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

Background

We are requesting emergency approval of a revision to this collection to reflect changes implemented by the Deficit Reduction Act of 2005 (DRA). The DRA added a monthly data collection requirement and a quarterly data element.

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. For purposes of this law, a drug labeler is defined as one who holds legal title to the National Drug Code number for a prescription drug, non-prescription drug or biological product.

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. In addition, the DRA added nominal price as another quarterly data element submitted by manufacturers.

To reduce the number of pages necessary for data submittal, 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). The former approved 367a (Supplemental Data Sheet) to collect manufacturer contact information becomes the 367d and has not changed.

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. Numeric values only, 4-digit field, right justified, zero-filled.

Package Size Code: Third segment of National Drug Code. Numeric values only, 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's Price (AMP): The AMP per unit for the period covered. 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. Numeric values, 12-digit field: 5 whole numbers, the decimal ('.') and 6 decimal places; right-justified, zero-filled. Zero-fill for Non-innovator Multiple Source drugs.

Nominal Price (NP): Sales that meet the statutory/regulatory definition of NP. Total dollar figure per NDC, rounded to nearest dollar. 9-digit field; 9 whole numbers. If no sales for an NDC, labelers must zero-fill.

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. Numeric values only, 4-digit field, right justified, zero-filled.

Package Size Code: Third segment of National Drug Code. Numeric values only, 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's Price (AMP): The AMP per unit for the period covered. 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.

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. Numeric values only, 4-digit field, right justified, zero-filled.

Package Size Code: Third segment of National Drug Code. Numeric values only, 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, (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: If marketed prior to 10-01-90, first day of the first month that the drug was marketed for the entire month; otherwise, actual date the product is marketed. Numeric values, 8-digit field, (MMDDYYYY).

Termination Date: The date a drug is withdrawn from market or the drug's last lot expiration date. Numeric values, 8-digit field, (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 or over-the-counter (OTC).

1 = Rx
2 = OTC

Baseline AMP: The AMP per unit for the period that establishes the Baseline AMP for innovator drugs. 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.

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.

DRA Baseline AMP: For active innovator drugs with a Market Date less than 10/1/2006, the Baseline AMP excluding CPP discounts. If no CPP discounts were given in the quarter that established Baseline AMP, the labeler restates the current Baseline AMP in this field. There will be one weighted DRA 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 Deficit Reduction Act of 2005.

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.

3. Improved Information Technology

CMS is developing a web-based application for all drug data collection that will be implemented concurrent with the new monthly reporting requirements beginning with the effective date of the DRA (1/1/2007). The first monthly reporting is due via the new application on March 2, 2007. The new application, Drug Data Reporting for Medicaid (DDR) will be available at no charge to all participating labelers. Labelers will 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

CMSO 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. We anticipate that the DDR will help 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 DRA requires monthly and quarterly drug data reporting by labelers.

7. Special Circumstances

Section 1927 of the Act requires 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-2238-P), which require labelers to retain such data for ten years.

8. Federal Register Notice/Outside Consultations

An emergency Federal Register notice allowing a 30-day comment period was published on February 2, 2007.

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 540 respondents reporting drug information to CMS. Of the 540 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.

540 labelers X 16 responses per year X 12.3 hours per response
=106,272 total hours across all labelers

TOTAL ANNUAL BURDEN HOURS 106,272

The estimated annualized cost to labelers is $5,313,600. This cost is based on a private industry pay rate of $50 an hour for this function.

13. Total Costs as a Result of Data Collection

The new DRA data reporting requirements will require some labelers to modify their existing systems. The larger labelers will likely want to utilize the file transfer option within DDR to submit their data. Due to the increased reporting time frames, these labelers will likely opt to modify their existing systems to accommodate these changes. The calculation below assumes that half of the labelers might opt to update their systems ($60,000 for 270 labelers or spread out to each at $30,000 per labeler).

540 labelers X $30,000 (systems upgrade costs) = $16,200,000

14. Federal Costs

The estimate to build, upload and test the DDR is $2,000,000

15. Changes in Burden/Program

As a result of statutory changes, CMS is now required to collect monthly data as well as quarterly data, increasing the total number of collections per year from 4 to 16. Because of these changes, there will be an increased burden on the manufacturers.

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.