Supporting Statement
Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements
(CMS-104245; OCN:0938-New)

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 2718 of the Public Health Services Act (PHS Act) requires a health insurance issuer (issuer) offering group or individual health insurance coverage to submit a report to the Secretary of HHS concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes, licensing and regulatory fees, and earned premium. An issuer must provide a rebate to enrollees if the amount it spends in a reporting year on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing and regulatory fees) is below a certain ratio, referred to as the medical loss ratio (MLR). Specifically, section 2718(b) requires an issuer to provide a rebate to each of its enrollees if the MLR for the respective reporting year is less than 85 percent in the large group market or less than 80 percent in the small group or individual market. The implementing regulations for this provision are located in Part 158 to Title 45 of the Code of Federal Regulations.
The following information collections are included in this request:

Annual Report. Under §158.110, issuers are required to submit an annual report to the Secretary by June 1 of the year following the end of an MLR reporting year. The first annual report must be submitted to the Secretary by June 1, 2012. Section 158.120 sets out the data requirements for this report. In addition, under §158.260, each issuer must also submit a report to the Secretary concerning the rebates provided to and on behalf of enrollees. Section 158.260(d) requires that this report be submitted with the annual report under §158.110 for the subsequent reporting year.

Notices (Third-Party Disclosures). As specified in §158.240(a), an issuer must provide rebates to its enrollees when the issuer's MLR does not meet the applicable minimum MLR standard. Section 158.250 requires an issuer to provide information in the form of a rebate notice to enrollees who are owed rebates, regardless of the form in which the rebate payment is made (e.g., check or future premium credit). As also provided in §158.250, CMS has developed a form for the rebate notice that each issuer must send by August 1 of the following year to enrollees entitled to a rebate based upon the prior MLR reporting year. The first rebate notice must be sent by August 1, 2012.
In addition, CMS previously solicited comments in the Final Rule published on December 7, 2011 (76 FR 76574, CMS-9998-FC) on whether to require the provision of notices with MLR information to subscribers and policyholders not receiving rebates at the same time that subscribers and policyholders receiving notices of rebates get theirs in 2012 and beyond. CMS recently finalized a one-year notice requirement for the 2011 MLR reporting year at §158.251. Although third-party disclosures (for example, notice requirements) are generally subject to the Paperwork Reduction Act, the implementing regulations at 5 CFR 1320.3(c)(2) include an exclusion for "information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public." Because the notification required by §158.251 will be provided by the Federal government, and does not contain text that must be

customized, this exclusion applies and therefore CMS does not seek PRA approval for that notice in this request.

Recordkeeping. The MLR regulations contain two recordkeeping requirements. Section 158.502 requires an issuer to maintain all documents and other evidence necessary to enable CMS to verify that the data submitted by the issuer is in compliance with 45 CFR Part 158, including all documents, records, and other evidence used to calculate the MLR and any rebates, and to provide any rebates owing in accordance with Part 158. Section 158.501 requires an issuer to preserve and maintain all such documents, records, and other evidence for the MLR reporting year as well as six prior years unless a longer period is required under §158.501.

2. Purpose and Use of Information Collection

The data collection of annual reports provided by an issuer for each State's individual, small group, and large group markets will be used by CMS to ensure that consumers are receiving value for their premium dollar by calculating each issuer's MLR and any rebate payments due for the respective MLR reporting year, as well as verifying the provision of any rebates owed to and on behalf of enrollees.

The notices will be used to ensure that consumers are receiving information about how their issuer is using health care premium dollars and about the value they are receiving for their premium dollar. The notices will help provide greater transparency to consumers. The recordkeeping requirements will be used by CMS to determine issuers' compliance with the MLR requirements, including compliance with how issuers' experience is to be reported, their MLR and any rebates owing are to be calculated, and distribution of rebates to enrollees

3. Use of Improved Information Technology and Burden Reduction

Each issuer will submit its annual report electronically to the Secretary for each respective State and market in which it conducts business. Information will be collected electronically through our HIOS system (OMB Control Number **0938-1086**). This will require registration of the issuer, providing issuer information for the purpose of the collection.

