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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 158

[CMS-9998-F]

RIN 0938-AR41

Medical Loss Ratio Requirements under the Patient Protection and Affordable Care Act

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations implementing medical loss ratio (MLR) standards for health insurance issuers under the Public Health Service Act in order to establish notice requirements for issuers in the group and individual markets that meet or exceed the applicable MLR standard in the 2011 MLR reporting year.

DATES: Effective date. This rule is effective on **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

Applicability date. The amendments to part 158 generally apply beginning July 1, 2012, to health insurance issuers offering group or individual health insurance coverage.

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SUPPLEMENTARY INFORMATION:

I. Background

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) was enacted on March 30, 2010. In this preamble, we refer to the two statutes collectively as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of Part A of

title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

A request for information relating to the medical loss ratio (MLR) provisions of section 2718 of the PHS Act was published in the **Federal Register** on April 14, 2010 (75 FR 19297). On December 1, 2010, the Department of Health and Human Services (HHS) published an interim final rule (75 FR 74864) with a 60-day public comment period, entitled “Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act,” that added a new 45 CFR part 158. A technical correction to the interim final rule was issued on December 30, 2010 (75 FR 82277).

On December 7, 2011, the Centers for Medicare & Medicaid Services (CMS) published an interim final rule (76 FR 76596) with a 60-day public comment period entitled, “Medical Loss Ratio Rebate Requirements for Non-Federal Governmental Plans,” establishing rules governing the distribution of rebates by health insurance issuers in group markets for non-Federal governmental plans. Also on December 7, 2011, CMS published a final rule (76 FR 76574) with a 30-day public comment period, entitled “Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act,” that addressed the treatment of “mini-med” and expatriate policies under the MLR regulations for years after 2011; modified the way the regulations treat International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) conversion costs; changed the rules on deducting community benefit expenditures; and revised the rules governing the distribution of rebates by issuers in group markets.

In the December 7, 2011 final rule with comment period, we noted that the notice requirements finalized in the rule only applied to issuers that owed rebates as a result of not meeting the applicable MLR standard. Consequently, policyholders and subscribers of issuers

meeting or exceeding the MLR standard would not receive MLR information, an important tool to increase transparency to consumers. In the rule, we noted that extending a notice requirement to such cases would serve the policy goal of greater transparency in how premium dollars are used, and provide an additional incentive for issuers that already met the minimum standard to achieve the highest MLR possible. We therefore solicited comments on whether an issuer that meets or exceeds the MLR standard for the applicable MLR reporting year should send a notice to policyholders and subscribers with information about the MLR standard and its own MLR, as a measurement of issuer performance. We also solicited comments on whether it would be useful to include information in the notices about the issuer's prior year MLR in addition to the current year MLR. We noted that this approach would allow enrollees to determine if the issuer was doing a better or worse job of efficiently using premium revenue than in the prior year.

Based on the comments received and weighing consumer transparency and competition gains with burden on issuers, this final rule establishes a simple, straightforward notice requirement for health insurance issuers that meet or exceed the MLR standards established by the Affordable Care Act, but only requires the notice for the 2011 MLR reporting year, the first year that the MLR rules are in effect, and does not require issuers to include information about the current or prior year MLR. The notice will direct enrollees to the HHS Web site for specific information about issuers' MLRs.

II. Analysis of and Responses to Public Comments

We received 56 public comments on the December 7, 2011 final rule with comment period. Commenters included consumer and patient advocacy organizations, insurance regulators, health insurance issuers, business advocacy organizations, provider groups, an actuarial professional group, and others. In addition, we received 11 public comments in

response to the draft MLR Notices and Instructions contained in the MLR Paperwork Reduction Act (PRA) package (CMS-10418) posted on February 16, 2012. Commenters consisted of consumer groups, health insurance issuers, an issuer trade association, and a business trade association. Several of these commenters recommended technical corrections to the draft notices and instructions. We note that their comments will be addressed through the PRA process. In addition, commenters recommended several amendments to the December 1, 2010 interim final rule that were beyond the scope of this final rulemaking; therefore, we are not making changes in this final rule based on these comments. In this final rule, we only address the public comments received on the following issues: (1) whether a notice requirement should apply to issuers that meet or exceed the applicable MLR standards in a particular MLR reporting year; and (2) whether MLR notices should include information on an issuer's prior year MLR. The comments received are summarized below with our responses.

