Supporting Statement
for the Medicaid Drug Program
CMS-367a, 367b and 367c
0938-0578

Background

We are requesting a revision of this collection.

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. In order for payment to be made under Medicaid, the drug labeler must supply information within 30 days after the end of each calendar quarter and month on the average manufacturer price (AMP) of the drugs.

As part of that information, we are adding a check-box for drug manufacturers to indicate whether or not their drug is used exclusively for pediatric indications, and we are adding a new, optional Affordable Care Act (ACA) baseline AMP field.

Additionally, per the ACA, the Federal upper limit (FUL) will be calculated as no less than 175 percent of the weighted average of the most recently reported monthly AMP. Section 1927 of the Act requires manufacturers to report the total number of units that are used to calculate the monthly AMP for each covered outpatient drug no later than 30 days after the last day of the month. We plan to require manufacturers to report these units by the same unit type used to calculate the AMP and then we will use these units to calculate the weighted AMP-based FULs prices.

We do not anticipate any additional burden on drug manufacturers for any of the new fields. The new exclusively pediatric indication field is a yes/no checkbox that need only be checked once for each applicable drug product and the burden is so light that it cannot be quantified. The new ACA baseline AMP field is optional, need only be entered once for applicable NDCs, and can be entered on-line; therefore, it will not affect the manufacturers' annual burden. After initial manufacturer systems changes are implemented to enable transfer this data, we do not expect any additional or ongoing cost for manufacturers to report the total number of units that are already used by labelers to calculate the monthly AMP.

To reduce the number of pages necessary for data submittal, the Centers for Medicare & Medicaid Services (CMS) does not display the disclosure statement on the form itself. Instructions to the manufacturers (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 collection (CMS-367a, CMS-367b and CMS-367c) required (electronic record attached).

DATA FIELDS – CMS-367a

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled for 4-digit labeler codes.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled for 3-digit product codes.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled for 1-digit package size codes.

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's 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

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled for 4-digit labeler codes.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled for 3-digit product codes.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled for 1-digit package size codes.

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's 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's Price (AMP) Unit: Average Manufacturer Price (AMP) Units – 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:

DATA FIELDS – CMS-367c

Labeler Code: First segment of National Drug Code that identifies the labeler. Numeric values only, 5-digit field, right-justified and zero-filled for 4-digit labeler codes.

Product Code: Second segment of National Drug Code. Alpha-numeric values, 4-digit field, right justified, zero-filled for 3-digit product codes.

Package Size Code: Third segment of National Drug Code. Alpha-numeric values, 2-digit field, right justified, zero-filled for 1-digit package size codes.

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.

FDA 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 manufacturer (i.e., NDA holder). For N drugs, the date the drug was first marketed under the manufacturer'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. (Note: This field is grayed-out and is viewable as historical data only. It has been replaced by the Rebate Eligibility Code field.)

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).

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 (was 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 had 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.

Purchased Product Date: The date the company currently holding legal title to the NDC purchased the product from another company. Zero or blank fill if not applicable. Numeric values, 8-digit field, format: MMDDYYYY

Package Size Introduction Date: The date the package size is first available on the market. Zero or blank fill if not present. Numeric values, 8-digit field, format: MMDDYYYY

Pediatric Exclusivity Indicator: Identifies a product that is used exclusively for pediatric indications.

Y = Yes
N= No

ACA Baseline AMP (Optional): For active innovator drugs, the OBRA '90, OBRA '93 or DRA Baseline AMP revised in accordance with relevant regulations and program guidance. There will be one weighted ACA Baseline AMP for the product, which will be the same for all package sizes. 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.

A. Justification

1. Need and Legal Basis

The authority for requiring this data collection is section 1927 of the Act as modified by the ACA.

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 will be 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

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 as modified by the Deficit Reduction Act and the ACA 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

A 60-day Federal Register notice was published on June 18, 2010.

The program has been in place since 1991, and since that time, labelers have requested that CMS update the data collection mechanism as many labelers have had to invest in costly older technologies to retrofit their computer systems in order to report using the current reporting technologies.

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 drug program is for labelers to gather and report existing sales and product information on an additional monthly basis and an expanded quarterly basis.

Currently, there are approximately 580 respondents reporting drug information to CMS. Of the 580 total respondents reporting, 100% will report data via the DDR, with two reporting options (online and file transfer). The following is a calculation of the annual burden estimates for electronic data reporting.

580 labelers X 16 responses per year X 14.8 hours per response
=137,344 total hours across all labelers

TOTAL ANNUAL BURDEN HOURS 137,344

The estimated annualized cost to labelers is $8,240,640. This cost is based on a private industry pay rate of $60 an hour for this function.

For the new fields, we do not anticipate any additional burden on drug manufacturers because the pediatric exclusivity indicator field is a yes/no checkbox, and the ACA baseline AMP field is optional and may be reported on-line. We do not expect any additional or ongoing cost for manufacturers to report the total number of units that are already used by labelers to calculate the monthly AMP.

13. Total Costs as a Result of Data Collection

The pediatric exclusivity indicator field is a yes/no checkbox, and the ACA baseline AMP field is optional. Both fields may be reported on-line; therefore, there is no systems burden to labelers other than changing the file layout, which is already being changed due to the new AMP unit field.

In evaluating the capital cost for implementing the new requirement for manufacturer units to be submitted, we contacted a medium sized labeler, who estimated that a one-time investment of $10,000.00 was needed in order to make the system changes for the AMP unit data submission. Further, the labeler stated that they would not recognize any on-going cost to submit this information once the systems were programmed. Based on that figure, we estimate that labelers with less or more drug products would have less or more start up costs, proportionately, with no ongoing cost to sustain.

14. Federal Costs

The estimated federal cost to implement the Pediatric indicator, ACA base AMP and the Monthly AMP units would be roughly $750,000.

15. Changes in Burden/Program

For these new fields, we do not anticipate any additional reporting burden on drug manufacturers because the pediatric exclusivity indicator field is a yes/no checkbox, and the ACA baseline AMP field is optional and may be reported on-line. The manufacturer units are already collected to calculate the monthly AMP, and reporting these units will just become part of the customary and usual business practices, after any start up costs as outlined above. However, the numbers of manufacturers and private industry hourly pay rates have increased causing a corresponding rise in burden estimates. The burden increase is based on an increase in the number of manufacturers. The number has risen from 540 to 580.

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.