4. Efforts to Identify Duplication and Use of Similar Information

There are no similar information collections related to MLR.

5. Impact on Small Businesses or Other Small Entities

As stated in the Regulatory Impact Analysis of OCIIO-9998-IFC (75 FR 74864 (December 1, 2010)), 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. CMS estimates that of the 527 issuers who must report annually to the Secretary in compliance with OCIIO-9998-IFC, there are only approximately 28 small entities, or roughly six percent, who must comply with the reporting mandate.

6. Consequences of Collecting the Information Less Frequently

Section 2718 of the PHS Act requires reports to be submitted annually. CMS will use the information reported to assess whether each issuer is in fact providing enrollees with health care value in return for their premium dollars.

Regarding notices, section 2718 of the PHS Act requires issuers to provide rebates annually if they do not meet the applicable MLR standard. Since rebates are provided annually, notices of rebates are required to be provided to enrollees annually in order to inform enrollees about any rebates owing.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

No special circumstances apply to these collections.

8. Comments in Response to the Federal Register Notice/Outside Consultation

60-day Comment Period plus 15-day Extension Period

The 60-day Federal Register notice published on 12/16/2011. The original comment period closed on February 14, 2012, but on February 16, was reopened until March 2, 2012 to accommodate comments on the amendments to the PRA package - Notices to consumers and instructions for such notices - that were published on February 16. We received 15 comment letters in response to the Annual Reporting Form and 11 comment letters in response to the notices to consumers and instructions for the notices. Due to the large number of comments, we will not be referencing each comment individually in this section.

Comments regarding Annual Reporting Form

CMS received numerous comments pertaining to technical formula errors, typographical errors, minor inconsistencies, and improper cell references in the MLR Form (an Excel spreadsheet) and in the accompanying Instructions. Corrections related to such comments do not change the data nor the substance of what is being reported, but will make it easier for health insurance issuers to complete the MLR Form.

Several issuers suggest clarification regarding the years for which the Instructions are applicable. Based on these comments the Instructions are being revised to indicate that they are applicable to an issuer's 2011 MLR experience. Guidance for 2012 and beyond will be issued at a later date.

Regarding page 4 of the Instructions (Business as of 12/31 of Current MLR Reporting Year), a commenter suggests that CMS clarify the business that is to be included in the 12/31 column of data. As an example, the commenter asked whether premiums should include earned premiums only for the current MLR reporting year regardless of the incurred date or whether this column should include only incurred dates within the MLR reporting year. The Instructions are being revised to indicate that the information to be reported in the 12/31 columns should represent issuer experience for each of the relevant markets for the MLR reporting year regardless of incurred date as reported to the department of insurance in the issuer's State of domicile or as filed on the NAIC Supplemental Health Care Exhibit (SHCE).

Regarding page 18 of the Instructions (Claims Paid Line 2.1), two commenters suggest that CMS indicate which expenses should be added or subtracted from claims paid. Based on this comment, the instruction for this item is being clarified to indicate the items that should be included, excluded, and/or deducted from the "claims paid" total.

Regarding page 18 of the Instructions, a commenter suggests that CMS revise the instruction for "Claims Paid Line 2.1" to indicate that incentive and bonus payments to providers should only be included in Line 2.11. As published, the instruction for lines 2.1 and 2.11 both allow that incentives and bonuses payments should be included. The instruction for this item is being revised to reflect that incentive and bonus payments to providers should only be included in Line 2.11.

Comments Regarding Notices to Consumers and Instructions

We received several comments supporting as well as several comments opposing the requirement that every subscriber receive a notice when the issuer meets or exceeds the MLR standard. In the alternative, issuers urged CMS to allow issuers to post notices on the issuer's website or on CCIIO website when issuers meet or exceed the MLR standard. Issuers also assert that the information would be duplicative of the MLR information already required to be posted pursuant to PHSA § 2718(a)(3). As noted above, CMS recently finalized the notice requirements for issuers that meet or exceed the MLR standard in the first year, and is no longer seeking PRA approval for that notice.