Comments: We received comments that both support and oppose expanding the notice to issuers that do not owe rebates because they meet or exceed the MLR standards. Commenters who opposed expanding the notice rules generally claimed that requiring issuers that do not owe rebates to provide an MLR notice would impose a burden on issuers that meet the MLR requirement and provide little value to consumers. Specifically, issuers, an issuer trade association, and a business advocacy organization stated that MLR data would confuse or mislead consumers who may misinterpret the information or who may mistakenly believe they are owed a rebate. Commenters in support of expanding the notice rules, such as consumer and patient advocacy organizations, stated that expanding the notice rules would increase health plan transparency and ensure that every enrollee receives information about the meaning of the MLR, rather than only those owed a rebate.

We also received several comments on the question of whether all MLR notices should include the issuer's MLR from the prior MLR reporting year. Issuers and trade associations opposed this requirement, noting that an issuer's MLR from the prior MLR reporting year is not necessarily a reliable indicator of health plan performance. These commenters stated that numerous factors other than health plan efficiency, such as variation in incurred claims, premium revenue, and adjustments, affect issuers' year-to-year MLRs and that consumers may be misled when comparing MLRs for multiple years. Several commenters noted that MLR information will be publicly available on the HHS Web site and suggested that CMS maintain historical data so that consumers may monitor changes in issuers' MLR over time. In contrast, consumer and patient advocacy organizations expressed support for including an issuer's prior year MLR, noting that it would help consumers to better use the MLR information when making plan selections and better understand how premium dollars are spent by health insurers. They indicated that consumers could benefit from more detailed information and that the notice should include specific information that explains how premium dollars are being spent, not just whether the MLR was being met.

Response: Expanding the notice of MLR information to all issuers would further the goals of improving transparency of health insurance markets, supporting more informed purchase decisions, and promoting competition and efficiency. At the same time, we appreciate the concerns about administrative costs. Further, we recognize that under the Affordable Care Act, issuers' MLR information will be available on the HHS Web site, HealthCare.gov, providing an efficient method of public disclosure.¹

¹ Section 2718(a) of the PHS Act provides that "The Secretary shall make reports [concerning an issuer's MLR and its components] received under this section available to the public on the Internet website of the Department of Health and Human Services." In addition, section 1103(b) of the Affordable Care Act provides that the Federal health care reform insurance Web portal created by the Secretary under section 1103 to present information relating

In light of these considerations and after further review and consideration of the costs and benefits of different notice alternatives, we are adding a new 45 CFR 158.251 that establishes a basic notice requirement for issuers in the group and individual markets that meet or exceed the applicable MLR standard. This new notice will use standard language to inform policyholders and subscribers of group health plans, and subscribers in the individual market, that the issuer has met the minimum MLR standards established by the Affordable Care Act, but it will not include the issuer's MLR for the current or prior reporting year or other specific measures of issuer performance. Instead, the notice will help educate consumers about the MLR measures and direct them to the HHS Web site, HealthCare.gov, for information about issuers' actual MLRs. Additionally, under this final rule, issuers will only need to produce this notice for the 2011 MLR reporting year, when consumer knowledge of the MLR is low and the greatest benefit can be achieved by providing enrollees with educational information. By leveraging existing Federal information resources while ensuring adequate notice to enrollees in the first year of applicability, we believe this new notice requirement balances issuers' interest in administrative efficiency and consumers' interest in health plan transparency.

This notice rule will ensure that all consumers, not just those owed a rebate, are informed whether their issuer meets the minimum MLR standards established by the Affordable Care Act. It will provide greater transparency to consumers regarding how their premium dollars are used, promote informed decision-making in the purchase of health insurance, and ensure that efficiency in the use of premium dollars is properly valued by consumers. Notifying consumers of the MLR standards will also reduce confusion as to why certain individuals receive rebates, while others, such as coworkers or family members with different insurance plans, do not.

to affordable coverage options shall, among other things, "require the inclusion of information on the percentage of total premium revenue expended on nonclinical costs (as reported under section 2718(a) of the Public Health Service Act)."

