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

Background

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.

Under the Medicaid program, states may provide coverage of prescribed drugs as an optional service under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for federal financial participation (FFP) in state expenditures for these drugs. Section 1927 of the Act governs the Medicaid Drug Rebate (MDR) Program and payment for covered outpatient drugs (CODs), which are defined in section 1927(k)(2) of the Act.

In general, for payment to be made available under section 1903(a) of the Act for CODs, manufacturers must enter into a National rebate agreement (agreement) as set forth in section 1927(a) of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, and requirements for states for CODs.

A. Justification

1. Need and Legal Basis

The authority for requiring this data collection is section 1927 of the Act as modified by the Affordable Care Act and the February 1, 2016 Covered Outpatient Drug Final Rule with Comment (81 FR 5170) (Final Rule). The Final Rule implements changes to section 1927 of the Act made by sections 2501, 2503, and 3301(d)(2) of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148, enacted on March 23, 2010), and sections 1101(c) and 1206 of the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111-152, enacted on March 30, 2010) (collectively referred to as the Affordable Care Act). It also implements changes to section 1927 of the Act as set forth in section 202 of the Education Jobs and Medicaid Assistance Act (Pub. L. 111-226, enacted on August 10, 2010).

2. Information Users

Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each NDC and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto the CMS-64. 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 individual 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. Please note that these screen shots are from the pre-production test database and have been updated to reflect the new data fields requested as part of this collection revision.

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

We require respondents to report information to the agency more often than quarterly. Section 1927 of the Act requires monthly and quarterly drug data reporting by labelers.

Otherwise, this information collection request does not include any other special circumstances. More specifically, this information collection does not do any of the following:

-Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;

-Require respondents to submit more than an original and two copies of any document;

-Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years.;

-Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,

-Require the use of a statistical data classification that has not been reviewed and approved by OMB;

-Includes a pledge of confidentiality that is not supported by authority established in statue or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

-Require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultations

The 60-day Federal Register notice published on May 2, 2016 (81 FR 26235). 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 sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimate of Burden and Costs to Respondents

The burden associated with our CMS-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, as well as one time changes that may be required to product data.

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.

The following provides a breakdown of the burden associated with this collection.

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Hourly Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialist	13-1199	35.33	35.33	70.66
Computer System Analysts	15-1121	43.36	43.36	86.72
General & Operations Managers	11-1021	57.44	57.44	114.88
Lawyers	23-1011	65.51	65.51	131.02
Operations Research Analysts	15-2031	40.47	40.47	80.94

Training & Development Managers	11-3131	53.69	53.69	107.38

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

12.2 Burden Estimates

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.

CMS-367a - Quarterly Pricing Data

Burden Due to Miscellaneous Quarterly Pricing Data Fields: On a quarterly basis manufacturers are to report pricing data for each of their covered outpatient drugs to CMS. This data includes a Record ID, Labeler Code, Product Code, Package Size, Period Covered (Quarter/Year), the Average Manufacturer Price (AMP), the Best Price, Nominal Price and Customary Prompt Pay Discounts.

We estimate that these requirements affect the approximately 610 drug manufacturers participating in the MDR program. The quarterly burden associated with the reporting of these miscelleanous data fields is the time and effort it takes to report these miscelleanous fields through the file transfer process or manual data entry through the DDR system.

We estimate that it will take a computer system anaylst 8 hours at $86.72/hr, a general and operations manager 2 hours at $114.88/hr, a training and development manager 1 hour at $107.38/hr, and a operations research anaylst 3.8 hours at $80.94/hr (for a total of $1,338.47across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous data fields. This equates to an annual burden of 59.2 hours per manufacturer. In aggregate, we estimate 36,112 hours (610 drug manufacturers participating in the MDR program x 59.2 hr) at a cost of $3,265,867 ($1,338.47 per response x 4 responses/year x 610 manufacturers).

These fields are included on form CMS-367a as “Record ID”, “Labeler Code”, “Product Code”, “Package Size”, “Period Covered”, Average Mfg Price”, “Best Price”, “Nominal Price” and “Customary Prompt Pay Disc.”