Two commenters suggest that the notices should be required in different languages. CMS appreciates the concern of commenters, but it is not practical to require it in different language for the notices due August 1, 2012. CMS will consider this suggestion for future years' notices.

Several commenters suggest we require issuers to state the refund amount to each subscriber or policyholder. This is not required by 45 CFR §158.250, and therefore this information will remain optional for the issuer.

Several commenters request that more flexibility be allowed regarding who signs the notices. They state that officers of the issuers, and not just the president of an issuer, typically sign informational notices to subscribers and group policyholders. CMS has revised the notices and instructions in response to these comments.

One commenter suggests we add a website and/or email address in addition to the phone number for consumers to contact with questions. Based on the comment, CMS is adding this information to the notices.

We received several comments suggesting various tweaks to the language in the notices. We have revised the notices to incorporate many of the suggestions, including using the term "rebate" instead of "refund", and using "efforts to improve patient safety" as an example of a quality improving activity rather than "wellness programs".

We received several comments stating that the notices do not address non-credible plans and mini-med plans. CMS has clarified the instructions to note that non-credible issuers are

presumed to meet or exceed the applicable MLR standard and do not pay rebates; thus they are not required to send notice of rebate (notices 1-3). However, issuers of mini-med plans and expatriate plans that owe a rebate are required to provide notice to consumers, as are other issuers who owe rebates.

One health plan requests clarification that Notices may be sent prior to or after payment of rebates so long as notice is provided by Aug 1. CMS is clarifying the Instructions to note this.

Two commenters note that Notice 2 is applicable to both group policyholders and subscribers in group plans that will receive a rebate, and that it should be made clear that the rebate is being paid only to the group policyholder. These commenters note that otherwise subscribers receiving the notice would be looking for a rebate from health plans. CMS has revised Notice 2 to clarify that the rebate is being sent to the employer or group policyholder.

One health plan requests that CMS allow plans to specify the name of the State for which the notice pertains, suggesting that it would reduce the potential for confusion among subscribers. CMS is clarifying the instructions to allow issuers the option to do this.

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. Assurance of Confidentiality Provided to Respondents

As required by section 2718(a) of the PHS Act, CMS does intend to publish issuers' annual reports on its internet website. However, no individually identifiable personal health information will be collected and cannot, consequently, be disclosed.

11. Justification for Sensitive Questions

These collections do not contain sensitive questions.

12. Estimates of Annualized Burden Hours (Total Hours and Wages)

The burden estimates associated with the annual report, the notices, and the recordkeeping requirements are discussed below.

Annual MLR Report, Including MLR and Rebate Calculations and Information Regarding Prior Year Rebates

An issuer is required to submit an annual report to the Secretary for each market segment and State in which it issues health insurance coverage. As described in the regulatory impact analysis (RIA) of OCIIO-9998-IFC, the preparation and submission of reports is expected to require a mix of skills. We also estimate that issuers will use a mixture of professional staff, accounting staff, and clerical staff to prepare, review, and issue rebate checks or premium credits, and to perform recordkeeping activities and to upload the report to the HIOS system.

The average hourly compensation, including fringe benefits and overhead expenses is $51.89 for ongoing annual reporting.

Beginning June 1, 2012, 527 issuers are expected to file a total of 5,530 annual reports with the Secretary[1]. The RIA of the MLR IFR discusses both one-time and ongoing compliance costs that are associated with the reporting requirements of 45 CFR Part 158. The estimates from the RIA of the MLR IFR have been updated using 2010 Supplemental HealthCare Exhibit (SHCE)[2] data, and costs have been updated using 2010 mean hourly wage estimates and are stated in 2011 dollars. It is estimated that each issuer will incur a one-time cost of approximately $174,759 ($76.05 x 2,297.95 burden hours). The one-time costs incurred by an issuer will be associated with the development of policy, procedures, and systems required to prepare the annual report for the Secretary.

