DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 158

OCIIO-9998-IFC

RIN 0950-AA06

Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements under the Patient Protection and Affordable Care Act

AGENCY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rule with request for comments.

SUMMARY: This document contains the interim final regulation implementing medical loss ratio (MLR) requirements for health insurance issuers under the Public Health Service Act, as added by the Patient Protection and Affordable Care Act (Affordable Care Act).

DATES: Effective date: This interim final regulation is effective January 1, 2011.

Comment date: Comments are due on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER].**

Applicability dates: This interim final regulation generally applies beginning January 1, 2011, to health insurance

issuers offering group or individual health insurance coverage.

ADDRESS: Written comments may be submitted to the address specified below.

All comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, please refer to file code OCIIO-9998-IFC. Because of staff and resource limitations, we cannot accept comments by 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: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO-9998-IFC, Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW, Washington, DC 20201.

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: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO-9998-IFC, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the following address:
Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO-9998-IFC, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, 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 OCIIO 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.)

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

FOR FURTHER INFORMATION CONTACT: Carol Jimenez, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (301) 492-4457.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will also be available for public inspection as they are received, generally beginning approximately three 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 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Customer Service Information: Individuals interested in obtaining information on health reform can be found http://www.healthcare.gov.

Table of Contents

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.

The Department of Health and Human Services (HHS, or the Department) is issuing regulations in several phases in order to

implement revisions to the PHS Act made by the Affordable Care Act. All of the previous regulations were issued jointly with the Departments of Labor and the Treasury. 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) (notice, or request for information). Additionally, a series of interim final regulations were published earlier this year implementing PHS Act provisions added by the Affordable Care Act. Specifically, interim final rules were published implementing (1) section 2714 (requiring dependent coverage of children to age 26) (75 FR 27122 (May 13, 2010)); (2) section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan) (75 FR 34538 (June 17, 2010)); (3) sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections) (75 FR 37188 (June 28, 2010)); (4) section 2713 (regarding preventive health services) (75 FR 41726 (July 19, 2010)); and (5) section 2719 (regarding internal claims and appeals and external review processes) (75 FR 43330 (July 23, 2010)). Most recently, HHS, Department of Labor, and Department of the Treasury published an amendment to the interim final regulations relating to status as a grandfathered health plan (regarding

change in health insurance issuers) in the **Federal Register** on November 17, 2010 (75 FR 70114). The Departments have also published sub-regulatory guidance regarding various issues related to the implementation of the Affordable Care Act, available at http://www.dol.gov/ebsa and http://www.hhs.gov/ociio.

This interim final regulation adopts and certifies in full all of the recommendations in the model regulation of the National Association of Insurance Commissioners (NAIC) regarding MLRs. It is being published to implement section 2718(a) through (c) of the PHS Act, relating to bringing down the cost of health care coverage through a new MLR standard. Subpart A implements the requirements for reporting the data to be considered in determining that ratio. Subpart B addresses the requirements for health insurance issuers (issuers) in the group or individual market, including grandfathered health plans, to provide an annual rebate to enrollees, if the issuer's MLR fails to meet minimum requirements: generally, 85 percent in the large group market and 80 percent in the small group or individual market. In Subpart C, this interim final regulation provides a process and criteria for the Secretary of Health and Human Services (the Secretary) to determine whether application of the 80 percent MLR in the individual market in a State may destabilize that individual market. Finally, enforcement of the

reporting and rebate requirements of section 2718(a) and (b) are addressed in Subparts D-F, as specifically authorized in section 2718(b)(3). This interim final regulation is generally applicable for plan years beginning on or after January 1, 2011. Self-insured plans are not a health insurance issuer, as defined by section 2791(b)(2) of the PHS Act, and thus are not subject to this interim final regulation.

II. Provisions of the Interim Final Rule

A. Introduction and Overview

Section 2718 of the PHS Act includes two provisions designed to achieve the objective in the section title: "Bringing down the cost of health care coverage." The first is the establishment of greater transparency and accountability around the expenditures made by health insurance issuers. The law requires that issuers publicly report on major categories of spending of policyholder premium dollars, such as clinical services provided to enrollees and activities that will improve health care quality. The second is the establishment of MLR standards for issuers, which are intended to help ensure policyholders receive value for their premium dollars. Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improving activities, in relation to the premiums charged, is less than the MLR standards established pursuant to

the statute. The rebate provisions of section 2718 are designed not just to provide value to policyholders, but also to create incentives for issuers to become more efficient in their operations. Section 2718 also contains provisions which allow for modifications to the standards under certain circumstances, which are described in this regulation. To inform decisions about definitions and methodologies for calculating MLRs, the Affordable Care Act directed the NAIC to make recommendations to the Secretary, subject to certification by the Secretary. As described below, this interim final regulation adopts to these recommendations.

As to the reporting provisions, section 2718(a) requires health insurance issuers to "submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums." The statute, as implemented by this interim final regulation, requires health insurance issuers to submit data to the Secretary that will allow enrollees of health plans, consumers, regulators, and others to take into consideration MLRs as a measure of health insurance performance as described in section 2718 of the PHS Act. More specifically, this interim final regulation is intended to provide consumers with information needed to better understand how much of the premium paid to the issuer is used to reimburse providers for

covered services, to improve health care quality, and to pay for the "non-claims," or administrative expenses, incurred by the issuer. The caption of subsection (a) reflects this purpose, which is to provide the Secretary and other parties with a "clear accounting for costs."

As quoted above, the statute requires issuers to submit a report that "concerns" the ratio of the "incurred loss" to "earned premium." The statute does not simply require the issuer to report the numeric ratio of the incurred loss to earned premium. In addition, subsection (a)(3) requires issuers to provide an explanation of the "nature" of "non-claims costs." This interim final regulation accordingly describes the type of information that is to be included in the report to the Secretary and made available to consumers, in addition to the numerical ratio. To increase transparency and avoid confusion, this interim final regulation provides that the data to be reported according to section 2718(a) of the PHS Act will include all of the elements of revenue and expenditures that will be needed to calculate the amount of rebates under subsection 2718(b).

For this information to be meaningful to consumers, the report provided to the Secretary and made available to the public must include the amount of premium revenue received as well as the amount expended on each of the types of activity

identified in subparagraphs (1), (2), and (3) of section 2718(a) of the PHS Act:

(1) Reimbursement for clinical services provided to enrollees under the health insurance plan (subparagraph (1));

(2) Activities that improve health care quality for enrollees (subparagraph (2));

(3) All other "non-claims" costs (subparagraph (3)); and

(4) Federal and State taxes and licensing or regulatory fees (subparagraph (3)).

In addition, the rebate requirements established by section 2718(b) allow for a State to provide for higher ratios than those required by section 2718(b)(1)(A)(i) and (ii) of the PHS Act. In order to allow a State to do so, the reporting required of health insurance issuers under subsection (a) must be done on a State level. Section 2718(b) also requires a separate calculation of the MLR for the large group market, the small group market, and the individual market. Consequently, the data required under subsection (a) must be reported for the large group market, the small group market, and the individual market within each State.

NAIC model regulation and recommendations. Section 2718(c) of the PHS Act directs the NAIC, subject to certification by the Secretary, to establish:

(1) uniform definitions of the activities reported under

section 2718(a);

(2) standardized methodologies for calculating measures of the activities reported under section 2718(a); and

(3) definitions of which activities and in what regard such activities constitute activities that improve health care quality.

Section 2718(c) also directs that the standardized methodologies for calculating measures of the activities reported under section 2718(a) "shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans."

The NAIC provided its recommendations to the Secretary on October 27, 2010 regarding the above three areas, and made additional recommendations regarding other aspects of section 2718, in the form of a model regulation entitled Regulation for Uniform Definitions and Standardized Methodologies for Calculation of the Medical Loss Ratio for Plan Years 2011, 2012 and 2013 per Section 2718(b) of the Public Health Service Act (hereinafter "NAIC model regulation") (http://www.naic.org/documents/committees_ex_mlr_reg_asadopted.pdf). The NAIC model regulation is discussed in more detail in connection with the specific provisions of this interim final regulation. The NAIC, in discharging its statutory obligations, conducted a thorough and transparent process in which the views

of regulators and stakeholders were discussed, analyzed, addressed and documented in numerous open forums held by staff from State insurance departments, by NAIC staff, and by the commissioners, directors, and superintendents of insurance from the States. This interim final regulation certifies and adopts the NAIC's model regulation in full.

The NAIC model regulation includes definitions to be used for purposes of reporting the types of activities mandated by section 2718(a), and standardized methodologies for calculating measures of such activities including those that improve health care quality. This interim final regulation certifies and adopts these definitions in the NAIC model regulation. Consistent with the mandate of section 2718(b), the NAIC and this interim final regulation require that health insurance issuers aggregate data at the State level by the large group market, small group market, and individual market, and define these markets. The reporting requirements, which follow NAIC's recommendations, are discussed in connection with Subpart A.

The NAIC model regulation addresses in several different ways, as does this interim final regulation, the statutory requirement that the methodologies used to calculate the measures of the activities reported "shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans." The NAIC

recommendations address the special circumstance of newer plans and smaller plans. They address newer plans by adjusting when newer plans' experience is to be reported, which is addressed in Subpart A. The special circumstance of smaller plans, which do not have sufficient experience to be statistically valid for purposes of the rebate provisions, are addressed by the NAIC through credibility adjustments to the calculation of the MLR. Because credibility adjustments are necessary to calculate the rebates under section 2718(b), they are addressed in Subpart B of this interim final regulation. The NAIC model regulation does not address the special circumstances of different types of plans such as so-called mini-med plans or expatriate plans, although it does address expatriate plans in a letter to the Secretary. HHS addresses both mini-med plans and expatriate plans in this interim final regulation, and discusses them in connection with Subpart A.

The NAIC model regulation details the MLR rebate calculation for each of the next three MLR reporting years and notes the incurred claims and expenses related to improving health care quality that may be included. HHS has adopted these provisions in Subpart B.

As noted above, the statute directs the NAIC, subject to certification by the Secretary, to establish uniform definitions and methodologies for calculating measures of activities that

are used to calculate an issuer's MLR. HHS has reviewed these recommended definitions and methodologies and has decided to certify and adopt the NAIC recommendations in its October 27 model regulation. The NAIC held public, weekly meetings for several months during which interested parties were encouraged to provide both written and oral comments, and the details surrounding the reporting requirements were thoroughly analyzed. In making the determination to certify the NAIC's recommendations, HHS also considered the NAIC's Issue Resolution Documents, which were produced as a result of the NAIC's process and which contain the NAIC's position regarding numerous related issues. In addition, HHS considered the public comments received by the NAIC as well as comments submitted to HHS in response to its request for information published on April 14, 2010 in the **Federal Register**. HHS also considered the letters submitted by the NAIC to the Secretary with respect to MLR issues, which are also public records.

Organization of this regulation. The basis, scope, applicability, and definitions for this interim final regulation are set forth in §§158.101 through 158.103. The structure of Subpart A of this interim final regulation follows the organization of section 2718(a). The obligation to report is established in §158.110. The way in which issuers are to aggregate data in the required reports is explained in §158.120.

The special circumstances of mini-med plans and expatriate plans are also included in §158.120. Newer experience is addressed in §158.121. Section 158.130 addresses provisions that relate to premium revenue. Section 158.140 clarifies what may be reported as reimbursement for clinical services provided to enrollees, also known as incurred claims. Sections 158.150 through 158.151 explain the criteria for determining whether expenditures are for activities that improve health care quality, allocation of such expenses, and treatment of health information technology (HIT) expenses required to accomplish such activities. Section 158.160 clarifies reporting of non-claims costs. Sections 158.161 and 158.162 address the Federal and State taxes and licensing or regulatory fees that may be excluded from non-claims costs pursuant to PHS Act section 2718(a)(3). Section 158.170 addresses allocation of expenses among categories reported as well as an issuer's lines of business.

Similarly, the structure of Subpart B of this interim final regulation follows the organization of section 2718(b). The applicable MLR standards for the large group, small group and individual markets are addressed in §158.210. States are permitted to establish a higher MLR standard than provided by the Affordable Care Act, and if a State has done so, the State's standard applies, as stated in §158.211. Section 158.220 explains which MLR reporting year's data is to be used to

calculate an issuer's MLR, and §158.221 directs which data elements should be in the ratio's numerator and which should be in the denominator. Credibility adjustments are delineated in §158.230, and the details as to how to calculate them are addressed in §158.231 and §158.232. Sections 158.240 through 158.242 provide that enrollees must receive a rebate if the applicable MLR standard is not met, and establish who receives the rebate in certain circumstances, and the manner in which the rebate must be made. The de minimis amount below which a rebate need not be provided and how to handle de minimis rebates are addressed in §158.243. Section 158.250 establishes a requirement for issuers to provide rebate recipients with an explanatory notice, while §158.260 establishes a requirement for issuers to report to the Secretary data regarding rebate payments.

Subpart C of this interim final regulation addresses the Secretary's discretion in section 2718(b)(A)(ii) to adjust the MLR percentage for the individual market in a State if the Secretary determines that application of an 80 percent MLR standard may destabilize the individual market in such State. This interim final regulation provides that such determinations will be made pursuant to a State request and based on standards that include recommendations made to HHS in a letter from the NAIC on October 13, 2010.

Subparts D, E and F of this interim final regulation implement section 2718(b)(3), Enforcement, which directs the Secretary to promulgate regulations for enforcing section 2718, and allows for providing appropriate penalties as part of the enforcement scheme. Subpart D addresses the enforcement scheme. Subpart E sets forth the requirements for maintaining records and information. Subpart F, Federal Civil Penalties, details the basis for imposing civil penalties, factors that HHS will consider in assessing civil penalties, the amount of the penalties, and the process for assessing them.

B. Scope, Applicability and Definitions

1. Scope and Applicability (§§158.101 through 158.102)

Section 158.101 sets forth the topics and issues covered in Part 158 of this interim final regulation.

Section 158.102 provides that Part 158 applies to health insurance issuers offering group or individual health insurance coverage. Section 2718(a) of the PHS Act expressly provides that this includes grandfathered health plans. Grandfathered health plans are defined in 26 CFR §54.9815-1251T, 29 CFR §§2590.715 through 1251, and 45 CFR §147.140, which implements the provisions in the Affordable Care Act regarding status as a grandfathered health plan (see Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Affordable Care Act, 75 FR

34538 (June 17, 2010), as amended, 75 FR 70114 (November 17, 2010)).

Although Section 2718(a) of the PHS Act does not exempt specific categories of plans from its requirements, subparagraph (c) requires that the reporting requirements and methodologies for calculating measures of the activities reported "be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans." Smaller plans, different types of plans, and newer plans are subject to this interim final rule, and their special circumstances are addressed through the reporting requirements and calculation of the MLR provisions in Subparts A and B.

2. Definitions (§158.103)

Section 2718(c) of the PHS Act directs the NAIC, subject to certification by the Secretary, to "establish uniform definitions of the activities reported under subsection (a) and standardized methodologies for calculating measures of such activities, including definitions of which activities, and in what regard such activities, constitute activities described in section (a)(2)."

The NAIC model regulation includes definitions of the activities reportable under section 2718(a) of the PHS Act and this interim final regulation adopts those definitions. Many of the terms defined in the NAIC model regulation refer to specific

lines on NAIC financial reporting forms that are broader than the reporting required for the PHS Act MLR provisions.

Any defined term that is used in only one section of this Subpart is defined in that section and is not also contained in the "Definitions" section of the regulation. Such terms include "aggregation," "incurred claims," and "quality improving activities." Thus, these terms are discussed in the preamble section regarding that topic, rather than here. For example, "aggregation" is addressed in §158.120, "incurred claims" is defined in §158.140, and "quality improving activities" is defined in §158.150. Each of these terms is discussed in the section of the preamble regarding the regulation pertaining to it.

Definitions that are used in the regulation as commonly used in the health care industry are not of particular note and therefore are not discussed here. We do discuss several definitions that are unique to this regulation or that may be of particular interest to enrollees, health plans, consumers, regulators and others. The definitions in §158.103 apply to all of Part 158. Also, in the public comments regarding uniform definitions for activities reported on under section 2718(a) of the PHS Act, the only definition we received any significant amount of comments on is "plan year." Those comments are discussed below with regard to MLR reporting year. Finally, we

note that the interim final regulation uses the term "market" as it is used in the statute, to differentiate the small group, large group, and individual market, even if in some contexts these are also referred to as "market segments."

"MLR reporting year." Section 2718(a) requires each health insurance issuer to submit a report to the Secretary "with respect to each plan year." The NAIC has recommended, and HHS concurs, that for purposes of MLR reporting and calculation, the term "plan year" in section 2718 should be interpreted to refer to the calendar year for that plan, and not necessarily the plan year that applies for other purposes. In adopting the NAIC's definition, HHS uses the term "MLR reporting year." Accordingly, this regulation interprets "plan year," as used in section 2718(a), as referring to the "MLR reporting year," and defines the MLR reporting year as the calendar year. We recognize that this definition is different than the definition of the term "plan year" currently in the regulations implementing the PHS Act. This current regulatory definition of "plan year" would continue to apply for all purposes other than the period to be used for MLR reporting and rebate calculation. Specifically, for purposes other than the period for MLR reporting and rebate calculation, the term plan year is defined as "the year that is designated as the plan year in the plan document of a group health plan," although the plan year may

under certain conditions be the deductible year, the policy year, the employer's tax year, or the calendar year. We also note that, in the case of individual health insurance coverage, a similar term - "policy year" - is defined. Under these definitions, the "plan year" or "policy year" is specific to the group or individual policy, and can be determined by the issuer. The NAIC recognized that requiring reporting of MLR data for each plan year under this generally applicable definition would be problematic. Meaningful reporting of the data required by section 2718 of the PHS Act requires aggregation of an issuer's experience across health insurance policies and policy forms in each State's large group, small group, and individual markets.

As stated above, the NAIC recommends and requires calendar-year reporting and we adopt this recommendation and require reporting on a calendar-year basis. Issuers will report the premium earned, claims, quality improvement expenses and other non-claims costs incurred under health insurance that is in force during the calendar year. Calendar year reporting will increase the reliability of the experience data that will be reported and that will be used as the basis for rebate calculations. It will reduce the reporting burden on issuers, as they will be required to prepare and file a single loss ratio report and to calculate and pay rebates only once each calendar year. All enrollees under any of the health insurance coverage

whose experience is reflected in the report to the Secretary will be eligible for rebates on the premiums paid during that calendar year. To avoid confusion with other uses of the term "plan year," and to make for a clearer presentation and discussion of the MLR reporting requirements, we have adopted the term "MLR reporting year" to refer to the "plan year" referenced in section 2718 for use in the regulation.

The Secretary invited the public to comment on uniform definitions for activities to be reported to the Secretary pursuant to section 2718(a). The only comments received regarding the terms defined in §158.103 were with respect to "plan year."

Since section 2718 of the PHS Act uses the term "plan year" without specifying whether it means a plan-specific year or a generally applicable reporting period, several commenters requested that we simply clarify its meaning. As explained above, we have done so. A minority of commenters preferred reporting to correspond to the effective dates of each health plan, arguing that non-calendar year plans may have difficulty gathering data on a calendar year basis as health plans are issued at various times throughout the calendar year. However, the calendar year reporting method used in this regulation was supported by several State regulators, health insurance issuers and others because it allows issuers to combine experiences

across all policies and will therefore produce more uniform and reliable premium, claims and cost data. They also supported such a calendar-year based reporting period because it is consistent with current industry financial reporting practices, is simpler for consumers to comprehend, and allows States to get the data at one time.

"Enrollee." Section 158.103 defines the term "enrollee" as "an individual who is enrolled, within the meaning of 45 CFR, section 144.103, in group health insurance coverage, or an individual who is covered by individual insurance coverage, at any time during an MLR reporting year." The NAIC does not define the term "enrollee." However, we believe it is important to clarify that, for reporting purposes, "enrollee" refers to anyone covered by a group plan, including dependents of the subscriber or employee, as well as anyone covered by an individual policy, despite the fact that this term is not ordinarily used in the individual market.

"Small group market" and "Large group market." The reporting regulations require in general that issuers report data for the large group market, small group market, and individual market, as that separation of data will be required in order to calculate the ratios and rebates provided for in PHS Act section 2718(b). There is currently more than one option for how to distinguish the small group market and the large

group market. The small and large group markets, respectively, refer to coverage sold to a "small employer" or a "large employer." The determination of whether an employer is large or small depends on how many employees it has at particular times. Prior to the Affordable Care Act, the PHS Act defined a small group in terms of 2-50 employees, and a large group in terms of 51 or more employees, while a group with only one employee was considered to be in the individual market. However, the States were permitted to regulate very small groups ("groups of one") in the small group market rather than the individual market. While most States used the statutory definition, several States have chosen to regulate these very small groups in the small group market.

Section 1304(b) of the Affordable Care Act amended the definitions of large and small employer in the PHS Act, defining a small employer as 1-100 employees and a large employer as 101 or more employees. However, section 1304(b)(3) of the Affordable Care Act also allows States to continue to define an employer with up to 50 employees as a "small employer" until 2016.

This interim final regulation provides that for purposes of section 2718 of the PHS Act, consistent with the provisions in the Affordable Care Act, until 2016 a State may continue to provide a definition of small group as having a maximum of 50

members, and that for States that do so, that definition shall apply to the MLR reporting and rebate requirements set forth in section 2718. This regulation does not address the definition of the term "small employer" as used in ERISA or the Internal Revenue Code, or how the definition in these statutes interact with the definition in the PHS Act for purposes other than the MLR provisions in section 2718. We anticipate that these provisions will be addressed in future guidance.

C. Subpart A – Disclosure and Reporting

1. Reporting Requirements (§158.110)

Section 2718(a) of the statute requires issuers to submit a report to the Secretary for each plan year concerning information related to earned premiums and expenditures in various categories, including reimbursement for clinical services provided to enrollees, activities that improve health care quality, and all other non-claims costs. In §158.110 of this interim final regulation, HHS requires that the report be submitted to the Secretary by June 1 of the year following the end of an MLR reporting year. This allows issuers to include in the report claims for services provided during the MLR reporting year that are processed and paid in the three months following the end of the MLR reporting year, as provided in §158.140(a)(1), and gives issuers another two months to compile and submit the required data. As discussed in sections 4. and

5. below, mini-med plans and expatriate plans wishing to receive the "special circumstances" adjustment discussed in those sections would be required under §158.110(b)(1) to submit data on an accelerated schedule.

The precise form and content of the data that issuers must report to the Secretary will be announced in a subsequent *Federal Register* notice. It is anticipated that the data to be submitted will be closely coordinated with the data included on the Supplemental MLR Exhibit that is filed by issuers with State departments of insurance as part of their Annual Statement.

A common practice in insurance is the sale or transfer of blocks of policies between issuers. This practice creates two issues for the reporting requirements under section 2718 of the PHS Act. Consistent with the NAIC's recommendation, §158.110(c) requires an issuer that has ceded all of the risk associated with a block of policies to another issuer to exclude any experience under those policies from its report. As specified in §158.110(c), the issuer acquiring the policies must report all of the claims, premium and expenses associated with the acquired policies, including claims and costs incurred and premiums earned during the MLR reporting year by the ceding issuer prior to the effective date of the agreement to transfer responsibility for the policies. The ceding issuer must not include experience under these policies in its report to the

Secretary. A second practice in insurance with implications for the reporting requirements under section 2718 of the PHS Act is the use of so-called "assumption reinsurance" to transfer a block of business or group of insurance policies from one issuer to another.

2. Aggregate Reporting (§158.120)

Section 158.120 of this interim final regulation requires issuers to report premium, claims and other expenses for all group and individual health insurance coverage (as defined above) on an aggregate basis by State and health insurance market. This follows the approach recommended by the NAIC. That is, a health insurance issuer will submit, for each State in which it writes coverage, data on the aggregate premiums, claims experience, quality-improvement expenditures, and non-claims costs it incurs in connection with the policies it issues in the large group, small group, and individual markets. HHS believes that reporting by State is clearly intended in section 2718 of the PHS Act, which allows a State to set a higher MLR standard than the 80 or 85 percent required by the statute. Reporting by health insurance market - i.e., by large group, small group, and individual markets - is also required by section 2718 of the PHS Act, which requires that MLR standards be met for each such market. The experience for group coverage issued by a single issuer that covers employees in multiple

States must be attributed to the State that regulates the insurance contract between the employer and the issuer, as stated in §158.120(b) of this interim final regulation. Section 158.120(d) also (1) specifies how to attribute experience related to policies sold through associations and trusts, (2) establishes special rules that should be followed in reporting experience under group health insurance coverage offered by multiple affiliated issuers in connection with a single group health plan that gives participants a choice of coverage options, and (3) provides for separate reporting in 2011 for mini-med plans that have a total annual limit of $250,000 or less and for expatriate plans.

The aggregation rules adopted in the regulation are designed to accomplish several objectives. First, the data that are reported and subsequently used to calculate MLRs and rebates should be based on sufficient experience to provide a reliable estimate of the issuer's administrative performance and pricing strategy. To the extent possible, the data used to calculate the MLRs and rebates should not simply represent unpredictable fluctuations in use of services by those covered by the issuer. Second, the reported data should reflect the responsibility of State insurance departments to (1) license issuers to sell insurance within a State (and, where applicable, to approve the products that can be offered in the State by the issuer), and

(2) exercise oversight over the premium amounts that are charged for coverage. Third, HHS sought to minimize the burden associated with reporting MLR data, including the quality-improvement expense and non-claims costs that would be reported in connection with each "aggregation."

In developing the regulation, a rule was considered that would disaggregate products by type of coverage—for example, HMO, PPO, and high-deductible coverage—even if offered by the same licensed issuer. The purpose of such a disaggregation would be to have the reported MLRs and rebates reflect experience under more uniform product designs, and to reduce possible inequities in the treatment of different types of plans. However, disaggregation would increase the number of reporting aggregations since one licensed issuer could have to report multiple aggregations, thus reducing the reliability of reported experience and rebates. HHS agrees with the NAIC and has decided against this type of disaggregation. In response to the Request for Comments, commenters generally supported aggregation by State and, within State, by the three market segments identified in the statute: the large group market, the small group market, and the individual market. Consumer advocacy groups generally noted that aggregation would tend to mask variations in MLRs across products. However, other commenters noted that aggregation across policies is needed to

calculate reliable MLRs and to reflect the pooling of risk across policies or policy forms. After considering the arguments presented by the commenters, as well as public comments submitted to the NAIC, HHS decided to follow the recommendations submitted to the Secretary by the NAIC and aggregate at the market level within each State, for reasons described below.

a. Attribution to State-of-Issue

The regulation requires issuers to report experience based on the State-of-issue for each policy that it writes. This requirement is intended to result in a report that describes experience under policies whose benefits and premiums either are regulated, or could be regulated, by a State, since it is at the State level that insurance regulation occurs. The regulation generally defines the State-of-issue based on the "situs" of the insurance contract between the issuer and the policyholder. HHS defines "situs" as the State in which the contract is issued or delivered as stated in the contract. Consistent with NAIC guidance, HHS interprets this as the State that has primary jurisdiction over, or governs, the policy. Special rules that apply to determining the "situs" of a policy marketed to individuals and employers through associations or trusts are discussed below.