Burden Due to the Initial Drug Available for LE and Initial Drug Fields: For each drug identified as a line extension drug, manufacturers must identify an initial brand name listed drug each quarter that has the highest additional rebate (calculated as a percentage of AMP) for any strength of the initial brand name listed drug. As a result, an “Initial Drug Available for LE” and an “Initial Drug” field are included on form CMS 367a (i.e., quarterly pricing format) so that a manufacturer can identify on a quarterly basis whether a line extension drug has an active initial drug, and then also report the initial drug itself. It is our understanding that each drug manufacturer should have some knowledge regarding the drug from which each line extension product is derived.

We estimate that these requirements affect the approximately 610 drug manufacturers participating in the MDR program. The quarterly burden associated with the reporting of the Initial Drug information is the time and effort it takes to identify whether a line extension product has an initial drug for the quarter/year combination being reported, to report the initial drug (if applicable), and to calculate the alternative URA for each line extension drug.

We estimate that it will take a computer system analyst 5 hours at $86.72/hr, a general and operations manager 5 hours at $114.88/hr, a training and development manager 5 hours at $107.38/hr, and an operations research analyst 5 hours at $80.94/hr (for a total of $1,949.60 per quarter across all four positions) to complete the reporting of the Line Extension and Initial Drug information, as well as perform the ongoing quarterly calculation of the alternative URA. The annual burden for the 610 drug manufacturers participating in the MDR program is estimated to be 48,800 hours (610 drug manufacturers x 20 hr/response x 4 responses/year) with a cost of $4,757,024 ($1,949.60 per response x 4 responses/year x 610 manufacturers).

CMS-367a - Quarterly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting ($/hr)	Total Annual Cost ($)
Misc data fields	610	2,440 (4 quarterly responses per year)	14.8	36,112	Varies	3,265,867
Initial Drug Available for LE			10	24,400		
Initial Drug			10	24,400		4,757,024
Currently Approved Burden	**610**	**2,440**	**34.8**	**84,912**	**Varies**	**8,022,891**

CMS-367b – Monthly Pricing Data

Burden Due to Miscellaneous Monthly Pricing Data Fields: On a monthly basis manufacturers are to report pricing data for each of their covered outpatient drugs to CMS. This data includes a Record ID, Labeler Code, Product Code, Package Size, Month, Year, AMP and AMP Units.

We estimate that these requirements affect the approximately 610 drug manufacturers participating in the MDR program. The monthly burden associated with the reporting of these miscelleanous data fields is the time and effort it takes to report these miscelleanous fields through the file transfer process or manual data entry through the DDR system.

We estimate that it will take a computer system anaylst 8 hours at $86.72/hr, a general and operations manager 2 hours at $114.88/hr, a training and development manager 1 hour at $107.38/hr, and a operations research anaylst 3.8 hours at $80.94/hr (for a total of $1,338.47 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous data fields. This equates to an annual burden of 177.6 hours per manufacturer. In aggregate, we estimate 108,336 hours (610 drug manufacturers participating in the MDR program x 177.6 hr) at a cost of $9,797,600 ($1,338.47 per response x 12 responses/year x 610 manufacturers).

These fields are included on form CMS-367b as “Record ID”, “Labeler Code”, “Product Code”, “Package Size”, “Month, Year”, “AMP” and “AMP Units”.

Burden Due to Monthly 5i Threshold Determination: In accordance with §447.507(b)(1), the drug manufacturer is required, on a monthly basis, to determine whether the percentage of sales for 5i drugs has met

the threshold to be considered not generally dispensed through only a retail community pharmacy. We estimate that it will take a computer system analyst 5 hours at $86.72/hr, a general and operations manager 5 hours at $114.88/hr, a training and development manager 10 hours at $107.38/hr, and an operations research analyst 10 hours at $80.94/hr (for a total of $2,891.20 per month across all four positions) for each drug manufacturer to identify whether each 5i drug is or is not generally dispensed through a retail community pharmacy. This equates to an annual burden of 360 additional hours (30 hr/response x 12 responses/year) per drug manufacturer. In aggregate, we estimate 219,600 hours (610 drug manufacturers participating in the MDR program x 360 hr) at a cost of $21,163,584 ($2891.20 per response x 12 responses/year x 610 manufacturers).

This field is included on form CMS-367b as a "5i Threshold."

