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.

The currently approved information collection request is entitled, "Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP)". This iteration revises the title by replacing "Report" with "Data Form". The new title is: "Medical Loss Ratio (MLR) Data Form for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP)".

Background

Sections 1857(e)(4) and 1860D-12 of the Act (which incorporates section 1857(e)(4) of the Act 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 proposed rule (CMS-4182-P; 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 addition to the title change mentioned above, this iteration significantly reduces the amount of MLR data that MA organizations and Part D sponsors must submit to CMS on an annual basis. Under the current MLR reporting requirements, MA organizations and Part D sponsors are required to report to CMS the information needed to calculate and verify the MLR and remittance amount, if any, for each contract, such as the amount of incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS. Under the proposed changes, MA organizations' and Part D sponsors' annual MLR data submissions 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. Consistent with the proposed changes to the type and amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis, we are revising the format of the data form that MA organizations and Part D sponsors use to enter/report their MLR data, as well as the instructions for submitting MLR data to CMS.

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 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 proposed rule (CMS-4182-P; RIN 0938-AT08), we are proposing that, for contract year 2019 and 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.

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). MLR sanctions do not apply to non-credible contracts, as defined in the regulations. These contracts are not required to submit their MLR or remittance amount to CMS; however, they must inform CMS that they are non-credible in the manner prescribed by CMS.

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

2. Purpose and Use of Information Collection

The following information collections are included in this request:

Annual Data Submission. (Revised Requirements and Adjusted Burden) Plan sponsors are required to submit MLR data to the Secretary on an annual basis. MLR data for MA and Part D contracts will generally be submitted in December of the year following the end of a 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 plan sponsors' 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

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. Efforts to Identify Duplication and Use of Similar 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

The November 28, 2017 (82 FR 56336), proposed rule (CMS-4182-P, RIN 0938-AT08) serves as the 60-day Federal Register notice.

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

MLR data submitted by plan 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. 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 2016 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 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)
Computer and Information Systems Managers	11-3021	70.07	70.07	140.14

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 Data Submission. (Revised Requirements and Adjusted Burden)

MA organizations and Part D sponsors will be submitting MLR data for each contract. CMS' 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 PD contracts is fairly stable annually and continues to be current.

CMS used the commercial MLR RIA (May 23, 2013 (78 FR 31303-04)) 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.

	(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	Estimated Average Cost ($/hr)	Estimated Total Cost ($)	Estimated Average Cost per Contract ($)
Ongoing annual costs	587	36	21,132	140.14	2,961,438	5,045

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 plan sponsor is obligated to maintain all documents, records, and other evidence that support the MLR data that it submits to the Secretary. Each plan sponsor that is required to submit MLR data to the Secretary 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 422.2480(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 of approximately $6.54 per contract on average.

	(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	Estimated Average Cost ($/hr)	Estimated Total Cost ($)	Estimated Average Cost per Contract ($)
Ongoing annual costs	587	0.045	26.42	140.14	3,702.50	6.31

Collection of Information Instruments and Instruction/Guidance Documents

- MLR Data Form (Attachment B) (New)

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 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.).

The currently approved data collection will continue to be used until early 2019. The MLR Data Form will be used for the submission of CY 2018 MLR data in late 2019. The Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2019 proposed rule (CMS-4182-P; RIN 0938-AT08)), and the proposed regulatory provisions at §§ 422.2460(b) and 423.2460(b) (as amended) list the specific data fields of the MLR Data Form, which are a subset of the current data collection.

- MLR Data Submission Instructions (Attachment C) (No Changes)

The current instructions for submitting MLR data to CMS are tailored to the current data collection, which as noted above will continue to be used until 2019.

- MLR Data Submission Instructions (Attachment TBD/Revisions TBD)

The revised MLR Data Submission Instructions will be available in 2018 for the PRA process. The submission process for the MLR Data Form will be automated through HPMS, as with the currently approved collection. We believe that the instructions for submitting the MLR Data Form will be simple and involve few steps, meaning respondents will require minimal time to review and understand any changes to the submission process. Respondents can continue to use the current instructions to familiarize themselves with the guidance specific to the calculation of the MLR, as we expect that the revised instructions will make few changes to this portion of the instructions.

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/2017/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 $77.58 x 20 hours	$1,551.60
2 GS-14 (step 10): 2 x $69.71 x 80 hours	$11,153.60
2 GS-13 (step 10): 2 x $59.05 x 40 hours	$4,724.00
Subtotal	*$17,429.20*
Total Annual Cost to the Government	$217,429.20

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 the ongoing costs of MLR reporting based on the current version of the MLR Report, which collects the data needed by an MA organization or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS. In the Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2019 proposed rule (CMS-4182-P; RIN 0938-AT08)), we are proposing that, for contract year 2018 and subsequent contract years, MA organizations' and Part D sponsors' annual data MLR submissions 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.

The revised MLR information collection will eliminate or reduce the burden associated with each of the following tasks: (1) reviewing MLR Report filing instructions and external materials referenced therein and inputting figures and plan-level data in accordance with the instructions; (2) drafting narrative descriptions of methodologies used to allocate expenses; (3) performing an internal review of the MLR Report prior to submission; (4) uploading and submitting the MLR Report; and (5) correcting or providing explanations for any suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR Report.

We estimate that the administrative burden associated with the MLR reporting requirements will be reduced from 47 hours per contract under the current collection to 36 hours per contract under the revised collection. 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 gathering this data, we do not anticipate that MA organizations and Part D sponsors will incur any additional first time costs in connection with this data collection.

The currently approved Supporting Statement estimates that 616 MA and Part D contracts will be subject to the MLR data submission requirements for each contract year. Our previous estimate of 616 was based on the number of MA and Part D contracts that we expected would be subject to the MLR requirements at the time that we published the May 23, 2013 final rule (78 FR 31284). We are revising this estimate to reflect the average number of MA and Part D contracts subject to the MLR data submission requirements for contract years 2014 to 2018. Based on this more recent data, we estimate that 587 MA and Part D contracts will be subject to the MLR data submission requirements for each contract year.

The table below compares the estimated administrative costs related to the MLR reporting requirements under the currently approved collection and under the proposed collection. As explained above, we expect that 587 contracts will be subject to the MLR requirements, which is 29 fewer contracts our previous estimate of 616. The table below also indicates that the proposed reduction in the amount of MLR data that is submitted to CMS on an annual basis will result in MA organizations and Part D spending on average 36 hours per MA or Part D contract on administrative work, compared to 47 hours per contract under the currently approved collection. We estimate that, as a result of the reduction in the number of contracts subject to the MLR requirements, and the reduction in the number of hours spent on administrative work, the total burden of the MLR reporting requirements across all MA organizations and Part D sponsors will decrease by 7,820 hours, from 28,952 hours under the currently approved collection to 21,132 hours under the revised collection. The table also indicates that the estimated average cost per contract will decrease from $6,372 under the currently approved collection to $5,045 under the proposed collection (-$1,542 per contract).

	(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	Estimated Average Cost ($/hr)	Estimated Total Cost ($)	Estimated Average Cost per Contract ($)
Ongoing annual costs (currently approved)	616	47	28,952	135.58	3,925,312	6,372
Ongoing annual costs (proposed)	587	36	21,132	140.14	2,961,438	5,045

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

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. CMS has proposed to revise the provisions that provide for the release of Part C and Part D MLR data, to correspond to changes in the type of data that will be collected.

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.