The NAIC concluded, and the Department agrees with its

conclusion, that the State is the appropriate level of geographic aggregation. Regulation of insurance has been and continues to be primarily the responsibility of States. Benefits offered, premiums, and marketing activities are all regulated under State law. It is the States that review and approve rates, and oversee solvency, and rebates are essentially a retrospective adjustment or correction to premiums. In addition, the statute specifically provides an opportunity for individual States to adopt loss ratio standards that are higher than those required by section 2718(b). It also allows for State-by-State adjustments to the medical loss ratio standard when justified by potential destabilization in the individual market. Applying State-level and State-specific MLR standards would be difficult if experience were aggregated across States that may have different MLR standards. Adopting the State as the basic unit of geographic aggregation will make the reports submitted under section 2718 more meaningful to the exchanges. The Department agrees with the NAIC determination and has decided not to aggregate the experience of a single issuer across States. A rule that would permit aggregation of experience across issuers with common ownership was also considered. Under such a rule, the experience of all issuers owned by a common holding company or corporate group would be combined. Aggregation across such affiliated issuers would have

two possible advantages: it would increase the total experience used to prepare the report, thereby increasing the reliability of the data for smaller issuers; and it would combine similar coverage provided in the same market by two related companies. However, aggregation across affiliated issuers might also combine the experience of issuers offering dissimilar coverage or that use different pricing policies. HHS has concluded, as did the NAIC, that reporting should not be done at the level of the holding company in this interim final regulation.

In response to both the April request for information notice and the NAIC's solicitation of comments, extensive comments were received from issuers, regulators, and consumers. In general, comments received from regulators and consumers supported aggregation at no higher than the State level. The reasons given for State aggregation included consistency with the statute, greater meaningfulness of State-level information to consumers and purchasers, consistency with the responsibility of the States for regulation of issuers and oversight of insurance premiums, and the calculation of rebates that appropriately reflect the relationship between premium and claims experience. Many health issuers also recommended aggregation at the State level, although some recommended aggregation at the national level for coverage sold to large employers. Advocates of aggregation at a national level pointed

to the greater reliability of reported loss ratios when based on the experience of the combined national enrollment of an issuer and, in the case of large group coverage, the use of experience rating for national or regional employers, and the complexity of allocating certain expenses, particularly Federal taxes, to experience within a single State. Several comments addressed aggregation at a geographic region smaller than a State. Reasons identified for regional aggregation within a State included claims of geographic variations within States of utilization and expenditure patterns and differences across issuers in geographic adjustments that are used to set premiums.

The NAIC considered the arguments made for different approaches to geographic aggregation, including the issues related to multi-State level employers, and decided that aggregation should be at the State level. HHS agrees with and adopts the NAIC's approach. As discussed previously, particularly as to the individual and small group markets, State aggregation is most consistent with the requirements of the statute, particularly provisions permitting State-level exceptions to the minimum loss ratio, and will result in information that is more meaningful to consumers. In addition, aggregation at a national level would preclude States' flexibility to set higher MLR standards as prescribed in the Affordable Care Act. Aggregation at the State level will also

ensure value for their health care dollars for consumers in every State.

Some issuers have expressed concern that the reporting and rebate requirements recommended by the NAIC, and adopted in this regulation, would disadvantage large or multi-state employers, including those with a small number of employees in one State and a larger presence in another. This regulation does not require these businesses to change the manner in which they operate, and accommodates issuers that provide coverage to such employers in a number of ways.

First, where an issuer insures employees of a business located in multiple States, the NAIC recommended and HHS agrees that MLR reporting should be based on the "situs of the contract." Under this approach, incorporated in this regulation, the premiums and claims experience attributable to employees in multiple States are combined and reported by the issuer in the MLR report for the State identified in the insurance policy or certificate as having primary jurisdiction over the policy - often the headquarters of the company. This avoids separating the experience of employees from a single company in multiple States.

Second, the NAIC recommended, and HHS adopts, combined reporting across affiliates for "dual contracts." Under these types of insurance contracts, a single group health plan obtains

coverage from two affiliated issuers, one providing in-network coverage, and a second affiliate providing out-of-network benefits to the plan. The experience of these two affiliated issuers providing coverage to a single employer can be combined and reported on a consolidated basis as if it were entirely provided by the in-network issuer. This maintains the experience of employees in a single reporting entity.

Thirdly, where affiliated issuers offer blended insurance rates to an employer – rates based on the combined experience of the affiliates serving the employer – the NAIC recommended and HHS agrees that the incurred claims and expenses for quality improving activities can be adjusted among affiliates to reflect the experience of the employer as a whole.

Taken together, these provisions recommended by the NAIC and adopted by HHS are a reasonable accommodation of the needs of affiliated issuers and the multi-state employers for which the issuers provide coverage.

b. Attribution to Health Insurance Markets Within States

The interim final regulation requires issuers to report experience within a State for each of the three markets referenced by the statute: the individual market, the small group market and the large group market. Experience under a health insurance policy or certificate is to be attributed to the individual market if the policy is not offered in connection

with a group health plan, as defined by the PHS Act.

In response to the April request for information notice, HHS received extensive comments on a separate aggregation question: whether to combine the small group and individual markets. In general, comments supported separate reporting for the individual, small group, and large group markets. Concern was expressed that merging any of these markets would tend to conceal differences in medical loss ratios and perpetuate the pricing of individual or small group policies to achieve a medical loss ratio substantially below the minimums specified in the statue. On the other hand, HHS received comments from both regulators and industry supporting the consolidation of the individual and small group markets, and some comments recommended giving issuers the option of combining or not combining the individual and small group markets. Consolidated reporting could increase the reliability of reported loss ratios by reflecting a larger base of experience. However, it could also deprive consumers in one of these markets of the value of the statutory MLR standard.

The NAIC, in its model regulation, permits an issuer to combine the individual and small group markets for purposes of calculating the MLR rebate if the State in which the coverage is issued requires that the two markets be combined for rating purposes. HHS adopts this approach. This exception is

consistent with section 1312(c)(3) of the Affordable Care Act, which allows a State to require the merger of the individual and small group markets. Under such a merger, risk is pooled between individuals and small groups, and it would be appropriate to base rebates on the combined experience in the two markets. While we agree with this approach, it is important that the experience of the small group and individual markets be reported separately even if experience is combined for purposes of calculating the MLR, for a number of reasons. The statute allows the Secretary to adjust the MLR percentage in the individual market of a State if the Secretary determines that the application of the 80 percent MLR may destabilize the individual market in that State. Also, the law states that the Secretary may adjust the MLR "if the Secretary determines appropriate on account of the volatility of the individual market due to the establishment of State Exchanges." In order for the Secretary to make these determinations, reporting of data for the individual market is needed. Separately reported data will also enable HHS to evaluate the impact of the MLR standards on the market, consumers, and the industry, and to consider making changes to the interim final regulation as appropriate based on actual experience.

HHS has considered the arguments made for different approaches to aggregation across markets. It has decided to

follow the recommendation to the Secretary submitted by the NAIC and require separate reporting of experience by the three markets.

c. Associations or Trusts

The aggregation rules, in §158.120(d), adopts the NAIC's approach and also provide guidance for insurance coverage offered through associations or trusts. Under the definition of "group health insurance coverage," only coverage offered to individuals through associations or trusts that are offered in connection with a group health plan should be attributed to the group market. Coverage obtained through an association or trust that is not offered in connection with a group health plan should be attributed to the individual market. Although such coverage is generally considered to be "group" coverage under the conventions of statutory accounting, it is to be reported as individual coverage consistent with the requirements of the PHS Act. This is consistent with ERISA's definition of group health plan, as incorporated in title XXVII of the PHS Act, as well as the NAIC's recommended approach. Although such coverage is generally considered to be "group" coverage for other purposes (for example, the conventions of statutory accounting), this interim final regulation requires non-employment based coverage to be reported as individual coverage consistent with the requirements of the PHS Act. As noted earlier, this interim

final regulation does not apply to self-insured plans, including self-insured plans offered through an association or trust.

d. Expatriate Plans

The NAIC model regulation does not address the special circumstances of different types of plans, such as expatriate plans and plans with low annual limits, commonly called "mini-med" plans. However, in a letter dated October 13, 2010 to the Secretary of Health and Human Services, the NAIC expressed its opinion that expatriate plans should be excluded from the requirements of section 2718. HHS has considered the NAIC's views, as well as the public comments received by HHS and by the NAIC regarding these types of plans. Expatriate policies generally cover: employees working outside their country of citizenship; employees working outside of their country of citizenship and outside the employer's country of domicile; and citizens working in their home country. Their unique nature results in a higher percentage of administrative costs in relation to premiums than plans that provide coverage primarily within the United States, for two reasons. One, administrative costs are related to identifying and credentialing providers worldwide in countries with different licensing and other requirements from those found in the United States, processing claims submitted in various languages that follow various billing procedures and standards, providing translation and

other services to enrollees, and helping subscribers locate qualified providers in different countries. Two, because these plans primarily cover care in other countries, issuers are less able to provide quality improving activities.

We note initially that some expatriate plans are not subject to the provisions of the Affordable Care Act, including the MLR reporting and rebate provisions of section 2718. Policies issued by non-U.S. issuers for services rendered outside of the U.S. are not subject to the Affordable Care Act. Therefore, if an expatriate policy is written on a form that was not filed and approved by any State insurance department, or its equivalent, experience under that policy would not be reported for purposes of calculating an issuer's MLR.

HHS agrees with the NAIC that expatriate policies that are issued by U.S. domestic issuers on forms approved by a State insurance department have special circumstances that should be addressed in this interim final regulation. Therefore, the experience of these expatriate policies is to be reported separately from other coverage, as provided in §158.120(d)(4), and the calculation of claims and quality improving activities is to be multiplied by a factor of two, as provided in §158.221(b). HHS believes that this factor is sufficient to account for the special circumstances of expatriate plans, while still requiring that they meet the statutory MLR standards.

However, because HHS thinks additional data is necessary to inform this adjustment, this special circumstance adjustment applies for 2011 only. Also, in order to determine whether, and if so what type of, an adjustment may be appropriate for 2012, expatriate plans that wish to avail themselves of this special circumstances adjustment in §158.221(b)(4) for 2011 will be required to report MLR data on a quarterly schedule under §158.110(b). We will revisit the special filing circumstances for expatriate plans after reviewing the quarterly filings.

e. "Mini-med" Plans

HHS has received requests from issuers of so-called mini-med plans to be exempted entirely from the MLR and rebate provisions of section 2718. The term "mini-med" plan does not have a statutory basis, and we use it here to generally refer to policies that often cover the same types of medical services as comprehensive medical plans but have unusually low annual benefit limits, often capping coverage on an annual basis for one or more benefits at $5,000 or $10,000, although some have limits above $50,000 or even $250,000. Our analysis of this segment of the insurance market suggests that a large majority of such plans have limits at or below $250,000. As discussed below, we therefore are using this figure as a proxy for capturing this type of plan.

Issuers of mini-med plans assert that their administrative

costs are higher as a percentage of the premium collected than is the case for plans having higher annual limits and thus a higher premium base. They assert that they have special administrative burdens because the populations they serve generally have high turnover rates. This high turnover rate may also result in lower claims costs. Mini-med plans are also less likely to spend as much on quality improving activities because of their lower annual limits. Both of these factors would result in administrative costs being a higher percentage of premium dollars than for plans with higher amounts of coverage. These issuers therefore ask that mini-med coverage be exempted entirely from the requirements of section 2718, and have indicated that in the absence of an exemption some may no longer be able to offer coverage. Some consumer groups have disagreed, suggesting that mini-med plans have higher profit margins than do traditional plans with significantly higher limits and should not be exempt from the MLR standards. The Blue Cross and Blue Shield Association sent a letter to Secretary Sebelius on November 1, 2010 in which it urged that HHS not grant "any MLR exceptions for particular companies or product types." However, an issuer, which according to company materials has a relationship with the Blue Cross and Blue Shield system and provides coverage to at least one large employer, asserted that the company would be forced to drop this coverage without an

exemption.

The application of the Affordable Care Act to mini-med plans has already arisen in the context of restrictions on annual benefit limits under section 2711 of the PHS Act. HHS has established a process under which certain health plans with annual limits below those established in the interim final regulation implementing section 2711 may be granted a temporary waiver from the application of higher limits if compliance with the standards would result in a significant decrease in access to benefits or a significant increase in premiums. See 26 CFR §54.9815-2711T; 29 CFR §2590.715-2711; 45 CFR §147.126; and OCIIO Sub-Regulatory Guidance (OCIIO 2010 - 1), September 3, 2010. Data from the applications for waivers described above suggest that over one million individuals have coverage in mini-med plans. There are little publicly available data on these plans because current financial reporting to the States does not separate mini-med experience from other experience on which issuers report.

HHS is concerned about the possibility of the over one million individuals who have coverage through mini-med plans losing that coverage. Based on this concern and the limited data that indicate mini-med plans may have a higher percentage of administrative costs due to lower claims and quality improving activities, HHS has decided to exercise its authority

in section 2718(c) to "take into account the special circumstances of smaller plans, different types of plans, and newer plans."

Therefore, for the reporting year 2011, HHS will apply a methodological change to address the special circumstances of mini-med plans. The mini-med issuers, for policies that have a total of $250,000 or less in annual limits, will be permitted to apply an adjustment to their reported experience to address the unusual expense and premium structure of these plans. Specifically, under §158.221(b)(3), in the case of a plan with a total of $250,000 or less in annual limits, the total of the incurred claims and expenditures for activities that improve health care quality reported under §158.221(b) are multiplied by a factor of two. We believe this factor is sufficient to account for the special circumstances of mini-med plans based on the limited data available.

Because little information is available to inform this adjustment, this special circumstances adjustment applies for 2011 only. Also, in order to determine whether, and if so what type of, an adjustment may be appropriate for 2012, mini-med plans that wish to avail themselves of this special circumstances adjustment in §158.221(b)(3) for 2011 will be required to report MLR data on a quarterly schedule under

§158.110(b). We will revisit the special filing circumstances for mini-med plans after reviewing the quarterly filings.

3. Newer Experience (§158.121)

Section 2718(c) specifically charges the NAIC with establishing methodologies that take into consideration the special circumstances of newer plans. HHS follows the NAIC's approach in the model regulation, which allows an issuer to defer the experience associated with newly issued health insurance policies under certain circumstances. Specifically, an issuer may defer to the next MLR reporting year the premium and claims experience, as well as the life-years, associated with policies first issued after the start of the MLR reporting period if these policies account for more than half of the issuer's experience in a market segment for an individual State. This condition means that more than half of an issuer's overall premium revenue for a market sector within a State would have to be from newly issued policies that are issued after the first of the year.

The rationale for this provision, as set forth by the NAIC and certified and adopted herein by HHS, has two parts: (1) the rationale for deferring experience under newly issued policies; and (2) the rationale for limiting the deferral of experience to issuers that derive more than half of their premium revenue from newly issued policies. The rationale for deferring experience

under newly issued policies is that claims experience is generally expected to be substantially less than the premium revenue from those policies during the year in which the coverage is issued. This is particularly true for policies with substantial deductibles. Applying the rebate provision to these policies would create a substantial barrier to the entry of new issuers into a market.

The rationale for allowing the deferral of experience only when more than half of the premium revenue is derived from newly issued policies is twofold. First, if newly issued policies account for a small percentage of an issuer's total experience in a market, they would have a very limited effect on the aggregated MLR for an issuer. Second, the principal purpose of allowing the deferral of newly issued business in the MLR calculation is to reduce barriers to market entry. Because claims experience is generally low compared to premiums under newly issued policies, including new business would generally result in lowering an issuer's MLR simply because of the new business. Deferral of reporting new business encourages companies to enter new markets, and new companies to enter the market.

In response to the HHS notice requesting public comments regarding section 2718 of the PHS Act, HHS received comments from issuers, consumer advocates, and providers urging that

special consideration be given to newer plans. Reasons for this included concern both about the effect on the market if newer plans are not given special consideration, and about the impact on the reliability of reported MLRs if newer plans' experience is included. HHS agrees with these concerns and addresses them by adopting, in §158.121, the NAIC's method for recognizing the special circumstances of issuers that have substantial new business.

4. Premium Revenue (§158.130)

Section 2718(a) of the PHS Act requires health insurance issuers to report information concerning "earned premium," and section 2718(b) provides that these reported data would be used in determining rebates to enrollees. Section 2718(c) charges the NAIC with establishing a uniform definition of premium revenue, subject to certification by the Secretary. HHS is adopting the NAIC definition of premium revenue, as described below.

The NAIC defines "earned premium" as the sum of all monies paid by a policyholder as a condition of receiving coverage from a health insurance issuer subject to section 2718, including any fees or other contributions associated with the health plan, and accounting for unearned premiums. HHS is adopting this NAIC approach in §158.130(a), and these adjustments to earned premium are discussed below. The NAIC calls for reporting of premium on

a direct basis as set forth in §158.130(a)(1). Earned premium is addressed in §158.130 and includes any fees or other contributions associated with the health plan.

Adjustments to premium revenue are addressed in §158.130. Unearned premium is that portion of the premium paid in the MLR reporting year for coverage during a period beyond the MLR reporting year. Any premium for a period outside of the MLR reporting year must not be reported in earned premium for the MLR reporting year. Earned premium is net of premiums associated with group conversion charges that the issuer collects in connection with transfers between group and individual lines of business. Group conversion charges are the portion of earned premium allocated to providing the privilege for a certificate holder terminated from a group health plan to purchase individual health insurance without providing evidence of insurability. In addition, earned premium excludes premium assessments paid to or subsidies received from Federal and State high risk pools. High risk pool subsidies include grants provided under section 2745 of the PHS Act. Earned premium excludes adjustments for experience rating refunds, as provided in §158.130(b). Experience rating refunds are retrospective premium adjustments arising from retrospectively rated contracts.

Earned premium is to be reported prior to deducting premium

refunds to enrollees for health and wellness promotion. These refunds are considered quality improvement expenditures, so they should not be double counted as a reduction in premium, as provided in §158.130(b)(4).

We have adopted the NAIC's approach to assumption and indemnity reinsurance, in §158.130(a)(2) and (3). Earned premium for policies that originally were issued by one entity and later assumed by another entity via assumption reinsurance are to be reported as direct earned premium by the assuming entity and are to be excluded from premium revenue reported by the ceding entity. Similarly, if a block of business was subject to indemnity reinsurance and administrative agreements effective prior to the effective date of the Affordable Care Act, such that the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, then the assuming entity and not the ceding entity should report the reinsured earned premium as part of its premium revenue.

Section 2718 makes specific reference to "Federal and State taxes and licensing or regulatory fees" in two places: first, in the reporting requirements of subsection (a) it excludes these items from "all other non-claims costs"; second, it excludes these costs from premium revenue in determining the ratio of expenditures on claims and activities to improve

quality health care to premium revenue. For reporting purposes, therefore, taxes are excluded from "all other non-claims costs," and are addressed in §§158.161 and 158.162, separate from but immediately following the requirements set forth in §158.160 related to reporting of non-claims costs. Taxes are also discussed in the section of this preamble describing calculation of the MLR.

The PHS Act section 2718(a) requires reporting of "premium revenue, after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance." Because this language so closely parallels the three programs added by the Affordable Care Act (the transitional reinsurance program established by section 1341; the risk-corridor program established by section 1342; and risk-adjustments under section 1343 of the Affordable Care Act), we interpret this requirement as applying exclusively to payments under those provisions, which are not effective until 2014. HHS anticipates providing guidance on these provisions at a later time. Consistent with the statute, §158.130(b)(v) of this interim final regulation treats payments and collections under these provisions of the Affordable Care Act as adjustments to premium revenue.

In response to the HHS notice requesting public comments regarding section 2718 of the PHS Act, HHS received a number of comments from the industry regarding premium revenue. A few

industry commenters recommended adjusting premium revenue for the change in unearned premium reserves. HHS agrees that changes in unearned premium reserves should be reflected in premium revenue, and has provided for this in §158.130(a). A few industry commenters recommended adjusting premium revenue for commercial reinsurance ceded and assumed. HHS is not adjusting premium revenue for commercial reinsurance (with the exception of 100 percent assumption reinsurance) because this largely would provide a tool for issuers to manipulate reported premiums.

The NAIC considered allowing an adjustment to premium for commercial stop-loss or similar reinsurance, but rejected allowing such adjustments. We adopt the reasoning and recommendation of the NAIC. The argument for allowing such adjustments for reinsurance was that it might increase the reliability of the medical loss ratio that is used for purposes of calculating rebates. However, the NAIC concluded that allowing adjustments for reinsurance created too much of an opportunity for manipulation of the reported loss ratio and would require extensive and complex regulation of the use of reinsurance. An industry commenter suggested subtracting experience rating refunds from premium revenue. The NAIC recommended, and HHS agrees, that there should be an adjustment for experience rating refunds. A consumer advocate suggested

that total revenue (including investment income) be used in place of premium revenue, so consumers would know the universe of funds available to be spent on medical services. However, the commenter points out – and both the NAIC and we agree – that the statute instructs issuers to report "premium revenue" and not total revenue.

5. Reimbursement for Clinical Services Provided to Enrollees (§158.140)

Section 2718(a)(1) of the PHS Act requires reporting of "reimbursement for clinical services provided to enrollees under such coverage." The Affordable Care Act charges the NAIC with establishing a uniform definition of reimbursement for clinical services. The NAIC defines reimbursement for clinical services as direct claims paid and incurred claims during the applicable MLR reporting year. In this interim final regulation, HHS is adopting this NAIC approach, at §158.140. The definition and guidance regarding adjustments to claims are discussed below.

The interim final regulation defines incurred claims as the sum of direct paid claims incurred in the MLR reporting year, unpaid claim reserves associated with claims incurred during the MLR reporting year, the change in contract reserves, reserves for contingent benefits, the claim portion of lawsuits, and any experience rating refunds paid or received. Experience rating refunds exclude rebates based on an issuer's MLR, as required by

§158.140. If there are any group conversion charges for a health plan, the conversion charges should be subtracted from the incurred claims for the aggregation that includes the conversion policies, and this same amount should be added to incurred claims for the aggregation that provides coverage that is intended to be replaced by the conversion policies. Incurred claims must not include claims recovered as a result of fraud and abuse programs. Treatment of the amount expended to reduce fraudulent claims is discussed below in the section regarding quality improving activities. Additionally, if the issuer transfers portions of earned premium associated with group conversion privileges between group and individual lines of business in its Annual Statement accounting, these amounts should be added to or subtracted from incurred claims.

Unpaid claims reserves are included in incurred claims. Unpaid claim reserves are the reserves for claims that were incurred during the reporting period but that had not been paid by the date on which the report was prepared. To minimize reliance on estimates for the amount of the reserve, unpaid claim reserves shall be calculated based on claims that have been processed within three months after the end of the MLR reporting year. This claims collection period provides a better estimate of outstanding liability than the reserve established at the end of the MLR reporting year. Claims reserves are

included in incurred claims in order for claims to be paid effectively and to allow for the insurance company to continue operating year after year.

The NAIC includes the change in contract reserves in reimbursement for clinical services, and HHS has followed this approach. The NAIC and this interim final regulation define contract reserves as reserves that are established which, due to the gross premium pricing structure at the time of issue, account for the value of the future benefits that at any time exceeds the value of any appropriate future valuation of net premiums at that time. In the early years of a new product being introduced, reserves are established to cover losses in the future, but as reserves are drawn down to cover current losses the amount collected from reserves will be deducted from claims. An issuer may establish contract reserves to reduce the need to increase premiums for a newly introduced product as the experience under that policy matures. As a policy matures, the reserves that were set aside in the beginning of the policy's existence are used to cover claims that are incurred in the future.

Contract reserves must not include premium deficiency reserves. Premium deficiency reserves are reserves that are established when premium is no longer adequate to cover losses. They are excluded because contract reserves would provide for

these future losses over time to the extent that such losses were anticipated and factored into the premiums charged during the reporting period. Contract reserves shall not include reserves for expected MLR rebates.

Guidance is also provided as to types of expenses or revenue that are to be treated as adjustments to claims. The NAIC recommended that prescription drug costs should be included in incurred claims and prescription drug rebates should be deducted from incurred claims. Prescription drug rebates are rebates that pharmaceutical companies pay to issuers based upon the drug utilization of the issuer's enrollees at participating pharmacies. We agree with the NAIC that drug rebates should be accounted for, and under §158.140(b)(1)(i) we treat such rebates as an adjustment to incurred claims.

The NAIC allows an adjustment to claims for State stop loss, market stabilization, and claims/census based assessments. HHS agrees that these types of expenses should be allowed as an adjustment to incurred claims. These assessments include:

(1) any market stabilization payments or receipts by issuers that are directly tied to claims incurred and other claims based or census based assessments;

(2) State subsidies based on a stop-loss payment methodology; and

(3) unsubsidized State programs designed to address distribution

of health risks across health issuers via charges to low risk issuers that are distributed to high risk issuers.

The NAIC also considered but rejected the inclusion of an adjustment to incurred claims for so-called "large claim pooling" as a means of reducing the need for and magnitude of credibility adjustments. NAIC rejected large claim pooling for two reasons. First, it would not have not addressed the needs of issuers that either are not part of a holding company or company group or that are operate in a single State. Second, it would require extensive and complex regulations and close oversight. We have accepted the NAIC's recommendations.

Incurred medical incentive pools and bonuses to incurred claims are also allowed as an adjustment to incurred claims, and this is reflected in §158.140(b)(2)(iii) of the interim final regulation. Medical incentive pools are arrangements with providers and other risk sharing arrangements whereby the reporting entity agrees to either share savings or make incentive payments to providers. These payments may not be counted under quality improvement expenditures.

HHS received numerous comments from consumer groups, issuers, and regulators regarding whether, and to what extent, reserves should be included in incurred claims. A consumer advocacy group felt that only paid claims should be used, arguing that the use of actual claims paid is reasonable because

the review is historical; this would avoid the possibility of issuers gaming the system by manipulating reserves. However, several issuers and regulators support the inclusion of unpaid claims reserves in incurred claims. A State regulator indicates that the advantage of such inclusion is that it deals only with data for the one year in which claims are incurred, and avoids any distortion due to possible errors in the estimate of the unpaid claim reserve as of the beginning of the year. The disadvantage is that the result is unduly influenced by the unpaid claim reserve as of the end of the year.

HHS acknowledges the consumer group concern for the potential that reserves can be manipulated, and in particular overstated, and can thus produce a reported MLR for a given calendar year that is higher than the true MLR for that year. Nevertheless, over the long run such over-reserving for one year necessarily results in a reduction, or "releasing," of reserves in future years. HHS concurs with the NAIC that including contract reserves in claims is fair to consumers over the long run, and has adopted this approach.

6. Activities that Improve Health Care Quality (§§158.150 through 158.151)

Section 2718(a)(2) of the PHS Act requires health insurance issuers to submit an annual report to the Secretary concerning the percent of total premium revenue that is spent on activities

that improve health care quality. Section 2718(c) of the PHS Act directs the NAIC, subject to certification by the Secretary, to establish uniform definitions of activities that improve health care quality. In developing the definition of a quality improvement activity, the NAIC has relied upon section 2717 of the PHS Act. HHS concurs with the NAIC in this approach and has followed the recommendations of the NAIC.

