Supporting Statement
Medicaid Drug Program
CMS-367a, 367b, 367c, and 367d; OCN 0938-0578

Background

We are requesting an extension 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. In accordance with the DRA, the labeler must 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.

Listed below is a line-by-line description of the quarterly, monthly and product data collections (CMS-367a, CMS-367b and CMS-367c) required (electronic record attached).

DATA FIELDS – CMS-367a – Quarterly Pricing Data

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

Period Covered: Calendar quarter and year covered by data submission. 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.

Average Manufacturer Price (AMP): The AMP per unit per product code for the period covered. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which is the same for all package sizes. Compute to 7 decimal places, and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal place ('.') and 6 decimal places; right-justified, zero-filled.

Best Price: Per the statute and rebate agreement, the lowest price available per product code, regardless of package size. Compute to 7 decimal places and round to 6 decimal places. Zero-fill for Non-Innovator Multiple Source drugs. Numeric values, 12-digit

field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled.

Nominal Price (NP): Sales that meet the statutory/regulatory definition of NP. Total dollar figure per 11-digit NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers; right-justified, 0-filled. If no sales for a package size, fill with all zeroes.

Customary Prompt Pay Discount (CPP): Labelers may 1) allocate an individual CPP discount dollar amount per 11-digit NDC in each package size's record, or 2) report an aggregate discount dollar amount, by adding up all package sizes, and report this aggregate CPP discount dollar amount in one package size record and zero-fill the remaining package sizes. 9-digit field; 9 whole numbers; right-justified, 0-filled.

DATA FIELDS – CMS-367b – Monthly Pricing Data

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

Month: Calendar month covered by data submission. Numeric 2-digit field, MM.
Valid values for MM:

01 = January	07 = July
02 = February	08 = August
03 = March	09 = September
04 = April	10 = October
05 = May	11 = November
06 = June	12 = December

Year: Calendar year covered by data submission. Numeric 4-digit field, YYYY. Valid values for YYYY: 4-digit calendar year.

Average Manufacturer Price (AMP): The AMP per unit per product code for the period covered. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which is the same for all package sizes. Compute to 7 decimal places and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal place ('.') and 6 decimal places; right-justified, zero-filled.

Average Manufacturer Price (AMP) Unit: The total sum of all units included in the calculation of the AMP per product code for the monthly reporting period covered. If a drug is distributed in multiple package sizes, there will be one AMP unit for the product, which is the same for all package sizes. Numeric values, 14-digit field: 11 whole numbers, the decimal place (".") and two (2) decimal places; right-justified; zero-filled.

Filler: Spaces

DATA FIELDS – CMS-367c – Product Data

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled.

Drug Category: Alpha-numeric values, 1 character.

Valid values:

S = Single source
I = Innovator multiple source
N = Non-innovator multiple source

Unit Type: One of the 8 unit types by which the drug is dispensed. Alpha-numeric values, 3-character field, left justified.

Valid values:

AHF = Injectable Anti-Hemophilic Factor
CAP = Capsule
SUP = Suppository
GM = Gram
ML = Milliliter
TAB = Tablet
TDP = Transdermal Patch
EA = EACH

FDA Approval Date: NDA or monograph approval date. Numeric values, 8-digit field, format: MMDDYYYY.

TEC: FDA-assigned Therapeutic Equivalence Codes. Alpha-numeric values, 2 character field.

Valid values:

AA	BC	BS
AB	BD	BT
AN	BE	BX
AO	BN	NR - Not rated
AP	BP	A1 thru A9 = AB value
AT	BR	

Market Date: For S and I drugs, the date the drug was first marketed by the original labeler (i.e., NDA holder). For N drugs, the date the drug was first marketed under the labeler's rebate agreement. If a Market Date falls on a date that is earlier than 9/30/1990, CMS will change it to 9/30/1990 in both the Medicaid Drug Rebate (MDR) system and the Drug Data Reporting for Medicaid (DDR) system since dates earlier than the start of the Drug Rebate Program have no bearing on the program. Numeric values, 8-digit field, format: MMDDYYYY.

Termination Date: The date a drug is withdrawn from the market or the drug's last lot expiration date. Zero or blank fill if not present. Numeric values, 8-digit field, format: MMDDYYYY.

DESI Indicator: Drug Efficacy Study Implementation code. Numeric value, 1 digit.

Valid values:

2 = Safe and effective
3 = Drug under review (no NOOH issued)
4 = LTE/IRS drug for SOME indicators
5 = LTE/IRS drug for ALL indicators
6 = LTE/IRS drug withdrawn from market

Drug Type Indicator: Identifies a drug as prescription (Rx) or over-the-counter (OTC).

Valid Values:
1 = Rx
2 = OTC

OBRA'90 Baseline AMP: The AMP per unit for the period that establishes the OBRA'90 Baseline AMP for innovator drugs. There will be one weighted baseline AMP for the product, which will be the same for all package sizes. Compute to 7 decimal places and round to 6 decimal places. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled.

Units Per Package Size: Total number of units in the smallest dispensable amount for the 11-digit NDC. Numeric values, 11-digit field: 7 whole numbers, the decimal ('.') and 3 decimal places; right-justified, zero-filled.

FDA Product Name: Drug name as it appears on FDA listing form. Alpha-numeric values, 63 characters, left justified, blank-fill unused positions.

DRA Baseline AMP (optional): For active innovator drugs with a Market Date less than July 1, 2007, the OBRA'90 or OBRA '93 Baseline AMP revised in accordance with relevant regulations and program guidance. There will be one weighted DRA Baseline AMP for the product, which will be the same for all package sizes. Per CMS-2238-FC, labelers will have 4 quarters (i.e., January 2, 2008 – October 30, 2008) to report this optional field. Numeric values, 12-digit field; 5 whole numbers, the decimal ('.') and 6 decimal places, right- justified, zero-filled. Compute to 7 decimal places and round to 6 decimal places.

Package Size Introduction Date: The date the package size is first available on the market. Numeric values, 8-digit field, format: MMDDYYYY

Purchased Product Date: The date the company currently holding legal title to the NDC first markets the drug under this NDC (this date can result, for example, from the purchase of an NDC from one company by another company, the re-designation of an NDC from one of a company's labeler codes to another of that same company's labeler codes, cross-licensing arrangements, etc.). Zero or blank fill if not applicable. Numeric values, 8-digit field, format: MMDDYYYY

A. Justification

1. Need and Legal Basis

The authority for requiring this data collection is section 1927 of the Act as modified by the Deficit Reduction Act of 2005 and the CMS-2238-FC.

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.

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 May 31, 2013 (78 FR 32659). No comments were received.

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 590 respondents reporting drug information to CMS. Of the 590 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. The following is a calculation of the annual burden estimate for electronic data reporting. The burden is based on a total of 590 labelers reporting data on a both a quarterly and monthly basis at a private industry pay rate of $60/hour. (The previously approved PRA package included 580 labelers. We have since added an additional 10 labelers to the Medicaid Drug Rebate Program.)

590 labelers x 16 responses per year x 14.8 hours per response
=139,712 total hours across all labelers

TOTAL ANNUAL BURDEN HOURS: 139,712

The estimated annualized cost to labelers is $8,382,720.

13. Capital Cost

There are no capital costs associated with this information collection request at this time.

14. Federal Costs

There are no systems upgrade costs or any other costs associated with this collection extension request.

15. Changes in Burden/Program

There are no new systems collections or program changes. The number of labelers has increased from 580 to 590 labelers, thereby causing a corresponding rise in our burden estimates.

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.