Burden Hours and Costs per Respondent

Type of Respondent	**Number of Respondents**	**Average Number of Reports per Respondent**	**Frequency**	**Estimated Burden Hours per Respondent**	**Wage per Hour (incl. fringe)**	**Burden Cost Per Respondent**
Private Company (One time-IT development)	527	10.5	1	2,298	$76.05	$174,759.10
Private Company (Ongoing/ Annual)	527	10.5	1	669	$51.89	$34,714.41
Total	**527**	**10.5**	**1**	**2,967**		**$209,473.51**

It is estimated that, each issuer will on average spend approximately $34,714 ($51.89 x 669 burden hours) annually and, because of operating in several States and markets, will submit on average between 10 and 11 (10.5) reports a year. Each issuer will spend approximately $209,474 in one-time costs for MLR reporting year 2011. The total first-year estimated burden for the average issuer in compiling annual reports (including one-time start up and ongoing reporting) for the Secretary is expected to be approximately 2,967 hours.

Total Estimated Burden Hours

Forms (if necessary)	**Type of Respondent**	**Number of Respondents**	**Average Number**	**Frequency**	**Estimated Burden**	**Total Estimated**

[1] A report includes data for multiple markets (individual, small group, large group) for an issuer in a State. An issuer may combine multiple reports in one filing.

[2] The SHCE is a report of data that States require issuers to submit to the National Association of Insurance Commissioners (NAIC).

			per Respondent		Hours per Respondent (Ongoing)	Burden Hours (Ongoing)
Annual Report, Rebate Calculation, and Rebate Disbursement Report	Private Company	527	10.5	1	669	352,563

Notice of Rebate and disbursement of rebate checks

The regulation also requires each issuer that does not meet or exceed the minimum MLR standard to provide rebates to its enrollees as well as notice of such rebates.

It is estimated that approximately 84 issuers in the individual market will disburse some form of rebate to or on behalf of enrollees by August 1 of the year following the end of the MLR reporting year, whether by premium credit, check, or refund via credit or debit card. Assuming that the issuers will disburse 50% of the rebates in the form of an actual check, we project that each of these 84 issuers will issue approximately 32,446 checks. Each issuer is estimated to expend approximately $33,119 ($40.83 x 811.15 burden hours) in labor costs and an additional $1,622 (32,445.66 checks x $0.05 processing cost per check) in processing costs, for a total ongoing cost of approximately $34,741 a year. The remaining rebates will be issued through premium credit or refunds via credit or debit card. Costs of paying rebates through one-time electronic reimbursement are expected to be negligible. It is estimated that 132 issuers in the group market will provide rebates to policyholders for disbursement to enrollees. Costs of issuing rebates to policyholders are expected to be negligible.

Total Estimated Burden Hours – Disbursement of Rebate Checks

Forms (if necessary)	Type of Respondent	Number of Respondents	Average Number per Respondent	Frequency	Estimated Burden Hours per Respondent (Ongoing)	Total Estimated Burden Hours (Ongoing)
Disbursement of Rebate Checks	Private Company	84	32,446	1	811	68,136

It is estimated that each of the 177 issuers will provide rebate notices to approximately 40,707 policyholders and subscribers. We estimate that approximately 20,781 notices will be sent per issuer electronically and approximately 19,925 notices will be sent per issuer by first class U.S. mail. If such notices are sent by first class U.S. mail rather than being sent electronically, each issuer will expend roughly $10,213.11($30.67 per hour x 333 burden hours) in labor costs and will spend approximately $9,962 (19,925 notices x $0.50 mailing and supply costs per notice) in mailing costs, for a total ongoing cost of approximately $20,168 a year.

