Attachment A

**Supporting Statement Part A**
**Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP)**
**CMS-10476, OMB 0938-1232**

*Supporting regulations are contained in 42 CFR 422.2400, 422.2401, 422.2410, 422.2420, 422.2430, 422.2440, 422.2450, 422.2460, 422.2470, 422.2480, 422.2490, 423.2300, 423.2401, 423.2410, 423.2420, 423.2430, 423.2440, 423.2450, 423.2460, 423.2470, 423.2480, and 423.2490.*

## Background

Under the Affordable Care Act (ACA), and implementing regulations at 42 CFR, Medicare Advantage (MA) organizations and Prescription Drug Plan (PDP) sponsors are required to submit annual medical loss ratio (MLR) reports (at the contract level) to the Secretary of HHS concerning the amount spent on claims, quality improvement expenses, non-claims costs, Federal and State taxes, licensing and regulatory fees, and revenue. Plan sponsors must provide a remittance to the Secretary if the amount spent in a reporting year on certain costs compared to its revenue (excluding Federal and States taxes and licensing and regulatory fees) is below a certain ratio, referred to as the medical loss ratio (MLR).

Consistent with the statutory requirements, MA organizations and Part D sponsors are required to report their MLR to CMS, and are subject to financial and other penalties for a failure to meet a statutory requirement that they have an MLR of at least 85 percent. The Affordable Care Act requires several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination.

Plan sponsors use the MLR Reporting Tool to provide contract-level MLR information to CMS. The information provided in this MLR Report is the basis for computing the contract's MLR percentage and remittance amount, if any, for a contract year.

## A. Justification

1. Circumstances Making the Collection of Information Necessary

The Patient Protection and Affordable Care Act (Pub. L. 111–148), was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (Pub. L. 111–152) ("Reconciliation Act"), was enacted on March 30, 2010.

Section 1103 of Title I, Subpart B of the Reconciliation Act amends section 1857(e) of the Social Security Act (the Act) to add new medical loss ratio (MLR) requirements. An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care, rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)

(D) of the Act incorporates by reference the requirements of section 1857(e), these new Affordable Care Act medical loss ratio requirements also apply to the Part D program.

Under these new requirements, MA organizations and Part D sponsors (collectively referred to here as "plan sponsors") are required to report their MLR, and are subject to financial and other penalties for a failure to meet the new statutory requirement that they have an MLR of at least 85 percent. The Affordable Care Act requires several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and, ultimately, contract termination.

In the May 23, 2013 Federal Register (78 FR 31284), CMS published a final rule regarding implementation of these new MLR requirements for the MA and Part D programs. MA organizations and Part D sponsors are required to submit annual reports (at the contract level) to the Secretary of HHS concerning the amount spent on claims, quality improvement expenses, non-claims costs, Federal and State taxes, licensing and regulatory fees, and revenue. MA organizations and Part D sponsors must provide a remittance to the Secretary if the amount spent in a reporting year on certain costs compared to its revenue (excluding Federal and States taxes and licensing and regulatory fees) is below a certain ratio, referred to as the medical loss ratio (MLR). Sanctions do not apply to non-credible contracts, as defined in the regulations.

More specific information can be found in the 42 CFR references listed above. Copies of these references are available at: http://www.gpo.gov/fdsys/pkg/FR-2013-05-23/pdf/2013-12156.pdf

2. Purpose and Use of Information Collection

The following information collections are included in this request:

Annual Report. Plan sponsors are required to submit an annual report to the Secretary in December of the year following the end of an MLR reporting year.

The annual reports will be used by CMS to ensure that beneficiaries are receiving value for their premium dollar by calculating each contract's MLR and any remittances due for the respective MLR reporting year.

Recordkeeping. The MLR regulations contain recordkeeping requirements that require plan sponsors to maintain evidence of the amounts reported to CMS, to enable CMS to verify that the data submitted is in compliance with MLR regulations, including all documents, records, and other evidence used to calculate the MLR. Documents, records, and other evidence must be preserved and maintained for 10 years from the date such calculations were reported to CMS with respect to a given MLR reporting year.

The recordkeeping requirements will be used by CMS to determine plan sponsor' compliance with the MLR requirements, including compliance with how plan sponsors' experience is to be reported, and how their MLR and any remittances are calculated.

