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<PREAMB>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 158

CMS-9998-IFC2

RIN 0938-AR35

Medical Loss Ratio Rebate Requirements for Non-Federal Governmental Plans

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

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule with comment period revises the regulations implementing medical loss ratio (MLR) requirements for health insurance issuers under the Public Health Service Act in order to establish rules governing the distribution of rebates by issuers in group markets for non-Federal governmental plans.

DATES: Effective date. This rule is effective on **January 1, 2012.**

Comment date. To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[OFR--insert date 60 days after date of publication in the Federal Register].**

Applicability Date. The amendments to Part 158 generally apply beginning January 1, 2012 to health insurance issuers offering group health insurance coverage.

ADDRESSES: In commenting please refer to file code CMS-9998-IFC2. Because of staff and resource limitations, we cannot accept comments by email or facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9998-IFC2,

P.O. Box 8010,

Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address only:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9998-IFC2,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, S.W.,
Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (800) 743-3591.

FOR FURTHER INFORMATION CONTACT:

Carol Jimenez, (301) 492-4457.

SUPPLEMENTARY INFORMATION:

Comment Subject Areas: We will consider comments on the rules for providing rebates to group enrollees in non-Federal governmental plans, as discussed in this interim final rule with comment period, that are received by the date and time indicated in the **DATES** section of this interim final rule with comment period.

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 PHS Act section 2718 was published in the **Federal Register** on April 14, 2010 (75 FR 19297). On December 1, 2010, HHS published an interim final rule (75 FR 74864) with 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). The Department of Health and Human Services (HHS) published a final rule entitled “Medical Loss Ratio Requirements under the Patient Protection and Affordable Care Act,” published elsewhere in this Federal Register (hereinafter referred to as the Medical Loss Ratio final rule).

II. Provisions of the Interim Final Rule

Rebates to Enrollees in Non-Federal Governmental Plans in Group Markets (45 CFR 158.242(b))

As stated in the Medical Loss Ratio final rule published elsewhere in this **Federal Register**, with respect to non-Federal governmental plans, there currently is no legal framework set forth in Federal law governing the use of rebates received from an issuer under the MLR regulations. However, CMS has direct authority over non-Federal governmental plans. Accordingly, for reasons discussed in the preamble of the Medical Loss Ratio final rule, under the authority in section 2792 of the PHS Act to promulgate regulations determined “appropriate” to “carry out” the provisions of part A of title XXVII of the PHS Act, which include PHS Act section 2718, this interim final rule with comment period directs that issuers distribute the entire rebate to the group policyholder and the group policyholder is required to use the portion of rebates attributable to the amount of premium paid by subscribers of non-Federal governmental plans for the benefit of subscribers, ensuring that enrollees in such plans receive the benefit of rebates. For example, if an issuer whose MLR is lower than the applicable MLR standard owes a rebate of \$20,000 to the policyholder and subscribers of a group health plan, the issuer would provide the \$20,000 directly to the policyholder. If the non-

Federal governmental plan's subscribers paid 40 percent of the total premium, then the policyholder must use 40 percent of the rebate, or \$8,000, for the benefit of the subscribers.

With respect to rebates paid to non-Federal governmental plans, we direct in this interim final rule with comment period that the subscriber portion of the rebate be used, at the option of the policyholder, in one of the following ways--(1) to reduce subscribers' portion of the annual premium for the subsequent policy year for all subscribers covered under any group health policy offered by the plan; (2) to reduce subscribers' portion of the annual premium for the subsequent policy year for only those subscribers covered by the group health policy on which the rebate was based; or (3) to provide a cash refund only to subscribers that were covered by the group health policy on which the rebate is based. In all three options, the rebate is used to reduce premiums or is paid to subscribers enrolled during the year in which the rebate is actually paid, rather than the MLR reporting year on which the rebate was calculated. We believe that this results in administrative simplicity, as it does not require tracking former enrollees or determining who was covered by which issuer the prior year while maintaining the law's intent of benefitting enrollees.