CMS-367b – Monthly Pricing Data

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting ($/hr)	Total Annual Cost ($)
Misc data fields	610	7,320 (12 monthly responses per year)	14.8	108,336	Varies	9,797,600
5i Threshold			30	219,600		21,163,584
Currently Approved Burden	**610**	**7,320**	**44.8**	**327,936**	**Varies**	**30,961,184**

CMS-367c – Product Data

Burden Due to Miscellaneous Product Data Fields: When a manufacturer reports a new drug to CMS or makes a change to the product data of an existing drug, the manufacturer is responsible for reporting these product data. This data may include a Record ID, Labeler Code, Product Code, Package Size, Drug Category, Unit Type, FDA Approval Date, FDA Therapeutic Equivilency Code, Market Date, Termination Date, Drug Type Indicator, OBRA '90 Baseline AMP, Units Per Package Size, FDA Product Name, DRA Baseline AMP, Package Size Introduction Date, Purchase Product Date, ACA Baseline AMP, COD Status, and FDA Application Number/OTC Monograph Number.

We estimate that these requirements affect the approximately 610 drug manufacturers participating in the MDR program. The annual burden associated with the reporting of these miscelleanous product data fields is the time and effort it takes to report these miscelleanous fields through the file transfer process or manual data entry through the DDR system.

We estimate that it will take a computer system anaylst 8 hours at $86.72/hr, a general and operations manager 1.5 hours at $114.88/hr, a training and development manager 1 hour at $107.38/hr, and a operations research anaylst 7 hours at $80.94/hr (for a total of $1,540.04 across all four positions) for each drug manufacturer to complete the reporting of these miscellaneous product data fields. In aggregate, we estimate 10,675 hours (610 drug manufacturers participating in the MDR program x 17.5 hr) at a cost of $939,424 ($1,540.04 per response x 1 response/year x 610 manufacturers).

These fields are included on form CMS-367c as a "Record ID", "Labeler Code", "Product Code", "Package Size Code", "Drug Category", "Unit Type", "FDA Approval Date", "FDA Thera. Eq. Code", "Market Date," "Termination" Date", "Drug Type Indicator", "OBRA '90 Baseline AMP", "Units Per Package Size", "FDA Product Name", "DRA Baseline AMP", "Package Size Introduction Date", "Purchase Product Date", "ACA Baseline AMP", "COD Status", and "FDA Appl. No./OTC Mono. No.".

Burden Due to the Line Extension Drug Indicator Field: Under §447.509(a)(4), drug manufacturers participating in the rebate program that have line extension drugs are required to compute a quarterly alternative rebate amount in addition to the traditional quarterly rebate amount. To compute the alternative rebate calculation for a line extension drug of a brand name in an oral solid dosage form, the drug manufacturer must first perform a one-time identification of each line extension drug. The Line Extension Drug Indicator field exists onform CMS 367c (i.e., product data format) so that a manufacturer can identify whether or not each product is a line extension drug.

We estimate that this requirement affects the approximately 610 drug manufacturers participating in the MDR program. The one-time burden associated with the reporting of the Line Extension Drug Indicator is the time and effort it takes each drug manufacturer to identify whether each drug is a line extension product.

We estimate that it will take a computer system analyst 10 hours at $86.72/hr, a general and operations manager 5 hours at $114.88/hr, a training and development manager 1 hour at $107.38/hr, and an operations research analyst 10 hours at $80.94/hr (for a one-time total of $2,358.38 across all four positions) to complete the reporting of the Line Extension Drug Indicator. The annual burden for the 610 drug manufacturers participating in the MDR program is estimated to be 15,860 hours (610 drug manufacturers x 1 response) with a cost of $1,438,612.

One-Time Burden to Apply for Narrow Exception to Drug Category Classification: Section 1927(k)(7)(A) of the Act provides a definition for each of the drug categories that are used in the Medicaid Drug Rebate (MDR) program to identify the rebate percentage used to calculate the unit rebate amount (URA) for each drug. Specifically, section 1927(k)(7) of the Act defines drugs to include single source drugs, innovator multiple source drugs, and noninnovator multiple source drugs. Section 1927(k)(7)(A)(iv) of the Act defines a single source drug, in part, to mean a covered outpatient drug produced or distributed under an original new drug application (NDA), including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. Our understanding is that a single source drug is typically the first drug on the market; it has been produced or distributed under an NDA, other than an abbreviated new drug application (ANDA), approved by the FDA for the drug and has no therapeutic equivalents. Similarly, our understanding is that an innovator multiple source drug is a drug that was initially marketed under an NDA, other than an ANDA, approved by FDA but is rated therapeutically equivalent to at least one other product in the FDA's 'Approved Drug Products with Therapeutic Equivalence Evaluations' (Orange Book) that is sold or marketed in the United States during the rebate period. Section 1927(k)(7)(A)(iii) of the Act defines noninnovator multiple source drugs as multiple source drugs that are not innovator multiple source drugs, which are typically marketed under an ANDA, as opposed to an NDA, approved by FDA.