3. Use of Improved Information Technology and Burden Reduction

Similar to the commercial MLR form, the Medicare MLR Report is programmed in Microsoft Excel. This software is used by CMS for numerous activities and builds on the knowledge of the organizations' users regarding this common business software. Excel's design is a user-friendly format, and used commonly in business applications. These factors limit the time required by organization users to gain experience and familiarity with the MLR Report.

The hardcopy screen prints in Attachment B present an overview of the MLR Report, and may not fully capture the streamlining effect of the software on the data collection and calculations. The use of Excel reduces the burden on the organizations to calculate the MLR percentage and remittance by using standard formulas. The Excel format allows for plans to easily copy information into the MLR Report and to use many other automation techniques.

The submission process for the MLR Report is entirely automated (electronically) through CMS's Health Plan Management System (HPMS). No paper/hardcopy submissions are required.

HPMS is already used by plan sponsors to submit other annual Part C and Part D reporting requirements to CMS (contracting information, bid pricing tools, plan benefit packages, formularies, DIR data submission, attestations, etc.).

4. Efforts to Identify Duplication and Use of Similar Information

There are no similar information collections that capture the requirements of MLR reporting for Part C and Part D.

5. Impact on Small Businesses or Other Small Entities

As stated in the Regulatory Impact Analysis of CMS-4173-F (78 FR 31284, May 23, 2013), CMS does not believe that the required submission of annual reports to the Secretary will have a significant impact on a substantial number of small entities.

6. Consequences of Collecting the Information Less Frequently

CMS must collect this information annually, as required by the Affordable Care Act. MA organizations and Part D sponsors are required to report their MLR, and are subject to financial and other penalties for a failure to meet the new statutory requirement that they have an MLR of at least 85 percent. The Affordable Care Act requires several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and, ultimately, contract termination.

The MLR Report is necessary to fulfill the statutory requirements of the ACA. If CMS did not collect these reports annually, it would not be possible to fulfill the statutory mandate to assess whether each plan sponsor is in fact providing beneficiaries with health care value in return for their premium dollars.

7. Special Circumstances

There are no special circumstances. More specifically, this information collection does not do any of the following:

-Require respondents to report information to the agency more often than quarterly;

-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 die information's confidentiality to the extent permitted by law.

8. Federal Register Notice

The non-rule related Federal Register notice published on September 2, 2016 (81 FR 60704). The notice provided a 60-day public comment period. No comments were received.

Rule related changes published in the July 15, 2016, proposed rule (81 FR 46161) (RIN 0938-AS81; CMS-1654-P). The final rule published on November 15, 2016 (81 FR 80170). The changes do not have any burden implications, nor does it revise or add any respondent requirements. See section 16 of this Supporting Statement for additional information.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts as a condition of complying with this information collection request.

10. Confidentiality

Similar to the commercial MLR, CMS reserves the right to publish plan sponsors' annual reports, to achieve greater market transparency and improved ability of beneficiaries to make informed insurance choices.

Data in plan sponsors' annual reports will be published pursuant to the authority at §422.2490 and §423.2490.

CMS already publishes annual reports from the comparable MLR requirement for commercial plans participating in the federal marketplace.

No individually identifiable personal health information will be collected and, consequently, cannot be disclosed.

11. Justification for 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. Collection of Information Requirements and Burden Estimates

*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 (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

Estimated Hourly Wages

| Occupation Title | Occupation Code | Mean Hourly Wage ($/hr) | Fringe Benefit ($/hr) | Adjusted Hourly Wage ($/hr) |
|---|---|---|---|---|
| Computer and Information Systems Managers | 11-3021 | 67.79 | 67.79 | 135.58 |

Except where noted, 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.

*Requirements/Burden Estimates*

Annual Report

The estimated total number of MLR reports that MA organizations and Part D sponsors will be required to submit to the Secretary depends on the number of contracts held. MA organizations and Part D sponsors will be submitting a separate MLR report for each contract. CMS' analysis is based on 553 MA contracts and 63 Part D stand-alone contracts, for a total of 616 reports. The 616 contracts are comprised of 605 contracts subject to the reporting and remittance requirement plus 11 non-credible contracts that are subject to reporting requirements.

The 616 estimate is based on established contract information from CMS' Health Plan Management System (HPMS). The total number of MA/PD contracts is fairly stable annually and continues to be current.

CMS used the commercial MLR RIA (May 23, 2013 (78 FR 31305) as a basis for estimating the total hours of administrative work related to the Medicare MLR requirements.

