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

This is a revised package which is associated with our "Medicaid Program; Covered Outpatient Drugs" final rule that published in the Federal Register on February 1, 2016 (81 FR 5170) (RIN 0938-AQ41; CMS-2345-FC).

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 February 1, 2016, 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).

Section 2501(d) of the Affordable Care Act added a new section 1927(c)(2)(C) of the Act effective for drugs paid for by a state on or after January 1, 2010. This provision modifies the unit rebate amount (URA) calculation for a drug that is a line extension (new formulation) of a single source or innovator multiple source drug that is an oral solid dosage form.

Section 2503(a)(1) of the Affordable Care Act amended section 1927(e) of the Act by revising the Federal upper reimbursement limit (FUL) to be no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. Additionally, it specifies that the Secretary shall implement a smoothing process for AMP

which shall be similar to the smoothing process used in determining the average sales price (ASP) of a drug or biological product under Medicare Part B. Section 2503(a)(2) of the Affordable Care Act amended section 1927(k) of the Act by revising the definition of AMP to now mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drug distribution to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

Section 3301(d)(2) of the Affordable Care Act included a conforming amendment to the definition of best price (BP) under Medicaid at section 1927(c)(1)(C)(i)(VI) of the Act. This amendment provides that any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A of the Act are exempt from a manufacturer's best price calculation, effective for drugs dispensed on or after July 1, 2010.

Section 1101(c) of HCERA also includes a conforming amendment to the definition of AMP under Medicaid at section 1927(k)(1)(B)(i) of the Act by providing that discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A are excluded from a manufacturer's determination of AMP, effective March 30, 2010.

Section 202 of the Education, Jobs and Medicaid Assistance Act (Pub. L. 111-226), enacted on August 10, 2010 and effective on October 1, 2010, amended the definition of AMP under section 1927(k)(1)(B)(i)(IV) of the Act to include sales for inhalation, infusion, instilled, implanted, or injectable drugs that are not generally dispensed through retail community pharmacies.

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-prodcution 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

Serving as the 60-day notice, the NPRM (RIN 0938-AQ41; CMS-2345-P) published in the Federal Register on February 2, 2012 (77 FR 5317). Comments were received. A summary of the comments along with our response is attached to this package. Changes that were made from the NPRM to the Final Rule are highlighted below:

With regard to our proposed changes to §447.507, several commenters noted that our 20 hr estimate (associated with a drug manufacturer’s burden to identify 5i drugs and determine whether such drugs are not generally dispensed through retail community pharmacies) is low. We received one specific comment estimating that it would take 40 hours per drug manufacturer to perform the analysis for this requirement. Upon considering the comment, we increased our 20 hour proposed estimate to 30 hours per month per response and added 1.0 hour

per month for drug manufacturers to report this information to CMS.

We have also revised proposed §447.507(b)(2) by removing the reference to a quarterly basis. In accordance with §447.507(b)(1), the drug manufacturer is 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 on a monthly basis.

With regard to comments concerning our proposed changes to §447.510 we have revised our estimates pertaining to the implementation of the revised definitions of AMP and best price under the existing presumed inclusion approach. The revised estimate reflects that reconfiguring the manufacturers' pricing systems to implement the AMP and best price definitions will require 1,200 hours per drug manufacturer, for a one-time total of 732,000 hours with a one-time total cost of $67,175,884 for 610 participating drug manufacturers.

In addition to the one-time burden of reconfiguring pricing systems, based on comments received, we now estimate a one-time start-up cost to include the cost of training drug manufacturer staff on the new, reconfigured pricing systems.

With regard to the estimate we proposed for the calculation of the alternative rebate for a line extension drug of a brand name that is an oral solid dosage form, we have revised our initial estimate from the NPRM to reflect not only the quarterly calculation and reporting requirements but the time burden required for the drug manufacturer to identify the line extension drug and the initial brand name listed drug that has the highest additional rebate ratio (calculated as a percentage of AMP) for any strength of the initial brand name listed drug. The one-time burden associated with the reporting of the Line Extension Drug Indicator is estimated to be 15,860 hours with a one-time total cost of $1,407,550.60 for 610 participating drug manufacturers. In addition, for the drugs that have been determined to be a line extension product, we estimate the annual burden to be 48,800 hours with a cost of $4,675,528 for the 610 participating drug manufacturers.

