drug Indicator and 5i Route of Administration Fields, and the Monthly Reporting of the 5i Threshold Field: Section 202 of the Education Jobs and Medicaid Assistance Act modified the statutory definition of AMP such that the AMP for certain 5i drugs will be calculated using a different methodology from that which will be used for other 5i and non-5i drugs. In order to easily identify 5i drugs, and specifically, those that use the alternative AMP methodology for a particular monthly reporting period, CMS is adding a 5i Drug Indicator and 5i Route of Administration field to the 367c form, and a 5i Threshold field to the 367b form. These requirements would affect approximately 610 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the one-time reporting of the 5i Drug Indicator and 5i Route of Administration fields is the time and the effort it would take for each drug manufacturer to initially identify whether each drug is a 5i drug or not. It is our understanding that each drug manufacturer should have some knowledge as to which drugs are 5i based on the approval information received from the FDA, as well as the Route of Administration list that CMS has identified. Therefore, we believe that the new reporting requirements will require a one-time total of 1,525 burden hours for manufacturers to identify the 5i drugs at a one-time total estimated burden cost of $91,500. We estimate that once the manufacturer has established its initial list of 5i drugs, the burden associated with reporting the monthly 5i Threshold field to CMS would add an additional hour of burden to each monthly manufacturer response (the 5i Threshold is not reported quarterly). Adding 1 hour per response with 12 monthly responses per year for each manufacturer equates to a total estimate of 12 additional hours annually per manufacturer. The total annual burden hours for the 610 drug manufacturers participating in the Medicaid Rebate Program is estimated to be 7,320 hours with a total cost of $439,200.

Addition of Optional Baseline AMP Field: Section 2503 of the Patient Protection and Affordable Care Act modified the definition of AMP described in Section 1927(k)(1) of the Social Security Act; therefore, these statutory changes to the definition of AMP may necessitate an optional, voluntary, update to the Baseline AMPs that were previously reported by manufacturers. The amount of time associated with reporting the Baseline AMP field is negligible; therefore, we do not believe that it will result in an increase in the burden for manufacturers.

Addition of Optional Email Fields and Reactivation Date Field
The new optional e-mail fields, the Reactivation Date and the ACA Baseline AMP field are voluntary. The burden associated with the reporting of each of these fields is negligible; therefore, no explicit burden increase is included on the charts below.
The table below identifies the specific fields being added to the CMS-367 forms, along with the burden impact associated with each field.

Field	Respondents	Frequency	Total # of Responses	Hourly Burden per Response	Total # of Hours	Hourly Labor	Total Cost
COD Status and FDA App. # / OTC Mono. #	610	One-Time	610	5 hours (one-time set-up)	3,050 (1,016 annual)	$60	$183,000 ($61,000 annual)
5i Drug Indicator/5i Route of Admin.	610	One-Time	610	2.5 hours (one-time set-up)	1,525 (508 annual)	$60	$91,500 (30,500 annual)
5i Threshold	610	Monthly (12 time per year)	7,320	1 hour per reporting period	7,320	$60	$439,200

Respondents x Frequency = Total # of Responses
Total # of Responses x Hourly Burden Per Response = Total # of Hours
Total # of Hours x Hourly Labor ($60) = Total Cost

13. Total Costs as a Result of Data Collection

The estimated annualized cost to labelers is $9,526,980. This cost is based on a private industry pay rate of $60 an hour for this function.

14. Federal Costs

The estimated federal cost to implement these manufacturer requirements in the Drug Data Reporting for Medicaid (DDR) and Medicaid Drug Rebate (MDR) systems would be roughly $750,000.

15. Changes in Burden/Program

We have adjusted the number of respondents from 590 to 610 (or +20 respondents).

We are also adding one field to form CMS-367b (5i Threshold); five fields to form CMS-367c (5i Drug Indicator, 5i Route of Administration, Covered Outpatient Drug (COD) Status, FDA Application Number/OTC Monograph Number, and optional ACA Base AMP); and two optional e-mail address fields

on CMS-367d for the legal contact and the invoice contact.

As a result of the new fields added to form 367c, we are removing the DESI Indicator field, which is no longer needed.

The new optional e-mail fields, the Reactivation Date and the ACA Baseline AMP field are voluntary. The burden associated with the reporting of each of these fields is negligible; therefore, no explicit burden increase is expected.

The increased burden associated with adjusting the number of respondents amounts to +320 responses/year or +4,736 hr (aggregate). The increased burden associated with each of the other new fields amounts to +610 responses or +11,895 hr (aggregate).

16. Publication and Tabulation Data

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

17. Display of Expiration Date

CMS is willing to 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.