Section 2717 provides for the development of "reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that—

"(A) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage;

"(B) implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post-discharge

reinforcement by an appropriate health care professional;

"(C) implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology under the plan or coverage; and

"(D) implement wellness and health promotion activities."

The NAIC model regulation contains definitions of activities that improve health care quality that track the categories set forth in section 2717. After considering the NAIC's definitions, and public comments thereon, HHS has decided to certify and adopt them. In addition, the NAIC provided examples to illustrate activities that qualify as quality improving activities and these are also certified and adopted *in toto* in this interim final regulation. Finally, the NAIC designated certain activities as not qualifying as quality improving, and we certify and adopt these exclusions as well.

As recommended by the NAIC, this interim final regulation allows a non-claims expense incurred by a health insurance issuer to be accounted for as a quality improvement activity only if the activity falls into one of the categories set forth in section 2717 and meets all of the following requirements:

(1) It must be designed to improve health quality;

(2) It must be designed to increase the likelihood of desired health outcomes in ways that are capable of being objectively

measured and of producing verifiable results and achievements;
(3) It must be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees; and
(4) It must be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations. These criteria are recommended by the NAIC in its model regulation.

In this interim final regulation HHS recognizes that some quality improvement activities may be what are sometimes referred to as "population-directed" and may not involve face-to-face interaction between an employee of the health insurance issuer (or a contractor of the issuer) and the enrollee. However, such activities must be directed to identified segments of the issuer's enrollees. The issuer must be able to measure the level of engagement with these enrollees in addition to tracking the effect(s) of these activities on health outcomes in this population through a process that is well defined, well developed, and utilized.

Any quality improvement activity that results in cost

savings to an issuer should not, by itself, cause expenditures on that activity to be classified as non-quality improving expenditures, if they meet the criteria set forth in this interim final regulation. However, if the activity is designed primarily to control or contain costs, then expenditures for it may not be included as a quality improvement activity, as provided in §158.150(d). This approach follows the NAIC's model regulation.

As many quality improvement activities are fluid in nature, they may properly be classified in more than one quality improvement activity category. However, following the recommendation of the NAIC, the interim final regulation does not permit issuers to count any occurrence of a quality improvement activity more than once, as explained in §158.170(a). Moreover, shared expenses among related entities as well as expenses that are for or benefit lines of business or products other than those being reported, including self-funded plans, must be apportioned among the entities and among the lines of business or products. For example, a quality improvement program that is developed and implemented for self-funded plans and fully insured plans must be pro-rated among the lines of business, and the portion of expenditures for the program that are for the self-funded plans may not be included in quality improvement activities reported under section 2718(a)

of the PHS Act.

The NAIC recommended, and HHS adopts in its entirety, the list of activities that are not to be reported as a quality improving activity. Section 158.150(c) sets forth types of activities that are not to be reported as a quality improvement activity. These include:

(1) Those activities which are designed primarily to control or contain costs;

(2) Concurrent and retrospective Utilization Review;

(3) Fraud Prevention activities (beyond the scope of those activities which recover incurred claims);

(4) Development, execution, and management of a provider network;

(5) Provider credentialing;

(6) Marketing expenses;

(7) Costs associated with calculating/administering individual enrollee or employee incentives;

(8) Clinical data collection without any subsequent data analysis

(9) Establishment and/or maintenance of a claims adjudication system; and

(10)24-hour customer service/or health care professional hotline addressing non-clinical member questions.

HHS requested public comments regarding the types of

activities that would improve the quality of health care. Numerous consumer advocacy groups, issuers, State regulators, and other interested parties responded with various suggestions as to the type of activities that should be included in the definition of quality improving activities.

Many issuers and interest groups advocated for a broad definition for 'quality improving activities' that allows for future innovations. However, numerous providers and consumer advocacy groups asserted that HHS should develop a definition for 'quality improving activities' that is not so broad that issuers may improperly classify administrative activities as improving quality. Several commenters also advocated for a definition that requires issuers to clearly articulate the activity's purpose and to provide detailed accounts of the underlying activity with measurable evidence as to the effects of the activity on the quality of care received by enrollees.

This interim final regulation provides a set of criteria in §158.150 which issuers must comply with in order for the activity in question to be treated as improving quality. The definition, or foundational criteria, of a quality improvement activity should be specific enough so as to provide clear guidance without overly prescribing acceptable activities and possibly stifling future innovative quality improving activities; the NAIC's definition which we have adopted achieves

these goals.

Numerous consumer groups advocated for a definition that includes only evidence-based quality improving initiatives, and excludes alleged quality-improving activities that have not been demonstrated to improve quality. Some consumers and providers want issuers to provide specific data illustrating the success of a proposed quality improving measure prior to HHS acknowledging the validity of such an activity. Issuers argue, however, that imposing a specific data requirement prior to engaging in a quality improvement activity will stifle development in future innovations, as data demonstrating the effectiveness of such activity may not yet be available.

The NAIC recommended and HHS agreed that, as provided in §158.150, a quality improvement activity is "grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized medical associations, accreditation bodies, government agencies, or other nationally recognized health care quality organizations." This interim final regulation further requires any proposed quality improving activities to be designed to improve the quality of care received by an enrollee and capable of being objectively measured (taking into account the individual needs of the patient) and of producing verifiable results and achievements. While an issuer does not have to present initial evidence

proving the effectiveness of a quality improvement activity, the issuer will have to show measurable results stemming from the executed quality improvement activity.

A consumer advocacy group called for issuers to be required to spend a specified percentage of premiums on preventive and health-lifestyle promotional activities. Several interested parties, including issuers, other interest groups and providers, asserted that capping or limiting quality improvement initiatives would deter issuers from engaging in such activities. Issuers further commented that although these types of activities "add value to the health care system," issuers would be deterred from engaging in such activities if HHS limited the amount an issuer could spend on quality improving activities.

The Affordable Care Act does not dictate the amount an issuer must expend on quality improving activities, nor did the NAIC make a recommendation in this regard, nor does this interim final regulation. Section 158.150 requires that a quality improvement activity be provided by an issuer or through a third party to whom it delegated such responsibilities by contract in connection with which the issuer remains ultimately responsible for the underlying insurance policy. In calculating its MLR, an issuer may allocate any percentage of its expenses to quality improvement activities, so long as the activities comply with

the criteria established under §158.150.

Some industry groups argued that network fees associated with third party provider networks should be classified as quality improving activities, because they increase enrollees' access to providers. Consumer groups argued that these fees are traditional administrative expenses which should not be classified as improving quality. While HHS agrees that administrative expenses such as network fees should not be counted as quality improving, some traditional administrative activities can qualify as quality improving if they meet the criteria set forth in §158.150. For example, expenses for prospective utilization review and fraud recovery activities up to the amount of fraudulent claims recovered may be classified as expenses for quality improving activities. Prospective utilization review is considered a quality improving activity because it is rendered before care is given and can help ensure that the most appropriate medical treatment is given in the most appropriate setting. In contrast, the network fees associated with third party provider networks do not stem from a quality improving activity and therefore only count as an administrative expense.

Issuers pointed out that the recovery of fraudulently paid claims reduces their MLR. They argued, therefore, that costs of preventing and discovering fraud should be counted as a quality

improving activity; otherwise, there would be a reduced incentive to incur these costs. We agree with this concern. The NAIC model regulation addresses this concern by allowing fraud recovery expenses as a quality improving activity expense up to the amount of fraudulent claims recovered. This treatment would help mitigate whatever disincentive might occur if fraud recovery expenses were treated solely as non-claims and non-quality improving expenses. We adopt the NAIC's approach.

HHS also adopts the NAIC's recommendation to exclude the conversion of International Classification of Disease code sets from ICD-9 to ICD-10 as a quality improvement activity with the following qualification. As a general matter, the development and maintenance of claims adjudication systems are not designed primarily to improve the quality of care received by an individual and, therefore, are not classified as a quality improvement activity. However, there is general recognition that the conversion to ICD-10 will enhance the provision of quality care through the collection of better and more refined data. The difficulty is in parsing expenses associated with ICD-10 conversions that may be solely "development and maintenance of claims adjudication systems" as opposed to those that are uniquely conversion costs. As with some other reporting categories defined in this regulation, little public data currently exist to guide decision making regarding this

distinction. Although the NAIC excluded these costs as a quality improving activity, the NAIC supplemental forms allow for the collection of data relating to the conversion for the calendar year 2010 that will be reported in 2011. HHS intends to examine the reported conversion costs along with other quality activity costs and other administrative costs in the NAIC supplemental form in 2011 to determine whether the policy in this regulation should be revisited. HHS solicits further comments on whether ICD-10 expenses should be included as a quality improving activity.

Health Information Technology (Section 158.151). Section 158.151 of this interim final regulation provides guidance on the use of Health Information Technology ("HIT") in conjunction with quality improving activities. Although HIT is not specifically addressed in section 2718(a) of the PHS Act, it is addressed in other provisions within the Affordable Care Act, and HHS has determined that it is important to address HIT's role in quality improvement activity. HHS recognizes HIT as its own separate category of quality improving activities, provided that the use of HIT meets certain requirements. In doing so, HHS has followed the approach of the NAIC.

HIT offers providers, issuers and patients the capability to share clinical information in a real-time setting. Any HIT expenditure that is attributable to improving health care,

preventing hospital readmissions, improving patient safety and reducing errors, or promoting health activities and wellness to an individual or an identified segment of the population, is classified as a quality improvement activity. HIT resources that are designed to improve the quality of care received by an enrollee include the provision of electronic health records and patient portals, as well as the monitoring, measuring, and reporting of clinical effectiveness measures. As indicated in §158.151, HIT expenses that are consistent with Medicare/Medicaid meaningful use requirements may be treated as an expenditure to improve health care quality. This treatment of HIT is also recommended by the NAIC.

7. Other Non-Claims Costs (§158.160)

The report required by section 2718(a) of the PHS Act must include information on expenditures for "all other non-claims costs, including an explanation of the nature of such costs, and excluding Federal and State taxes and licensing or regulatory fees." "Other non-claims costs" refers to expenditures that are not used to adjust premiums, incurred claims, or activities that improve quality care. HHS interprets this to mean that issuers must account for the use of all premium revenue, not just claims expenses and expenses to improve quality. The NAIC includes in these non-claims expenses sales expenses, agents' and brokers' fees and commissions, other taxes, community benefit

expenditures, and general administrative expenses. HHS supports the NAIC approach to defining non-claims costs and has followed it in §158.160 of this interim final regulation. For example, direct sales salaries and work force salaries and benefits should be allocated as non-claims costs unless a specific position can be directly correlated with an activity that improves health care quality, as defined in this regulation. The NAIC's inclusion of "other taxes" as non-claims expenses does not refer to taxes that section 2718(a) of the PHS Act excludes from "all other non-claims costs" and which section 2718(b) allows to be excluded from premium revenue. Rather, "other taxes" refers to taxes that may not be excluded from premium revenue, such as taxes of a foreign country and sales taxes (excluding State sales taxes) if an issuer does not exercise the option of including such taxes with the cost of goods and services produced. Another type of expense included in non-claims costs is cost containment expenses not included as an expenditure related to a quality improving activity under §158.150.

Notably, in correspondence with HHS, the NAIC raised concerns regarding the potential impact of this regulation on agents' and brokers' fees and commissions. Some companies in some States may be particularly reliant on producers to distribute their products. Agents and brokers perform a range of

functions on behalf of consumers and companies. In some cases, issuers may have entered into longer term compensation arrangements with agents and brokers which the MLR standard may stress. The NAIC considered, but declined to incorporate in the model regulation, special treatment for such expenses in the MLR calculations. The NAIC opted instead to establish a working group with HHS to address the impact of the Affordable Care Act on agents and brokers, especially during years leading up to 2014. As discussed below, the potential impact of the MLR standard on agents and brokers merits recognition, and in this regulation the impact of the MLR standard on agents and brokers will be a factor in considering whether a particular individual markets would be destabilized. HHS seeks comments on the approach taken in this regulation and on the issues related to agents and brokers during years leading up to 2014.

Loss adjustment expense is part of other non-claims costs that cannot be excluded from premium revenue and cannot be considered part of reimbursement for clinical services to enrollees or a quality improving activity. Loss adjustment expense is referred to as "claims adjustment expenses" in the forms the NAIC has developed for reporting by issuers. Claims adjustment expenses are not reported as an adjustment to premium revenue or as an adjustment to claims. Instead, they are expenses associated with claims and are reported as "other non-

claims costs." One type of claims adjustment expenses is cost containment expenses. Such expenses reduce either the number of health services provided or the cost of such services. They may include: post and concurrent claim case management activities associated with past or ongoing specific care; utilization review; detection and prevention of payment for fraudulent requests for reimbursement; expenses for internal and external appeals processes; and network access fees to preferred provider organizations and other network-based health plans (including prescription drug networks), and allocated internal salaries and related costs associated with network development and/or provider contracting.

Examples of other types of claims adjustment expenses include: estimating the amounts of losses and disbursing loss payments; maintaining records, general clerical, and secretarial; office maintenance, occupancy costs, utilities, and computer maintenance; supervisory and executive duties; and supplies and postage. As previously explained, claims adjustment expenses are other non-claims costs.

8. Federal and State Taxes and Licensing and Regulatory Fees (§§158.161-158.162)

Section 2718 of the PHS Act requires that Federal and State taxes and licensing and regulatory fees be reported. Section 2718(a) lists these expenses as an exclusion from non-claims

costs. Section 2718(b)(1)(A) requires that Federal and State taxes and licensing or regulatory fees be excluded from the total amount of premium revenue when calculating an issuer's MLR. Section 2718(b)(1)(B)(i)(II) also requires that such taxes and fees be excluded from the total amount of premium revenue when determining any rebates. However, section 2718 does not specifically define what is included in Federal and State taxes.

The NAIC defines Federal taxes as all Federal taxes and assessments allocated to health insurance coverage reported under section 2718 of the PHS Act, excluding Federal income taxes on investment income and capital gains. This interim final regulation adopts the NAIC recommendation that Federal income taxes on investment income and capital gains are not taxes based on premium revenues, and thus should not be used to adjust premium revenues, as specified in §158.162, while all other Federal taxes allocated to health insurance coverage should be excluded from non-claims costs for purposes of the report required by section 2718. Section 158.162 also makes clear that Federal taxes which are excluded from non-claims costs are to be excluded from premium revenue when calculating an issuer's MLR.

We have adopted the NAIC's recommended approach to reporting State taxes and assessments. State taxes and assessments that must be separately identified and reported to

the Secretary include: any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly, or premium subsidies that are designed to cover the costs of providing indigent care or other access to health care throughout the State; assessments of State industrial boards or other boards for operating expenses or for benefits to sick unemployed persons in connection with disability benefit laws or similar taxes levied by States; advertising required by law, regulation or ruling, except advertising associated with investments; State income, excise, and business taxes other than premium taxes; State premium taxes plus State taxes based on policy reserves, if in lieu of premium taxes; State sales taxes, if the issuer does not exercise the option of including such taxes with the cost of goods and services purchased; and any portion of commissions or allowances on reinsurance assumed that represents specific reimbursement of premium taxes.

The NAIC has interpreted the language in section 2718(a)(3) that refers to "excluding Federal and State taxes and licensing or regulatory fees" from non-claims costs as encompassing the community benefit expenditures by not-for-profit health plans that they are required to make in lieu of State and Federal taxes. As discussed below, we adopt the NAIC's approach.

Under the NAIC's recommendation, "community benefit expenditures" are limited to expenditures that the non-profit issuer is required to make under State law in lieu of State taxes that would otherwise apply, or that the Federal government requires them to make in order to preserve their Federal tax exempt status, and that they report to the Federal government. The proceeds of such expenditures fund activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden.

Under the NAIC's interpretation, these mandated community benefit expenditures are essentially deemed to be the equivalent of State and Federal taxes for non-profit issuers for purposes of the exclusion in section 2718(a)(3). The NAIC recommended that non-profit issuers be permitted to report community benefit expenditures as a deduction from premium revenue, and further recommended that they be permitted to split such expenditures between Federal and State taxes as applicable, but not to report them more than once.

HHS believes that NAIC's interpretation avoids an inequity between for-profit and non-profit plans, and that it is reasonable to interpret community benefit expenditures by non-profits that they are required by the State or Federal government to make as the equivalent of taxes for purposes of

the exclusion in section 2718(a)(3). Thus, in §158.162(c) and (e), HHS has adopted the NAIC's approach and allows such mandatory community benefit expenditures by not-for-profit plans, made in lieu of income taxes, to be excluded from premium revenue to the same extent as State taxes. In order to implement the NAIC recommended approach that community benefit expenditures may be split between Federal and State taxes as applicable, §158.162(e) of this interim final regulation provides that the NAIC's approach applies equally to Federal and to State taxes, and that community benefit expenditures made in lieu of income taxes, whether Federal or State, may be reported as a deduction from premium revenue.

A commenter representing not-for-profit plans asserted that community benefit expenditures should be more broadly recognized in the MLR calculation, and not be limited to the amount required to be paid in lieu of taxes. This commenter pointed out that not all States impose a premium tax, that the amount of premium tax varies among States, and that the NAIC rule would discourage not-for-profits from making these contributions to the community.

Although the NAIC did not recognize community benefit expenditures beyond the amount of taxes that would have been paid, we share the concern that the MLR standard should not create a disincentive for not-for-profits to make community

benefit expenditures beyond those required in lieu of taxes. Thus, we invite comments on the proper treatment of community benefit expenses.

The NAIC defines and specifies the licensing and regulatory fees that must be reported and whether they may be included as an adjustment to premium revenue. In §158.161, we adopted the NAIC approach under which statutory assessments to defray operating expenses of any State or Federal department, and examination fees in lieu of premium taxes as specified by State law are included in the licensing and regulatory fees that may be used as an adjustment to premium revenue. HHS believes that, consistent with the Affordable Care Act, examination fees under State law should also be included as an adjustment to premium revenue, and §158.161 of the interim final regulation has such a provision. Fines and penalties of regulatory authorities and fees for examinations by State and Federal departments other than referenced above must be separately reported, but may not be used as an adjustment to premium revenue.

9. Allocation of Expenses (§158.170)

Section 2718(a)(3) of the PHS Act requires health insurance issuers to submit an annual report to the Secretary concerning the percentage of total premium revenue spent "on all other non-claims costs, including an explanation of the nature of such costs, and excluding Federal and State taxes and licensing or

regulatory fees." However, section 2718(a) does not provide a standardized method for allocating such expenditures. Section 2718(c) directs the NAIC to develop definitions and methodologies, which are subject to the certification of the Secretary, to assist issuers in reporting the information stipulated under section 2718(a). The NAIC's model regulation and this interim final regulation require issuers to report their expenses by State and by line of business. Section 158.170 of this interim final regulation addresses the allocation of claims and non-claim related expenses as well as expenses stemming from quality improving activities. Issuers operating within the individual market, small group market, and large group market who also offer products, such as Medicare supplemental insurance, or services, such as administration of group health plans, must report and properly allocate all related expenses stemming from each individual line of business.

There are several different methods for allocating costs incurred by health issuers allowable under statutory accounting principles. The NAIC model regulation requires issuers to allocate costs consistent with these principles. HHS has therefore not prescribed a standardized method for allocating costs beyond the allocation method designated in §158.170. All costs reported by issuers must be allocated according to generally accepted accounting methods that yield the most

accurate results and are well documented. An issuer's allocation method must illustrate the costs associated with a specific activity and any resulting effect the activity has had on a particular line of business. Section 158.170(d) further provides that issuers must maintain records containing an explanation of all incurred expenditures allocated as non-claims costs and quality improving activities. If the expense is related to a specific activity, the allocation of such expenditure must be on a direct basis. If an expense is not easily attributable to a specific activity, then the expenses must be apportioned based on pertinent factors or ratios, such as studies of employment activities, salary ratios or similar analyses. Section 158.170(b) provides that any shared expenses between two or more affiliated entities must be "apportioned pro rata to the entities incurring the expense" even if the expense has been paid solely by one of the incurring entities.

Each expense that is allocated by an issuer for each State in which it is licensed to conduct an insurance business must be appropriately attributed using a generally accepted accounting method to each line of business in each State, as designated in §158.170(b). However, all Federal taxes paid by a health insurance issuer must be attributed proportionately and appropriately to each State in which the issuer reports. While Federal taxes are not typically allocated to health insurance

issuers on a State-by-State basis, for purposes of complying with the reporting requirements in §158.110 all health insurance issuers are required to report some percentage of Federal taxes paid on their behalf.

HHS received a number of comments regarding allocation issues in response to the April Federal Register solicitation. Several State regulators and issuers noted that issuers currently have considerable flexibility in establishing and utilizing product and State-by-State allocation methods and that such flexibility should be maintained. Numerous regulators and issuers also advocated for allowing multiple methods of approved allocation, including the current financial reporting requirements provided by statutory accounting principles. A few State regulators, medical providers and other interested parties called for a standardized methodology for allocating administrative and quality improvement expenses among States and lines of business. In contrast, issuers stated that a revamped reporting methodology would be costly, administratively burdensome and less efficient in distinguishing a subcontractor's medical versus administrative expenses. A few industry groups also indicated that HHS should not develop an allocation methodology that is inflexible and inconsistent with current statutory accounting requirements and the accounting guidance provided under generally accepted accounting

principles.

The NAIC did not mandate the use of a specific methodology for apportioning non-claims costs to health insurance issuers. Section 158.170 adopts this flexible approach and requires health insurance issuers to explain how premium revenue is used to pay for non-claims expenditures (as provided for in §158.160). Health insurance issuers are required to allocate their non-claims and quality improving expenses on a State-by-State basis, and further allocate such expenses to each line of business within a State, as stated in §158.170. If an expense is attributable to a specific activity, then an issuer should allocate the expense to that particular activity. However, if it is not feasible for an issuer to allocate such expenditure to a specific activity, then the issuer must apportion the costs using a generally accepted accounting method that yields the most accurate results. Each reporting health insurance issuer must identify in its required report under §158.110 the specific basis used to allocate to each State its reported expenses, and within each State, to each line of business which the issuer operates. HHS believes that a clear allocation method for all expenses stemming from services provided by issuers includes allocation to each line of business as designated in §158.170(c). This level of detailed expense reporting is crucial in order to verify that issuers are properly allocating and

reporting such expenses.

D. Subpart B – Calculating and Providing the Rebate

1. Applicable MLR Standard and States with Higher MLR Standards (§§158.210-158.211)

Section 158.210 mirrors PHS Act section 2718(b)(1)(A)(i) and (ii) by stating the general requirement that issuers must provide their enrollees a rebate if their MLR is less than 85 percent in the large group market or less than 80 percent in the small group market and individual market. While explained in greater detail in subsequent sections of Subpart B of this interim final regulation, this means that issuers must spend at least 85 or 80 percent, respectively, of each premium dollar, as adjusted for taxes and regulatory and licensing fees, on reimbursement for clinical services provided to enrollees and activities that improve health care quality. Additionally, §158.210 acknowledges that the Secretary may, in her discretion, adjust the MLR standard that applies in the individual market in a State if the Secretary determines, upon application by the State, that the application of the 80 percent MLR may destabilize the individual market in such State. The requirements related to that statutory provision are delineated in Subpart C of this interim final regulation.

Section 158.211 provides that in States that have established under State law a higher MLR standard than that

prescribed by section 2718, such higher percentage applies to issuers in that State and should be substituted for the percentages set forth in §158.210. In States that have established, under State law, a lower MLR standard than that of section 2718, the higher percentage set forth in section 2718 applies to issuers.

2. Calculating an Issuer's MLR (§§158.220 through 158.221)

The NAIC model regulation addresses the calculation of an issuer's MLR, and HHS has certified and adopted the NAIC's uniform definitions and methodologies. The NAIC, in its model regulation, combines calculating the MLR with instructions related to how an issuer should aggregate data in certain instances, such as in connection with employer groups with blended rates, newer experience (deferring reporting of business with less than 12 months' experience), and other related issues such as a credibility, or statistical adjustment for smaller issuers. The requirements for reporting data and handling special circumstances, such as group policies with blended rates, mini-med plans, expatriate plans, and issuers with newer experience, are set forth in Subpart A of this interim final regulation. These special circumstances are discussed in section II.B of the preamble.

Sections 158.220 and 158.221 of this interim final regulation contain the instructions for calculating an issuer's

MLR for each MLR reporting year for purposes of determining whether any rebate is owed and, if so, in what amount. In the 2013 MLR reporting year, an issuer's MLR is calculated using the data for a three-year period, consisting of the MLR reporting year whose MLR is being calculated, and the data for the two prior MLR reporting years. Numerous commenters strongly support the use of a three year, rolling average MLR calculation in determining rebates, and some also support beginning it with the first MLR reporting year, or 2011. One commenter questioned whether the three year MLR was based on averaging three different one-year MLR values or based on accumulating experiences over the three year period and calculating an MLR for that three-year period. The Department adopts the recommendation that the data should consist of the accumulated experience, rather than the average three MLRs.

For the 2011 and 2012 MLR reporting years, there will not be sufficient data reported to use a three-year average. The NAIC has addressed this in its model regulation, and in §158.220(b), HHS has adopted the NAIC's approach. For the 2011 MLR reporting year, an issuer's MLR will be calculated using only the data reported for the 2011 MLR reporting year. For the 2012 MLR reporting year, the data that should be used in calculating an issuer's MLR depends in part upon whether the issuer's experience is credible. Credible experience refers to

whether an issuer insures a sufficiently large number of lives to be statistically valid, and is defined and discussed later in this preamble. If an issuer's experience for the 2012 MLR reporting year is fully credible, then its MLR for that year is calculated using only the data reported for the 2012 MLR reporting year. If an issuer's experience for the 2012 MLR reporting year is partially credible or non-credible, then its MLR is calculated using the data reported for both the 2011 and 2012 MLR reporting years. To prevent double counting, an adjustment will be made to incurred claims when any rebate owed for the 2012 and 2013 MLR reporting years is calculated using data from 2011 or 2012, as provided in §158.221(b)(1).

With respect to the issue of which portions of the data reported by an issuer are to be used to determine the numerator of the MLR and which portions of the data reported are to be used to determine the denominator of the MLR, the numerator equals the issuer's incurred claims and expenditures for activities that improve health care quality, and the reporting of data for these categories of expenses is detailed in §§158.140, 158.150 and 158.151. As discussed above, Section 158.221(b)(3) provides, for 2011 only, in the case of a mini-med plan reporting separately under §158.120(d)(3) and an expatriate plan reporting separately under §158.120(d)(4), that the numerator amount specified in §158.221(b) shall be multiplied by

a factor of two. The purpose of this adjustment is to recognize the "special circumstances" applicable to these plans by restating claims and quality improvement expense (if any) associated with these types of plans so that they are commensurate with the higher administrative expenses of these plans relative to premium. These types of plans are discussed at greater length under Subpart A.