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 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.

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.

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 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)
Computer System Analysts	15-1121	41.98	41.98	83.96
General & Operations Managers	11-1021	56.35	56.35	112.70
Lawyers	23-1011	64.17	64.17	128.34
Operations Research Analysts	15-2031	39.88	39.88	79.76
Training & Development Managers	11-3131	53.38	53.38	106.76

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.

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 Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting ($/hr)	Total Annual Cost ($)
Currently Approved Burden	610	2,440 (4 quarterly responses per year)	14.8	36,112	Varies	3,459,349
Initial Drug Available for LE*			10	24,400		4,674,796
Initial Drug*			10	24,400		
Total Burden	**610**	**2,440**	**34.8**	**84,912**	**Varies**	**8,134,145**

*New requirement (see section 15 for details).

CMS-367b – Monthly Pricing Data

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	7,320 (12 monthly responses per year)	14.8	108,336	Varies	10,286,503
5i Threshold*			30	219,600		20,851,020
Total Burden	**610**	**7,320**	**44.8**	**327,936**	**Varies**	**31,137,523**

*New requirement (see section 15 for details).

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 ($/hr)	Total Annual Cost ($)
Currently Approved Burden	610	610 (1 response per year)	17.5	10,675	Varies	947,390
Line Extension Drug Indicator*			26	15,860		1,407,551
Total Burden	**610**	**610**	**43.5**	**26,535**	**Varies**	**2,354,941**

*New requirement (see section 15 for details).

*CMS-367d – Supplemental Data Sheet**

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting ($/hr)	Total Annual Cost ($)
Currently Approved Burden	610	1,220 (2 responses per year)	1.0	1,220	83.96	102,431

*No changes.

Other Requirements/Burden

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

Additional Burden Due to the One-Time Reconfiguration of Labeler Drug Pricing Systems: Consistent with §447.510 of the final rule, 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.

This final rule significantly revises 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 $83.96/hr, a General and Operations Manager 180 hours at $112.70/hr, a Training and Development Manager 180 hours at $106.76/hr, a Lawyer 40 hours at $128.34/hr, and an Operations Research Analyst 400 hours at $79.76/hr (for a one-time total of $110,124.40 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 $67,175,884.

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.

Additional Burden Due to the 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. We are including this additional estimate based upon comments we received in response to the proposed rule. To perform this training, we believe it will take a General and Operations Manager 600 hours at $112.70/hr, a Training and Development Manager 1,700 hours at $106.76/hr, and an Operations Research Analyst 1,700 hours at $79.76/hr (for a one-time total of $384,704 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 $234,669,440.
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.

Summary of Burden Estimates

gulation ction(s) Title 42 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 Co ($)**
	CMS-367a	Quarterly	610	2,440	34.8	84,912	8,134,145	0	8,134,14
	CMS-367b	Monthly	610	7,320	44.8	327,936	31,137,523	0	31,137,5
	CMS-367c	Occasionally	610	610	43.5	26,535	1,407,551	0	1,407,55
	CMS-367d	Occasionally	610	1,220	1	1,220	102,431		102,43
447.51	One-Time Reconfiguration of Labeler Drug Pricing Systems	Once	610	610	1,200	732,000	67,175,884	0	67,175,8
447.51	One-Time Cost of Training Drug Manufacturer Staff s	Once	610	610	4,000	2,440,000	0	234,669,440	234,669,4
Total	**--**	**--**	**610**	**12,810**	**--**	**3,612,603**	**107,957,534**	**234,669,440**	**342,626,9**

13. Total Costs as a Result of Data Collection

The estimated annualized cost to labelers is $328,778,690.60. This cost is based on the average private industry pay rate for several positions within the pharmaceutical industry, including Computer Systems Analysts, General and Operations Managers, Operations Research Analysts, etc.