Finally, the distribution of MLR notices to consumers with the HHS Web site, HealthCare.gov, will promote a more competitive market by creating an incentive for issuers to spend as high a percentage of premium dollars on health care and quality improvement as possible, rather than spending just enough to avoid paying rebates.

III. Provisions of the Final Rule

In paragraph (a)(1) of new §158.251 of this final rule, we set forth the general requirement that an issuer whose MLR meets or exceeds the applicable MLR standard required by §158.210 or §158.211 must provide each policyholder and subscriber of a group health plan, and each subscriber in the individual market, a notice of MLR information. The required language for the notice is specified in paragraph (a)(4). This notice requirement applies only for the 2011 MLR reporting year.

In paragraph (a)(2), we generally align the timing of this new notice with the timing specified in §158.240(d) for providing any rebates that are due and the accompanying notice of rebates. We specify that the MLR notice must be provided with the first plan document (for example, open enrollment materials) that is provided to enrollees on or after July 1, 2012.

In paragraph (a)(3), we direct that the notice be prominently displayed in clear, conspicuous 14-point bold type on the front of the plan document, insurance policy or certificate, or as a separate notice. The MLR notice may be included in the same mailing as other mailed notices. Further, we specify that the notice may be provided electronically, consistent with the policy for providing the summary of benefits and coverage under section 2715 of the PHS Act.

In paragraph (b), we specify certain exceptions to the MLR notice requirement. We are not requiring health insurance issuers that sell plans with total annual benefit limits of \$250,000 or less (“mini-med” plans) or expatriate policies, as described in §158.120(d)(3) and (d)(4),

respectively, to provide MLR notices to policyholders and subscribers if they meet or exceed the applicable MLR standard. As discussed in the preamble to the December 7, 2011 final rule with comment period, issuers of mini-med and expatriate policies will use a separate methodology for calculating the MLR numerator for reporting and rebate purposes and are subject to separate notice rules. We note that issuers of mini-med and expatriate plans must continue to provide notice of rebates, if any, to current group health plan policyholders and subscribers, and to subscribers in the individual market, as provided under §158.250.

In addition, we are not requiring issuers whose experience is non-credible, as defined in §158.230(c)(3) and determined in accordance with §158.231, to provide MLR notices to policyholders and subscribers. An issuer that has fewer than 1,000 covered life-years does not have sufficiently credible data to determine whether the MLR standard has been met and thus, under §158.230(d), is presumed to meet or exceed the applicable minimum MLR standard. Because non-credible issuers do not have an MLR to report, the MLR notice requirement in this final rule does not apply.

Finally, we note that issuers of student health insurance coverage are not required to provide the MLR notices under this final rule, because the MLR reporting and rebate requirements of 45 CFR part 158 generally apply for such experience beginning January 1, 2013.

IV. Collection of Information Requirements

This final rule establishes a notification requirement. Although third-party disclosures (for example, notification requirements) are generally subject to the Paperwork Reduction Act of 1995 (PRA), 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 will be provided by the Federal government, and does not contain text that must be customized, this exclusion applies.

V. Regulatory Impact Analysis

A. Summary

This final rule amends the regulations implementing MLR standards for health insurance issuers under section 2718 of the Public Health Service Act in order to establish notice requirements for issuers in the group and individual markets that meet or exceed the applicable MLR standard in the 2011 MLR reporting year.

CMS developed this rule to accomplish its intended benefits in the most economically efficient manner possible. We have examined the effects of this rule as required by Executive Order 13563 (76 FR 3821, January 21, 2011), Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)). In accordance with the Office of Management and Budget (OMB) Circular A-4, CMS has quantified the benefits, costs, and transfers where possible and provided a qualitative discussion of some of the benefits, costs, and transfers that may stem from this final rule.

B. Executive Orders 13563 and 12866

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 (76 FR 3821, January

21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a final rule--(1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by OMB. As discussed below, CMS has concluded that this rule is not likely to have an economic impact of \$100 million or more in any 1 year, and therefore does not meet the definition of a “significant rule” under Executive Order 12866. Nevertheless, CMS has provided an assessment of the potential costs, benefits, and transfers associated with this final rule. Accordingly, OMB has reviewed this final rule pursuant to the Executive Order.