The denominator of the MLR equals the issuer's premium revenue minus the issuer's Federal and State taxes and licensing and regulatory fees. The reporting of data for premium revenue is detailed in §158.130 and the reporting of data regarding Federal and State taxes and licensing and regulatory fees is set forth in §§158.161 and 158.162. Section 2718(b)(1)(A) also provides that the total amount of premium revenue used for the denominator of the MLR shall take into account payments or receipts for risk adjustment, risk corridors, and reinsurance. However, in the reporting requirements related to premium revenue in §158.130, the Department has provided that the premium revenue reported be adjusted for these types of payments or expenses. Because these issues have been addressed in the cited earlier sections of this interim final regulation, there is no need to address them again in §158.221 regarding the calculation of an issuer's MLR.

This interim final regulation also provides that an

issuer's MLR must be rounded to the nearest one-tenth of one percentage point, after dividing the numerator by the denominator when calculating the MLR. HHS has adopted the NAIC's approach in this regard.

3. Credibility Adjustment (§§158.230-158.232)

Section 2718(c) of the PHS Act charges the NAIC with developing uniform methodologies for calculating measures of the expenditures that make up the MLR calculation, and provides that "such methodologies shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans." To address the special circumstances of smaller plans, the NAIC model regulation allows smaller plans to adjust their MLRs by applying a so-called "credibility adjustment." HHS adopts this method of "credibility adjustment" in §158.230.

A credibility adjustment is a method to address the impact of claims variability on the experience of smaller plans. All issuers experience some random claims variability, where actual claims experience deviates from expected claims experience. In a health plan with a large customer base the impact of such random deviations is less than in plans with fewer insureds. One source of variability is the impact of large claims, which are infrequent, but have greater impact on financial experience than average or typical claims. Large claims have a disproportionate

impact on small plans because the higher claim cost is spread across a smaller premium base. These random variations in the claims experience for enrollees in a smaller plan may cause an issuer's reported MLR to be below or above the statutory standard in any particular year, even though the issuer estimated in good faith that the combination of the premium it projected it would collect and the claims it projected would produce an MLR that meets the statutory standard.

The credibility adjustment is a method to address the problem associated with this random variation. A credibility adjustment serves to modify the reported MLR of an issuer by adding to the reported percentage additional percentage points in recognition of the statistical unreliability of the reported number. A number of stakeholders in the NAIC proceedings have supported credibility adjustments in concept, including the American Academy of Actuaries and a number of the consumer representatives to the NAIC.

In evaluating the desirability of including a credibility adjustment, it is important to emphasize that health insurance rates are the product of assumptions, estimates, and projections, and not of calculations based entirely on hard data. When an actuary projects that the rate it has calculated will produce an 80 percent MLR, whether in fact it will produce an 80 percent MLR depends on whether the assumptions the actuary

has made—such as those concerning the mix of business it will attract, the intensity and frequency with which its insureds will use health care services, and unit costs - turn out to be correct. All things being equal, it is more likely that those assumptions will turn out to be correct when an issuer insures a large number of risks rather than a small number.

Credibility adjustments have advantages and disadvantages. Issuers benefit from credibility adjustments because such adjustments—and thus the ability to report a higher MLR than what the issuer's MLR would be using the methodology that applies to other plans—make it less likely that an issuer will be required to pay a rebate. For consumers, on the other hand, credibility adjustments eliminate some rebates that would otherwise have been paid.

In general, the smaller the size of the insured population whose experience is used to calculate the MLR, the more variable the reported MLR will be. Statistical analysis conducted for the NAIC by an independent actuarial consulting firm based on historical data for companies offering coverage in the group and individual markets examined the statistical variation that would be expected in reported MLR. The consultants concluded that if a company estimates that its premium will produce an MLR of 80 percent, random variation would cause the company to pay a rebate of:

- 0.9 percent or more in 1 out of every 4 years if it insures 75,000 lives,
- 2.6 percent or more in 1 out of every 4 years if it insures 10,000 lives, and
- 8.8 percent or more in 1 out of every 4 years if it insures only 1,000 lives.

After extensive analysis and public discussion, the NAIC adopted a credibility adjustment table designed to result in an issuer that charges premiums intended to produce an 80 percent MLR to pay a rebate less than 25 percent of the time. Toward the conclusion of its public proceedings on these issues, the NAIC gave some consideration to setting the base credibility factors so that such an issuer would be required to pay a rebate less than ten percent of the time. The credibility factors in that case would have been roughly twice as large as the factors the NAIC adopted. The argument made in favor of making this change is that it would reduce the likelihood of requiring a plan to pay a rebate simply because of chance variation in claims experience. However, it would also have increased the likelihood that a plan setting premiums to achieve an MLR that is less than the applicable MLR standard would avoid paying a rebate, and it would have reduced the size of the rebates that plans pricing below the MLR standard would have to pay. The NAIC concluded, and HHS agrees, that the credibility factors it

adopted more equitably balance the consumers' interest in requiring plans that should pay rebates to pay rebates against the issuers' interest in minimizing the risk of paying rebates as a result of chance variations.

HHS adopts the NAIC credibility adjustment methodology in §158.230. The NAIC recommends that the credibility factors be evaluated and updated as the Affordable Care Act reforms are implemented over the next several years. HHS concurs with this recommendation and notes its intention both to monitor the effects of the credibility adjustment and, as appropriate, to update the credibility adjustment method.

This interim final regulation adopts the approach taken by the NAIC by, in §158.230(c)(3), designating as "non-credible" any reported MLR that is based on experience from fewer than 1,000 life-years. Thus, §158.240(a)(1) provides that issuers with non-credible experience do not owe rebates because there is no valid data to determine that the issuer has failed to meet the MLR standard.

This interim final regulation also adopts the NAIC's assumption that variations of less than approximately one percent are reasonably to be expected based on ordinary variation in claims experience of very large plans. The experience of such plans is "fully credible," and such a plan therefore should be required to pay a rebate based on its

reported MLR. The model regulation designates as "fully credible" any reported MLR that is based on experience from 75,000 or more life-years, and this definition is adopted, as provided in §158.230(b)(1) of this interim final regulation.

The NAIC model regulation provides that a reported MLR that is based on experience from 1,000 to 75,000 life-years is "partially credible" and entitled to a credibility adjustment, as stated in §158.230(b)(2) of the interim final regulation. The magnitude of the "credibility adjustment" for "partially credible" aggregations is intended to represent the amount by which an issuer's reported MLR would be expected to vary as a result of random variation in claims experience. Under the credibility provisions of the NAIC model regulation, which HHS adopts in §158.232 of the interim final regulation, the "credibility adjustment" for a specific issuer is the product of two components: a "base credibility factor," determined by the number of life-years of experience used to calculate the issuer's reported MLR; and a "deductible factor," determined by the average deductible of the policies whose experience went into the reported MLR. The credibility adjustment will be added to the reported MLR, as provided in §158.221(a), before calculating rebates. As stated above, the credibility adjustment applies to partially credible issuers.

The base credibility factor recommended by the NAIC is

based on an actuarial analysis of anticipated claims experience. The results of this analysis are summarized in Table 1, below.

Table 1: Base Credibility Factors

Life-Years	Base Credibility Factor
<1,000	Not credible
1,000	8.3%
2,500	5.2%
5,000	3.7%
10,000	2.6%
25,000	1.6%
50,000	1.2%
75,000	0.0%

The deductible factor recommended by the NAIC is also based on the independent actuarial consulting firm's analysis. It is intended to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles. Few people incur claims above $10,000, which means that high cost claims represent a much larger portion of the total claims experience in a higher deductible policy than in a lower deductible policy. As a result, issuers who write a small number of high deductible policies are more likely to report a low MLR than an issuer who covers the same number of lives under a low deductible policy, even if the premium they establish is set to achieve the MLR required by section 2718. Therefore, the deductible factor takes into account greater variability among high deductible plans. The deductible factors recommended by the

NAIC are shown in Table 2.

Table 2. Deductible Factors

Deductible	Deductible Factor
$0	1.000
$2,500	1.164
$5,000	1.402
$10,000	1.736

Under the NAIC model regulation, an issuer would use the deductible factors from Table 2 to determine a deductible factor for the average deductible of the coverage whose experience was used to calculate the reported MLR. The factors included in Table 2 were developed by the actuarial consultants to the NAIC using methods consistent with standards of professional actuarial practice.

NAIC methodology uses "linear interpolation" to determine life year factors for experience between the life year categories in table 1. HHS adopts this methodology in §158.230. When the number of life-years reported by an issuer falls between two numbers on Table 1, the base credibility factor is calculated by first determining where, by percentage of the difference between those two numbers, the reported number of lives falls. Thus if Issuer X reports 4,000 life-years, its number of life-years falls 60 percent of the way between 2,500 and 5,000. To calculate the interpolated adjustment factor it

is necessary to determine the base credibility factor for the number of lives 60 percent of the way between 2,500 and 5,000. Therefore, this percentage is multiplied by the difference between the base credibility factor corresponding to the number of life-years on Table 1; 0.60 x (.052-.037) = .009. To find the base credibility factor, this amount is then subtracted from the factor corresponding to the lower number of lives on Table 1. Thus, 0.052 –.09 is equal to .043, which is the base credibility factor for an issuer covering 4,000 lives.

The deductible factor is based on the average deductible of all policies whose experience is included in the reported MLR. When the average deductible is greater than $2,500 and is between two of the deductible categories shown in Table 2, the NAIC model regulation calls for the deductible adjustment to be calculated by linear interpolation. In §158.232 of this interim final regulation, HHS adopts the methodology using linear interpolation.

The NAIC specifies that the number of life-years used to calculate the base credibility factor matches the number of life-years that comprise an issuer's experience as reported under subpart A. HHS adopts this approach in §158.231. An issuer's credibility adjustment for the 2011 MLR reporting year is based on the life-years and weighted-average deductible for the 2011 MLR reporting year. An issuer's 2012 MLR reporting year

credibility adjustment is based on experience from the 2012 MLR reporting year, unless issuer experience for 2012 is less than 75,000 life-years. In that circumstance, the 2012 MLR reporting year experience is combined with 2011 MLR reporting year experience to calculate the 2012 credibility adjustment.

An issuer's credibility adjustment for 2013 is based on three years' experience, comprised of the current MLR reporting year and the two previous MLR reporting years. In 2013, an issuer is not eligible for a credibility adjustment if (1) the MLR (prior to any credibility adjustment) in each of the three MLR reporting years was below the MLR standard for each year, and (2) each of the three MLR reporting years included 1,000 life-years or more. This exception prevents issuers from receiving a credibility adjustment when the issuer consistently sets its prices to produce an MLR below the statutory 80 percent MLR standard.

In responding to HHS's request for comments, many issuers, industry associations, and State departments of insurance emphasize that to avoid requiring issuers to pay rebates due to statistical variations, rather than due to their underlying pricing and benefits structure, it is important to assess MLRs on sufficient numbers of lives for statistical credibility. Commenters also argue that requiring issuers to pay rebates when statistical variations lead to surpluses (low MLRs) but

requiring issuers to absorb losses when statistical variations lead to losses (high MLRs) will lead to product volatility, market exit, and inadequate levels of surplus to ensure solvency. HHS agrees that rebates should be based on the underlying premium pricing, rather than chance variation in claims experience. But as noted above, any credibility adjustment can also serve to deprive insureds of rebates to which they would otherwise be entitled under the Affordable Care Act. HHS has concluded that the NAIC credibility adjustment methodology provides an acceptable balance between the interests issuers have in not paying rebates when a low MLR is the result of ordinary variation in claims experience, and the interests consumers have in receiving rebates when issuers provide coverage and establish prices that do not result in MLRs, and therefore the value, required by the Affordable Care Act.

4. Rebating Premium if MLR Standard Not Met (§158.240)

Section 158.240, subsections (a), (b) and (c), delineates the general requirement regarding rebates, the calculation of the rebate amount, and the time frame for payment of any rebate that may be due. Section 158.240(a) simply provides that if an issuer does not meet the applicable MLR standard set forth in §158.210 and, if applicable, §158.211, then the issuer must provide a rebate to each enrollee unless the issuer has too little experience to calculate a reliable MLR. As discussed

above, because an issuer that has fewer than 1,000 covered lives does not have sufficiently credible data to determine that the MLR standard has not been met, a non-credible issuer is not required to pay any rebates.

Section 158.240 explains the amount of the rebate due to enrollees. The Affordable Care Act provides a rebate that is the amount by which the applicable MLR standard exceeds the issuer's actual MLR multiplied by "the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance . . .)." This language describing premium revenue as the premium paid minus taxes and other adjustments is the same as statutory language describing the denominator of the MLR. The NAIC model regulation matches the statutory methodology, and HHS adopts this methodology. Therefore, the rebate paid to each enrollee is based on the earned premium paid by or on behalf of the enrollee minus taxes and other permissible adjustments.

The Affordable Care Act requires the issuer to "provide an annual rebate to each enrollee under such coverage, on a pro rata basis." The NAIC determined, and the Department concurs, that this requirement is most simply met by requiring the rebate returned to the enrollee to be proportional to the amount of premium paid by or on behalf of the enrollee. As noted above,

the total rebate owed by the issuer is required, by statute, to be a percentage of the issuer's total earned premium. An individual who was covered by an issuer for only three months would have paid substantially less than an individual who was covered by the issuer for the entire MLR reporting year. It would be unfair to pay both individuals the same dollar rebate. Similarly, an individual or group that purchases coverage from the issuer that has a higher deductible but lower premium should not receive the same dollar rebate as an individual or group that paid a higher premium for a product with a lower deductible. The rebate paid to a policyholder or enrollee would be based upon the amount of premium paid minus taxes and other permissible adjustments, multiplied by the amount by which the issuer MLR is below the applicable MLR standard; the result is the actual rebate.

For example, take an issuer who owes a five percent rebate to its enrollees in the individual market. An enrollee may have paid $2,000 in premiums for the MLR reporting year. If the Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as provided in §§158.161(a), 158.162(a)(1) and 158.162(b)(1) are $150 for a premium of $2,000, then the issuer would subtract $150 from premium revenue, for a base of $1,850 in premium. The enrollee would be entitled to a rebate of five percent of $1,850, or

$92.50.

section 158.240(d) requires issuers to provide any rebates that are due no later than August 1 following the end of the MLR reporting year. Since the report is due by June 1 of the year following the MLR reporting year, this allows issuers two full months (a) to provide any rebate that may be due, (b) for the group market, to notify their employer clients to arrange for the distribution of the rebates, if applicable, and (c) to prepare and send the notice of rebate that is required by §158.250.

5. Form of Rebate (§158.241)

While the NAIC model regulation does not specifically address some of the administrative details of section 2718(b)(1)(A) of the PHS Act, which requires an issuer offering group or individual health insurance coverage to provide an annual rebate to each enrollee if the issuer's MLR is less than the statutory minimum, the NAIC advisory group's proposals in this regard have been adopted. The statute does not specify the particular form of rebate that is to be provided to enrollees. For example, must the rebate be provided in the form of cash or check, or may it be provided through a credit to premium? Does the requirement differ based on whether the enrollee to whom a rebate is owed is a current or former enrollee? Section 158.241 of this interim final regulation addresses the method by which

an issuer must provide any rebate owing to enrollees and the issuer has the choice as to form of the rebate for then-current enrollees but not for former enrollees, who must receive an actual payment.

Several commenters addressed the administrative expenses involved in distributing rebates. Although the NAIC model regulation does not specifically address the form in which an issuer must disburse rebates, an NAIC advisory group suggested that an issuer should be able to choose whether to disburse rebate payments to current enrollees as a premium credit or a cash lump sum. The NAIC advisory group also proposed that an issuer should have to disburse rebate checks to former enrollees. HHS considered the comments it received and has concluded that the proposals made by the NAIC advisory group may reduce the administrative burden felt by an issuer in providing rebates to its enrollees.

Section 158.241(a) of this interim final regulation thus states that an issuer may choose to provide current enrollees with a rebate in the form of a premium credit (i.e., reduction in a premium owed), lump-sum check, or, if an enrollee paid by credit card or debit card, by lump-sum reimbursement to the same account that the enrollee used to pay the premium. We believe that this ensures that enrollees receive any rebate owing while giving issuers the ability to provide the rebate in a way that

has the least administrative burden. If an issuer chooses to provide a premium credit to a recipient, the issuer must apply the full amount of the rebate owing to the first premium due on or after August 1. If the rebate exceeds the amount of the first premium due on or after August 1, the issuer must apply any overage to succeeding premium payments until the entire rebate has been credited. With respect to rebates owing to former enrollees, §158.241(b) requires the rebate to be made in a lump-sum, but allows an issuer the flexibility to provide it by check or using the same method that was used for payment of the premium, such as credit card or debit card. Regardless of the method used to pay rebates, all enrollees eligible for rebates must be notified as required by §158.250.

6. Recipients of Rebates (§158.242)

Section 2718(b) requires an issuer to provide a rebate to each enrollee on a pro rata basis if the issuer has not met the applicable MLR standard. However, it does not prescribe how rebates must be distributed. This interim final regulation establishes methods for distributing rebates that are efficient and cost-effective, and that ensure that enrollees receive any rebate to which they may be entitled.

The NAIC, in an Issue Resolution Document on which it did not vote, discussed that the rebates should be provided to the group policyholder and that the group policyholder should be

advised that enrollees may have a claim to some or all of the rebate to the extent that they have contributed to the premium. Numerous commenters also suggested that any rebate should go to the company or person who actually paid the premium, and not to the enrollee. They point out that under a group policy the employer often pays a portion, or even all, of the premium. In addition, when an employee pays a portion of the premium, it is generally the employee and not every enrollee in the employee's family who makes payment. This concept applies in the individual market as well; it is often one family member who pays the premium on behalf of all enrollees in the family. The Department agrees with the NAIC's and the commenters' concerns. A technical reading of section 2718(b)(1)(A) requires that the rebate shall be provided "to each enrollee under such coverage, on a pro rata basis." However, the purpose of the section 2718 is to ensure that value is achieved for the premium paid. It would frustrate the purpose of the section to deprive those who actually paid premiums of the rebate, and to instead provide a windfall to those who did not pay premiums with the "value" that was returned by the issuer. Consistent with the NAIC discussion, HHS therefore interprets this provision as requiring any rebate be provided on a pro rata basis to the person or entity that paid the premium on behalf of the enrollee. This requirement is addressed in §158.242.

Several comments HHS received in response to its April request for information pertaining to this regulation also pointed out that group policyholders may be in a better position to determine the rebate amount each individual enrollee should receive. They suggested that issuers be permitted to pay rebates to group policyholders for distribution to enrollees. The Department agrees that group policyholders and subscribers are in a better position than issuers to fairly distribute rebates to individual enrollees given that it is the group policyholders and subscribers, and not the issuers, who know the extent to which the enrollees made the original premium payments. However, the statute provides that it is the issuer's obligation to provide the rebate, if any.

HHS has adopted an approach which satisfies both the statutory requirement that an issuer provide any rebates and the practical reality that group policyholders and subscribers are in a better position to distribute any rebates. Section 158.242 of this interim final regulation allows an issuer to enter into an agreement with a group policyholder to distribute the rebates on behalf of the issuer. HHS invites public comment on to whom rebates should be paid.

The regulation specifies that, regardless of whether an issuer provides rebates to enrollees directly or indirectly through a group policyholder, an issuer must take steps to

ensure that each enrollee receives a rebate that is proportional to the amount of premium paid by that enrollee and that the group policyholder does not retain more of the rebate than is proportional to the amount of premium it paid.

Therefore, this interim final regulation allows an issuer to delegate its rebate distribution functions to a group policyholder, but provides that the issuer remains liable for complying with all of its obligations under the statute and maintains records received from the group policyholder demonstrating that rebates were accurately distributed.

7. *De Minimis* Rebates (§158.243)

Although the NAIC model regulation does not specifically address de minimis rebate payments because the distribution of rebates was outside the scope of the NAIC's statutory mandate, an NAIC actuarial subgroup suggested that issuers should not be required to provide rebates in minimal amounts that are largely of symbolic value. It argued that setting the minimum threshold somewhere in the range of $1 to $20 should be sufficient to avoid requiring largely symbolic rebates to enrollees. HHS agrees with this approach.

Section 2718(b) is also silent on the subject of whether there is a de minimis amount below which issuers need not pay a rebate to an enrollee. Without a minimum threshold, each enrollee would receive the rebate owed to him or her, but the

cost of processing and distributing the rebate might be greater than the amount of the rebate.

The Department received several comments from issuers and others who recommended that HHS set a minimum threshold for issuer payment of rebates because of this potential for relatively high administrative expenses associated with the provision of very small rebates.

We agree that it does not make sense for issuers to provide rebates when the administrative cost of providing them exceeds their value to enrollees. Thus, §158.243 provides that an issuer need not provide rebates when the combined dollar amount of a rebate owed to the policyholder and subscribers under a group policy, or to the subscriber in the individual market, is less than five dollars per subscriber covered by the policy. Five dollars is an amount that is commonly used by States when setting de minimis levels for issuer refunds.

Although each de minimis rebate may seem insignificant, the aggregate amount of such rebates by market type may be quite substantial. Thus, consistent with the rebate requirements of the Affordable Care Act, issuers should not be allowed to retain these unpaid rebate funds, which belong to enrollees. Furthermore, if issuers retained the unpaid rebate funds, it would in essence lower their MLR. Instead, issuers must aggregate the de minimis rebates and distribute them in equal

amounts to all then-current enrollees who receive a premium credit.

8. Unclaimed Rebates (§158.244)

The Affordable Care Act does not specifically address the situation of rebates being unclaimed. This situation is likely to occur either because an issuer has not been able to locate certain enrollees, or enrollees have not redeemed their rebate payments.

Some consumer representatives recommended that an issuer be required to make all reasonable efforts to provide a rebate to an enrollee and that an issuer be prohibited from keeping any unclaimed funds. At least one consumer group recommended that such funds be directed to a State consumer assistance program that has been approved by the Department, or if such a program is unavailable, to the Department itself. Another group recommended that rebates for any individuals who cannot be located should be applied toward reduction of premiums for all policyholders in the subsequent plan year.

We agree that an issuer should be required to make a good faith effort to locate enrollees and to distribute to them any rebate that is owed. This requirement is reflected in §158.244. We also believe that an issuer should be prohibited from retaining unclaimed rebates. However, unclaimed rebates will be subject to relevant State law provisions

9. Notice of Rebates to Enrollees (§158.250)

The Affordable Care Act and the NAIC model regulation provide that an issuer must provide enrollees with rebates if its MLR falls below the statutory standard, but neither specifies what information should accompany a rebate. Section 158.250 of this interim final regulation requires issuers to provide enrollees with a rebate notification along with any rebate check or premium credit.

There are several reasons for this notification. Enrollees may not understand why they are receiving a rebate and may not be familiar with the significance of the MLR and the rebate requirement in the Affordable Care Act. Without the information provided by this notification, enrollees have no explanation as to how rebates are calculated. In addition, MLR transparency is a way to educate consumers and promote informed decision-making in the purchasing of health insurance.

The rebate notification must accompany the rebate check or be sent at the same time as the premium credit is applied. The rebate notification must include a brief explanation of what an MLR is, why the Affordable Care Act created the policy (for example, increased transparency, incentive to lower premiums), and why the enrollee is receiving a rebate. It must also include the aggregate amount of premium revenue reported by the issuer during the MLR reporting year, the issuer's MLR (taking

into account any adjustment allowed by the regulation), the required MLR threshold, the percentage of premium being rebated, and the total amount being paid or credited to enrollees, including the amount paid or credited to an employer based on its having paid all or a portion of the premium. In addition, the notification to enrollees must explain that rebates to current enrollees are being provided in the form of premium credit, and that rebates to former enrollees are being provided either by check or in the same form as the premium was paid. For example, an issuer has the option of reimbursing enrollees who paid the premium by credit card or debit card by applying the rebate amount back to the credit or debit card. The form of the rebate notification will be established by the Secretary and published in guidance.

HHS is not requiring issuers who do not have to provide a rebate to provide notification to enrollees about the MLR and the fact that no rebate is owed. However, issuers who do meet the MLR standard may choose to provide such notice to their enrollees.

10. Reporting Rebates to the Secretary (§158.260)

Section 2718(b) of the PHS Act is meant to ensure that consumers receive value for their premium payments, and does so by requiring an issuer that does not meet a specified MLR to rebate a portion of the premium to enrollees. In order to

provide for appropriate oversight and enforcement for which regulations are specifically authorized by section 2718(b)(3), HHS needs the ability to validate an issuer's calculation and distribution of rebates. Accordingly, the interim final regulation prescribes certain data retention, data access, and reporting requirements.

Subpart A of this interim final regulation requires an issuer to report to the Secretary data concerning premium revenue, how premium revenue is spent, and the various categories of expenses that go into determining the issuer's MLR. In Subpart B, the Department implements the statutory requirement for rebates to enrollees, and as part of this implementation, requires issuers to report to the Secretary certain information regarding rebates.

The interim final regulation requires issuers to report, for each MLR reporting year, information regarding the rebates it makes to enrollees. Consistent with the reporting requirements in Subpart A, §158.260(b) requires that the information reported regarding rebates be aggregated by State, and by the large group, small group, and individual markets within a State. The information required includes:

(1) the number and percent of enrollees who receive a rebate;

(2) the amount of rebates provided to enrollees, including

a breakdown of how much of the rebates were paid to policyholders and how much of the rebates were paid to subscribers;

(3) the amount of de minimis rebates that were aggregated and a breakdown of how they were disbursed to enrollees; and

(4) the amount of unclaimed rebates, a description of the good faith efforts that were made to locate the applicable enrollees, and a description of how the unclaimed rebates were disbursed.

HHS considered several options for the timing of reporting the information required by §158.260. In doing so, HHS has tried to balance the need for timely information and the desire to minimize the administrative burden on issuers. Almost all of the information required by §158.260 should be available to issuers at the time they submit the report required under §158.110 for each MLR reporting year. Thus, for that set of information, the Department is requiring that it be submitted with the report required under §158.110. The amount of unclaimed rebates would be the only information that would not be available to the issuer at the time it reports its data for the MLR reporting year, since the issuer needs time to make a good faith effort to locate former enrollees and to know if certain enrollees fail to cash their rebate checks. HHS is requiring that this information be submitted with the report

required under §158.110 for the subsequent MLR reporting year.

11. Effect of Rebate Payments on Solvency (§158.270)

Section 158.270 addresses concerns expressed in some comments that the obligation to pay rebates might cause an issuer's surplus to decline to levels threatening its solvency. The NAIC also raised concerns about issuer solvency in its October 13, 2010 letter to the Secretary. Issuer solvency is, of course, an important consideration and is a major focus of State insurance regulators. Consistent with the NAIC's concern, this interim final regulation provides, therefore, that the Secretary may permit the payment of rebates by an issuer to be deferred if the insurance commissioner in its State of domicile informs the Secretary that the timely payment of rebates would cause the issuer's risk based capital (RBC) level to fall to a level that causes concern about its solvency.

Section 158.270 provides that a State's insurance commissioner, superintendent, or other responsible official must notify the Secretary if the payment of rebates by a domestic issuer will cause the issuer's RBC level to fall below specific regulatory thresholds. The State must provide the Secretary with the domestic issuer's RBC reports for the current year and the prior two years, along with a calculation of the amount of rebates that would be owed by the issuer.