CMS anticipates that the level of effort relating to these activities will vary depending on the scope of an MA organization or Part D sponsor's operations. The complexity of each MA organization or Part D sponsor's estimated reporting burden is likely to be affected by a variety of factors, including the number of contracts it offers, enrollment size, the degree to which it currently captures relevant data, whether it is a subsidiary of a larger carrier, and whether it currently offers coverage in the commercial market (and is therefore subject to the commercial MLR requirements).

Unlike the initial package where we set out one-time burden for the initial reporting year, the following table sets out ongoing burden since we continue to estimate 616 contracts.

| | (a) | (b) | (c) = (a) x (b) | (d) | (e) = (c) x (d) | (f) = (e) / (a) |
|---|---|---|---|---|---|---|
| | Number of contracts/ reports | Estimated Average Hours per report | Estimated Total Hours | Estimated average cost ($/hr) | Estimated Total Cost ($) | Estimated Average Cost per Report ($) |
| Ongoing annual costs | 616 | 47 | 28,952 | 135.58 | 3,925,312 | 6,372 |

Recordkeeping Requirements. CMS estimates that each MA organization and Part D sponsor will incur annual administrative costs (per report) related to complying with the MLR recordkeeping requirements.

Each plan sponsor is obligated to maintain all documents, records and other evidence that supports the data submitted by the issuer in its annual report(s) to the Secretary. Each of the plan sponsors that is expected to submit an annual report to the Secretary must maintain the supporting documentation for ten years from the date such calculations were reported to CMS with respect to a given MLR reporting year.

MLR record retention costs are assumed to be relatively low, since MA organizations and Part D sponsors already retain similar data for general MA and Prescription Drug audits and per the established requirements in §422.504(f)(2) and §423.505(f)(2).

To arrive at an estimate for MA organizations and Part D sponsors, we adjusted downward the 3.5 minute-per-report estimate that appears in the RIA for the commercial MLR rule. CMS estimates that MA organizations and Part D sponsors will incur annual ongoing costs relating to the MLR recordkeeping requirements of approximately $6 per report on average, in maintaining the supporting documents for the respective MLR reporting year.

| | (a) | (b) | (c) = (a) x (b) | (d) | (e) = (c) x (d) | (f) = (e) / (a) |
|---|---|---|---|---|---|---|
| | Number of contracts/ reports | Estimated Average Hours per report | Estimated Total Hours | Estimated average cost per hour ($/hr) | Estimated Total Cost ($) | Estimated Average Cost per Report ($) |
| Ongoing annual costs | 616 | 0.045 | 27.72 | 135.58 | 3,758 | 6.10 |

*Collection of Information Instruments and Instruction/Guidance Documents*

- MLR Report (Attachment B)

Similar to the commercial MLR form, the Medicare MLR Report is programmed in Microsoft Excel. This software is used by CMS for numerous activities and builds on the knowledge of the organizations' users regarding this common business software. Excel's design is a user-friendly format, and used commonly in business applications. These factors limit the time required by organization users to gain experience and familiarity with the MLR Report.

The hardcopy screen prints in Attachment B present an overview of the MLR Report, and may not fully capture the streamlining effect of the software on the data collection and calculations. The use of Excel reduces the burden on the organizations to calculate the MLR percentage and remittance by using standard formulas. The Excel format allows for plans to easily copy information into the MLR Report and to use many other automation techniques.

The submission process for the MLR Report is entirely automated (electronically) through CMS's Health Plan Management System (HPMS). No paper/hardcopy submissions are required.

HPMS is already used by plan sponsors to submit other annual Part C and Part D reporting requirements to CMS (contracting information, bid pricing tools, plan benefit packages, formularies, DIR data submission, attestations, etc.).

- MLR Report Instructions (Attachment C)

13. Capital Costs

Not applicable. This collection does not impose any capital costs.