1. Need for Regulatory Action

On December 7, 2011, CMS published a final rule (76 FR 76574) that invited comment on whether the MLR notice requirement finalized in that rule should apply not only to issuers that owe rebates but also to issuers that meet or exceed the applicable MLR standard and therefore do not owe rebates. For the reasons discussed above and in section V.B.3.a. below, and

based on public comments we received, this final rule establishes a basic, one-time notice requirement for issuers in the group and individual markets that meet or exceed the applicable MLR standard in the 2011 MLR reporting year. This approach is consistent with Executive Order 13563, which directs agencies to “identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include . . . disclosure requirements as well as provision of information to the public in a form that is clear and intelligible.”

2. Summary of Impacts

In accordance with OMB Circular A-4, Table 1 below depicts an accounting statement summarizing CMS’s assessment of the benefits, costs, and transfers associated with this regulatory action. The RIA is limited to 2012 when the notice for the 2011 MLR reporting year will be provided.

CMS anticipates that the provisions of this final rule will help ensure greater transparency for consumers regarding how their premium dollars are used, educate consumers about the MLR standards established by the Affordable Care Act, and provide an incentive for issuers to maximize the percentage of premium dollars they spend on health care and activities that improve health care quality, promoting greater efficiency in health insurance markets. Issuers that meet or exceed the applicable MLR standards will incur administrative costs related to providing the notices to policyholders and subscribers. In accordance with Executive Order 12866, CMS believes that the benefits of this regulatory action justify the costs.

Table 1--Accounting Table

<p>Benefits:</p> <p>Qualitative:</p> <ul style="list-style-type: none"> * Greater transparency regarding how premium dollars are used by issuers * Incentive for issuers to maximize the percentage of premium dollars they spend on health care and activities that improve health care quality

* Improved information to assist consumers in making plan choices					
Costs and Transfers:	Low Estimate	Medium Estimate	High Estimate	Year dollar	Period covered
Annualized Monetized (\$millions/year)	\$2.8	\$2.9	\$3.0	2012	2012

3. Anticipated Benefits, Costs, and Transfers

This final rule extends a notice requirement to issuers in the group and individual markets that meet or exceed the applicable MLR standard in the 2011 MLR reporting year. The notice must use standard language specified in this final rule. Issuers may provide the notice with other plan documents or through electronic transmittal, as permitted for the summary of benefits and coverage under section 2715 of the PHS Act.

a. Benefits

The MLR notices will ensure that consumers are informed whether their issuer's coverage meets or exceeds the applicable minimum MLR thresholds established by the Affordable Care Act. Accordingly, the notices will provide greater transparency to consumers and may help to reduce consumers' confusion regarding why they did not receive a rebate. The MLR notices will also provide consumers with educational information in the first year of applicability when consumer knowledge of the MLR is low. Additionally, the notices will inform enrollees of the HHS Web site where they can find issuers' actual MLRs and compare MLR information across issuers and over years. This will provide an incentive to issuers to spend as high a percentage of premium dollars on health care and quality improvement as possible, rather than just enough to avoid paying rebates. Finally, notice of MLR information will assist individuals in comparing plans and making plan choices. We believe that such information disclosure will result in a more efficient, competitive market.

b. Costs and Transfers

Issuers that meet or exceed the applicable MLR standard will incur the administrative cost of preparing and mailing the notices. It is estimated that these costs will total approximately \$3 million in 2012.