Section 158.270 provides that the Secretary will review

this information, along with any other information requested from the issuer, and will determine whether the timely payment of rebates would cause the issuer's RBC level to fall below the specified regulatory action level. When the Secretary makes this determination, the Secretary will provide that the issuer must pay these rebates, with interest, in a future year in which payment of the rebates would not cause the issuer's RBC level to fall below the specified regulatory action level.

E. Subpart C – Potential Adjustment to the Medical Loss Ratio for a State's Individual Market

1. Introduction

Section 2718(b)(1)(A) of the PHS Act establishes MLR standards for insurance coverage sold in the individual market, the small group market, and the large group market. For the small group and individual markets, the MLR standard is 80 percent. For the large group market, the MLR standard is 85 percent. However, if a State sets a higher MLR within its State, that higher MLR must be met.

Section 2718(b)(1)(A)(ii) also provides that "the Secretary may adjust" the 80 percent level with respect to the individual market of a State "if the Secretary determines that the application of such 80 percent may destabilize the individual market in such State." The PHS Act does not, however, define "destabilize the individual market" or provide the process or

criteria for making a determination regarding potential destabilization of that market. In addition, the section does not specify the kind or amount of adjustment the Secretary may make.

Subpart C of this interim final regulation implements this provision of section 2718(b)(1)(A)(ii) by addressing these important considerations, and adopts the recommendations of the NAIC on this issue. It sets forth the process by which the Secretary may exercise the authority provided under section 2718(b)(1)(A)(ii). It also establishes the criteria the Secretary will apply in determining whether to lower the MLR standard applicable to the individual market in a State.

2. Subpart C's Approach and Framework

HHS has received comments from many interested parties regarding the application of MLR standards in the individual market and the process for granting requests to adjust the required standard.

Notably, in an October 13, 2010 letter to the Secretary, the NAIC observed that the MLR standard "may enhance the value of plans for consumers and improve carrier accountability for spending and pricing decisions," but also that improper application of it "could threaten the solvency of insurers or significantly reduce competition in some insurance markets." The NAIC further stated that "the threshold consumer protection

is ensuring a health insurance company is solvent." HHS agrees with the NAIC on the importance of maintaining issuer solvency. If an insurance company does not have enough money to pay claims, then any MLR standard becomes irrelevant.

Further, while the focal point of any market destabilization analysis must be the manner in which any requested MLR adjustment may affect consumers, as the NAIC points out, consumers have numerous interests that extend beyond whether they will receive rebates, including an interest in multiple health insurance options. To that end, this interim final regulation adopts the recommendation the NAIC Consumer Representatives made in an October 25, 2010 letter to the Secretary, that the Secretary "establish a formal process that provides ample opportunity for consumers and consumer advocate input and involvement in determining whether and to what extent adjustments should be made in any State." The Department believes the recommendation by the Consumer Representatives should apply to all stakeholders, including issuers, agents and brokers, health care providers, as well as consumers, and has therefore established a process by which all stakeholders may provide information and input.

This interim final regulation does not require the Secretary to find that adherence to the 80 percent MLR standard is certain to result in market destabilization in order to grant

an adjustment from it. Nor does it allow the Secretary to grant an adjustment in the case where market destabilization is a remote possibility. Rather, this interim final regulation both allows and requires an adjustment to a State's MLR to be granted when there is a reasonable likelihood that market destabilization, and thus harm to consumers, will occur.

Subpart C establishes the procedure and criteria the Secretary will use to assess requests to adjust the MLR standard that applies in the individual market in a State. We note that the law allows adjustments of the MLR for the individual market in a State and does not apply to the small group market or to the large group market.

Section 158.301 states the criteria the Secretary will apply in considering requests to adjust the minimum individual market MLR standard applicable to a State. Subpart C then proceeds to address the four major issues that HHS believes are relevant to any potential requests for adjustments to the statutory MLR standard. The first is who may submit a request and the duration of such a request. The second is the information the submitter of such a request will be required to supply. The third is the criteria the Secretary will use in making her decision regarding the request. The fourth is the process by which the Secretary will receive information and make her determination. Each of those issues is discussed separately

below.

Finally, in its October 13, 2010 letter, the NAIC did not recommend a national transition, but instead wrote that "while *some* states seek national relief from the 2011 MLR, all states recognize that transitional relief may be appropriate for *some* state insurance markets." (Emphasis added.) Commenters in the industry have also advocated for a "national" transition or "national" relief from the MLR standards. As indicated above, the Affordable Care Act does not contemplate or provide for such relief in the context of §158.301 which, as required by section 2718(b)(1)(A)(ii), provides for State-specific relief.

However, it is clear that other sections of this regulation do in fact provide for national rather than State-specific relief from the immediate application of the MLR standards, and not just in the individual market. The credibility adjustments provided for in §§158.230-158.231 are national in scope and apply without regard to State-specific market conditions. First, the credibility adjustments result in many issuers being presumed to meet the MLR standards altogether because of their small size. Second, the adjustments add up to 8.3 percent to an issuer's reported MLR for smaller plans that are not presumed to meet the MLR standard already. Third, issuers with policies that have large deductibles may receive an additional adjustment of up to 6.1 percent on top of the 8.3 percent. Other

components of the MLR formula, such as treatment of expenses for quality improving activities and treatment of Federal and State taxes, also better enable issuers to meet the MLR standard. In addition, the process set out in Subpart C provides further opportunity to modify MLR standards in the individual market to address state-specific circumstances. The rationale for a national transition - which is to provide accommodation for issuers to meet the MLR standards - we believe is satisfied by these many adjustments.

3. Who May Request Adjustment to the MLR and Duration of Request (§§158.310-158.311)

Section 158.310 provides that a request for an adjustment to the MLR standard for a State must be submitted by that State's insurance commissioner or other applicable State official. State insurance commissioners have valuable local knowledge of their State's insurance market and share a responsibility to protect consumers, which makes them best qualified to attest to the impact of the MLR standard on consumers within their State. State insurance regulators also often have considerable power to compel or influence issuers to take steps that may reduce the risk of market destabilization.

It is appropriate for three reasons that requests for an adjustment to the MLR standard come from State insurance commissioners on behalf of the State individual insurance market

as a whole. First, the statute allows such an adjustment only for all issuers in the individual market in a State; it does not allow an adjustment for specific issuers. Second, only the State commissioner has knowledge of all issuers' experience and market conduct in the State and as to any action the State might deem appropriate to address any potential for market destabilization. Third, State insurance commissioners have responsibility for protecting the interests of the general public, policyholders, and enrollees within their respective States.

Section 158.311 provides that a request for an adjustment to the MLR standard may be for one, two, or three MLR reporting years. This permits a State to request an adjustment for up to three years, as deemed appropriate by the State, based on the condition of its individual health insurance market. Allowing for multi-year adjustments, when necessary, will provide certainty to issuers within the State regarding the applicable MLR standard, which in turn enhances stability of the market.

4. Required Information (§§158.320-158.323)

Subpart C requires the applicable State official to provide the Secretary with information on the applicant State and the market that is the subject of the request. Section 158.323 requests contact information for the person submitting the State's request. This information is needed because the

Secretary anticipates working closely with individual States regarding their requests.

The remaining information requested by Subpart C falls into two general categories. The first is information about how the individual health insurance market is organized and functions in the State. Section 158.321 requests the following structural and operational information about the submitting State's individual health insurance market:

- the State's current MLR standard for the individual market, if any. Such an MLR is relevant to determining the effect the statute's 80 percent MLR may have in the State.
- any requirements that an issuer seeking to withdraw from the State's individual health insurance market must meet before doing so.
- any limitations imposed by the State on issuers regarding rating based on health status.
- mechanisms available in the State to provide consumers with options in the event an issuer in the individual market withdraws from the State, such as a guaranteed-issue or issuer-of-last-resort requirement or a State-operated high-risk pool.
- operational and financial information about the issuers operating in the State's individual market, including the capacity of incumbent issuers to write additional business, the premiums such issuers charge and the benefits they offer, and

the amount they pay to agents and brokers.

Notably, in its October 13, 2010 letter to the Secretary, the NAIC stated that among the factors State regulators would consider in making their own determinations as to whether application of the statutory 80 percent MLR standard would destabilize the individual market are the "potential impact on premiums paid by current policyholders," the "potential impact on benefits and cost-sharing of existing products," and "the potential impact on consumer access to agents and brokers." This information will assist the Secretary in understanding the insurance market in the State submitting a request and will enable her to better address the criteria for assessing the request set forth in this subpart.

The second general category of information a State must provide is its own assessment of how best to address any risk of destabilization through an adjustment to the MLR standard. In its October 13 letter, the NAIC stated that "when recommending to HHS that a transitional exception should be applied to a state or insurance market, the regulator shall also propose a solution to the factors on which the recommendation is based." The NAIC also suggested that HHS give deference to its analysis and recommendations. HHS agrees with the NAIC that, just as a State commissioner is best qualified to request an adjustment to the MLR standard, a State commissioner seeking an MLR adjustment

is also best qualified to suggest an appropriate alternative MLR standard for each of the reporting years for which the State is requesting an adjustment. Thus, §158.322 further requires any request for an MLR adjustment to estimate the rebates that would be paid under the 80 percent individual market MLR standard and under the alternate proposal a State official submits for each year for which the State is requesting an adjustment.

Section 158.320 also provides some flexibility in the event certain data are unavailable or collection of certain data is unduly burdensome. In such situations, a State may provide notice of this to the Secretary and the Secretary may request alternative supporting data or move forward with her determination on the State's request without the data the State is unable to provide.

5. Assessment Criteria (§158.330)

Section 158.330 sets forth the criteria the Secretary will use in determining the risk of destabilization. It does not set forth a single test for determining that risk, but rather states that the Secretary may consider five main criteria in assessing such risk.

The first criterion the Secretary will consider, as set forth in §158.330(a), is the number of issuers reasonably likely to exit the individual market or cease offering specific products in a State absent an adjustment to the 80 percent MLR

and the resulting impact on competition in the State. In making this determination, the Secretary may consider (1) each issuer's MLR relative to an 80 percent MLR, (2) each issuer's profitability and risk-based capital level, (3) the requirements and limitations within the State with respect to market withdrawals, and (4) the number of issuers that may not be required to pay rebates pursuant to §158.240.

Second, the Secretary may consider the number of individual market enrollees covered by issuers that are reasonably likely to exit the State absent the adjustment. All other things being equal, the greater the number of policyholders in a market who are enrollees of issuers reasonably likely to exit the market, the greater the likelihood of market destabilization.

Third, the Secretary will consider whether, absent an adjustment to the MLR standard, consumers may be unable to access insurance agents or brokers. Access could be restricted if, in order to comply with MLR standards, issuers reduced compensation to agents or brokers to the point where agents or brokers were not available to assist consumers in finding coverage and other options for consumers were limited. In its October 13th letter, the NAIC noted the important role that agents and brokers will play in the next four years as markets transition to Exchanges, and encouraged HHS to "recognize the essential role served by producers and accommodate producer

compensation arrangements in any MLR regulation promulgated." This criterion recognizes that role.

Fourth, the Secretary will consider the alternate coverage options available within the State for enrollees of issuers that are reasonably likely to exit the market—or as the NAIC puts it in its October 13 letter, she will consider "the ability of consumers to find easily affordable products in the State should their carrier leave the State market." Section 158.330(d) provides that, in assessing alternative coverage options, the Secretary will take into account (1) any requirement that issuers who exit the State's individual market must have their block(s) of business assumed by another issuer, (2) which issuers may remain in the State if the adjustment request were denied, and the breadth and price of the products offered by such issuers, (3) the capacity of incumbent issuers to write additional business, (4) the mechanisms, such as guaranteed-issue products, an issuer of last resort, or a State high risk pool, available to the State to provide coverage to consumers to the extent, if any, that issuers withdraw from the market, and (5) any authority the insurance commissioner might have that would help stabilize the State's individual insurance market.

Fifth, the Secretary will consider the impact on premiums charged, the benefits offered, and the cost-sharing provided to consumers by issuers remaining in the market in the event one or

more issuers were to withdraw from the market. For example, premiums may rise if the loss of one or more issuers reduced competition to an extent that allowed remaining issuers to increase premiums beyond what competitive conditions would have allowed.

Section 158.330 also states that the Secretary will consider any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

6. Process (§§158.340 through 158.350)

Section 158.340 provides that the request for adjustment must be submitted in electronic format, and §158.340(a) provides that all the information that Subpart C requires in support of a request must be submitted electronically. HHS has determined that these requirements are necessary if, as the PHS Act envisions and the public interest demands, State requests for MLR adjustments are to be handled as expeditiously as possible. Section 158.340(b) permits a State, solely at its option and only if it wishes, also to submit to the Secretary a copy of its request by regular or express mail.

Section 158.341 provides that the State's request will be promptly posted on the Secretary's healthcare.gov website. In addition, §158.342 states that the Secretary will invite public comment upon the request when it is posted, and will, when

assessing the request, consider any comments filed by the public within 10 days of that posting. Section 158.343 provides that any State that submits a request may, at its option, hold a public hearing and create an evidentiary record with respect to its request. If the State does so, the Secretary will consider the evidentiary record of the hearing in making her determination as to the State's request for an adjustment. Section 158.344 provides that the Secretary may also hold a public hearing with respect to a State's request, at the Secretary's discretion. HHS believes that a transparent yet expeditious process will allow all interested parties to provide input while satisfying the need to come to a prompt determination.

Once the Secretary determines that the request has sufficiently satisfied the information required by the interim final regulation and the public comment period has expired, the Secretary will make a determination within 30 days as to whether to grant a State's request for an adjustment to the MLR standard. Section 158.345 also allows the Secretary to extend that 30-day period up to an additional 30 days at her discretion. The Secretary believes that it is in the interests of both issuers and consumers in a State to have certainty about the applicable MLR for the individual market in the State at the earliest practicable date.

Section 158.350 provides that a State submitting a subsequent request for an adjustment shall "submit information as to what steps the State has taken since its initial and other prior requests, if any, to increase the likelihood that enrollees who have health coverage through issuers that are considered likely to exit the State's individual market will receive coverage at a comparable price and with comparable benefits if the issuer does exit the market."

A State that disagrees with the Secretary's initial decision regarding its request for an adjustment to the statutory 80 percent MLR standard may request reconsideration of a denial if it does so in writing within 10 days of the initial decision. Section 158.345(b) provides that the Secretary will issue her determination on the request for reconsideration within 20 days of receiving the request. Section 158.345(a) makes clear that a State may include any additional information it wishes in support of its reconsideration request.

The process established in Subpart C seeks to give States and interested parties full opportunity to present all information necessary and helpful to a determination of requests for adjustments to the statutory 80 percent MLR standard while ensuring that States and issuers will know as early as possible the standard that issuers in the State will be required to meet.

7. Public Comments

In creating this framework for considering a State's request for an adjustment of the MLR for the individual market, HHS reviewed and took into consideration the public comments submitted in response to its Notice. Only a relatively few of the comments received mentioned the authority granted to the Secretary regarding potential destabilization in a State's individual market and offered suggestions with respect to the process and criteria for determining destabilization.

Commenters specifically suggested that markets may become destabilized if issuers choose to withdraw from the market or terminate or materially change existing policies. Commenters also suggested that markets may become destabilized if customers losing coverage have insufficient product choice or are unable to find new coverage that covers pre-existing conditions. The determination whether to adjust the MLR standard should, commenters suggested, take into account guaranteed issue options, issuers of last resort, requirements that issuers offer individual coverage, and eligibility flexibility under State high risk pools. HHS agrees that these are important considerations, and has incorporated into this Subpart consideration of both the potential causes of destabilization and the systems in place that mitigate destabilization risks.

Other commenters suggested potential warning signals of market destabilization. These included volatility in premium

rates, decreases in issuers' reported capital levels, increases in assumption reinsurance, changes in marketing, increases in complaints from brokers or consumers, declines in insurance coverage, increases in applications to State high risk pools, and significant changes in benefit design. State insurance commissioners may wish to further comment on these factors and other local trends in their requests for an adjustment.

One insurance issuer's comment letter suggested that whether at least 10 percent of enrollees are impacted by exiting issuers or at least 10 percent of products are withdrawn from the marketplace may be valid criteria for determining market destabilization. While HHS agrees that market destabilization could not occur absent a significant impact on consumer welfare, HHS believes it is difficult to generalize and create a single numeric test given the different characteristics of State insurance markets, different State laws, and different types of issuers.

As the NAIC Consumer Representatives noted in their letter, the NAIC addressed market destabilization in an "issue resolution document." That document suggested the Secretary consider existing State laws and historic MLRs in each State. The Secretary seeks information regarding existing State laws and issuers' MLRs in order to consider them in connection with a State's request for an adjustment of the MLR standard in the

individual market. HHS notes that although State MLR standards are, in general, lower than the 80 percent MLR standard, many issuers are currently above both the 80 percent MLR standard and the applicable State regulatory standard. HHS also received comments suggesting that the MLR standard in all States be adjusted to historic MLR levels and increased to 80 percent over a three year period until 2014. The NAIC did not recommend a national transition. Instead, while noting in its October 13th letter that "some states seek national relief from the 2011 MLR, all states recognize that transitional relief may be appropriate for some State insurance markets." (Emphasis added.)

Finally, an NAIC advisory subgroup suggested that the Secretary may consider State laws and regulations regarding cancellation and non-renewal of health insurance and the cost to issuers of withdrawing from the individual health insurance market. HHS agrees that in making a determination regarding market destabilization, alternatives available to a State and to an issuer should be considered, and has provided that these are factors to be considered in assessing whether to grant an adjustment to the 80 percent MLR for a State's individual market.

F. Subparts D - F – HHS Enforcement, Additional Requirements on Issuers, and Federal Civil Penalties

Section 2718 of the PHS Act created two requirements for

health insurance issuers. Under section 2718(a) of the PHS Act, all health insurance issuers in the group and individual markets are required to report to the Secretary certain data concerning the amount of premium revenue as well as the amounts spent on clinical care, quality improvement activities, and adjusted non-claims expenses. Section 2718(b) requires the calculation of MLR and payments of rebates to enrollees if the MLR standard is not met.

The data that must be reported to the Secretary under section 2718(a) of the PHS Act are addressed in Subpart A of this interim final regulation. The calculation of rebates is addressed in Subpart B. Subparts D through F of this interim final regulation implement enforcement authority in section 2718(b)(3) and provide for enforcement of the reporting obligations set forth in section 2718(a) and rebate requirements in section 2718(b).

Section 2718(b)(3) of the PHS Act [as added by the Affordable Care Act] specifically requires the Secretary to promulgate regulations to enforce the provisions of section 2718. It makes HHS responsible for direct enforcement of the reporting and rebate provisions of section 2718. This interim final regulation implements this statutory mandate.

Section 2718(a) requires issuers to report the data specified directly to the Secretary, rather than to the States.

HHS is thus best situated, consistent with the mandate in section 2718(b)(3), to directly enforce the requirement that data be reported to it. This does not mean, however, that the States should play no role in enforcement of these provisions.

States are currently responsible for solvency and, in many States, rate oversight as well. In performing these functions, many states collect and review data and conduct audits of issuer information related to MLRs. In addition, some twenty-nine States already have experience in regulating MLRs either prospectively through rate filing or retrospectively through rebate requirements. States already receive detailed financial reporting from issuers for solvency purposes. Finally, section 2718 of the PHS Act gives States the discretion to impose a higher MLR standard than that prescribed in section 2718. Taking all of these factors into consideration, together with the historical role that States have had in regulating insurance, it is appropriate for the States to have an oversight role with respect to the reporting provisions of section 2718(a), even though the statute gives HHS direct enforcement authority.

Under the regulation, while HHS is responsible for enforcing the reporting provisions and for conducting audits to test the validity and accuracy of the data reported (§158.401), HHS may also, in its discretion, accept the findings of audits

conducted by State regulators, so long as certain specified conditions are met (§158.403). In particular, HHS may accept the findings of audits from a State which report on:

(1) the validity of data on expenses and premiums reported to the Secretary, including the appropriateness of the allocations of expenses, taxes, and revenues used in such reporting;

(2) whether the activities associated with the issuer's reported expenditures for quality improving activities meet the definition of such activities; and

(3) the accuracy of rebate calculations and the timeliness and accuracy of rebate payments.

In addition, in order to accept the findings of audits from a State, the State's laws must permit the public release of the audit findings of health insurance issuers and the State must submit its audit findings to HHS within 30 days of finalization and submit all preliminary or draft reports within six months of the completion of audit field work unless the audit findings have already been finalized and reported to HHS.

While this interim final regulation provides that HHS may accept audit findings from a State, it makes clear that pursuant to the statutory requirement in section 2718(b)(3), HHS is responsible for direct enforcement of the MLR reporting and rebate provisions, and retains the discretion to conduct its own

audits of issuers, including in States that have acceptable audit programs as defined in the regulation. This approach recognizes that although States have traditionally conducted financial examinations for the purpose of determining solvency, the type of audit needed to assess whether the data reported pursuant to section 2718 is accurate and valid is quite different. As HHS and the States develop greater experience and expertise in conducting these audits, it is likely that the States' role will increase.

This interim final regulation sets forth the procedure to be followed by HHS when it conducts an audit of an issuer to determine whether the reports it has submitted pursuant to this regulation are accurate and valid. The procedure set forth is comparable to the procedures used by HHS when conducting audits of Medicare Advantage plans pursuant to 42 CFR Part 422.

This interim final regulation contains provisions requiring issuers to retain documentation relating to the data reported, and requiring issuers to provide access to that data to HHS or its outside auditors. These provisions are intended to make it possible for HHS or the relevant State to have access to the information needed to determine whether the reports submitted are accurate and valid.

Finally, this interim final regulation provides for the imposition of civil monetary penalties in the event an issuer

fails to comply with the reporting and rebate requirements set forth in the regulation. It provides criteria and a process for determining whether and in what amount such penalties should be imposed. While HHS's intent is not to be punitive to issuers, given the importance of receiving timely and accurate reporting and making appropriate rebates, and given the desire to bring down the cost of health care for consumers as soon as practicable following the effective date of the Affordable Care Act, this regulation strikes a balance between penalties that are severe enough so as to encourage compliance with the requirements of the regulations but not so severe as to be punitive. The civil monetary penalties provided for are identical to those for violations of title XXVII that are set forth in the current regulations on enforcement, 45 CFR 150.301 et seq. They provide for a penalty for each violation of $100 per entity, per day, per individual affected by the violation. HHS is interested in public comments as to the proper amount or range of penalties for violations of various provisions of this interim final rule. This interim final regulation also adopts the provisions in the existing enforcement regulation regarding factors in aggravation and mitigation that HHS will take into account in determining whether to impose civil monetary penalties and if so, in what amount.

The interim final regulation also provides that if a State

has assessed a penalty against an issuer, then HHS will take that into account in considering whether it should assess any penalty for violation of the requirements of this Part.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking and Delay of Effective Date

Section 2792 of the PHS Act authorizes the Secretary to promulgate any interim final rules determined to be appropriate to carry out the provisions of Part A of title XXVII of the PHS Act. The provisions of these interim final regulation requirements in section 2718, and the foregoing interim final rule authority applies to this interim final regulation.

In addition, under section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et* seq.) a general notice of proposed rulemaking 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. Although, the provisions of the APA that ordinarily require a

notice of proposed rulemaking do not apply here because of the specific authority granted by section 2792 of the PHS Act, even if the APA were applicable, the Secretary has determined that it would be impracticable and contrary to the public interest to delay putting the provisions of this interim final regulation in place until a public notice and comment process was completed.

Prior notice and comment in this situation is impracticable because section 2718 of the PHS Act directs the NAIC, not later than December 31, 2010, and subject to certification by the Secretary, to establish uniform definitions of the activities reported as reimbursement for clinical services, activities that improve health care quality, and non-claims costs. However, the reporting required by section 2718 of the PHS Act applies to plan years beginning not later than January 1, 2011. The NAIC transmitted its recommendations to the Secretary on October 27, 2010, in the form of a model regulation. The regulation implementing the reporting requirements must be in effect on or before January 1, 2011, so that issuers, regulators, and consumers know what information must be reported and how to aggregate it prior to the time period which they must report. There are fewer than 60 days between when HHS would be able to review the NAIC's recommendations, certify them, and issue an implementing regulation.

Therefore, we find good cause to waive the notice of

proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

In addition, the Congressional Review Act, at 5 U.S.C. §801(a)(3), ordinarily requires that the effective date of a "major rule" such as this interim final rule be at least 60 days after publication. However, under 5 U.S.C. §808(2), this delay of effective date may be modified when an agency "for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." Specifically, where "good cause" is found to waive prior notice and comment, the rule may "take effect at such time as the Federal agency promulgating the rule determines." 5 U.S.C. §808. Given the exigencies discussed above, and the fact that the provisions of this rule apply, by statute, on January 1, 2011, we find good cause under section 808 to make this interim final rule effective on that date.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section

3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding MLR and Rebate Reporting Requirement (§158.101 through §158.170)

This interim final regulation describes the information that will be reported by health insurance issuers on an annual basis to the Secretary starting in 2012, and quarterly in 2011 only for certain plans. Issuers' submissions will include information regarding reimbursement for clinical services, expenditures for activities that improve health care quality, other non-claim costs, earned premiums, and Federal and State

taxes and regulatory fees, among other data elements. Issuers will be required to calculate MLRs and rebates as part of their submission to the Secretary.

Generally, the data and methodologies that the regulation instructs issuers to use follow the NAIC 2010 blank, approved August 17, 2010 and the NAIC MLR model regulation, which was finalized on October 27, 2010. Most issuers file information with the NAIC on a regular basis, in accordance with State laws; it is expected that issuers who typically file information with the NAIC will file the supplemental exhibit and the rebate reporting documents that the NAIC created in fulfilling its mandate in section 2718. We expect the NAIC to collect MLR and rebate information beginning for plan year 2010 and to continue collecting such data for the foreseeable future.

HHS's data collection requirements described in this interim final regulation are very similar to the NAIC's. One exception is that we are requiring health insurance issuers who sell expatriate plans or mini-med plans to disaggregate that business from the rest of their business in that market segment and report the MLR data separately. As discussed above in the impact analysis section, HHS estimates that approximately 442 entities will submit reports for each of the States and markets in which they operate; further, we estimate that approximately 25 health insurance issuers will report data for expatriate

plans and 50 health insurance issuers will report data for mini-med plans.

At this time, HHS has not developed the MLR and rebate forms that health insurance issuers will have to complete on an annual basis beginning for plan years starting January 1, 2011. In addition, as described above, we are requiring issuers who opt to separately report the experience for expatriate plans and mini-med plans to submit quarterly reports in 2011, so that we can better understand these products. We will revisit the special filing circumstances for expatriate plans and mini-med plans after reviewing the quarterly filings. We plan to publish the instructions and forms that issuers must file for all plans in future guidance. At that time we will solicit public comments on both the forms the estimated burden imposed on health insurance issuers for complying with the provisions of this interim final regulation. The information collection requirements associated with §§158.101-158.170 will become effective upon OMB approval. HHS will publish a notice in the Federal Register notifying the public of OMB approval at the appropriate time.