14. Annualized Cost to Federal Government

The initial burden to the Federal government for the collection of the MLR Report was borne through the initial development cycle, as a one-time cost. The MLR Report is now in

maintenance mode with regard to development and enhancements. The maintenance cost and the cost for enhancements are estimated in the table below. (The CMS employees' hourly wage schedule can be obtained https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB_h.pdf under the Washington-Baltimore-Northern Virginia locality.)

| | |
|---|---|
| Annual Maintenance and Enhancements | $350,000.00 |
| Annual Defining Requirements | |
| 1 GS-15 (step 10): 1 x $76.81 x 20 hours | $1,536.20 |
| 2 GS-14 (step 10): 2 x $67.83 x 80 hours | $10,852.80 |
| 2 GS-13 (step 10): 2 x $57.40 x 40 hours | $4,592.00 |
| *Subtotal* | *$16,981.00* |
| Total Annual Cost to the Government | $366,981.00 |

Additional costs to the government to prepare these files for release are already accounted for in current estimates (existing staff assignments and contracts), and therefore the cost impact is zero.

15. Explanation for Program Changes and Burden Adjustments

The currently approved Supporting Statement sets out a one-time burden for the initial reporting year. We are removing the one time burden since the requirement has been met. While the burden was set out in the 2014 Supporting Statement, it was inadvertently missing from the ROCIS submission to OMB.

| | (a) | (b) | (c) = (a) x (b) | (d) | (e) = (c) x (d) | (f) = (e) / (a) |
|---|---|---|---|---|---|---|
| | Number of contracts/ reports | Estimated Average Hours per report | Estimated Total Hours | Estimated average cost per hour ($/hr) | Estimated Total Cost ($) | Estimated Average Cost per Report ($) |
| One-time cost for the initial reporting year | 616 | (164) | (101,024) | 94.88* | (9,585,157.12) | (15,560.32) |

*Estimate approved by OMB under this control number on April 21, 2014.

Additionally, CMS has made the following minor modifications to the MLR Report, for user clarity. None of these changes result in any burden adjustments.

(1) Update labels: Annual update of year references. (ex: CY2014, CY2015, CY2016, etc.)
Locations: Filenames
MLR Worksheet 1 cells A1, A96, C5, C38, C39, C54, C57, C96, H1
MLR Worksheet 2 cells A1, A4, C36
MLR Worksheet 3 cells A1, A4

Reason: Update MLR Report to reference Contract Year reported.

(2) Add input cells.
Locations: MLR Worksheet 1 cells H23, H24, H63
Reason: To improve user clarity and reporting accuracy of MLR Report.

(3) Revise calculations (for newly added input cells).
Locations: MLR Worksheet 1 cells H35, I23, I24, I63, H46

MLR Workbook 2 cells D23, D37
Reason: To improve user clarity and reporting accuracy of MLR Report.

(4) Revise/add labels (for newly added cells).
Locations: MLR Worksheet 1 cells C23, C24, C25, C26, C63, G96
MLR Worksheet 2 cells C32
Reason: To improve user clarity and reporting accuracy of MLR Report.

CMS-specific (non-respondent) changes are discussed under section 16 of this Supporting Statement.

16. Plans for Tabulation and Publication and Project Time Schedule

The annual report of MLR data for the reporting year is due to the Secretary in December following the end of the contract year.

Similar to the commercial MLR, CMS reserves the right to publish plan sponsors' annual reports, to achieve greater market transparency and improved ability of beneficiaries to make informed insurance choices. Data in plan sponsors' annual reports will be published pursuant to the authority at §422.2490 and §423.2490.

Sections 422.2490 (for Part C) and 423.2490 (for Part D) provides for the public release of Part C and Part D MLR data for each contract year, which would occur no sooner than 18 months after the end of the contract year for which the MLR Report was submitted. For each contract year, each MAO and Part D sponsor must submit an MLR Report to CMS which includes the data needed by the MAO or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract. The November 15, 2016, final rule provides for the release of the Part C and Part D MLR data contained in the MLR Reports, with specified exceptions to release.

Within the final rule, new §422.272 provides for an annual public release of MA bid pricing data (with specified exceptions from release), which will occur after the first Monday in October and will contain MA bid pricing data that was approved by CMS for a contract year at least 5 years prior to the upcoming calendar year. Under Part C, MA organizations (MAOs) are required to submit bid data to CMS each year for MA plans they wish to offer in the upcoming contract year (calendar year), under current authority at §422.254.

The release of MA bid pricing data and the release of Part C and Part D MLR data does not change any of the currently approved requirements regarding submission of bid data and MLR data by MAOs or Part D plan sponsors.

17. Display of OMB Expiration Date

CMS has no objections to displaying the expiration date.

18. Certification Statement

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

**B. Collections of Information Employing Statistical Methods**

Not applicable. The information collection does not employ statistical methods.