14. Federal Costs

The estimated federal cost for our contractor to implement these manufacturer requirements in the Drug Data Reporting for Medicaid (DDR) and Medicaid Drug Rebate (MDR) systems would be roughly $500,000.

15. Changes in Burden/Program

In accordance with final rule CMS-2345-FC, CMS is amending the following requirements under this collection.

Additional 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 $83.96/hr, a General and Operations Manager 5 hours at $112.70/hr, a Training and Development Manager 10 hours at $106.76/hr, and an Operations Research Analyst 10 hours at $79.76/hr (for a total of $2848.50 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 $20,851,020 (2848.50 per response x 12 responses/year x 610 manufacturers).

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

Additional Burden Due to the New 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. Consequently, we are adding a Line Extension Drug Indicator field to form 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. However, based upon the approval information that a drug manufacturer receives from the FDA, it is our understanding that each drug manufacturer should have some knowledge regarding which drugs are line extensions.

We estimate that it will take a Computer System Analyst 10 hours at $83.96/hr, a General and Operations Manager 5 hours at $112.70/hr, a Training and Development Manager 1 hour at $106.76/hr, and an Operations Research Analyst 10 hours at $79.76/hr (for a one-time total of $2,307.46 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 $1,407,550.60.

This field has been added to form CMS-367c as a "Line Extension Drug Indicator."

Additional Burden Due to the New Line Extension 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, we are adding an Initial Drug Available for LE and an Initial Drug field to 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. However, 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 $83.96/hr, a General and Operations Manager 5 hours at $112.70/hr, a Training and Development Manager 5 hours at $106.76/hr, and an Operations Research Analyst 5 hours at $79.76/hr (for a total of $1,915.90 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 $4,674,796.

As indicated above, the following fields have been added to form CMS-367a: (1) “Initial Drug Available for LE” and (2) “Initial Drug.”

Additional Burden Due to the One-Time Reconfiguration of Labeler Drug Pricing Systems: Consistent with §447.510 of the final rule, 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.

This final rule significantly revises 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 $83.96/hr, a General and Operations Manager 180 hours at $112.70/hr, a Training and Development Manager 180 hours at $106.76/hr, a Lawyer 40 hours at $128.34/hr, and an Operations Research Analyst 400 hours at $79.76/hr (for a one-time total of $110,124.40 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 $67,175,884.

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.

Additional Burden Due to the 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. We are including this additional estimate based upon comments we received in response to the proposed rule. To perform this training, we believe it will take a General and Operations Manager 600 hours at $112.70/hr, a Training and Development Manager 1,700 hours at $106.76/hr, and an Operations Research Analyst 1,700 hours at $79.76/hr (for a one-time total of $384,704 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 $234,669,440.

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.

Summary of Added Burden

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 ($)	Total Capital/Maintenanc Costs ($)
447.507(b)(4)	5i Determination (Form -367b)	Monthly	610	7,320	30	219,600	20,851,020	0
447.509(a)(4)	Line Extension Determination (Form - 367c)	Occasionally*	610	610	26	15,860	1,407,551	0
447.509(a)(4)	Line Extension Reporting (Form - 367a)	Quarterly	610	2,440	20	48,800	4,674,796	0
447.51	AMP/BP Reconfiguring Pricing System	Once*	610	610	1,200	732,000	67,175,884	0
447.51	AMP/BP Training / Start-up Costs	Once*	610	610	4,000	2,440,000	0	234,669,440**
Total	--	--	**610**	**11,590**	--	**3,456,260**	**94,109,251**	**234,669,440**

156,343 hours Currently approved burden (see 6/13/2014 Notice of Action)
+ 3,456,260 hours Burden added under CMS-2345-FC
3,612,603 hours 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 the expiration date for OMB approval.

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.