These options were created to provide maximum flexibility to policyholders and employers while ensuring that enrollees receive the benefits of the rebate. No single option is preferred by CMS. The first option allows all subscribers who receive health care coverage through the plan, and not just those participants that were covered by the policy that produced the rebate, to receive reduced premiums in the subsequent policy year. While this option allows some employees to benefit from a rebate despite the fact that they did not contribute to the premium paid to the particular issuer providing the rebate, we believe that this option provides

for ease of rebate calculation and administration, especially for large employers with enrollees in multiple states who offer multiple policy choices and may get rebates from several issuers.

We request comment on the treatment of rebates in the non-Federal governmental group market. Since we provide, in this interim final rule with comment period, three specific methods for non-Federal governmental plans to distribute to current subscribers rebates attributable to subscribers' aggregated contribution to premium, we request comments specifically on whether the mechanism provided in this interim final rule with comment period solves or meaningfully reduces the logistical challenges of providing rebates to non-Federal governmental plans and distributing them to their subscribers and on other potential solutions to these challenges while ensuring that enrollees benefit when rebates are paid.

III. Collection of Information Requirements

This interim final rule with comment period does not impose any new reporting requirements and generally conforms to the requirements under the interim final regulation published on December 1, 2010.

IV. Response to Comments

Because of the large number of public comments CMS receives on Federal Register documents, CMS is not able to acknowledge or respond to them individually. CMS will consider all comments CMS receives by the date and time specified in the DATES section of this preamble, and, when CMS proceeds with a subsequent document, CMS will respond to the comments in the preamble to that document.

V. Waiver of Proposed Rulemaking

This interim final rule with comment period includes in §158.242(b) a provision governing how a non-Federal governmental plan is required to distribute rebates. A non-Federal

governmental plan would not have had any reason to believe that the MLR regulations would impose any requirements on them, as this possibility was not discussed in the interim final rule published on December 1, 2010. Thus, ordinarily, before imposing such a requirement, the Administrative Procedure Act (APA) would require that they be provided with an opportunity for prior public comment.

Section 2792 of the PHS Act, however, authorizes the Secretary of HHS to promulgate interim final rules determined appropriate to carry out the provisions of part A of title XXVII of the PHS Act, which include PHS Act section 2718, without subjecting the rules to prior notice and comment. CMS accordingly is relying on the authority in section 2792 to implement this provision on an interim final basis without a prior opportunity for public comment. CMS will consider public comments received on this provision.

CMS notes that under the APA (5 U.S.C. 551 *et seq.*), while an opportunity for public comment is generally required before promulgation of regulations, this is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority in section 2792 of the PHS Act cited above.

However, even if the APA requirements for notice and comment were applicable to the revisions to §158.242(b), regarding permissible distribution of rebates by non-Federal governmental plans, these APA requirements have been satisfied. This is because the Secretary finds that providing an additional opportunity for public comment on this provision would be impractical and contrary to the public interest, for the reasons set forth below.

Specifically, the Department waives notice and comment for §158.242(b)(1) and (2), regarding permissible distribution of rebates by non-Federal governmental group plan policyholders, due to the immediate problematic operational impact a failure to put these changes in place would have on issuers and non-Federal governmental group plan policyholders (that is, mostly employers).

As stated in the Medical Loss Ratio final rule published contemporaneously with this interim final rule with comment period, the Department received many comments expressing significant concern with the requirement that issuers in the group markets distribute the enrollee portion of the rebate directly to the subscriber. Additionally, there are tax implications to distributing rebates directly to subscribers. To address these concerns, both the Medical Loss Ratio final rule and this interim final rule with comment period require issuers to send group policyholders the entire rebate attributable to the group health plan.

However, as noted in the preamble to the separate Medical Loss Ratio final rule, a provision that simply permits issuers to pay rebates to a non-Federal governmental plan would not ensure that enrollees in those plans would benefit from the rebate, as is ensured under Federal law in the case of plans governed by the Employee Retirement Income Security Act of 1974 (ERISA), as amended (29 CFR 1001 et seq). The new provisions eliminating burdens for making rebate payments in 2012 put in place by the Medical Loss Ratio final rule published today thus could not effectively be implemented for non-Federal governmental plans without measures to ensure that rebates are used for the benefit of enrollees. CMS has authority to regulate non-Federal governmental plans and, therefore, is setting requirements that are necessary in order to combine the efficiencies of paying rebates to the non-Federal governmental plan with the assurance that enrollees of the plan will benefit from such payments.

