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

Background

This package adds the proposed requirements and burden associated with CMS-2345-P (RIN 0938-AQ41) which published in the Federal Register on February 2, 2012 (77 FR 5318). The rule published as, "Medicaid Program; Covered Outpatient Drugs."

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 proposed rule, serving as the 60-day Federal Register notice, published on February 2, 2012 (77 FR 5318).

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 Approved Requirements/Burden

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.

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

Proposed Changes CMS-2345-P (RIN 0938-AQ41)

Section **447.509(b)** would add requirements for States to collect necessary drug utilization data from Medicaid MCOs in order to include MCO data in the quarterly rebate requests. These requirements would affect the 51 State Medicaid Programs, as well as the territories. The burden associated with the inclusion of Medicaid MCOs in the Drug Rebate Program is the time and effort it would take for the State Medicaid Program to gather the drug utilization information from the Medicaid MCOs and the subsequent inclusion of said data in the State's quarterly rebate request to manufacturers.

As referenced in §447.509(b) and §447.511, we believe the collection of drug utilization data from MCOs and the subsequent inclusion of said data in the State's quarterly rebate request to the manufacturers will add a total 678 hours per quarter or 2,712 hours annually to the current reporting burden for the States (which include the 50 States, District of Columbia, and the territories) at an estimated cost of $98,744.

Section **447.510** would significantly revise the definitions of AMP and best price and, therefore, would require the manufacturers to reconfigure their pricing systems to correctly calculate AMP and best price. In addition, manufacturers must submit the total number of units that are used to calculate the monthly AMP. Therefore, the burden associated with these new requirements is the time and effort it would take for a drug manufacturer to reconfigure its pricing systems to correctly calculate AMP and best price before it can submit the required data to CMS.

We estimate that these requirements would affect the approximately 600 drug manufacturers in the Medicaid Rebate Program. We believe the changes to the AMP and best price definitions will require 240 hours per

manufacturer, for a one-time total of 144,000 burden hours with a one-time total estimated burden cost of $8,640,000. Once the pricing systems have been reconfigured, there should be no additional burden in time or effort than that which already exists.

Manufacturers will be required to submit the FDA application number issued by FDA when the product is approved. If the product does not currently have an FDA application number, the manufacturer must submit evidence demonstrating that the product is otherwise a covered outpatient drug. CMS shall refer to this evidence of demonstration as covered outpatient drug status, or COD status. This information should not be difficult for the manufacturer to determine since the manufacturer should already know the FDA application number of the product when it was approved by FDA, or the reason it qualifies as a covered outpatient drug, if there is no application number.

We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the FDA application number or the COD status is the time and the effort it would take for each drug manufacturer to retrieve this information from their records and submit it to CMS. Therefore, we believe that the new requirements to report the FDA application number and the COD status will require a one-time total of 3,000 hours at a one-time total estimated burden cost of $180,000.

Manufacturers will also be required to identify drugs that are approved by the FDA exclusively for pediatric indications. These drugs will be referred by CMS as "Exclusively Pediatric" drugs. This information should not be difficult for manufacturers to determine and therefore would not add any significant hourly burden since the exclusively for pediatric indications will be provided by the FDA upon approval of these drugs. Additionally, manufacturers will need to consider certain requirements when it comes to the calculation of their AMP for inhalation, infusion, instilled, implanted, and injectable drugs (5i), when not generally dispensed through retail community pharmacies. Using the methodology proposed earlier in this rule, a manufacturer would be required to identify and determine the AMP of these drugs. It is our estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the initial reporting of the 5i drugs is the time and the effort it would take for each drug manufacturer to identify these drugs and then to determine which of the 5i drugs are not generally dispensed through a retail community pharmacy by using the methodology proposed earlier in this rule. However, it is our understanding that each drug manufacturer should have some knowledge as to which drug is a 5i based on the approval information the manufacturer received from the FDA as well as the FDA Route of Administration list that CMS has identified. Once the manufacturer has established its initial list of 5i drugs, it would then be required on both a monthly, as well as quarterly basis, to determine which of those drugs are not generally dispensed through a retail community pharmacy. Therefore, we believe that the new reporting requirements will require a one-time total of 1,500 burden hours for manufacturers to identify the 5i drugs at a one-time total estimated burden cost of $90,000.

In addition, on both a monthly and quarterly basis (12 months, plus 4 quarters, for a total of 16 times per year) the manufacturer will be required to determine whether the percentage of sales for the 5i drugs has met the threshold to be considered not generally dispensed through a retail community pharmacy. Specifically, we estimate that it will add 20 hours per response with 16 responses per year for each manufacturer to identify which 5i drugs are not generally dispensed through a retail community pharmacy. This equates to a total estimate of 320 additional hours annually per manufacturer. The total annual burden hours for the 600 drug manufacturers participating in the Medicaid Rebate Program is estimated to be 192,000 hours with a total cost of $11,520,000.

Manufacturers participating in the rebate program that have reformulated drugs are now required to calculate an alternative rebate calculation for certain drugs. In order to calculate the alternative rebate calculation for a line

extension drug of a brand name in an oral solid dosage form, the line extension drug and the initial brand name listed drug need to be identified. Although CMS will be identifying both the initial brand name listed drug and the line extension drug for the initial three quarters for manufacturers, they will be responsible for identifying the initial brand name listed drug and the line extension drug after the initial three quarters. Manufacturers are responsible for calculating the unit rebate amount for the line extension drug.

We estimate that these requirements would affect approximately 600 drug manufacturers that participate in the Medicaid Drug Rebate Program. The burden associated with the reporting of the initial brand name listed drug and the line extension drug is the time and the effort it would take for each drug manufacturer to identify these drugs. However, it is our understanding that each drug manufacturer should have some knowledge on which drug is the line extension based on the approval information that the manufacturer received from the FDA as well as the Chemical Type that CMS has identified as a line extension drug and the initial brand name listed drug. Therefore, we believe that the new reporting requirements to identify the initial brand name listed drug and the line extension drug would add 20 additional hours per quarter, per manufacturer; or 48,000 total hours annually to the drug manufacturers at a total estimated cost of $2,880,000.

Finally, a manufacturer is required to retain records for 10 years from the date the manufacturer reports data to CMS for that rebate period. While this requirement is subject to the PRA, we believe this is a usual and customary business practice as defined in 5 CFR 1320.3(b)(2) and, therefore, the associated burden is exempt from the PRA.

Revised Burden Estimates

	Hours	Cost
Existing	139,712	8,382,720
Proposed	391,212	23,408,744
Total Requested	**530,924**	**$31,791,464**

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 request.

15. Changes in Burden/Program

This package adjusts the estimated number of number of labelers from 590 to 600 and adds the following proposed requirements and burden associated with CMS-2345-P (RIN 0938-AQ41) which published in the Federal Register on February 2, 2012 (77 FR 5318).

Regulation Section(s)	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital/ Maintenance Costs ($)	Total Cost ($)
447.509(b) and 447.511	56	224	12.1	2,712	36.41	98,744	0	98,744
447.510	600	600	240	144,000	60	8,640,000	0	8,640,000
447.510	600	600	5	3,000	60	180,000	0	180,000
447.510	600	600	2.5	1,500	60	90,000	0	90,000
447.510	600	9600	20	192,000	60	11,520,000	0	11,520,000
447.510	600	2400	20	48,000	60	2,880,000	0	2,880,000
Total	**656**	**14,024**		**391,212**		**23,408,744**		**23,408,744**

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 exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.