When a manufacturer first enters a drug into the DDR system, the manufacturer must enter one of three values into the "Drug Category" field to classify the drug as a single source (S), innovator multiple source (I) or noninnovator multiple source (N) drug. It is the manufacturer's responsibility to enter the appropriate drug category of S, I, or N consistent with the definitions of each term as found in section 1927(k)(7)(A) of the Act.

In the February 1, 2016 final rule (81 FR 5191) we state that there may be very limited circumstances where, for the purposes of the MDR program, certain drugs might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug. We indicated that we would issue additional guidance on the scope of these very limited circumstances as well as a process by which manufacturers could submit materials to CMS for consideration of this narrow exception. For drugs marketed under an NDA and reported currently to MDR program as noninnovator multiple source drugs, manufacturers will have up to four quarters after the effective date of the final rule to apply for an exception and, if applicable, make the required data changes to bring their reporting efforts into statutory and regulatory

compliance before CMS takes any administrative action, if appropriate, against such manufacturers.

We estimate that it will take a general and operations manager 1 hour at $114.88/hr, an operations research analyst 3 hours at $80.94/hr, a lawyer 3 hours at $131.02/hour, and a business operations specialist 3 hours at $70.66/hour (for a total of $962.74 across all four positions) for each drug manufacturer gather the necessary documentation and submit the request to CMS for consideration of the narrow exception to the drug category classification requirement. This equates to an additional one-time burden of 10 hours per manufacturer. In aggregate, we estimate 6,100 hours (610 drug manufacturers participating in the MDR program x 10 hr) at a cost of $587,271 ($962.74 per response x 610 manufacturers).

The "Drug Category" field is already included on form CMS-367c. In addition, we have added a "Narrow Exception Indicator" to DDR (see section 15 below) that will only be populated in DDR if it has first been checked in the Medicaid Drug Rebate (MDR) system by CMS. This is not a field that manufacturers will have access to edit, as CMS will be entering this information for manufacturers if they apply for, and are granted, the narrow exception to drug category classification.

CMS-367c – Product Data

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting ($/hr)	Total Annual Cost ($)
Misc data field*s	610	610 (1 response per year)	17.5	10,675	Varies	939,424
Line Extension Drug Indicator*			26	15,860		1,438,612
Narrow Exception to the Drug Category**			10	6,100		587,271
Total	**610**	**610**	**53.5**	**32,635**	**Varies**	**2,965,307**

*Currently approved burden.
**Proposed requirements/burden (see section 15 below).

CMS-367d – Supplemental Data Sheet

Burden Due to Supplemental Data Sheet submission: The Supplemental Data Sheet is submitted to CMS when manufacturers have need to update CMS on contact information such as email address, phone number, or address, of their legal, invoice or technical contact for the MDR system.

We estimate that this requirement affects the approximately 610 drug manufacturers participating in the MDR program. Furthermore, we estimate that drug manufacturers need to submit the Supplemental Data Sheet to CMS on average twice a year. The annual burden associated with the submission of the Supplemental Data Sheet is the time and effort it takes to complete the form and fax, mail or email the form to CMS.

We estimate that it will take a computer system analyst 1 hour at $86.72/hour to complete the submission of the supplemental data sheet. This equates to an annual burden of 2 hours (1 hr/response x 2 responses/year) per drug manufacturer. In aggregate, we estimate 1,220 hours (610 drug manufacturers participating in the MDR program x 2 hrs) at a cost of $105,798 ($86.72 per response x 2 response/year x 610 manufacturers).

CMS-367d – Supplemental Data Sheet

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden	Hourly labor cost of reporting	Total Annual Cost ($)

				(hours)	($/hr)	
Currently Approved Burden	610	1,220 (2 responses per year)	1.0	1,220	86.72	105,798

Other Requirements/Burden

The following requirements and burden do not appear in any of the CMS-367 form data fields:

One-Time Reconfiguration of Labeler Drug Pricing Systems: Consistent with §447.510, drug manufacturers currently must report (electronically) product and quarterly pricing information to CMS not later than 30 days after the end of the rebate period. Monthly pricing and units are due no later than 30 days after the end of the month.

