Attachment A

**Supporting Statement Part A**

**Medical Loss Ratio (MLR) Data Form for Medicare Advantage (MA) Plans and**

**Prescription Drug Plans (PDP)**

**CMS-10476, OMB 0938-1232**

*Note: 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**

Sections 1857(e)(4) and 1860D-12 of the Social Security Act (which incorporates section 1857(e)(4) by reference), and implementing regulations at 42 CFR part 422, subpart X, and part 423, subpart X, set forth a requirement that Medicare Advantage (MA) organizations and Part D Prescription Drug Plan (PDP) sponsors report the medical loss ratio (MLR) for each MA or Part D contract to CMS for each contract year, and that such MLRs must meet a statutory standard of 85 percent. MA organizations and Part D sponsors are subject to 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.

MA organizations and Part D sponsors will use the MLR Data Form to provide contract-level MLR information to CMS for contract year 2018 and subsequent contract years, in accordance with §§ 422.2460 and 423.2460, as amended by the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs final rule (CMS-4182-F; RIN 0938-AT08). The information provided in the MLR Data Form will be used to determine whether an MA or Part D contract has satisfied the minimum MLR requirement with respect to a contract year, and whether the contract must remit funds to CMS or face additional sanctions.

In this 2020 iteration, our June 2, 2020 (85 FR 33796) final rule (CMS-4190-F, RIN 0938-AT97) amended § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA (medical savings account) contracts that receive a credibility adjustment. The action revises our currently approved (active) information collection request to take into account the additional burden (+0.67 hr) for MA organizations to calculate and apply the deductible factor to the MLR calculation.

While we are not making any changes to the MLR Data Form, we are revising the MLR Data Submission Instructions as a result of the replacement of the MLR Report workbook with the MLR Data Form.

### A. Justification

#### 1. Need and Legal Basis

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 amended section 1857(e) of the Social Security Act (the Act) by adding a minimum medical loss ratio (MLR) requirement to the MA program. 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), the minimum MLR requirement also apply to the Part D program. The MLR requirement for the MA and Part D programs took effect in contract year 2014.

Under the minimum MLR requirement, MA organizations and Part D sponsors are subject to financial and other penalties for a failure to meet the statutory requirement that they have an MLR of at least 85 percent. The statute 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 our May 23, 2013 final rule (78 FR 31284) regarding the implementation of these new MLR requirements for the MA and Part D programs, we established the requirement that MA organizations and Part D sponsors (collectively referred to as “plan sponsors” in this Supporting Statement) submit contract-level MLR data on an annual basis (§§ 422.2460 and 423.2460). However, in the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs final rule (CMS-4182-F; RIN 0938-AT08), we are finalizing that, for contract year 2018 data (submitted in 2019) and for subsequent contract years, this annual data submission for each contract year would consist of either (a) the MLR and the amount of any remittance due to CMS, for each credible or partially credible contract; or (b) a submission noting that the contract is not subject to the 85 percent minimum MLR requirement and the remittance requirement, for each non-credible contract.

MA organizations and Part D sponsors must provide a remittance to the Secretary if the amount spent in a contract year on certain costs compared to total revenues (excluding Federal and States taxes and licensing and regulatory fees) is below the 85 percent minimum MLR. MLR sanctions do not apply to contracts with non-credible experience, as defined in the regulations. These non-credible contracts are not required to submit their MLR or remittance amount to CMS; however, they must inform CMS that the contract’s experience is non-credible, in the manner prescribed by CMS.

More specific information can be found in the CFR references listed above.

#### 2. Information Users

The following information collections are included in this request:

*Annual Data Submission (Revised)* Plan sponsors are required to submit MLR data to the Secretary on an annual basis. Part C and Part D MLR data for a contract year will generally be submitted in December of the year following the end of the contract year.

The annual MLR data submissions will be used by CMS to ensure that beneficiaries are receiving value for their premium dollars based on each contract’s MLR and any remittances due.

*Recordkeeping (No Changes)* 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 MA organizations’ and Part D sponsors’ compliance with the MLR requirements, including requirements concerning how MLR data is to be reported, and how the MLR and any remittances are calculated.

#### 3. Use of Information Technology

The submission process for MLR data 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. Duplication of Information

There are no similar information collections that capture the requirements of MLR data submission for MA and Part D contracts.