B. ICRs Regarding Notice of Rebates to Enrollees (§158.250)

Within Subpart B of this interim final regulation, we describe the obligation of health insurance issuers to calculate and pay rebates to consumers in years when the issuer's MLR does

not meet the applicable minimum MLR threshold. In addition, the interim final regulation requires issuers to provide information to consumers about the rebate they are receiving. At this time, HHS has not developed the model disclosure language for the rebate notice to enrollees that issuers will be required to send beginning August 1, 2012, based upon plan years starting January 1, 2011. In the near future, HHS will publish the model disclosure language and will solicit public comment. At that time, and per the requirements outlined in the Paperwork Reduction Act, we will estimate the burden on health insurance issuers of complying with this provision of this interim final regulation. The information collection requirements associated with §158.250 will become effective upon OMB approval. HHS will publish a notice in the Federal Register notifying the public of OMB approval at the appropriate time.

C. ICRs Regarding Retention of Records (§§158.501–158.502)

Subpart E of the interim final regulations establishes the Secretary's enforcement authority regarding the reporting requirements under section 2718. Issuers must maintain all documents and other evidence necessary to enable HHS to verify that the data required to be submitted comply with the definitions and criteria set forth in this interim final regulation, and that the MLR is calculated and any rebates owing

are calculated and provided in accordance with this interim final regulation. The interim final regulation requires issuers to maintain all of the documents and other evidence for the current year and six prior years, unless a longer period is required under §158.501.

We expect all issuers will have to retain data relating to the calculation of MLRs; we expect only some issuers will have to retain information regarding the payment of rebates and the notice to enrollees. We believe that the burden associated with our record retention requirements do not exceed standard record retention practices in that issuers are already required to retain the records and information required by this interim final regulation in order to comply with the legal requirements of their States' departments of insurance. For that reason, we are assigning a minimal burden to these requirements. We estimate that 442 issuers must comply with the aforementioned requirements. We further estimate that it will take each issuer a total of one hour to file and maintain both the data for MLR calculations and the information regarding payment of rebates and notices to enrollees. The total estimated annual burden associated with the requirements in §§158.501 through 158.502 is 442 hours at a cost of $10,045.

However, we welcome comments regarding the burden associated with maintaining the information described in subpart E of this interim final regulation.

D. ICRs Regarding State Request for MLR Adjustment (§§158.301–158.350)

Subpart C of this interim final regulation implements the provisions of section 2718(b)(1)(A)(ii). The interim final regulation describes the data and narratives which States must submit that are seeking an adjustment to the applicable MLR in the individual market for their State. There is no standardized application form associated with a State's request. As discussed in §§158.321, 158.322, and158.323, the data elements that a requesting State must provide include:

- The applicable State minimum required MLR, if any;
- State individual market withdrawal requirements, if any;
- Any mechanisms to provide options to consumers in case of issuer withdrawal;
- Information on issuers in the State's individual market;
- The State's proposed adjustment to the minimum MLR for the State's individual market; and
- The contact information for the State representative.

In addition, a State whose request for adjustment to the MLR standard has been denied by the Secretary may request

reconsideration of that determination. A request for reconsideration must be submitted in writing to the Secretary within 10 days of her decision to deny the State's request for an adjustment, and may include any additional information in support of its request.

Based on preliminary data analysis and indications by a few States that they may apply for an adjustment, the Department estimates that approximately 20 States will submit applications and that it will take approximately ten working days for a State to complete the application. An exact time burden estimate is uncertain because some States may have better access to the required application information elements than others; some States may have to seek some of the required information from health insurance issuers in their States, which could increase their burden. Some States may, if providing the requested information is an undue burden, have the Secretary consider their application without some of the information elements.

The Department estimates that it will take a State 94 hours to complete an application including gathering data, developing data analyses, synthesizing information, and developing the adjusted MLR threshold. For the purposes of this estimate, the Department assumes that this application will take various professional staff approximately 75 hours (at an average rate of $125 an hour), an associate general counsel 10 hours (at $175 an

hour), a senior general counsel 5 hours (at $350 an hour), and the Commissioner 4 hours (at $450 an hour) to assemble and review the various components of the application.[1] The Department estimates that the total cost burden associated with the submission of a MLR adjustment application to be approximately $14,675 per response for a total estimated burden of $293,500.

The Department is soliciting public comments for 60 days concerning the process described in subpart C of the preamble whereby a State may request an adjustment of the minimum MLR applicable in the individual market. The Department has submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. If you comment on this information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Office, 9998-IFC

Fax: (202) 395-6974; or

E-mail: *OIRA_submission@omb.eop.gov*.

[1] Estimates were developed by interviewing two former insurance commissioners, a former insurance department actuary, and a former health plan employee familiar with the burden of submitting financial data to health insurance departments.

VI. Regulatory Impact Analysis

A. Summary

As stated earlier in this preamble, this interim final regulation implements sections 2718(a) through (c) of the PHS Act, which set forth requirements 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 the minimum statutory requirements. This interim final rule also establishes uniform definitions and standardized methodologies for calculating MLR-related data; provides a process and criteria for the Secretary to determine whether application of the 80 percent minimum MLR threshold may destabilize the individual market in a given State; and addresses enforcement of the reporting and rebate requirements. These provisions are generally effective for plan years beginning January 1, 2011.

The Department is publishing this interim final regulation to implement the protections intended by Congress in the most economically efficient manner possible. We have examined the effects of this rule as required by 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 OMB Circular A-4, the Department has quantified the benefits, costs and transfers where possible, and has also provided a qualitative discussion of some of the benefits, costs and transfers that may stem from this interim final regulation.

B. Executive Order 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).

Section 3(f) of the Executive Order 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 1 year); and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below, we have concluded that this rule is likely to have economic impacts of $100 million or more in any one year, and therefore meets the definition of "significant rule" under Executive Order 12866. Therefore, the Department has provided an assessment of the potential costs, benefits, and transfers associated with this interim final regulation. Accordingly, OMB has reviewed this interim final regulation pursuant to the Executive Order.

1. Need for Regulatory Action

Consistent with the provisions in Section 2718 of the PHS Act, this interim final rule requires health insurance issuers offering coverage in the individual and group markets to provide a rebate to consumers if they do not spend a specified portion of premium income on reimbursement for clinical services (i.e.,

incurred claims) and activities that improve quality. Section 2718(a) of the PHS Act (captioned "clear accounting of costs") requires health insurance issuers to "submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums." 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 standards, specifies how the rebate is to be calculated, and allows the Secretary to adjust the 80 percent minimum MLR threshold if the Secretary determines that applying this standard may destabilize the individual market in a given State. Section 2718(c) of the PHS Act directs the NAIC to establish uniform definitions and calculation methodologies subject to certification by the Secretary. As discussed elsewhere in this preamble, after considering the NAIC's recommendations, HHS in this interim final regulation certifies and adopts them in full. Consistent with Section 2718(b)(3) of the PHS Act, which requires the Secretary to promulgate regulations, this interim final regulation sets forth the provisions in Sections 2718 (a) through (c) and is needed for their implementation to provide

rules that issuers can use to implement effective processes for reporting the required data and calculating and paying applicable rebates.

2. Summary of Impacts

In accordance with OMB Circular A-4, Table VI.1 below depicts an accounting statement summarizing the Department's assessment of the benefits, costs, and transfers associated with this regulatory action. The Department limited the period covered by the regulatory impact analysis (RIA) to 2011–2013 Estimates are not provided for subsequent years both because there will be significant changes in the marketplace in 2014 related to the offering of new individual and small group plans through the exchanges, and because there will be statutorily required adjustments to the MLR formula to account for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Affordable Care Act that are not effective until 2014. Those provisions require additional regulations that have not yet been promulgated.

The Department anticipates that the transparency and standardization of MLR reporting in this interim final regulation will help consumers to ensure that they receive good value for their premium dollars. Additionally, the inclusion of activities that improve quality in calculating the MLR could help to increase the level of investment in and implementation

of effective quality improving activities, which could result in improved quality outcomes and lead to a healthier population. The Department estimates that issuers' total one-time administrative costs related to the MLR reporting, record retention, and rebate payment and notification requirements represent less than 0.02 percent of their total premiums for accident and health coverage, and their total annual ongoing administrative costs related to these requirements represent less than 0.01 percent of their total premiums for accident and health coverage. Executive Order 12866 also requires consideration of the "distributive impacts" and "equity" of a regulation. As described in this RIA, this regulatory action will help ensure that issuers spend at least a specified portion of premium income on reimbursement for clinical services and quality improving activities and will result in a decrease in the proportion of health insurance premiums spent on administration and profit. It will require issuers to pay rebates to consumers if this standard is not met. As the table shows, although we are unable to quantify benefits, the transfers (rebates from issuers to consumers) could be substantial – estimated monetized rebates of $0.6 billion to $1.4 billion annually. As noted, Executive Order 12866 requires consideration of "distributive impacts" and "equity." The rebates will help insure that issuers spend at least a specified

portion of premium income on reimbursement for clinical services and quality improvement, resulting in less disparate MLRs and value to consumers across issuers and States. In accordance with Executive Order 12866, the Department believes that the benefits of this regulatory action justify the costs.

Table VI.1 – Accounting Table

Benefits:						
Qualitative: * increased transparency relating to portion of premium spent on benefits and quality could help policyholders to select higher value coverage * increased quality of medical care as a result of increased spending on quality-improving activities by issuers * improved health as a result of increased spending on medical care by issuers						
Costs:	Low Estimate	Mid-range Estimate	High Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	24.8	37.4	57.0	2010	7	2011-2013
	23.0	34.7	52.8	2010	3	2011-2013
One-time costs to develop methods for capturing data, and annual costs related to reporting data to the Secretary and providing rebate notifications and payments.						
Qualitative: * increased spending on quality-improving activities by issuers * increased spending on medical care by issuers * potential market disruption if some issuers limit plan offerings as a result of the MLR requirements (offset, as with all benefits, costs, and transfers, to the extent that States obtain adjustments to the MLR due to such potential disruptions)						
Transfer:						
Annualized Monetized ($millions/year)	633.1	930.8	1,541.8	2010	7	2011-2013
	587.4	863.5	1,430.4	2010	3	2011-2013
Annual transfer from shareholders or nonprofit stakeholders to enrollees of rebates paid by issuers for coverage in the individual, small group, and large group markets that do not meet the minimum MLR standards (approximately 2.8 million to 9.6 million enrollees could receive rebates each year)						

Qualitative:
* savings for consumers and reduced profit for issuers

3. Qualitative Discussion of Anticipated Benefits, Costs and Transfers

The medical loss ratio (MLR) is an accounting statistic that, stated simply, measures the percentage of total premiums that insurance companies spend on health care and quality initiatives, versus what they spend on administration, marketing and profit. In the following sections, we discuss some of the anticipated benefits, costs and transfers associated with the Affordable Care Act MLR requirements.

a. Benefits

In developing this interim final regulation, the Department carefully considered its potential effects including both costs and benefits. Because of data limitations, the Department did not attempt to quantify the benefits of this regulation. Nonetheless, the Department was able to identify several potential benefits which are discussed below.

Health insurance markets in the United States are often not highly competitive. The share of the US population living in areas where markets are least competitive has been increasing.[2] Even in markets with multiple competing plans, lack of

[2] Dafny, Leemore S.. 2010. "Are Health Insurance Markets Competitive?" American Economic Review, 100(4): 1399–1431.

transparency in pricing may prevent adequate competition based on the value of product, since it is difficult to ascertain if a low premium is due to high efficiency, low coverage of medical claims, or a healthy underlying population of enrollees. As a result, insurers can provide an inefficient, low-value product without consumers being fully aware of what they are purchasing. A potential benefit to this regulation is greater market transparency and improved ability of consumers to make informed insurance choices. The uniform reporting required under this regulation, along with other programs required by Affordable Care Act such as www.HealthCare.gov, a website with plan-level information, will mean that consumers will have better data to inform their choices, enabling the market to operate more efficiently.

In addition, issuers that would not otherwise meet the MLR minimum defined by this regulation may increase spending on quality-promoting activities. These programs, which include case management, care coordination, chronic disease management and medication compliance, have the potential to create a societal benefit by improving outcomes and population health.

Issuers that would not otherwise meet the MLR minimum may also expand covered benefits or reduce cost sharing. To the extent that these changes result in increased consumption of effective health services, the regulation could result in

improved health outcomes, thereby creating a societal benefit.

b. Costs

The Department has identified the primary sources of costs associated with this regulation as the costs associated with reporting, recordkeeping, rebate notifications and payments, and other costs.

The Department estimates that issuers will incur approximately $33 million to $67 million in one-time administrative costs, and $11 million to $29 million in annual ongoing administrative costs related to complying with the requirements of this interim final regulation from 2011 through 2013. Additional details relating to these costs are discussed later in this regulatory impact analysis.

Other Costs – There are two other potential types of costs associated with this regulation: costs of potential increases in medical care use, the cost of additional quality-improving activities, and costs to consumers if some issuers decide to limit offered products as a result of this interim final regulation.

As discussed under benefits, there may be increases in quality-improving activities or in consumption of medical care due to this regulation. Both of these very likely have some benefit to enrollees but they also represent an additional cost to issuers and society.

It is also possible that some issuers in particular areas or markets will not be able to operate profitably when required to comply with the requirements of this regulation. They may respond by changing or reducing the number of products they offer. The Department anticipates that issuers' decisions regarding whether to limit offered products will not be governed solely by short-term profitability. Issuers are likely to consider whether they expect to be successful competitors in Exchanges in 2014 and beyond.[3] Some low MLR plans may decide to leave a given market entirely or be acquired by a larger company, while other low MLR plans (particularly those that are subsidiaries of larger organizations) may find ways to achieve higher MLRs through increased efficiencies.

To the extent that issuers do decide to limit product offerings, group purchasers or individual enrollees in these plans may bear some costs associated with searching for and enrolling in a new insurance plan. For employers, particularly small employers, these costs may include increased administrative expenses. For consumers, this may lead to reduced choice, the inability to purchase similar coverage, and higher search costs related to finding affordable insurance coverage. States may apply for an adjustment of the MLR

[3] Bernstein, Jill, "Recognizing Destabilization in the Individual Health Insurance Market," Changes in Health Care Financing and Organization (HCFO) Issue Brief, July 2010, accessed at www.hcfo.org/files/hcfo/HCFO%20Policy%20Brief%20July%202010.pdf.

threshold in the individual market if the Secretary concurs that the adjustment is necessary to prevent market destabilization. This could mitigate the potential costs.

c. Transfers

To the extent that insurers' MLR experience falls short of the minimum thresholds, they must provide rebates to enrollees. These rebates would reflect transfers of income from the insurers or their shareholders to the policy holders. Based on the methods described above, we have estimated ranges for the rebates that may occur during 2011-2013. These estimates are discussed later in this regulatory impact analysis (see Tables VI.7, VI.8, and VI.9).

4. Overview of Data Sources, Methods, and Limitations

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 called "Blanks" that issuers submit to the NAIC through State insurance regulators. The NAIC has four different Blanks for different types of insurers: Health, Life,

Property & Casualty, and Fraternal issuers.[4] A Technical Appendix for this analysis, available at http://www.hhs.gov/ociio/regulations/index.html, provides more detail on the precise NAIC data sources used for this analysis.

A total of 618 insurers 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. It is for this reason that we have restricted our analysis to Health and Life Blank companies. Comprehensive major medical coverage[5] – including both coverage offered in the individual and group markets that is subject to this interim final regulation – 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 regulation, the data contain certain limitations that should be noted. For example, the NAIC data do not include issuers regulated by

---

[4] 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, i.e. it files either the Life, Property& Casualty, or Fraternal Blank.

[5] Comprehensive major medical coverage sold to associations and trusts has been included in individual comprehensive major medical coverage for purposes of the RIA. The Department's estimates exclude Medigap, which is reported separately in the NAIC data from comprehensive major medical coverage offered in the individual and group markets. The NAIC data do not allow us to identify mini-med plans or expatriate plans.

California's Department of Managed Health Care (DMHC) as well as small, single-State insurers that are not required by State regulators to submit NAIC annual financial statements. When we compare the NAIC enrollment data to InterStudy data, we estimate that these limitations cause the NAIC data to exclude approximately 9 percent of the total fully insured, private comprehensive major medical market.[6] Additionally, the NAIC data do not break out small and large group coverage at the State level, and administrative expenses such as taxes are reported at the national level for all A&H lines of business. We developed imputation methods to account for these limitations. Finally, we made several edits to the data that led us to exclude from the analysis 176 of the companies that the NAIC data identify as reporting comprehensive major medical coverage.[7] However, these excluded companies represent a small portion of the overall comprehensive major medical market (3 percent of life years and 2 percent of earned premiums). The Technical Appendix (available at http://www.hhs.gov/ociio/regulations/index.html) contains a detailed description of the limitations of the NAIC data, and the data edits that were made by the Department. We

[6] This estimate is based on a comparison of 2008 NAIC and InterStudy data. Interstudy data report 79.7 million enrollees for comprehensive major medical coverage in 2008 whereas NAIC data report approximately 72.9 million enrollees. The NAIC enrollment number represents 91 percent of the Interstudy total enrollment figure.

[7] These exclusions reflect the restriction to Health and Life Blank companies, which drops 22 Fraternal and Property and Casualty companies from the analysis.

use the remaining 442 companies to estimate the regulatory impacts discussed below.

5. Estimated Number of Affected Entities Subject to the MLR Provisions

Section 2718 (a) of the PHS Act specifies that the MLR provisions apply to health insurance issuers offering group or individual health insurance coverage, including grandfathered health plans. As discussed earlier in this preamble, in this context, the term "issuer" has the same meaning provided in 45 CFR 144.103, which states that an issuer is "an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of ERISA)." As discussed elsewhere in this preamble, and consistent with the NAIC recommendations, the MLR provisions in this interim final rule apply to issuers that offer comprehensive major medical coverage, and these issuers will be required to report these data and determine if rebates are owed at the company, State, and market level (e.g., individual, small group, and large group).[8] The following sections summarize the

[8] This includes some issuers that offer mini-med plans which, as discussed elsewhere in the preamble, often cover the same types of medical services as comprehensive medical plans, but have low annual benefit limits and typically have lower premiums than plans providing higher ceilings on benefits. Data for mini-med plans are not broken out separately from other data that issuers

Department's estimates of the number of entities that will be affected by the requirements of this interim final regulation.

a. Estimated Number of Affected Entities

The MLR provisions will apply to all health insurance issuers offering comprehensive major medical coverage in the individual and group markets. For purposes of the regulatory impact analysis, we have estimated the total number of issuers that will be affected by the requirements of this interim final regulation at the company level because this is the level at which issuers currently submit their annual financial reports to the NAIC (including both company- and State-level exhibits where appropriate). However, because issuers will be required to report MLRs and calculate any rebates that are owed at the company / State level for each market in which they offer coverage (for example, individual, small group, large group), we have estimated rebates by "licensed entity" (company / State combination) for each market.

Table VI.2 shows the estimated distribution of issuers offering coverage in the individual, small group and large group markets for the analytic sample used in this RIA. [9] Approximately 70 percent (311) of these issuers offer coverage

---

reported to NAIC in 2009. Therefore, the regulatory impact analysis does not include separate estimates relating to mini-med plans.

[9] As noted above, the analytic sample excludes companies that are regulated by the Department of Managed Health Care in California, as well as small, single-State insurers that are not required by State regulators to submit NAIC annual financial statements.

in the individual market, 77 percent (342) offer coverage in the small group market, and 77 percent (338) offer coverage in the large group market. Approximately half (224) of these issuers offer coverage in all three markets that are subject to the MLR requirements, while the other half offer coverage in one or two of the markets that are subject to the requirements (118 and 100, respectively).

Additionally, the Department estimates that there are 74.8 million enrollees in the analytic sample in coverage that is subject to the requirements in this interim final rule, including approximately 10.6 million enrollees in individual market coverage (estimated based on "life years" for 2009 NAIC Health and Life Blank filers, which as discussed earlier excludes data for companies that are not required to file annual statements with the NAIC), 24.2 million enrollees in small group coverage, and 40.0 million enrollees in large group coverage (excluding enrollees in companies that did not file annual financial statements on the NAIC's Health or Life Blanks in 2009).[10]

[10] The estimate provided here of the size of the individual market differs from estimates provided in previous rulemaking for a number of reasons. First, as discussed in this regulatory impact assessment, issuers that are regulated by the Department of Managed Health Care in California do not file with the NAIC. Second, and more importantly, the estimate provided here is of enrollment at an average point in time, while previous estimates included people who were enrolled at some point during the year. Third, the Current Population Survey, which was the source of previous estimates, is thought by some analysts to overestimate the number of people purchasing individual coverage.

Table VI.2
Estimated Number of Issuers and Licensed Entities Subject to the Medical Loss Ratio Reporting Requirements By Market

Description	Issuers (1) Offering Comprehensive Major Medical Coverage		Licensed Entities (2) Offering Comprehensive Major Medical Coverage		Enrollees in Comprehensive Major Medical Coverage (3)	
	Number	% of Total	Number	% of Total	Number (thousands)	% of Total
Total Issuers (4)	442	100.0%	2,002	100.0%	74,830	100.0%
By Market:						
Individual Market	311	70.4%	1,429	71.4%	10,603	14.2%
Small Group Market (5)	342	77.4%	976	48.8%	24,189	32.3%
Large Group Market	338	76.5%	912	45.6%	40,039	53.5%
By Number of Markets:						
Single Market Only	118	26.7%	1,159	57.9%	3,722	5.0%
Individual Market Only	66	14.9%	792	39.6%	2,317	3.1%
Small Group Market Only	27	6.1%	187	9.3%	845	1.1%
Large Group Market Only	25	5.7%	180	9.0%	560	0.7%
Two Markets	100	22.6%	371	18.5%	9,934	13.3%
All Three Markets	224	50.7%	472	23.6%	61,173	81.7%

Notes: (1) Issuers represents companies (e.g., NAIC company codes). (2) Licensed Entities represents company / State combinations. (3) Enrollment represents "life years" (total member months divided by 12). (4) Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. (5) Small group is defined based on the current definition in the PHS Act.
Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

b. Characteristics of the Affected Entities

Table VI.3 provides additional information about the characteristics of the issuers that are subject to the MLR

requirements. Most (80 percent) of these companies are subsidiaries of larger carriers, and more than two thirds (315) only offer coverage in a single State. A third (143) of the issuers that are subject to the MLR requirements collected less than $50 million in earned premiums for individual and group comprehensive major medical coverage in 2009, 21 percent (92) collected $50 to $149 million, 31 percent (138) collected $150 to $999 million, and 16 percent (69) collected $1 billion or more in earned premiums that year. Meanwhile, 80 percent of the affected issuers also offer other types of accident and health coverage that is not subject to the requirements of this interim final regulation.

Table VI.3
Selected Characteristics of Issuers Subject to the Medical Loss Ratio (MLR) Reporting Requirements

Description		Number of Issuers (1)	Percent of Total
Estimated Total Number of Issuers Subject to the MLR Requirements (2)		442	100.0%
By Corporate Structure			
	Independent Company	87	19.7%
	Subsidiary of a Larger Carrier (3)	355	80.3%
By Number of States in Which Coverage is Offered			
	1 State	315	71.3%
	2 to 5 States	74	16.7%
	5 to 19 States	22	5.0%
	20 or More States	31	7.0%
By Total Earned Premiums for Individual and Group Comprehensive Major Medical Coverage			
	Less Than $10 Million	72	16.3%
	$10 million to $49 million	71	16.1%
	$50 million to $149 million	92	20.8%
	$150 million to $999 million	138	31.2%
	$1 billion or more	69	15.6%
By Scope of Coverage Offered			
	Only Offers Individual and Group Comprehensive Major Medical Coverage	82	18.6%
	Also Offers Other Types of Accident and Health Coverage	360	81.4%

Notes: (1) All data are based on the issuers' 2009 NAIC annual financial statements. (2) Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. (3) The Department estimates that in addition to the 87 independent companies, approximately 109 multi-company carriers offer coverage that is subject to the requirements of this interim final rule.
Sources: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

While all 442 of these issuers will be subject to the requirements of this interim final regulation, the Department estimates only a subset of these companies will be required to pay MLR-related rebates to policyholders during any given year. The following section contains estimates of the number of entities whose coverage will not meet the applicable minimum MLR thresholds, the estimated MLR rebate payments, and the estimated number of enrollees that would receive the MLR rebates.

6. Estimated MLR Rebate Payments

To date, there have been few published studies that document MLRs for comprehensive major medical coverage offered in the individual, small group and large group markets at the State and company levels nationwide.[11] Additionally, as discussed earlier, there are a number of challenges related to using the 2009 NAIC data. Despite these limitations, the Department believes that the 2009 NAIC data provide a reasonable basis for developing a model to be used for estimating the universe of entities that are likely to be affected by the MLR requirements, and estimating a potential range of other impacts

[11] For example, the Senate Commerce Committee used NAIC data to report on nationwide MLRs for selected companies, but did not analyze MLRs at the State level (see "Implementing Health Insurance Reform: New Medical Loss Ratio Information for Policymakers and Consumers: Staff Report For Chairman Rockefeller," U. S. Senate, Committee on Commerce, Science and Transportation, April 15, 2010, accessed at http://commerce.senate.gov/public/index.cfm?p=Reports). It is also important to note that MLRs calculated for other purposes may not provide an accurate picture of MLRs under the Affordable Care Act, which includes adjustments for administrative expenses related to quality improving activities and small plans.

including rebate amounts.[12] Specifically, the Department believes that a reasonable range of assumptions can be applied to the 2009 NAIC data making it the best available source for estimating the potential impacts of this interim final regulation. Therefore, using data from NAIC annual financial statements, the Department summarized data on traditional or unadjusted MLR values prior to the enactment of Affordable Care Act and estimated the impact of the Affordable Care Act's MLR provisions on the market.

In considering how to model the MLR impacts, the Department examined State experience with various types of related policies. Some States have traditionally used MLR standards for reviewing rate filings, others have set minimum standards, a few States require rebates to be made if minimum standards are not met, and many States have no requirements. The Department estimates that prior to the enactment of the Affordable Care Act, approximately 32 States (including the District of Columbia) had enacted requirements relating to minimum MLR standards or administrative expense limits for coverage in at

[12] The NAIC has developed a "Supplemental Blank" that will be used to collect 2010 comprehensive major medical data by company, State and market that are consistent with the uniform definitions and standardized calculation methodologies that NAIC was required to develop under Section 2718(c) of the PHS Act (subject to certification by the Secretary). However, this information will not be available until the Spring of 2011.

least some segments of the individual and group markets,[13] primarily in the context of submitting historical and anticipated loss ratios as part of their rate filings; approximately 19 States did not have any minimum MLR requirements for individual or group coverage prior to the enactment of the Affordable Care Act. State-level MLR requirements, where they existed, often varied by the type of coverage being offered, were sometimes optional, and lacked standardization in the way that the MLRs were to be calculated. In addition, States' minimum MLR requirements were often quite low – approximately 10 States had loss ratio requirements that were as low as 55 percent for at least some segments of the market, and another 13 States had minimum MLR thresholds between 60 and 75 percent for at least some segments of the market. The Department estimates that nine States have enacted minimum MLR thresholds or administrative expense limits requiring that at least 80 percent of premiums be spent on clinical services in at least some segments of the individual and group markets.