Informing issuers and non-Federal governmental plans of these changes as soon as possible is necessary so that they may take them into account in negotiating their group health insurance contracts for the 2012 MLR reporting year, as those preparations are currently underway. In addition, issuers are pricing their insurance products and the regulatory requirement regarding disbursement of rebates is a component of their pricing structure.

The changes CMS makes in this interim final rule with comment period are necessary in order for the provisions of the Medical Loss Ratio final rule simplifying the procedures that issuers must follow to work effectively, and thus are necessary in order to reduce administrative burdens. Issuers and policyholders will welcome and support these changes, which need to be communicated immediately, providing just cause for waiving the notice of proposed rulemaking. Therefore, CMS finds good cause to waive prior notice and comment with respect to the new rules governing distribution of rebates by non-Federal governmental plans. CMS is providing a 30-day public comment period on provisions in this interim final rule.

VI. Regulatory Impact Statement

A. Summary

This interim final rule with comment period is designed to address a specific issue that has arisen regarding section 2718 of the PHS Act, which sets forth standards for reporting of certain medical loss ratio (MLR) related data to the Secretary on an annual basis by issuers offering coverage in the individual and group markets, and calculating and providing rebates to policyholders in the event that an issuer's MLR fails to meet or exceed the statutory standard. This interim final rule with comment period establishes rules for the distribution of rebates in non-Federal governmental plans in the group market. These provisions are generally effective beginning January 1, 2012.

CMS is publishing this interim final rule with comment period to implement the protections intended by the Congress in the most economically efficient manner possible. CMS has examined the effects of this rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct 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 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more in any one 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 one year); and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB). CMS has concluded that this interim final rule with comment period is not likely to have economic impacts of \$100 million or more in any one year, and therefore does not meet the definition of "economically significant rule" under Executive Order 12866.

1. Need for Regulatory Action

Consistent with the provisions in Section 2718 of the PHS Act, this interim final rule with comment period establishes rules for providing rebates to enrollees in non-Federal governmental group health plans when the MLR standard is not met by an issuer. Section 2718(b) of the PHS Act (captioned "ensuring that consumers receive value for their premium payments") requires issuers to provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended on reimbursement for clinical services and activities that improve quality is less than the applicable minimum standard and specifies how the rebate is to be calculated. This interim final rule with comment period directs that issuers distribute the entire rebate to the group policyholder and the group policyholder is required to use the portion of rebates attributable to the amount of premium paid by subscribers of non-Federal governmental plans for the benefit of subscribers, ensuring that enrollees in such plans receive the benefit of rebates.

2. Summary of Impacts

This interim final rule with comment period provides for a more efficient and cost effective way for issuers to disburse rebate payments to subscribers of non-Federal governmental

plans by allowing issuers in group markets to provide rebates to the policyholders for distribution. As stated in the Medical Loss Ratio final rule published contemporaneously with this interim final rule with comment period, it is estimated that for the years 2012 and 2013, 0.8 million enrollees in the small group market and 1 million enrollees in the large group market would receive rebates each year. Only a fraction of these enrollees will be in non-Federal governmental plans. This provision will lower administrative costs related to rebate disbursement for issuers of group health plans and will largely eliminate the tax burden on employers and consumers inherent in the prior rebate mechanism as explained in the Medical Loss Ratio final rule published contemporaneously with this interim final rule with comment period. Policyholders will experience an increase in administrative costs related to the disbursement of rebates, although these administrative costs will be offset by eliminating the administrative burden and tax consequences inherent in the prior rebate mechanism that directed issuers to pay rebates directly to policyholders and each of their subscribers. As a result, CMS has concluded that the impacts are not economically significant.