#### 5. Impact on Small Businesses or Other Small Entities

CMS does not believe that the required submission of MLR data 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 in order to determine the amount of any remittances owed to CMS, and to implement sanctions, as required by the sections 1857(e) and 1860D–12(b)(3)(D) of the Social Security Act. MA organizations and Part D sponsors are required to report their MLR data, and are subject to financial and other penalties for a failure to meet the statutory requirement that they have an MLR of at least 85 percent. The statute 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.

Annual submission of MLR data is necessary for enforcement of the statutory remittance requirement and other sanctions mandated by the Act.

#### 7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

* Report information to the agency more often than quarterly;
* Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
* Submit more than an original and two copies of any document;
* Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
* Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
* Use a statistical data classification that has not been reviewed and approved by OMB;
* Include a pledge of confidentiality that is not supported by authority established in statute 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
* 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 Consultation

Serving as the 60-day notice, the proposed rule (CMS-4190-P, RIN 0938-AT97) filed for public inspection on February 5, 2020, and published on February 18 (85 FR 9002). Comments were due by April 6, 2020.

The final rule (CMS-4190-F, RIN 0938-AT97) published in the Federal Register on June 2, 2020 (85 FR 33796).

#### 9. Payment/Gift to Respondents

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

#### 10. Confidentiality

MLR data submitted by MA organizations and Part D sponsors will be published on the CMS website pursuant to the authority at §§ 422.2490 and 423.2490. No individually identifiable personal health information will be collected and, consequently, cannot be disclosed.

CMS first published Medicare MLR data on the CMS website in January 2017. CMS also publishes MLR data contained in annual MLR reports submitted by commercial plans, as required by section 2718 of the Public Health Service 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. 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 2019 National Occupational Employment and Wage Estimates for all salary estimates ([www.bls.gov/oes/current/oes\_nat.htm](http://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 overhead, and the adjusted hourly wage.

Estimated Hourly Wages

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Occupation Title | Occupation Code | Mean Hourly Wage ($/hr) | Fringe Benefits and Overhead ($/hr) | Adjusted Hourly Wage ($/hr) |
| Actuaries | 15-2011 | 58.16 | 58.16 | 116.32 |
| Computer and Information Systems Managers | 11-3021 | 75.19 | 75.19 | 150.38 |

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, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

*Collection of Information Requirements and Associated Burden Estimates*

Annual Data Submission (Revised Requirements)

MA organizations and Part D sponsors will be submitting MLR data for each contract on an annual basis. §§ 422.2460 and 423.2460. CMS’s analysis is based on an estimate of 587 MLR data submissions each year. The 587 figure is based on the average number of MA and Part D contracts subject to the MLR data submission requirements for contract years 2014 to 2018. The total number of MA and Part D contracts is fairly stable annually and continues to be current.

CMS used the commercial MLR RIA (May 23, 2013 (78 FR 31303 - 31304)) 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’s or Part D sponsor’s operations. The complexity of each MA organization’s 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 the 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).

The MLR information that MA organizations and Part D sponsors submit to CMS on an annual basis beginning with contract year 2018 was already being submitted as part of the detailed MLR Reports that MA organizations and Part D sponsors submitted to CMS for contract years 2014 through 2017. Because MA organizations and Part D sponsors will not need to establish any new processes for collecting this data, we do not anticipate that MA organizations and Part D sponsors will incur first time or ongoing costs that they were not already incurring in connection with this data collection.

Section 422.2440 provides for the application of a deductible factor to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The deductible factor serves as a multiplier on the credibility factor. MA organizations will need to spend additional time calculating the MLRs for MA MSA contracts that receive a credibility adjustment in order to apply the deductible factor. We estimate that for each of the 8 MA organizations that we anticipate will offer MSA contracts in 2021 and in each year through 2030, it will take an actuary approximately 5 minutes at a wage of $116.32/hr to calculate the deductible factor for the contract. In aggregate, we estimate an annual burden of 0.67 hours (5 min/60 \* 8 MA organizations) at a cost of approximately $78 (0.67 hr x $116.32/hr).