4. Overview of Data Sources, Methods, and Limitations

On December 1, 2010, we published an interim final rule (75 FR 74864) with a 60-day public comment period. In that rule, we indicated that the most complete source of data on the number of licensed entities offering fully insured, private comprehensive major medical coverage in the individual and group markets is the National Association of Insurance Commissioners' (NAIC) Annual Financial Statements and Policy Experience Exhibits database. These data contain multiple years of information on issuers' revenues, expenses, and enrollment, collected on various NAIC financial exhibits (commonly referred to as "Blanks") including Supplemental Health Care Exhibits (SHCEs) that issuers submit to State insurance regulators through the NAIC. The NAIC has four different Blanks for different types of issuers: Health; Life; Property & Casualty; and Fraternal issuers.²

In the December 1, 2010 interim final rule, our analysis relied on 2009 data from the NAIC database. A total of 618 issuers offering comprehensive major medical coverage filed annual financial statements in 2009, with the Health and Life Blank filers accounting for approximately 99 percent of all comprehensive major medical premiums earned. For this reason, we restricted our analysis to Health and Life Blank companies. Comprehensive major medical

² If a company's premiums and reserve ratios for its health insurance products equals 95 percent or more of their total business for both the current and prior reporting years, a company files its annual statement using the Health Blank. Otherwise, a company files the annual statement associated with the type of license held in its domiciliary State, for example, the Life, Property & Casualty, or Fraternal Blank.

coverage³ – including coverage offered in the individual and group markets subject to this final rule – accounted for approximately 47.8 percent of all Accident and Health (A&H) premiums in 2009. Although the NAIC data represent the best available data source with which to estimate impacts of the MLR rule, the data contain certain limitations; we developed imputation methods to account for these limitations, and we made several additional data edits that led us to exclude 176 companies from the analysis. We used the remaining 442 companies to estimate the regulatory impacts that were discussed in the December 1, 2010 interim final rule, as well as the regulatory impacts that are discussed below. We refer readers to the regulatory impact analysis of the December 1, 2010 interim final rule (75 FR 74892) for additional methodological information.

5. Estimated Number of Affected Entities

Given the combination of data limitations and behavioral uncertainties, the December 1, 2010 interim final rule provided a range of estimates, based on a various assumptions. For the analysis in this final rule, the high range estimates correspond to the low rebate estimates in the December 1, 2010 interim final rule, while the medium range estimates correspond to the medium rebate estimates, and the low range estimates correspond to the high rebate estimates.

As discussed above in the preamble, health insurance issuers that sell plans with total annual benefit limits of \$250,000 or less (“mini-med” plans) or expatriate policies, as described in §158.120(d)(3) and (d)(4), respectively, are not required to provide notice of MLR information to policyholders and subscribers. The 2009 NAIC data does not allow us to identify these types of policies separately. Under the December 1, 2010 interim final rule, for the 2011

³ Comprehensive major medical coverage sold to associations and trusts has been included in individual comprehensive major medical coverage for purposes of the RIA. CMS’s estimates exclude Medigap coverage, which in the NAIC data is reported separately from comprehensive major medical coverage offered in the individual and group markets, and which is not subject to the MLR requirements under 45 CFR Part 158.

MLR reporting year, issuers of mini-med and expatriate policies were required to report MLR data on a quarterly schedule under §158.110(b). Based on the quarterly reports, it was estimated that, in 2011, there were 25 issuers of mini-med policies with approximately 1 million enrollees and 8 issuers of expatriate policies with approximately 300,000 enrollees⁴. To the extent that enrollees in mini-med and expatriate plans were included in the 2009 NAIC data, this analysis overestimates the number of entities affected by these requirements, the number of notices to be sent by issuers of such policies, and the administrative costs of providing notices.

In addition, issuers whose experience is non-credible, as defined in §158.230(c)(3) and determined in accordance with §158.231, are not required to provide notice of MLR information to policyholders and subscribers. As discussed in the December 1, 2010 interim final rule, based on 2009 NAIC data, it was estimated that approximately 68 percent of licensed entities (State/company combinations) had less than 1,000 enrollees in at least one State in 2011 and accounted for approximately 1 percent of enrollees. The number of issuers with less than 1,000 enrollees in all market/State combinations is estimated to be 45 in 2011.

Further, issuers of student health insurance coverage are not required to provide the MLR notice since the MLR requirements apply beginning January 1, 2013 for such experience. In the Student Health Insurance Coverage Final Rule (77 FR 16453) published on March 21, 2012, we estimated that there are 75 issuers of student health insurance plans with approximately 1.1 million to 1.5 million enrollees. To the extent that enrollees in student health insurance plans were included in the 2009 NAIC data, this analysis overestimates the number of entities affected by these requirements, the number of notices to be provided by issuers of such policies, and the administrative costs of providing notices.