An alternative to the rebate distribution methodology set forth in this interim final rule with comment period is to require issuers to send rebate payments directly to subscribers of non-Federal governmental group health plans. As described previously, this would result in increased tax burden for consumers and for their employers, as well as increased administrative costs for issuers associated with rebate payments.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation 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"). HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

CMS has estimated that the provisions of the interim final rule with comment period do not impose any additional costs on small entities. Therefore, the Secretary has determined that this interim final rule with comment period will not have a 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 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 interim final rule with comment period would not affect small rural hospitals. Therefore, the Secretary has determined that this interim final rule with comment period would not have a significant impact on the operations of a substantial number of small rural hospitals.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one 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 2011, that threshold level is approximately \$136 million. This interim final rule with comment period has no consequential effect on State, local, or tribal governments in the aggregate, or by the private sector.

UMRA does not address the total cost of a 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.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This interim final rule with comment period does not impose substantial direct requirement costs on State and local governments, and also does not have effects on the distribution of power and responsibilities among the State and Federal governments.

Throughout the process of developing this interim final regulation the Department has attempted to balance the States’ interests and Congress’ intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Department’s view that we have complied with the requirements of Executive Order 13132. Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that the Centers for Medicare & Medicaid Services has complied with the requirements of Executive Order 13132 for the attached interim final regulation in a meaningful and timely manner.

F. Congressional Review Act

This interim final regulation is not subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.).

List of Subjects

45 CFR Part 158

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid 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 158.242 is amended by—
 - a. Adding new paragraphs (b)(1) and (2).
 - b. Revising paragraph (b)(3).

The additions and revision read as follows:

§158.242 Recipients of rebates.

* * * * *

(b) * * *

(1) In the case of a policyholder that is a non-Federal governmental group health plan, the policyholder must use the amount of the rebate that is proportionate to the total amount of premium paid by all subscribers under the policy, for the benefit of subscribers in one of the following ways, at the option of the policyholder:

(i) For all subscribers covered under any option offered under the policyholder’s group health plan at the time the rebate is received by the policyholder, to reduce the subscribers’ portion of premium for the subsequent policy year;

(ii) For subscribers covered, at the time the rebate is received by the policyholder, under the group health plan option for which the issuer is providing a rebate, to reduce the subscribers' portion of premium for the subsequent policy year;

(iii) A cash refund to subscribers enrolled in the group health plan option, at the time the rebate is received by the policyholder, for which the issuer is providing a rebate; and

(iv) The reduction in future premium or the cash refund provided under paragraphs (b)(1)(i), (ii), or (iii) of this section may, at the option of the policyholder, be: divided evenly among such subscribers; divided based on each subscriber's actual contributions to premium; or apportioned in a manner that reasonably reflects each subscriber's contributions to premium.

(2) In the case of a policyholder that is a non-Federal governmental group health plan, the portion of a rebate based upon former subscribers' contributions to premium must be aggregated and used for the benefit of current subscribers in the group health plan in any manner permitted by paragraph (b)(1) of this section.

(3) If the policyholder is a group health plan that is not a governmental plan and not subject to the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq*)(ERISA), rebates may only be paid to the policyholder if the issuer receives a written assurance from the policyholder that the rebates will be used as provided in paragraphs (b)(1) and (2) of this section; otherwise, the issuer must distribute the rebate directly to the subscribers of the group health plan covered by the policy during the MLR reporting year on which the rebate is based by dividing the entire rebate, including the amount proportionate to the amount of premium paid by the policyholder, in equal amounts to all subscribers entitled to a rebate without regard to how much each subscriber actually paid toward premiums.

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CMS-9998-IFC2

Dated: December 1, 2011

Donald M. Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: December 1, 2011

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

CMS-9998-IFC2

<FRDOC> [FR Doc. 2011–31291 Filed 12–2–11;
11:15 am]
<BILCOD>BILLING CODE 4150–28–P

[FR Doc. 2011-31291 Filed 12/02/2011 at 11:15 am; Publication
Date: 12/07/2011]