The February 1, 2016 (81 FR 5170) final rule significantly revised the definitions of AMP and best price, which are both part of the pricing information submitted by manufacturers on a monthly and/or quarterly basis. Consequently, drug manufacturers must reconfigure their pricing systems to correctly calculate AMP and best price. Specifically, the burden associated with these new requirements is the time and effort it takes 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 affect the approximately 610 drug manufacturers in the MDR program. We estimate it will take a computer system analyst 400 hours at $86.72/hr, a general and operations manager 180 hours at $114.88/hr, a training and development manager 180 hours at $107.38/hr, a lawyer 40 hours at $131.02/hr, and an operations research analyst 400 hours at $80.94/hr (for a one-time total of $112,311.60 across all five positions) to update a manufacturer's pricing system to incorporate the new requirements related to the changes to AMP and best price definitions. The one-time total burden for the 610 drug manufacturers participating in the MDR program is estimated to be 732,000 hours (610 drug manufacturers x 1,200 hr/ drug manufacturer) at a cost of $68,510,076 (610 drug manufacturers x $112,311.60).

This information is not located on the CMS-367 forms. As indicated above this burden requirement is to update a manufacturer's pricing system to incorporate the new requirements related to the changes to AMP and best price definition so that AMP and best price data can be reported on the CMS-367 forms.

One-Time Cost of Training Drug Manufacturer Staff: In addition to the one-time burden of reconfiguring pricing systems, we are also estimating a one-time cost to train drug manufacturer staff on the new, reconfigured pricing systems. To perform this training, we believe it will take a general and operations manager 600 hours at $114.88/hr, a training and development manager 1,700 hours at $107.38/hr, and an operations research analyst 1,700 hours at $80.94/hr (for a one-time total of $389,072 across all three positions). The one-time total burden associated with this training is estimated to be 2,440,000 hours (610 drug manufacturers x 4,000 hr/ drug manufacturer) at a cost of $237,333,920 (610 drug manufacturers x $389,072).

This information is not located on the CMS-367 forms. As indicated above this burden requirement is to update a manufacturer's pricing system to incorporate the new requirements related to the changes to AMP and best price definition so that AMP and best price data can be reported on the CMS-367 forms.

12.3 Summary of Burden Estimates

Regulation Section(s) in Title 42 of the CFR	Description / Form	Frequency	Respondents	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Total Labor Cost of Reporting ($)	Total Capital/Maintenance Costs ($)	Total Cost ($)
	CMS-367a	Quarterly	610	2,440	34.8	84,912	8,022,891	0	8,022,891
	CMS-367b	Monthly	610	7,320	44.8	327,936	30,961,184	0	30,961,184
	CMS-367c	Occasionally	610	610	53.5	32,635	2,965,307	0	2,965,307
	CMS-367d	Occasionally	610	1,220	1	1,220	105,798		105,798
447.510	One-Time Reconfiguration of Labeler Drug Pricing Systems	Once	610	610	1,200	732,000	68,510,076	0	68,510,076
447.510	One-Time Cost of Training Drug Manufacturer Staff s	Once	610	610	4,000	2,440,000	237,333,920	0	237,333,920
Total	**--**	**--**	**610**	**12,810**	**--**	**3,618,703**	**347,899,176**	**0**	**347,899,176**

13. Capital Costs

There are no capital costs.

14. Federal Costs

The estimated annual federal cost for our contractor to maintain the operation of the Drug Data Reporting for Medicaid (DDR) and Medicaid Drug Rebate (MDR) systems is roughly $2,000,000. Please note that this is not a new cost to the Federal government. During the review process for this submission we realized that past PRA packages incorrectly included a cost estimate that only reflected the change being requested in the package rather than the change plus the existing burden. Therefore, in this package we are correcting this error and reporting the annual cost for the contract.

15. Changes in Burden/Program

Previous PRA packages had set out cost estimates inconsistently and had not designated specific occupational titles and hours to the burden estimates. Therefore, this this iteration of the PRA package seeks to correct those omissions by setting out cost estimates for all of the package's information collection requests.

In line with final rule CMS-2345-FC (81 FR 5326) which indicated that the following requirements/burden will be set out under the regular PRA process, CMS proposes to add the following requirements. The 60-day notice published on May 2, 2016 while the 30-day notice published on July 11, 2016.