⁴For details, see final rule with comment period, entitled “Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act, published on December 7, 2011 (76 FR 76574).

Table 2 includes estimates of the number of issuers that will need to provide MLR notices pursuant to this final rule. Issuers are required to provide notices to group policyholders and each of their subscribers, and to subscribers in the individual market. If there are multiple enrollees in the same household enrolled in the same health plan, issuers would need to provide only one notice to the subscriber. It is estimated that in the 2011 MLR reporting year, between 278 and 337 issuers with 65.8 million to 72.2 million enrollees will meet or exceed the applicable MLR standard. According to a large issuer, there are 2.2 covered lives per family. Therefore, it is estimated that in 2012, between 278 and 337 issuers will send MLR notices for the 2011 MLR reporting year to 29.9 million to 32.7 million individual market and group market subscribers.

In addition, issuers are required to provide MLR notices to group policyholders. In the regulatory impact analysis for the Interim Final Rule for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act (75 FR 34538) published on June 17, 2010, it was estimated that there are approximately 3 million large and small group plans, which include self-insured plans (self-insured experience is not subject to the MLR requirements). According to Medical Expenditure Panel Survey data, in 2010, 35.8 percent of all private sector employers that offered health insurance self-insured at least one plan.⁵ In the December 1, 2010 MLR interim final rule, it was estimated that between 1 percent and 3 percent of enrollees in fully insured group health plans would receive rebates during the 2011 MLR reporting year. In the absence of data on the number of group health plans in the NAIC database used for this analysis, we use the

⁵ Source: Agency for Healthcare Research and Quality, Center for Financing, Access and Cost Trends, 2010 Medical Expenditures Panel Survey-Insurance Component, Table I.A.2.a, "Percent of private-sector establishments that offer health insurance that self-insure at least one plan by firm size and selected characteristics: United States, 2010", available at http://meps.ahrq.gov/mepsweb/data_stats/summ_tables/insr/national/series_1/2010/tia2a.pdf.

percentages of enrollees not receiving rebates and employers offering self-insured plans to estimate the number of fully insured group health plans whose enrollees would not receive rebates for the 2011 MLR reporting year. Therefore, it is estimated that approximately 1.9 million fully insured group policyholders would receive MLR notices, pursuant to this final rule, for the 2011 MLR reporting year.

6. Estimated Costs Related to Notice Requirement

CMS specifies in this rule standard language to be used for the notices, which will minimize the burden for issuers. Issuers have the option providing the notices with other plan documents or, if the requirements for electronic disclosure under section 2715 of the PHS Act are satisfied, by using electronic methods. In the Summary of Benefits and Coverage and Uniform Glossary Final Rule (77 FR 8668) published on February 14, 2012, we estimated that electronic distribution would account for 38 percent of all disclosures in the group market.⁶ In addition, according to a report by the Department of Commerce, 71 percent of homes in the U.S. had home Internet access in 2010.⁷ We therefore estimate that 38 percent of notices to subscribers in the group market and 71 percent of notices to subscribers in the individual market will be sent electronically, and the remaining notices will be sent by mail. Further, we assume that all notices to group policyholders or employers will be sent electronically. We assume that issuers will use clerical staff to prepare the notices that are distributed with other plan materials by mail and will need approximately 0.25 minutes (or 0.004 hours) to prepare each notice. The cost of supplies is assumed to be \$0.03 per notice, and labor costs are assumed to be \$30.67 per

⁶ The estimate was based on the methodology used to analyze the cost burden for the Department of Labor's claims procedure regulation (OMB Control Number 1210-0053), and refers to the ERISA e-disclosure rule at 29 CFR 2520.104b-1.

⁷ U.S. Department of Commerce, Exploring the Digital Nation - Computer and Internet Use at Home (November, 2011), available at <http://www.ntia.doc.gov/report/2011/exploring-digital-nation-computer-and-internet-use-home>.

hour (or \$0.13 per notice). Since the notice may be included with other plan documents, we assume there will be no additional mailing costs.