The per-contract burden for MA and Part D contracts is 0.00114 hours (0.67 hr / 587 contracts) or $0.13 per contract ($78 / 587 contracts).

|  | (a) | (b) | (c) = (a) x (b) | (d) | (e) = (c) x (d) | (f) = (e) / (a) |
| --- | --- | --- | --- | --- | --- | --- |
| Number of Contracts | Estimated Average Hours per Contract | Estimated Total Hours | Labor Cost ($/hr) | Estimated Total Cost ($) | Estimated Average Cost per Contract ($) |
| Actuary | 587 | 0.00114 | 0.67 | 116.32 | 78 | 0.13 |
| Computer and Information Systems Manager | 587 | 36 | 21,132 | 150.38 | 3,177,830.16 | 5,413.68 |
| **Total** | **587** | **36.00114** | **21,132.67** | **varies** | **3,177,908.16** | **5,413.81** |

Recordkeeping Requirements (No Changes)

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

Each MA organization and Part D sponsor is obligated to maintain all documents, records, and other evidence that support the MLR data that it submits to the Secretary. Each MA organization and Part D sponsor must maintain the supporting documentation for ten years from the date such data were reported to CMS with respect to a given contract year. §§ 422.2480(c) and 423.2480(c).

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 Plan program audits and per the established requirements in §§ 422.504(f)(2) and 423.505(f)(2).

To arrive at an estimate of the costs that MA organizations and Part D sponsors will incur in maintaining documentation that supports their MLR submissions, 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 in the following table.

|  | (a) | (b) | (c) = (a) x (b) | (d) | (e) = (c) x (d) | (f) = (e) / (a) |
| --- | --- | --- | --- | --- | --- | --- |
| Number of Contracts | Estimated Average Hours per Contract | Estimated Total Hours | Labor Cost ($/hr) | Estimated Total Cost ($) | Estimated Average Cost per Contract ($) |
| Recordkeeping Requirements | 587 | 0.045 | 26.42 | 150.38 | 3,973.04 | 6.77 |

*Summary of Annual Requirements/Burden Estimates*

|  | Number of Contracts | Estimated Average Hours per Contract | Estimated Total Hours | Labor Cost ($/hr) | Estimated Total Cost ($) | Estimated Average Cost per Contract ($) |
| --- | --- | --- | --- | --- | --- | --- |
| Annual Data Submission | 587 | 36.00114 | 21,132.67 | varies | 3,177,908.16 | 5,413.81 |
| Recordkeeping Requirements | 587 | 0.045 | 26.42 | 150.38 | 3,973.04 | 6.77 |
| **TOTAL** | **587** | **36.04614** | **21,159.09** | **varies** | **3,181,881.20** | **5,420.58** |

*Collection of Information Instruments and Instruction/Guidance Documents*

* Attachment B: MLR Data Form (No Changes)

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

HPMS is already used by MA organizations and Part D 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 submissions, attestations, etc.).

The MLR Data Form is available on the CMS.gov website at <https://www.cms.gov/files/zip/cy2018-mlr-workbook-and-instructionszip>.

* Attachment C: MLR Data Submission Instructions (CY 2018) (Revised)

The MLR Data Submission Instructions have been revised as a result of the replacement of the MLR Report workbook with the MLR Data Form. For contract years prior to CY 2018, the MLR Report workbook collected detailed data across three worksheets. The previous iteration of the MLR Data Submission Instructions provided line-by-line instructions for completing all three worksheets of the MLR Report workbook. The MLR Data Form now contains one worksheet, which collects the Adjusted MLR percentage and Remittance Amount. The instructions have been revised to provide line-by-line instructions for each field in the MLR Data Form.

Previously, in order to complete the MLR Report workbook, a separate add-in file (MLRyyyy.xlam) was required to be saved under C:\MLR\MLRyyyy. The functionalities/macros of the previous add-in file have now been incorporated into the MLR Data Form workbook. The “Technical Instructions” section of the MLR Data Submission Instructions has been revised to explain how users are to complete and finalize the MLR Data Form.

The submission process for the MLR Data Form is automated through HPMS, as with the MLR Report Workbook.