Additional One-Time Burden to Apply for Narrow Exception to Drug Category Classification:
Section 1927(k)(7)(A) of the Act provides a definition for each of the drug categories that are used in the Medicaid Drug Rebate (MDR) program to identify the rebate percentage used to calculate the unit rebate amount (URA) for each drug. Specifically, section 1927(k)(7) of the Act defines drugs to include single source drugs, innovator multiple source drugs, and noninnovator multiple source drugs. Section 1927(k)(7)(A)(iv) of the Act defines a single source drug, in part, to mean a covered outpatient drug produced or distributed under an original new drug application (NDA), including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. Our understanding is that a single source drug is typically the first drug on the market; it has been produced or distributed under an NDA, other than an abbreviated new drug application (ANDA), approved by the FDA for the drug and has no therapeutic equivalents. Similarly, our understanding is that an innovator multiple source drug is a drug that was initially marketed under an NDA, other than an ANDA, approved by FDA but is rated therapeutically equivalent to at least one other product in the FDA's 'Approved Drug Products with Therapeutic Equivalence Evaluations' (Orange Book) that is sold or marketed in the United States during the rebate period. Section 1927(k)(7)(A)(iii) of the Act defines noninnovator multiple source drugs as multiple source drugs that are not innovator multiple source drugs, which are typically marketed under an ANDA, as opposed to an NDA, approved by FDA.

When a manufacturer first enters a drug into the DDR system, the manufacturer must enter one of three values into the "Drug Category" field to classify the drug as a single source (S), innovator multiple source (I) or noninnovator multiple source (N) drug. It is the manufacturer's responsibility to enter the appropriate drug category of S, I, or N consistent with the definitions of each term as found in section 1927(k)(7)(A) of the Act.

In the Final Rule (81 FR 5191) we state there may be very limited circumstances where, for the purposes of the MDR program, certain drugs might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug. We indicated that we would issue additional guidance on the scope of these very limited circumstances as well as a process by which manufacturers could submit materials to CMS for consideration of this narrow exception. For drugs marketed under an NDA and reported

currently to MDR program as noninnovator multiple source drugs, manufacturers will have up to four quarters after the effective date of the final rule to apply for an exception and, if applicable, make the required data changes to bring their reporting efforts into statutory and regulatory compliance before CMS takes any administrative action, if appropriate, against such manufacturers.

We estimate that it will take a general and operations manager 1 hour at $114.88/hr, an operations research analyst 3 hours at $80.94/hr, a lawyer 3 hours at $131.02/hour, and a business operations specialist 3 hours at $70.66/hour (for a total of $947.60 across all four positions) for each drug manufacturer gather the necessary documentation and submit the request to CMS for consideration of the narrow exception to the drug category classification requirement. This equates to an additional one-time burden of 10 hours per manufacturer. In aggregate, we estimate 6,100 hours (610 drug manufacturers participating in the MDR program x 10 hr) at a cost of $587,271 ($962.74 per response x 610 manufacturers).

The “Drug Category” field is already included on form CMS-367c. In addition, we have added a “Narrow Exception Indicator” to DDR that will only be populated in DDR if it has first been checked in the Medicaid Drug Rebate (MDR) system by CMS. This is not a field that manufacturers will have access to edit, as CMS will be entering this information for manufacturers if they apply for, and are granted, the narrow exception to drug category classification.

Summary of Added Burden

Description / Form	Frequency	Respondents	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Total Labor Cost of Reporting ($)	Total Cost ($)
Narrow Exception to the Drug Category (CMS 367c)	Once	610	610	10	6,100	587,271	587,271
TOTAL	**--**	**610**	**610**	**10**	**6,100**	**587,271**	**587,271**

3,612,603 hours	Currently approved burden (see the April 4, 2016, Notice of Action)
+ 6,100 hours	Added requirements/burden for Narrow Exception Process of Drug Category Change
3,618,703	Revised burden estimate

16. Publication and Tabulation Data

There are no plans to publish the collected information.

17. Display of Expiration Date

CMS will display this collection of information's expiration date.

18. Exception to Certification Statement

We certify that this information collection complies with 5 CFR 1320.9. We do not seek any exemptions.

B. Collections of Information Employing Statistical Methods

CMS does not intend to employ statistical methods to the collected information.