[13] This is consistent with America's Health Insurance Plans (AHIP) data, which suggest that there are 32 States that have established MLR guidelines or imposed limitations on administrative expenses for comprehensive major medical insurance (excluding States that require filing of loss ratios, but have not established minimum standards), see "State Mandatory Medical Loss Ratio (MLR) Requirements for Comprehensive, Major Medical Coverage: Summary of State Laws and Regulations, as of April 15, 2010", AHIP, accessed at http://www.naic.org/documents/committees_lhatf_ahwg_100426_AHIP_MLR_Chart.pdf .

For several reasons, the State experience with MLR requirements was not useful for modeling the effects of imposing an 80 percent MLR requirement nationwide for the individual and small group markets, and an 85 percent MLR requirement nationwide for the large group market. First, as described above, the States varied considerably in terms of MLR definitions and policy implementation. The experience of the nine States that have enacted 80 percent or higher MLR thresholds for at least a portion of the affected market may have been relevant, but there was not sufficient data available to estimate the impact of their policies and generalize to the national level. For example, in five of these States, the 80 percent or higher thresholds only apply to a portion of the market.[14] Additionally, there is limited data available for several of these States; for example, there is limited availability of California HMO data because they do not file with the NAIC; New Jersey first imposed its 80 percent requirement for the individual and small group markets in 2009 (prior to that, the State had a 75 percent minimum MLR standard

[14] The 80 percent or higher minimum MLR requirements apply only to HMOs in California, only to HMO point of service plans in Arkansas, only to small group special health care plans in Connecticut, only to small group plans assessed 3 percent or more of the total annual amount assessed by the State's high risk pool in Minnesota, and only for nonprofit medical and dental indemnity or health and hospital service corporation individual direct payment contracts in New York.

for individual and small group coverage);[15] and New Mexico's 80 percent and 85 percent standards for the small group and large group markets, respectively, were just enacted on March 3, 2010 (prior to that, the State had a 55 percent minimum MLR standard for small group coverage, and no minimum MLR standard for the large group market). Additionally, in New York and New Jersey, the market for individual unsubsidized insurance is extremely small, largely as a result of rating rules. Finally, Ohio's provision limiting the administrative expenses that an insurer can spend to no more than 20 percent applies to the insurance company as a whole (e.g., the State does not have separate requirements for coverage offered in the individual, small group and large group markets, as required by the Affordable Care Act).[16] The State's regulators estimate that carriers will be close to the Affordable Care Act's minimum MLR thresholds for small group and large group coverage, but that some carriers will have to "raise the bar" in order to meet the standards for the individual market.[17]

---

[15] Carriers in New Jersey are required to pay rebates if they have a loss ratio below the minimum standard. In 2008, total standard and non-standard market refunds paid by carriers in the State were approximately $850,000. New Jersey Department of Banking and Insurance, "SEH Loss Ratio and Refund Reports for 2008," April 19, 2010, accessed at http://www.pdcbank.state.nj.us/dobi/division_insurance/ihcseh/sehrpts/seh08lossratiorpt.pdf.

[16] Ohio Revised Code §3923.022, accessed at http://codes.ohio.gov/orc/3923.

[17] Adamczak, Rick, "New Regs Unlikely to Have Much Impact on Ohio Insurers," Dayton Legal News, November 1, 2010, accessed at https://www.dailycourt.com/articles/index/id/7284.

It is difficult to draw general lessons from the experience in these nine States about the likely results of imposing an 80 percent MLR requirement for the individual and small group market nationwide – relevant data are not available in many of the States, the level of aggregation is not consistent in one of the States, and rating rules in two of the States are so different than in most of the rest of the country that results are not likely to be generalizable. Most importantly, in all nine States data were not available over a sufficient time period to establish causality between State policies and observed MLRs.

a. Data Limitations and Modeling Assumptions

As discussed earlier in section VI.B.4 of this regulatory impact analysis, and in a Technical Appendix that is available at http://www.hhs.gov/ociio/regulations/index.html, the available data are less than perfect for the task at hand. Among the larger imperfections: the data do not measure quality improving activities as defined by this interim final regulation; the data for some issuers and States are clearly in error; and the data capture administrative expenses at the national level, but do not allocate them to States or to markets (individual, small group, and large group).

The Department expects that as a result of this interim final regulation that issuer behavior may well change, and even

if the data could precisely measure MLRs in 2009, MLRs in 2011 may well be different as a result of issuer behavioral change. However, for purposes of this analysis we do not explicitly model these behavioral changes in our estimates. Potential behavioral changes as a result of this regulation and impact on our estimates are discussed below, including:

- Insurer Pricing Policy – Companies will likely consider a number of responses in pricing 2011 policies (e.g., reducing premium increases or increase health care expenditures) that would minimize or avoid rebates. As a result of these anticipated responses, estimates based on the 2009 data would result in upwardly biased estimates of potential rebates;
- Allocation of Expenses Across States and Markets and Affiliates – Issuers were not previously required to allocate company-level expenses by State and by line of business in their annual financial report submissions to the NAIC. However, companies are likely to focus more attention on the methodologies that they use for allocating administrative expenses now that this information will be used in determining if they owe rebates for a given company / State / market. The choices issuers make in determining allocation methods could have a material impact on MLR rebates;

- Activities That Improve Quality – Issuers may increase their quality-improving activities given the financial incentive to do so, or newly describe existing activities as such, and spending on these activities may vary significantly by State or company;
- Other Changes in Categorization – Companies are expected to carefully scrutinize all of their expenditures to determine whether some could legitimately be categorized as expenditures for clinical services or quality improvement based on the definitions implemented by this regulation;
- Other Behavioral Changes – It is unclear to what extent companies may make other behavioral changes that could affect MLR rebates (e.g., expanding coverage to increase medical claims, limiting premium increases, consolidation, etc.); and
- Potential Impact of Destabilization Policy – It is unknown to what extent State Commissioners of Insurance will request adjustments of the 80 percent individual market minimum MLR threshold under the destabilization policy, and unknown whether the justifications provided with these requests will be sufficient to allow the Secretary to grant the adjustments. Thus, it is unknown how these potential adjustments will affect the size of MLR rebates.

b. Methods for Estimating MLR Rebates

The analysis includes estimates that are based on both unadjusted and adjusted MLRs. Information on unadjusted MLRs, which are simply incurred claims divided by earned premiums, is included to assess the impact of the adjustments allowed by the regulation on companies' State-level MLRs.[18]

The adjusted MLRs include three sets of adjustments for: (1) taxes and fees; (2) credibility adjustments; and (3) quality improvements. First, the adjustments include deductions for Federal and State taxes and licensing and regulatory fees from premiums. These adjustments follow the policy described in the regulation.

Second, they apply estimates of the credibility adjustments for licensed entities that have partially credible experience, that is, issuers with life years that are greater than or equal to 1,000 life years but less than 75,000 life years, based on the 2009 NAIC data.[19] Section D of the preamble describes the rationale and method for calculating credibility adjustments. As stated in this section, there are two components to the credibility adjustment: a base factor that depends on the number

[18] As discussed earlier, data for mini-med plans are not broken out separately from other data that issuers reported to NAIC in 2009. Therefore, this regulatory impact analysis does not include separate estimates relating to mini-med plans.

[19] For purposes of this analysis, the Department has not made any assumptions relating to the potential for annual fluctuations in the estimated number of issuers with non-credible and partially credible experience.

of life years a company has in a particular market and State and a factor that depends on average per person deductible for the experience reported in the MLR for a particular market and State. The total credibility adjustment to the MLR equals the base factor times the deductible factor. We used linear interpolation to calculate the base credibility adjustment factor for life years that fall between the values in Table 1 of the preamble.

Third, the adjusted MLRs reported in this analysis also incorporate assumptions about the size of expenses for quality improvement activities, as well as assumptions about other actions that insurers might take to increase their reported MLR. Because the definitions of quality improving activities are new to this rule, the NAIC data collected in 2009 cannot be used to directly estimate how much insurers spent on quality improving activities in 2009 or how much they are expected to spend on these activities in 2011. The closest category in the NAIC data is "cost containment expenses", which averaged approximately 1 percent of premiums in 2009, but the definition of quality improving activities includes many activities that were not included in cost containment expenses. Discussions with industry experts suggest that quality improving activities are likely to account for an average of approximately 3 percent of premium, but there is substantial uncertainty concerning this estimate.

Few observers think that quality improving activities will be greater than 5 percent of premium, and few expect that they will be less than 1 percent of premium. In the mid-range estimate, the Department assumes that quality improving activities will account for 3 percent of premium, and uses the 1 percent and 5 percent estimates as the range in a sensitivity analysis.

In addition to uncertainty about the magnitude of quality improving activities, as discussed above, there are many other sources of uncertainty about how insurers will respond to this interim final regulation, and the effects of these responses on MLRs and rebate amounts.

Given the combination of data imperfections and behavioral uncertainties, the Department has chosen to provide a range of estimates, based on a range of assumptions. A reasonable range of assumptions is that, in the mid-range estimate, MLRs will increase by 1 percentage point relative to the data reported in 2009, with a reasonable bound for this assumption being on one end, no change from the 2009 data, and, on the other end, an assumption that MLRs will increase by 2 percentage points relative to the 2009 data.

Combined with the low-rebate assumption that quality improving activities will increase MLRs by 5 percentage points, the assumption that other behavioral changes may increase MLRs by an additional 2 percentage points will result in estimated

MLRs in the low-rebate scenario being 7 percentage points higher than they would be with no allowance for either quality improving activities or other behavioral changes. Consultation with industry experts suggests that this is a reasonable upper bound for the low-rebate assumption as an average for the industry. It is possible that some issuers may invest greater than 5 percent of premium in quality improving activities, or change their behavior in ways that result in a greater than 2 percentage point increase in MLR, but the Department thinks it is unlikely that the changes across the industry for quality improving activities and behavioral changes will be greater than 7 percentage points.

The Department further assumes that issuers with an MLR that is already above the minimum threshold (80 percent in the individual and small group markets, 85 percent in the large group market) will have less incentive to change their behavior in an attempt to increase their MLR than will issuers with lower MLRs that would require them to pay rebates. In the mid-range and low-rebate scenarios, the Department assumes that issuers whose adjusted MLR is above the minimum threshold after an assumed 3 percent increase for quality improving activities will not further increase the MLR with additional quality improving activities or other behavioral changes.

Table VI.4 summarizes the values that are added to the base MLR to adjust for quality improving expenses and other behavioral uncertainties.

Table VI.4
Assumptions used to estimate MLRs under a range of scenarios

Category	Low estimate for rebates *(in percentage points)*	Medium estimate for rebates *(in percentage points)*	High estimate for rebates *(in percentage points)*
Quality improvement activities	+5	+3	+1
Behavioral uncertainties	+2	+1	+0
Total impact on MLRs	+7	+4	+1

NOTE: In the low-range and mid-range scenarios, for issuers whose MLR is above the minimum threshold after 3 percentage points are added for quality improving activities, additional adjustments are not made.

These three sets of adjustments are combined to produce the following formula for estimating companies' adjusted MLRs for the individual, small group, and large group markets by State, rounded to the nearest thousandth decimal place as dictated in the regulation[20]:

[20] The text states that in the mid-range assumption, quality improving activities will account for 3 percent of premium. In the formula above, quality improving (and other behavioral change assumptions) are expressed as percentage point increases in the MLR amount. That is, in the mid-range assumption, we assume that quality improvement expenses will add 3 percentage points to the MLR. As a practical matter, because Federal and State taxes and licensing and regulatory fess are quite small, there is virtually no difference between assuming that quality improvement expenses account for 3 percent of premium or assuming that they will add 3 percentage points to the MLR.

Adjusted MLR = (c)/(p - t - f) + (b*d) + u,

where c = incurred claims

p = earned premiums

t = Federal and State taxes

f = licensing and regulatory fees

b = base credibility adjustment factor

d = deductible credibility adjustment factor

u = low, medium, or high assumptions to account for quality improving activities, unknown behavioral changes and data measurement error

We then calculate rebates for a company whose adjusted MLR value in a State falls below the minimum MLR standard in a given market using the following formulas:

Rebates = [(m – a)* (p - t - f)]

where m = minimum MLR standard for a particular market

a = adjusted State MLR for that market

Finally, to estimate impacts for each year covered by the regulation, we assume that the number of issuers, enrollment, and experience are stable over time. This interim final regulation requires that experience be combined across multiple years for issuers that are not fully credible based on a single

year of data. Given the assumption that enrollment is stable over time, the Department estimates that issuers which are not fully credible in 2011 will have twice as much enrollment in the combined experience for 2011 and 2012, and three times as much enrollment in the combined 2011 through 2013 data. As a result, the magnitude of the credibility adjustment in 2012 will be smaller than in 2011, and smaller again in 2013. The Department is unable to model the impact of losing the MLR credibility adjustment beginning in 2013 if licensed entities report partially credible experience for the current year and the two previous years and have MLRs below the minimum standard in all three years. Rebates are estimated in 2011 through 2013 by applying the projected growth rate in private health insurance premiums from the National Health Expenditures Accounts to the 2009 NAIC adjusted premiums. However, the analysis does simulate the impact of doubling life years in 2012 or tripling life years in 2013 for licensed entities that have non-credible or partially credible experience using a single year of data to estimate how this affects the portion of insurers that are deemed to have credible experience as well as their associated MLR values in those years. Additionally, rebates are estimated in 2011 through 2013 by applying the projected growth rate in private health insurance premiums from the National Health

Expenditures Accounts (per privately insured) to the 2009 NAIC adjusted premiums.

c. Estimated Number of Issuers and Individuals Affected By the MLR Rebate Requirements

As shown in Table VI.5, the Department estimates that 68 percent of the licensed entities (State/company combinations) nationwide selling comprehensive major medical insurance in the individual market in 2011 will have fewer than 1,000 enrollees in at least one State, and will be designated as "non-credible" according to the standards of this interim final regulation, 30 percent of licensed entities will be partially credible, and 2 percent will be fully credible.[21] As discussed elsewhere in this preamble, issuers with non-credible experience in a given State, for a given market, during a given MLR reporting year are not required to provide any rebate to enrollees in that State/market because the issuer does not insure a sufficiently large number of lives to yield a statistically valid MLR.

Although the Department estimates that more than two-thirds of licensed entities (State-company combinations) have non-

[21] As described above, insurers with non-credible experience are those with less than 1,000 life years in a particular State market and they are not subject to the rebate requirements. Insurers with partially credible experience are those with 1,000 or more life years but fewer than 75,000 life years. These insurers receive a credibility adjustment to their adjusted MLRs to account for statistical variability that is inherent in smaller blocks of business. Finally, insurers with fully credible experience are those with 75,000 life years or more. Reported MLR values for fully credible insurers are used without a credibility adjustment in a given reporting year to determine their rebate obligation.

credible 2011 experience for the individual market, and will not be required to provide rebates to their enrollees, there are relatively few enrollees in licensed entities that are non-credible – the non-credible licensed entities account for 68 percent of all entities, but only 1 percent of enrollees and 2 percent of earned premiums in the individual market. Fully credible licensed entities, accounting for only 2 percent of licensed entities, account for 50 percent of enrollees and 49 percent of premiums.

Table VI.5. Percent distribution of credible experience, by market and year (2011-2013)

Year	Measure	Individual Market			Small Group Market			Large Group Market		
		Licensed entities	Life years (Millions)	Premiums earned (Millions)	Licensed entities	Life years (Millions)	Premiums earned (Millions)	Licensed entities	Life years (Millions)	Premiums earned (Millions)
2011	Non-credible coverage(%)	68%	1%	2%	40%	0%	0%	32%	0%	0%
	Partially credible coverage(%)	30%	49%	50%	52%	30%	31%	54%	24%	22%
	Fully credible coverage(%)	2%	50%	49%	7%	70%	68%	15%	76%	78%
	Total	1,429	11	$28,540	976	24	$92,142	912	40	$164,337
2012	Non-credible coverage(%)	60%	1%	1%	33%	0%	0%	28%	0%	0%
	Partially credible coverage(%)	36%	34%	34%	54%	17%	18%	48%	12%	11%
	Fully credible coverage(%)	4%	65%	65%	13%	82%	82%	24%	88%	89%
	Total	1,429	11	$29,513	976	24	$95,283	912	40	$169,938
2013	Non-credible coverage(%)	56%	0%	1%	30%	0%	0%	26%	0%	0%
	Partially credible coverage(%)	38%	26%	26%	53%	13%	13%	44%	8%	8%
	Fully credible coverage(%)	7%	73%	73%	17%	87%	87%	30%	92%	92%
	Total	1,429	11	$30,146	976	24	$97,326	912	40	$173,583

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: The analysis assumes that number of licensed entities, life years, and experience are stable over time. Excludes data for companies that are regulated by non-Health and Life Blank filers.

Non-credible entities account for a smaller share of total entities, and a smaller share of enrollees and premiums in the small group market than in the individual market, and an even smaller share in the large group market than in the small group market. Conversely, fully credible entities are a larger share of the market in both the small group and large group markets than in the individual market.

As described above, the Department assumes that MLRs and enrollment are constant in 2012 and 2013. As a result of this assumption, the number of non-credible entities declines somewhat in 2012 and again in 2013, because experience is combined across multiple years.

d. Impact of Adjustments on MLRs

As shown in Table VI.6, the estimated average unadjusted MLR among all fully or partially credible entities in the individual market in 2011 is expected to be 79.5 percent – very close, on average, to the 80 percent minimum threshold required under the Affordable Care Act. When adjustments are made for taxes, licensing and regulatory fees, quality improving activities, and assumed behavioral changes, the Department's mid-range estimate is that the average MLR in the individual market in 2011 will be 86.5 percent, with a low-range estimate (where low-range refers to low-range for the rebate estimate) of

87.2 percent, and a high-range rebate estimate of 84.2 percent. The mid-range estimate is approximately 7 percentage points above the unadjusted estimate. Of this difference, 3.5 percentage points results from the assumption made about quality improving and other behavior assumptions (3 percentage points for quality improving activities and 0.5 percentage points for other behavioral assumptions), and 3.6 of the percentage point difference comes from the other adjustments, primarily the exclusion of Federal and State taxes and licensing and regulatory fees from the denominator, as well as the credibility adjustment.

The average adjusted MLR in the small group market in 2011 is estimated to be 90.8 percent for the mid-range estimate, and is estimated at 94.2 percent for the mid-range estimate in the large group market.

Table VI.6. Average unadjusted and adjusted MLRs all credible filers, by market and year (2011)

Year	Individual Market					Small Group Market					Large Group Market				
	Number of licensed entities	Average Unadjusted MLRs	Average adjusted MLRs			Number of licensed entities	Average Unadjusted MLRs	Average adjusted MLRs			Number of licensed entities	Average Unadjusted MLRs	Average adjusted MLRs		
			Low rebate estimate	Medium rebate estimate	High rebate estimate			Low rebate estimate	Medium rebate estimate	High rebate estimate			Low rebate estimate	Medium rebate estimate	High rebate estimate
2011	461	79.5%	87.2%	86.5%	84.2%	584	85.1%	90.8%	90.8%	88.7%	624	88.6%	94.2%	94.2%	92.2%

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: Average MLRs are weighted by premiums in the market. Estimates are for insurers that are subject to rebate requirements in a given year. The analysis assumes that number of licensed entities, life years, and experience are stable over time. The variation in the average MLRs across the years is due to doubling life years in 2012 and tripling life years in 2013 for licensed entities that have non-credible or partially credible experience using a single year of data. This simulation affects the pool of insurers that are subject to the rebate requirements in any given year and the credibility adjustment factors they receive for their adjusted MLRs. The low, medium, and high estimates reflect assumptions for the adjusted MLRs that will give a low to high range of rebate etimates. Consequently, the low rebate estimate will have the highest average MLRs and the high rebate estimate will have the lowest average MLRs. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers.

e. Estimated Range of MLR Rebates

As shown in Table VI.7, in the mid-range estimate in the individual market, rebates in 2011 are estimated to be $521 million. The $521 million accounts for approximately 7 percent of premium revenue at companies required to pay a rebate – that is, the average rebate at companies required to pay a rebate in the individual market is estimated to be 7 percent of premium. The $521 million accounts for approximately 2 percent of all premiums written in the individual market. Approximately 3.2 million people, accounting for approximately 30 percent of enrollees in the individual market are estimated to receive a rebate, and the average rebate per person receiving a rebate is estimated as $164.

Over the 2011-2013 period, the Department's mid-range estimate is that rebates will total $1.8 billion in the individual market, $770 million in the small group market, and $440 million in the large group market. Additionally, the Department estimates that 9.9 million enrollees in the individual market, 2.3 million enrollees in the small group market, and 2.7 million enrollees in the large group market will receive rebates over the 2011-2013 period under the mid-range estimate. Summing across all three markets, the mid-range estimate is a total of $3.0 billion in rebates over the 2011-2013 period. The low rebate estimate across all three markets

for 2011-2013 is $2.0 billion, and the high rebate estimate is $4.9 billion.

Table VI.7. Individual Market - Percent of market below minimum MLR threshold and total rebate amounts using unadjusted and adjusted MLR values, by year (2011-2013)

Year	Measure		Adjusted MLRs		
			Low rebate estimate	Medium rebate estimate	High rebate estimate
2011	Licensed entities	N	151	179	218
		% of total	11%	13%	15%
	Life years	N (Millions)	2.2	3.2	5.3
		% of total	21%	30%	50%
	Premiums	$ (Millions)	$5,364	$7,931	$13,329
		% of total	19%	28%	47%
	Rebates	$ (Millions)	$337	$521	$839
		% of total premiums	1%	2%	3%
		% of premiums below	6%	7%	6%
		Rebates per life year below	$150	$164	$157
2012	Licensed entities	N	204	233	277
		% of total	14%	16%	19%
	Life years	N (Millions)	2.4	3.3	5.4
		% of total	22%	31%	51%
	Premiums	$ (Millions)	$5,827	$8,564	$13,938
		% of total	20%	29%	47%
	Rebates	$ (Millions)	$392	$590	$935
		% of total premiums	1%	2%	3%
		% of premiums below	7%	7%	7%
		Rebates per life year below	$167	$177	$172
2013	Licensed entities	N	235	270	310
		% of total	16%	19%	22%
	Life years	N (Millions)	2.4	3.4	5.4
		% of total	23%	32%	51%
	Premiums	$ (Millions)	$6,250	$9,076	$14,563
		% of total	21%	31%	49%
	Rebates	$ (Millions)	$435	$646	$1,009
		% of total premiums	1%	2%	3%
		% of premiums below	7%	7%	7%
		Rebates per life year below	$179	$190	$185

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: Level estimates are for insurers that are subject to rebate requirements in a given year. "Percent of total" figures, however, reflect the percent of the entire market that is below the minimum MLR threshold for that market. The low, medium, and high estimates reflect assumptions for the adjusted MLRs that will give a low to high range of rebate esitmates. Additionally, premium and rebate totals estimated using 2009 data were inflated to 2011-2013 levels by applying the projected growth in private health insurance premiums from the National Health Expenditure Accounts. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Dollar values represent projected amounts for each year.

Table VI.8. Small Group Market - Percent of market below minimum MLR threshold and total rebate amounts using unadjusted and adjusted MLR values, by market and year (2011-2013)

Year	Measure		Adjusted MLRs		
			Low rebate estimate	Medium rebate estimate	High rebate estimate
2011	Licensed entities	N	32	54	91
		% of total	3%	6%	9%
	Life years	N (Millions)	0.3	0.7	1.7
		% of total	1%	3%	7%
	Premiums	$ (Millions)	$891	$2,876	$6,526
		% of total	1%	3%	7%
	Rebates	$ (Millions)	$166	$226	$359
		% of total premiums	0%	0%	0%
		% of premiums below	19%	8%	5%
		Rebates per life year below	$587	$312	$216
2012	Licensed entities	N	55	80	129
		% of total	6%	8%	13%
	Life years	N (Millions)	0.3	0.8	1.8
		% of total	1%	3%	7%
	Premiums	$ (Millions)	$1,043	$3,221	$7,112
		% of total	1%	3%	7%
	Rebates	$ (Millions)	$188	$260	$411
		% of total premiums	0%	0%	0%
		% of premiums below	18%	8%	6%
		Rebates per life year below	$595	$333	$232
2013	Licensed entities	N	70	95	147
		% of total	7%	10%	15%
	Life years	N (Millions)	0.3	0.8	1.9
		% of total	1%	3%	8%
	Premiums	$ (Millions)	$1,236	$3,597	$7,799
		% of total	1%	4%	8%
	Rebates	$ (Millions)	$201	$281	$444
		% of total premiums	0%	0%	0%
		% of premiums below	16%	8%	6%
		Rebates per life year below	$580	$335	$236

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: Level estimates are for issuers that are subject to rebate requirements in a given year. "Percent of total" figures, however, reflect the percent of the entire market that is below the minimum MLR threshold for that market. The low, medium, and high estimates reflect assumptions for the adjusted MLRs that will give a low to high range of rebate esitmates. Additionally, premium and rebate totals estimated using 2009 data were inflated to 2011-2013 levels by applying the projected growth in private health insurance premiums from the National Health Expenditure Accounts. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Dollar values represent projected amounts for each year.

Table VI.9. Large Group Market - Percent of market below minimum MLR threshold and total rebate amounts using unadjusted and adjusted MLR values, by market and year (2011-2013)

Year	Measure		Adjusted MLRs		
			Low rebate estimate	Medium rebate estimate	High rebate estimate
2011	Licensed entities	N	31	48	94
		% of total	3%	5%	10%
	Life years	N (Millions)	0.3	0.7	2.0
		% of total	1%	2%	5%
	Premiums	$ (Millions)	$831	$2,274	$6,765
		% of total	1%	1%	4%
	Rebates	$ (Millions)	$84	$121	$258
		% of total premiums	0%	0%	0%
		% of premiums below	10%	5%	4%
		Rebates per life year below	$312	$166	$127
2012	Licensed entities	N	41	72	116
		% of total	4%	8%	13%
	Life years	N (Millions)	0.3	1.0	2.2
		% of total	1%	2%	5%
	Premiums	$ (Millions)	$1,005	$3,176	$7,593
		% of total	1%	2%	4%
	Rebates	$ (Millions)	$100	$150	$309
		% of total premiums	0%	0%	0%
		% of premiums below	10%	5%	4%
		Rebates per life year below	$302	$156	$141
2013	Licensed entities	N	50	82	131
		% of total	5%	9%	14%
	Life years	N (Millions)	0.3	1.0	2.3
		% of total	1%	3%	6%
	Premiums	$ (Millions)	$1,096	$3,599	$8,257
		% of total	1%	2%	5%
	Rebates	$ (Millions)	$110	$165	$337
		% of total premiums	0%	0%	0%
		% of premiums below	10%	5%	4%
		Rebates per life year below	$321	$160	$148

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: Level estimates are for insurers that are subject to rebate requirements in a given year. "Percent of total" figures, however, reflect the percent of the entire market that is below the minimum MLR threshold for that market. The low, medium, and high estimates reflect assumptions for the adjusted MLRs that will give a low to high range of rebate esitmates. Additionally, premium and rebate totals estimated using 2009 data were inflated to 2011-2013 levels by applying the projected growth in private health insurance premiums from the National Health Expenditure Accounts. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Dollar values represent projected amounts for each year.