#### 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 MA and Part D MLR data was borne through the initial development cycle, as a one-time cost. The MA and Part D MLR data collection 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 at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB_h.pdf> under the Washington-Baltimore-Northern Virginia locality.

|  |  |
| --- | --- |
| Annual Maintenance and Enhancements | $200,000.00 |
| Annual Defining Requirements |  |
| 1 GS-15 (step 10): 1 x $81.84 x 20 hours | $1,636.80 |
| 2 GS-14 (step 10): 2 x $75.57 x 80 hours | $12,091.20 |
| 2 GS-13 (step 10): 2 x $63.95 x 40 hours | $5,116.00 |
| *Subtotal* | *$18,844.00* |
| Total Annual Cost to the Government | $218,844.00 |

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. Program Changes and Burden Adjustments

In this 2020 iteration, our June 2, 2020 (85 FR 33796) final rule (CMS-4190-F, RIN 0938-AT97) amended § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA (medical savings account) contracts that receive a credibility adjustment. The deductible factor would serve as a multiplier on the credibility factor. The application of the proposed deductible factor would increase the MLRs of MSA contracts that receive this adjustment.

As explained below, the finalized provision revises our currently approved (active) information collection request to take into account the additional burden (+0.67 hr) for MA organizations to calculate and apply the deductible factor to the MLR calculation.

MA organizations will need to spend additional time calculating the MLRs for MA MSA contracts that receive a credibility adjustment in order to apply the proposed deductible factor. We estimate that for each of the 8 MA organizations that we anticipate will offer MSA contracts in 2021 and in each year through 2030, it will take an actuary approximately 5 minutes at a wage of $116.32/hr to calculate the deductible factor for the contract. In aggregate, we estimate an annual burden of 0.67 hours (5 min/60 \* 8 MA organizations) at a cost of approximately $78 (0.67 hr x $116.32/hr). The per-contract burden for MA and Part D contracts is 0.00114 hours (0.67 hr / 587 contracts) or $0.13 per contract ($78 / 587 contracts).

While we are not making any changes to the MLR Data Form, we are revising the MLR Data Submission Instructions as a result of the replacement of the MLR Report workbook with the MLR Data Form.

*Impact of MSA/MLR*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | (a) | (b) | (c) = (a) x (b) | (d) | (e) = (c) x (d) | (f) = (e) / (a) |
| Number of Contracts | Estimated Average Hours per Contract | Estimated Total Hours | Labor Cost ($/hr) | Estimated Total Cost ($) | Estimated Average Cost per Contract ($) |
| Actuary | 587 | 0.00114 | 0.67 | 116.32 | 78 | 0.13 |

In addition to adding the above burden, we have updated our cost estimates using more recent BLS wage figures.

*Changes to Adjusted Hourly Wages*

We are adjusting our Computer and Information Systems Manager adjusted wage based on more recent BLS wage figures. Actuaries are an added occupation.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Occupational Title | Occupation Code | Currently Approved ($/hr)[BLS May 2018] | CMS-4190-F ($/hr)[BLS May 2019] | Difference ($/hr) |
| Computer and Information Systems Manager | 11-3021 | 140.14 | 150.38 | +10.24 |

*Burden Reconciliation*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Burden Type | Total Requested | Change Due to New Statute | Change Due to Program Discretion | Change Due to Program Adjustment | Total Currently Approved |
| Total Responses | 587 | 0 | 0 | 0 | 587 |
| Total Time (hr) | 21,159 | 0 | +1 | 0 | 21,158 |
| Time Per Response (hr) | 36.04614 | 0 | +0.00114 | 0 | 36.045 |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Burden Type | Total Annual Respondents | Response Frequency (per year) | Total Annual Responses | Time Per Response (hr) | Total Annual Time (hr) | Labor Cost ($/hr) | Total Annual Cost ($) |
| Currently Approved Burden | 587 | Annually | 587 | 36.045 | 21,158.42 | 140.14 | 2,965,141 |
| Proposed Burden | 587 | Annually | 587 | 36.04614 | 21,159.09 | varies | 3,181,881 |
| Adjustment | No change | No change | No change | +0.00114 | +0.67 | varies | +216,741 |

#### 16. Plans for Tabulation and Publication and Project Time Schedule

The annual submission of MLR data for a contract year is due to the Secretary generally in December following the end of the contract year.

CMS reserves the right to publish plan sponsors’ annual submissions of MLR data for purposes of to achieving greater market transparency and improving beneficiaries’ ability to make informed health insurance choices. Data in plan sponsors’ annual data submissions 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) provide 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 data was submitted. For each contract year, each MA organization or Part D sponsor must report to CMS the MLR for each contract that has credible or partially credible experience, and the amount of any remittance owed to CMS. If a contract has non-credible experience with respect to a contract year, the MA organization or Part D sponsor that holds the contract must inform CMS that the contract is non-credible. 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.

#### 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.