Table 2 includes the estimated total and average administrative costs to issuers of preparing and sending the notices by mail. We estimate that in 2012, issuers will incur total annual costs of about \$3 million and average costs between \$9,000 and \$10,000 per issuer to provide notices for the 2011 MLR reporting year. The average cost of preparing and sending a notice by mail is about \$0.16 (including labor and supply costs).

Table 2--Estimated Administrative Cost of MLR Notices in 2012

MLR Reporting Year	Estimated Number of Affected Issuers	Estimated Number of Notices Distributed by Mail	Estimated Total Hours for Preparing Notices Distributed by Mail	Estimated Supplies Cost per Notice Distributed by Mail	Estimated Total Cost of Distributing Notices by Mail	Estimated Average Cost Per Affected Issuer
High Range Estimate						
2011	337	19,000,000	79,000	\$0.03	\$3,002,919	\$8,911
Medium Range Estimate						
2011	305	18,700,000	78,000	\$0.03	\$2,946,544	\$9,661
Low Range Estimate						
2011	278	17,700,000	74,000	\$0.03	\$2,800,587	\$10,074

C. Regulatory Alternatives

Under the Executive Order, CMS is required to consider alternatives to issuing rules and alternative regulatory approaches. CMS considered the regulatory alternative of not requiring issuers that meet or exceed the applicable MLR standard to provide notices with MLR information to policyholders and subscribers. However, that would result in reduced transparency for consumers regarding the MLR of their issuer for their State and market, and how it compares to the applicable standard. CMS also considered the regulatory alternatives of requiring issuers that meet or exceed the applicable MLR standard to provide notices that include the issuer's MLR from the current and prior MLR reporting years and of making the notice an

ongoing annual requirement. However, this would result in increased burden for issuers, particularly since their MLR information will be available on the HHS Web site and consumer knowledge of MLR is expected to increase after rebates and MLR notices are provided in 2012. As discussed earlier, we believe that the greatest benefit can be achieved by providing consumers with educational information in the first year of applicability, when consumer knowledge of the MLR is low, and helping to reduce consumers' confusion regarding why they did not receive a rebate. CMS believes that the option adopted in this final rule strikes the best balance of providing valuable information to consumers while providing an incentive for issuers to maximize the percentage of premium dollars they spend on health care and quality improving activities.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a rule to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as--(1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of "small entity"). CMS uses as its measure of significant economic impact on a substantial number of small entities a change in revenue of more than 3 to 5 percent.

As discussed in the interim final rule with comment period published on May 5, 2010 (75 FR 24470) relating to the Federal health care reform insurance Web Portal requirements, CMS examined the health insurance industry in depth in the Regulatory Impact Analysis prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3,

2004). In that analysis, it was determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for “small” business established by the SBA (currently \$7 million in annual receipts for health issuers).⁸

For the December 1, 2010 interim final rule (75 FR 74892), we used the data set created from the 2009 NAIC Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and small group markets, and are therefore subject to the MLR reporting requirements. For purposes of this analysis, we used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. These estimates may overstate the actual number of small health insurance issuers that would be affected, since they do not include receipts from these companies’ other lines of business.

In the December 1, 2010 interim final rule, it was estimated that there are 28 small entities with less than \$7 million in A&H earned premiums that offer individual or group comprehensive major medical coverage, and would therefore be subject to the requirements of this final rule. These small entities accounted for 6 percent of the estimated 442 total issuers that would be affected by the MLR requirements. It was estimated that 86 percent of these small issuers are subsidiaries of larger issuers, 75 percent only offer coverage in a single State, 68 percent only offer individual or group comprehensive coverage in a single market, 46 percent also offer other types of A&H coverage, and 29 percent are Life Blank filers.

CMS estimates that in 2012, of the 28 small entities discussed above, 8 are subject to the requirements of this final rule and will incur approximately \$100 per issuer in administrative

⁸ “Table of Small Business Size Standards Matched to North American Industry Classification System Codes,” effective March 26, 2012, U.S. Small Business Administration, available at www.sba.gov.

costs related to providing notices for the 2011 MLR reporting year (accounting for less than 0.002 percent of their total A&H premiums).