Total Estimated Burden Hours – Rebate Notices

Forms (if necessary)	Type of Respondent	Number of Respondents	Average Number per Respondent	Frequency	Estimated Burden Hours per Respondent (Ongoing)	Total Estimated Burden Hours (Ongoing)
Notice of Rebate to Enrollees	Private Company	177	40,707	1	333	58,897

Recordkeeping Requirements

Each issuer is also 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. We estimate that each annual filing and rebate disbursement cycle will require on average slightly more than 401 person-days of effort per issuer (3,210 burden hours divided by 8-hour work days).

Each of the 527 issuers that are expected to submit annual reports to the Secretary must maintain the supporting documentation for seven years. We estimate that each issuer will spend approximately $30 ($47.69 x 0.63 burden hours) a year in maintaining the supporting documents for the respective MLR reporting year.

Total Estimated Burden Hours - Recordkeeping

Forms (if necessary)	Type of Respondent	Number of Respondents	Average Number per Respondent	Frequency	Estimated Burden Hours per Respondent (Ongoing)	Total Estimated Burden Hours (Ongoing)
Retention of Records	Private Company	527	10.5	1	0.63	332

<u>Cost Estimate for All Respondents Providing Notice of Rebates and Rebate Payments to Enrollees</u> (Annualized)

Burden Costs per Issuer – Rebate Notices

Type of Respondent	Number of Respondents	Average Number of Notices or	Average Mailing and	Estimated Burden Hours per	Wage per Hour	Burden Cost for Annual

		Checks per Respondent	Supplies Cost Per Notice or Check	Rebate Cycle	(incl. fringe)	Notice of Rebates Per Issuer
Private Company (notice of rebates)	177	40,707	$0.50	333	$30.67	$20,168.12
Private Company (Disburse-ment of checks)	84	32,445.66	$0.05	811.15	$40.83	$34,741
Private Company (ongoing)	350	200,571	1	3,350	$30.67	$203,016
Total						**$257,925.12**

13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs

Per § 158.501, CMS, or their designees may inspect, evaluate, and audit through 6 years from the date of the filing of a report. As such, the burden estimates per year for the retention of reports for auditing purposes is approximately $30 per respondent.

Burden Cost per Respondent – Recordkeeping

Type of Respondent	Number of Respondents	Average Number of Reports per Respondent	Frequency	Estimated Burden Hours per Respondent	Wage per Hour (including fringe)	Burden Cost for Annual Retention of Records Per Respondent
Private Company	527	10.5	1	0.63	$47.69	$30.04

14. Annualized Cost to Federal Government

Total Federal Government Costs

Type Federal Employee Support	Total Burden Hours per Reviewer	Total Reviewers	Hourly Wage Rate (GS 14 equivalent) – (includes fringe)	Total Federal Government Costs

Data Analysis	2 hr per data submission for each Annual filing (527filers once per year – 1054 hrs)[3]	1	$72	$75,888
Total				**$75,888**

Salaries are based on a 14 Grade/Step 1 in the Washington DC area with a benefit allowance for a total annual salary of $150,000.

15. Explanation for Program Changes or Adjustments

This is a revision to a previously approved information collection. We received comments from issuers, consumer groups, associations and many others suggesting that we modify the proposed annual reporting form and instructions, as well as the notices to consumers and instructions. The revisions to the annual reporting form were mostly technical changes. The annual reporting form instructions were clarified in response to most of the commenters' requests. The adjustments we made to the notices to consumers and instructions were primarily clarifications requested by commenters. Additionally, CMS has decreased the burden costs for MLR rebate notices and MLR information notices as we estimate almost half will be sent out electronically.

16. Plans for Tabulation and Publication and Project Time Schedule

The first annual report of MLR data is due by June 1, 2012 based upon the previous MLR reporting year.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Collection of Information Employing Statistical Methods

Not applicable. The information collection is transactional in nature and does not employ statistical methods or model development utilized by States.

[3] A data submission includes filings for all States by a single issuer.