CMS believes that these estimates overstate the number of small entities that will be affected by the requirements in this final rule, as well as the relative impact of these requirements on these entities, because CMS has based its analysis on issuers' total A&H earned premiums (rather than their total annual receipts). Therefore, the Secretary certifies that this final rule will not have significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a final rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This final rule would not affect small rural hospitals. Therefore, the Secretary has determined that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditures in any 1 year by State, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold level is approximately \$139 million.

UMRA does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from--(1) imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2)

increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

Consistent with policy embodied in UMRA, this final rule has been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector, while achieving the objectives of the Affordable Care Act.

This final rule contains MLR notice requirements for private sector firms (for example, health insurance issuers providing coverage in the individual and group markets), but it is estimated that these requirements will not cost issuers more than approximately \$3 million dollars in administrative costs in 2012. The rule contains no mandates on State, local or tribal governments. Thus, this final rule does not impose an unfunded mandate on State, local or tribal governments.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. The requirements specified in this final rule would not impose substantial direct costs on State and local governments.

Throughout the process of developing this final rule, CMS has attempted to balance States' interests in regulating health insurance issuers and the Congress' intent to provide uniform protections to consumers in every State. By doing so, it is CMS' view that it has complied with the requirements of Executive Order 13132. Under the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this rule, HHS certifies

that CMS has complied with the requirements of Executive Order 13132 for the attached final rule in a meaningful and timely manner.

G. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller General for review.

List of Subjects in 45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 158 as set forth below:

PART 158-ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

1. The authority citation for part 158 continues to read as follows:

Authority: Section 2718 of the Public Health Service Act (42 USC 300gg-18), as amended.

2. Section 158.251 is added to read as follows:

§158.251 Notice of MLR information.

- (a) Notice of MLR information when the MLR standard is met or exceeded. – (1)

General requirement. Except as provided in paragraph (b) of this section, for the 2011 MLR reporting year, an issuer whose MLR meets or exceeds the applicable MLR standard required by §158.210 or §158.211 must provide each policyholder and subscriber of a group health plan, and each subscriber in the individual market, a notice in accordance with the requirements of this section.

- (2) Timing. An issuer must provide the notice required in this paragraph (a) with the first plan document that the issuer provides to enrollees on or after July 1, 2012.

- (3) Form and appearance. The notice must be prominently displayed in clear, conspicuous 14-point bold type on the front of the plan document or as a separate notice. The notice may be provided electronically, if the requirements for electronic disclosure under section 2715 of the Public Health Service Act are met.

- (4) Language. The following language must be used to satisfy the notice requirement of this paragraph (a):

Medical Loss Ratio Information--The Affordable Care Act requires health insurers in the individual and small group markets to spend at least 80 percent of the premiums they receive on health care services and activities to improve health care quality (in the large group market, this amount is 85 percent). This is referred to as the Medical Loss Ratio (MLR) rule or the 80/20 rule. If a health insurer does not spend at least 80 percent of the premiums it receives on health care services and activities to improve health care quality, the insurer must rebate the difference.

A health insurer's Medical Loss Ratio is determined separately for each State's individual, small group and large group markets in which the health insurer offers health insurance. In some States, health insurers must meet a higher or lower Medical Loss Ratio. No later than August 1, 2012, health insurers must send any rebates due for 2011 and information to employers and individuals regarding any rebates due for 2011.

You are receiving this notice because your health insurer had a Medical Loss Ratio for 2011 that met or exceeded the required Medical Loss Ratio. For more information on Medical Loss Ratio and your health insurer's Medical Loss Ratio, visit www.HealthCare.gov."

(b) Exceptions. The requirements of paragraph (a) of this section do not apply to an issuer that reports its experience separately under §158.120(d)(3) or (d)(4), or to an issuer whose experience is non-credible as defined in §158.230(c)(3) and determined in accordance with §158.231.

CMS-9998-F

Dated: March 8, 2012

Marilyn Tavenner,
Acting Administrator,
Centers for Medicare & Medicaid Services.

Approved: May 10, 2012

Kathleen Sebelius,
Secretary,
Department of Health and Human Services.

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