In the low-rebate estimate, total rebates in the individual market are estimated at $337 million, with 21 percent of enrollees in the individual market estimated to receive a rebate, and in the high-rebate scenario, $839 million, with 50 percent of enrollees.[22]

Estimated rebates in the small group market range from $166 million to $359 million, with a mid-range estimate of $226 million (Table VI.8), and from $84 million to $258 million in the large group market, with a mid-range estimate of $121 million. In both the small group and large group (Table VI.9) markets a small fraction of enrollees are estimated to receive rebates – in the mid-range scenario, 3 percent in the small group market and 2 percent in large group.

f. Potential Impact of State Destabilization Adjustment Requests on MLR Rebates

Section 2718(b)(1)(A)(ii) provides that the Secretary may adjust the 80 percent level with respect to the individual market of a State "if the Secretary determines that the application of such 80 percent may destabilize the individual market in such State." Subpart C of this interim final regulation implements this provision by setting forth who may

[22] The average rebate per person receiving a rebate is slightly lower in the high rebate scenario than in the mid-range scenario because in the high rebate scenario there are a larger number of issuers and enrollees with MLRs that are close to the 80 percent threshold, and average rebates for these enrollees are relatively low.

apply, how to apply, the criteria used in assessing an application, and how the adjustment would be made. It proposes that States apply for a specific adjustment to the individual market threshold that would be approved only if, according to information provided to the Secretary and assessed by the proposed criteria, there is a reasonable likelihood that market destabilization would occur in the absence of such an adjustment.

Prior to the publication of this interim final regulation, several States have indicated their interest in an adjustment to the MLR threshold for their individual markets. However, this interest was expressed before the NAIC recommendations and proposed rules that may lessen the need for such an adjustment. For example, the credibility adjustments, newer plan adjustments, and treatment of Federal taxes may lessen what they had projected would be the impact of the MLR rules. In addition, as described earlier, the behavioral response of issuers to the proposed rules is uncertain. As such, the Department has not produced quantitative estimates of the potential impact of this authority.

However, if this authority is exercised, by definition, there would be fewer issuers and enrollees to whom rebates in the individual market apply. There would also be fewer benefits as well as costs than previously described. While the benefit

of transparency would persist regardless of whether a rebate is made, issuers may have less of an incentive to improve quality or benefits if the MLR threshold were lower than 80 percent. At the same time, the goal of the adjustment is prevent disruption, so individuals in States whose MLR threshold has been adjusted would have more health insurance options than they otherwise would.

7. Estimated Administrative Costs Related to MLR Provisions

As stated earlier in this preamble, this interim final regulation implements the reporting requirements of section 2718(a), describing the type of information that is to be included in the report to the Secretary and made available to consumers, as well as the rebate calculation, payment and enforcement provisions of section 2718(b). The Department has quantified the primary sources of start-up costs that issuers in the individual and group markets will incur to bring themselves into compliance with this interim final regulation, as well as the ongoing annual costs that they will incur related to these requirements. These costs and the methodology used to estimate them are discussed below and in the Technical Appendix available at http://www.hhs.gov/ociio/regulations/index.html. Additional detail on these estimates can be found in the Paperwork Reduction Act section of this preamble and we welcome comment on them.

a. Methodology and Assumptions for Estimating Administrative Costs

The Affordable Care Act MLR reporting requirements will affect health insurance issuers offering coverage in the individual and group markets, including both the small group and large group markets. As discussed earlier, most of the affected issuers currently report similar data to the NAIC as part of their annual financial statements. However, this interim final regulation includes requirements related to calculating some additional data elements, and allocating data by company, State and market.

As discussed earlier in this impact analysis, in order to assess the potential administrative burden relating to the requirements in this interim final regulation, the Department consulted with the NAIC and an industry expert to gain insight into the tasks and level of effort required. Based on these discussions, the Department estimates that issuers will incur one-time start-up costs associated with developing teams to review the requirements in this interim final regulation, and developing processes for capturing the necessary data (e.g., automating systems; writing new policies for tracking expenses in the general ledger; developing methodologies for allocating expenses by State, company and market; etc.). The Department estimates that issuers will also incur ongoing annual costs

relating to data collection, populating the MLR reporting forms, conducting a final internal review, submitting the reports to the Secretary, internal audit, record retention, and preparing and mailing rebate notifications / payments (where appropriate).

The Department anticipates that the level of effort relating to these activities will vary depending on the scope of an issuer's operations. Each issuer's estimated reporting burden is likely to be affected by a variety of factors that will affect the level of complexity of its filing – including the number of markets in which it operates (e.g., individual, small group, large group), the number of States and licensed entities through which it offers coverage, the degree to which it currently captures relevant data at the State / company / market level, firm size (e.g, claims, premiums, covered lives), whether it offers other types of A&H coverage, whether it is a Health Blank or Life Blank filer, and whether it is a subsidiary of a larger carrier. The assumptions used by the Department to estimate the administrative burden of reporting data needed to calculate MLRs, and information about the uncertainties associated with these assumptions is provided in the Technical Appendix, available at http://www.hhs.gov/ociio/regulations/index.html.

b. Estimated Costs Related to MLR Reporting

For each MLR reporting year (defined as a calendar year for purposes of this interim final regulation), issuers offering coverage in the individual and group markets must submit a report to the Secretary by June 1 of the following year that complies with the requirements this interim final rule on a form and in the manner prescribed by the Secretary. For purposes of these impact estimates, the Department assumes that there will be a single MLR data submission for purposes of both the NAIC annual report and reporting to the Secretary, and that this report would include data relating to both the amounts expended on reimbursement for clinical services, activities that improve quality and other non-clinical costs, as well as information relating to rebates.

The estimated total number of MLR data reports that issuers subject to the MLR reporting requirements will be required to submit to the Secretary under the provisions of this interim final regulation is 3,317. This is an upper-bound estimate, assuming that all issuers offering coverage in both the individual and small group markets will be submitting separate reports to the Secretary for this coverage. However, as discussed elsewhere in this preamble, the provisions of this interim final regulation allow issuers offering coverage in

States requiring that the individual and small group markets be combined to submit consolidated reports for these two markets.

Table VI.10 shows that the Department estimates that issuers will incur one-time costs relating to the MLR reporting requirements in this interim final rule of approximately $75,018 to $151,507 per issuer on average, and annual ongoing costs of about $17,261 to $32,259 per issuer annually thereafter.

Table VI.10
Estimated Administrative Costs Related to Medical Loss Ratio (MLR) Reporting Requirements

Description	Total Number of Issuers	Total Number of Reports	Estimated Total Hours	Estimated Average Cost Per Hour	Estimated Total Cost	Estimated Average Cost Per Issuer	Estimated Average Cost Per Report
LOW RANGE ASSUMPTIONS							
One-Time Costs	442	3,317	501,640	$66.10	$33,157,861	$75,018	$9,996
Ongoing Costs	442	3,317	150,817	$50.59	$7,629,237	$17,261	$2,300
Total Year One Costs	442	3,317	652,457	$62.51	$40,787,097	$92,279	$12,296
MID RANGE ASSUMPTIONS							
One-Time Costs	442	3,317	725,497	$66.31	$48,109,870	$108,846	$14,504
Ongoing Costs	442	3,317	211,214	$50.59	$10,684,490	$24,173	$3,221
Total Year One Costs	442	3,317	936,711	$62.77	$58,794,360	$133,019	$17,725
HIGH RANGE ASSUMPTIONS							
One-Time Costs	442	3,317	1,007,078	$66.50	$66,965,900	$151,507	$20,189
Ongoing Costs	442	3,317	281,863	$50.59	$14,258,342	$32,259	$4,299
Total Year One Costs	442	3,317	1,288,940	$63.02	$81,224,242	$183,765	$24,487

Notes: Issuers represents companies (e.g., NAIC company codes). Total number of reports represents the estimated total number of MLR reports that will be submitted to the Secretary (e.g., company / State / market combinations). Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Total administrative cost includes estimated costs relating to the MLR reporting, record retention, and rebate payment requirements. Estimated costs are stated in 2010 dollars.
Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

c. Estimated Costs Related to MLR Record Retention Requirements

Consistent with the assumptions discussed above, MLR record retention costs are assumed to be relatively negligible, since issuers already retain similar data for State audits. Table VI.11 shows that the Department estimates that issuers will incur annual ongoing costs relating to the MLR reporting requirements in this interim final rule of approximately $17 to $29 per issuer on average.

Table VI.11
Estimated Administrative Costs Related to Medical Loss Ratio (MLR) Record Retention Requirements

Description	Total Number of Issuers	Total Number of Reports	Estimated Total Hours	Estimated Average Cost Per Hour	Estimated Total Cost	Estimated Average Cost Per Issuer	Estimated Average Cost Per Report
LOW RANGE ASSUMPTIONS							
Ongoing Costs	442	3,317	200	$38.34	$7,668	$17	$2
MID RANGE ASSUMPTIONS							
Ongoing Costs	442	3,317	200	$50.22	$10,045	$23	$3
HIGH RANGE ASSUMPTIONS							
Ongoing Costs	442	3,317	300	$42.45	$12,734	$29	$4

Notes: Issuers represents companies (e.g., NAIC company codes). Total number of reports represents the estimated total number of MLR reports that will be submitted to the Secretary (e.g., company / State / market combinations). Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Total administrative cost includes estimated costs relating to the MLR reporting, record retention, and rebate payment requirements. Estimated costs are stated in 2010 dollars.
Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

d. Estimated Costs Related to MLR Rebate Notifications and Payments

Consistent with the assumptions discussed above, rebate notification and payment costs are expected to be relatively negligible on a per-notification and per-check basis, in particular because issuers have the option of paying rebates through premium withholds. However, the estimated total costs relating to rebate notifications and payments reflect the relatively large numbers of enrollees that could potentially receive rebates during any given year, and will be sensitive to annual fluctuations in the number of licensed entities that owe rebates for a given State and market.

Table VI.12 shows that the Department estimates that in 2011, approximately 60 to 119 issuers (companies) will pay rebates for at least one licensed entity / State / market combination, and that annual ongoing costs relating to the MLR rebate payment and notification requirements in this interim final rule will be approximately $58,010 to $122,891 per affected issuer during that year on average. This number will be sensitive to annual fluctuations in the number of licensed entities that owe rebates for a given State and market.

Table VI.12
Estimated Administrative Costs Related to Medical Loss Ratio (MLR) Rebate Notification and Payment Requirements

Description		Estimated Total Number of Affected Issuers	Estimated Total Number of Notifi-cations or Checks	Estimated Total Hours	Estimated Average Labor Cost Per Hour	Estimated Mailing and Supplies Cost Per Notifi-cation or Check	Estimated Total Cost	Estimated Average Cost Per Affected Issuer	Estimated Average Cost Per Notifi-cation or Check
LOW RANGE ASSUMPTIONS									
	Notifi-cations	60	2,796,623	46,610	$28.30	$0.49	$2,689,296	$44,822	$1
	Checks	18	838,987	20,975	$35.73	$0.05	$791,311	$43,962	$1
	Total Ongoing Costs	60	2,796,623	67,585	$30.60	$0.51	$3,480,606	$58,010	$1
MID RANGE ASSUMPTIONS									
	Notifi-cations	92	4,634,379	77,240	$28.30	$0.49	$4,456,523	$48,440	$1
	Checks	46	2,317,189	57,930	$35.73	$0.05	$2,185,512	$47,511	$1
	Total Ongoing Costs	92	4,634,379	135,169	$31.48	$0.51	$6,642,035	$72,196	$1
HIGH RANGE ASSUMPTIONS									
	Notifi-cations	119	9,016,911	150,282	$28.30	$0.49	$8,670,865	$72,864	$1
	Checks	83	6,311,838	157,796	$35.73	$0.05	$5,953,160	$71,467	$1
	Total Ongoing Costs	119	9,016,911	308,078	$32.10	$0.53	$14,624,026	$122,891	$2

Notes: Affected issuers = the estimated total number of companies (e.g., NAIC company codes) paying rebates or mailing rebate checks for at least one licensed entity / State / market in 2011. Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Estimated costs are stated in 2010 dollars.
Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

C. Regulatory Alternatives

Under the Executive Order, the Department is required to consider alternatives to issuing regulations and alternative regulatory approaches. The Department considers a variety of regulatory alternative below.

1. Credibility Adjustment

Section 2718(c) requires the NAIC to develop uniform definitions and calculation methodologies subject to certification by the Secretary. This section directs the NAIC to take into account the special circumstances of smaller plans. In response to this direction, the NAIC recommended a credibility adjustment for smaller plans. After considering the NAIC's recommendation on credibility adjustments, HHS has decided to certify and adopt it in full.

One alternative to the credibility adjustment in this interim final regulation would be to not make any adjustment for credibility, and to require smaller plans to make rebate payments on the same terms as larger plans. If the Department had not adopted a credibility adjustment, the estimated mid-range rebate in the individual market in 2011 would be approximately $682 million, or approximately $161 million larger than the estimate shown in Table VI.7 including the credibility adjustment. The mid-range estimated rebate in the small group

market would be $292 million, $66 million larger than the estimate in Table VI.8, and the mid-range estimate for the large group market would be $178 million, $57 million larger than the estimate in Table VI.9. As described elsewhere in this preamble, the Department has concluded that the credibility adjustment as proposed will best balance the goals of providing value to consumers assuring that issuers with relatively few subscribers will be able to function effectively.

2. Federal Taxes

As described elsewhere in this preamble, after considering the NAIC's recommendation on treatment of Federal taxes in the denominator of the MLR calculation, HHS has decided to certify and adopt it in full. An alternative would have been to adopt a narrower definition of the Federal taxes to be excluded. If the Department had decided that payroll and Social Security taxes should be included in the denominator, rather than excluded from the denominator as provided in this interim final regulation, the estimated rebate in the mid-range scenario in the individual market would have been $552 million, or $31 million higher than in the estimate shown in Table VI.7. Similarly, the effect of this regulatory alternative in the small group and large group markets would have been to increase the estimated rebate by $9 million in each of these two markets. As described elsewhere in this preamble, the Department has concluded that excluding

payroll taxes and Social Security taxes from the denominator balances the legitimate needs of insurers with the needs of consumers.

3. Quality Improving Activities

Section 2718(a)(2) of the PHS Act requires health insurance issuers to submit an annual report to the Secretary concerning the percent of total premium revenue that is spent on activities that improve health care quality, and Section 2718(c) of the PHS Act directs the NAIC, subject to certification by the Secretary, to establish uniform definitions of activities that improve health care quality.

As discussed elsewhere in this preamble, the NAIC recommended definitions of quality improving activities that are consistent with the categories set forth in Section 2717 of the PHS Act. After considering the NAIC's recommendation on the definition of quality improving activities, HHS has decided to certify and adopt it in full. As discussed elsewhere in this preamble, potential alternatives would have been to adopt narrower or broader definitions of quality improving activities. These distinctions can be made based on the criteria for selecting quality improving activities and/or the specific types of activities included in the definition.

This interim final regulation defines quality-improving activities as being grounded in evidence-based medicine,

designed to improve the quality of care received by an enrollee, and capable of being objectively measured and producing verifiable results and achievements. A narrower definition might include only evidence-based quality improving initiatives, while excluding activities that have not been demonstrated to improve quality. Similarly, a narrower definition would not allow for inclusion of future innovations before data are available demonstrating their effectiveness.

Conversely, a broader definition might allow additional types of administrative expenses to be counted as activities that improve quality – such as network fees associated with third party provider networks or costs associated with converting International Classification of Disease (ICD) code sets from ICD-9 to ICD-10. As discussed elsewhere in this preamble, while the Department agrees that certain administrative expenses should not be counted as quality improving, some traditional administrative activities can qualify as quality improving if they meet the criteria set forth in this interim final regulation.

The Department does not have data available to estimate the effects of alternative definitions of quality improving activities on MLRs, although it should be clear that if a broader definition of quality improving activities had been adopted that estimated rebates would be smaller, and if a

narrowed definition had been adopted, estimated rebates would be larger.

4. Level of Aggregation

As discussed elsewhere in this preamble, the NAIC could have recommended that MLRs be aggregated to the national level for multi-State companies, rather than be calculated separately in each State. If MLRs were calculated at the national level for multi-State companies, estimated rebates in the individual market in the mid-range scenario would have been $461 in 2011, or $60 million less than the estimates provided in Table VI.7. The estimated effects of national-level aggregation on the small group and large group markets are proportionally larger: in the small group market, estimated rebates in the mid-range scenario fall from $226 million to $97 million in 2011, and in the large group market, from $121 to $42 million.

Requiring issuers to aggregate their individual, small group and large group experience at the national level, rather than by State could reduce the administrative burden associated with these requirements because nearly a third of the issuers that would be affected by the requirements of this interim final regulation offer coverage in multiple States. For example, under the Department's mid-range estimates, the estimated number of MLR reports to the Secretary would decrease by 29 percent (from 3,317 to 972), and the estimated one-time and annual

ongoing costs associated with MLR reporting would decrease by approximately 49 percent compared with what is shown in Table VI.10.

Because insurance is regulated primarily at the State level, and because it is important for consumers in each State to receive value for their insurance premium, the Department has concluded that MLRs should be calculated at the issuer/market/State level, rather than aggregating results to the national level. After considering the NAIC's recommendation on the level of aggregation for purposes of MLR reporting and rebate calculation, HHS has decided to certify and adopt it in full.

We welcome comments on the likely costs and benefits of this rule as presented, on alternatives that would improve the consumer and small business purchaser information to be provided, and on our quantitative estimates of burden.

D. 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.

The Regulatory Flexibility Act only requires an analysis to be conducted for those final rules for which a Notice of Proposed Rule Making was required. Accordingly, we have determined that a regulatory flexibility analysis is not required for this interim final rule. However, the Department has considered the likely impact of this interim final rule on small entities.

As discussed in the Web Portal interim final rule (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis the Department 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 insurers).[23]

The Department has used the data set created from 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, the Department is using 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.

The Department estimates 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 interim final regulation. These small entities account for 6 percent of the estimated 442 total issuers that the Department estimates will be affected by these requirements. The Department estimates that 86 percent of these small issuers are subsidiaries of larger carriers, 75 percent only offer coverage

[23] "Table of Size Standards Matched To North American Industry Classification System Codes," effective November 5, 2010, U.S. Small Business Administration, available at www.sba.gov.

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.

As discussed elsewhere in this preamble, Section 2718(c) of the PHS Act directed the NAIC to take the special circumstances of small plans into account in developing uniform definitions and calculation methodologies relating to the data being reported to the Secretary in Section 2718(a). This has been accomplished through the credibility adjustment, which provides that issuers with non-credible experience in a given market, based on definitions established by the NAIC, are not required to provide any rebate to enrollees in that State/market because the issuer does not insure a sufficiently large number of lives to yield a statistically valid MLR. Additionally, issuers with partially credible experience in a given State/market are allowed to make a credibility adjustment to their MLR during that year.

The Department estimates that the 28 small issuers that are subject to the requirements of this interim final regulation offer individual and group coverage through 73 licensed entities (company / State combinations). For example, the Department estimates that all of the total 85 company / State / market

combinations offered by small entities will be either non-credible (92 percent) or partially credible (8 percent) in 2011.

The Department estimates that small entities will owe approximately $435,000 to $656,000 in rebates in 2011, accounting for 0.5 to 0.7 percent of their total A&H premiums during that year. By comparison, the Department estimates that small entities will owe approximately $1.8 to $3.0 million in rebates in 2013, accounting for 1.9 to 2.9 percent of their total A&H premiums during that year.

Additionally, the Department estimates that small entities will spend $44,656 to $62,518 per issuer in one-time costs (accounting for 1.3 to 1.9 percent of their total A&H premiums), and $10,240 to $14,031 per issuer in annual ongoing costs (accounting for 0.3 to 0.4 percent of their total A&H premiums) related to the MLR reporting, record retention, and rebate payment and notification requirements.

Table VI.13
Estimated Administrative Costs Related to Medical Loss Ratio (MLR) Rebate Notification and Payment Requirements By Firm Size, 2011

Firm Size		Total Number of Issuers	Total Number of Licensed Entities	Total Number of Reports	Number of Issuers Paying Rebates	Estimated Average Total Administrative Cost Per Issuer	
						One-Time	Ongoing
LOW RANGE ASSUMPTIONS							
	Small Entities (<$7 million in A&H Premiums)	28	73	85	1	$44,656	$10,240
	All Other Issuers	414	1,929	3,232	59	$77,071	$30,910
	Estimated Total Number of Issuers Subject to the MLR Reporting Requirements	442	2,002	3,317	60	$75,018	$29,601
MID RANGE ASSUMPTIONS							
	Small Entities (<$7 million in A&H Premiums)	28	73	85	1	$53,145	$12,135
	All Other Issuers	100	1,929	3,232	91	$112,613	$41,055
	Estimated Total Number of Issuers Subject to the MLR Reporting Requirements	442	2,002	3,317	92	$108,846	$39,223
HIGH RANGE ASSUMPTIONS							
	Small Entities (<$7 million in A&H Premiums)	28	73	85	1	$62,518	$14,031
	All Other Issuers	100	1,929	3,232	118	$157,525	$52,828
	Estimated Total Number of Issuers Subject to the MLR Reporting Requirements	442	2,002	3,317	119	$151,507	$50,370

Notes: Issuers represents companies (e.g., NAIC company codes). Licensed Entities represents company / State combinations. Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Total administrative cost includes estimated costs relating to the MLR reporting, record retention, and rebate payment requirements. Estimate costs are stated in 2010 dollars.
Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

As discussed earlier, the Department believes that these estimates overstate the number of small entities that will be affected by the requirements in this interim final regulation, as well as the relative impact of these requirements on these entities because the Department has based its analysis on issuers' total A&H earned premiums (rather than their total annual receipts). Therefore, the Secretary certifies that these interim final regulations 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 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 would not affect small rural hospitals. Therefore, the Secretary has determined that this 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 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 2010, that threshold level is approximately $135 million.

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.

This interim final regulation is not subject to the Unfunded Mandates Reform Act, because it is being issued as an interim final regulation. However, consistent with policy embodied in UMRA, this interim final regulation 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 interim final regulation contains MLR reporting, data retention and rebate notification and payment requirements for private sector firms (for example, health insurance issuers offering coverage in the individual and group markets), but these will not cost more than the approximately $32 million to $68 million in one-time administrative costs, and $11 million to $29 million in annual ongoing administrative costs related to

complying with the requirements of this interim final regulation that we have estimated. This interim final rule also contains requirements related to rebates paid by issuers to enrollees for coverage offered in the individual, small group, and large group markets that does not meet the minimum MLR standards. The Department's estimates that approximately 2.8 million to 9.6 million enrollees could receive $0.6 to $1.8 billion in rebates during any individual year between 2011 and 2013. It includes no mandates on State, local, or tribal governments. Under Section 2718 of the Affordable Care Act, issuers are required to submit MLR data reports directly to the Secretary. States may voluntarily choose to review the MLR data that issuers submit through the NAIC supplemental blank; develop or modify their regulations relating to MLR definitions and calculation methodologies, reporting and rebates; request adjustments of the 80 percent individual market minimum MLR threshold under the destabilization policy; or modify their audit methodologies to include a more comprehensive review of MLR data reported under Section 2718. However, if they choose not to do so, the Secretary has direct enforcement authority relating to this provision. Thus, the law and this regulation do not impose an unfunded mandate on States.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. In the Department's view, while this interim final rule does not impose substantial direct requirement costs on State and local governments, this interim final regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining and enforcing minimum MLR standards, reporting and rebate requirements relating to coverage that State-licensed health insurance issuers offer in the individual and group markets.

However, the Department anticipates that the Federalism implications (if any) are substantially mitigated because the Affordable Care Act does not provide any role for the States in terms of receiving or analyzing the data or enforcing the requirements of Section 2718 of the PHS Act. The enforcement provisions of this interim final rule state that the Secretary has enforcement authority and does not require the States to do anything. The States already require issuers to report the NAIC Annual Statement (Blanks) and audit those data. The regulation does contemplate that if a State includes MLR in its audit of

issuers, the Secretary has the discretion to accept that audit. But, again, the regulation does not require the States to do anything and, in fact, it is not clear that we even have statutory authority to require them to do anything with respect to the MLR. It is HHS' responsibility to do the audits and enforce the statutory requirements.

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to "prevent the application of" the Affordable Care Act, and be preempted. Additionally, States have an opportunity to request adjustments of the 80 percent individual market minimum MLR threshold under the destabilization policy, subject to the Secretary's approval. Accordingly, States have significant latitude to impose requirements on health with respect to health insurance issuers, insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, the Department has engaged in efforts to consult with and work cooperatively with affected States, including

participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this interim final regulation, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Department has attempted to balance the States' interests in regulating health insurance issuers, 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 Office of Consumer Information and Insurance Oversight has complied with the requirements of Executive Order 13132 for the attached interim final regulation in a meaningful and timely manner.

G. Congressional Review Act

This interim final regulation 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.) and have been transmitted to Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this interim final rule was reviewed by the Office of Management and Budget.

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 stated in the preamble, the Department of Health and Human Services amends 45 CFR Subtitle A, Subchapter B, by adding a new Part 158 to read as follows:

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

Sec.

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

§158.101 Basis and scope.

(a) Basis. This Part implements section 2718 of the Public Health Service Act (PHS Act).

(b) Scope. Subpart A of this Part establishes the requirements for health insurance issuers ("issuers") offering group or individual health insurance coverage to report information concerning premium revenues and the use of such premium revenues for clinical services provided to enrollees, activities that improve health care quality, and all other non-claims costs. Subpart B describes how this information will be used to determine, with respect to each medical loss ratio (MLR) reporting year, whether the ratio of the amount of adjusted premium revenue expended by the issuer on permitted costs to the

total amount of adjusted premium revenue (MLR) meets or exceeds the percentages established by section 2718(b)(1) of the PHS Act. Subpart B also addresses requirements for calculating any rebate amounts that may be due in the event an issuer does not meet the applicable MLR standard. Subpart C implements the provision of section 2718(b)(A)(ii) of the PHS Act allowing the Secretary to adjust the MLR standard for the individual market in a State if requiring issuers to meet that standard may destabilize the individual market. Subparts D through F provide for enforcement of this Part, including requirements for issuers to maintain records and civil monetary penalties that may be assessed against issuers who violate the requirements of this Part.

§158.102 Applicability.

General requirements. The requirements of this Part apply to issuers offering group or individual health insurance coverage, including a grandfathered health plan as defined in §147.140 of this subpart.

§158.103 Definitions.

For the purposes of this Part, the following definitions apply unless specified otherwise.

Contract reserves means reserves that are established by an issuer which, due to the gross premium pricing structure at issue, account for the value of the future benefits that at any

time exceeds the value of any appropriate future valuation of net premiums at that time. Contract reserves must not include premium deficiency reserves. Contract reserves must not include reserves for expected MLR rebates.

Direct paid claims means claim payments before ceded reinsurance and excluding assumed reinsurance except as otherwise provided in this Part.

Enrollee means an individual who is enrolled, within the meaning of §144.103 of this title, in group health insurance coverage, or an individual who is covered by individual insurance coverage, at any time during an MLR reporting year.

Experience rating refund means the return of a portion of premiums pursuant to a retrospectively rated funding arrangement when the sum of incurred losses, retention and margin are less than earned premium.

Group conversion charges means the portion of earned premium allocated to providing the privilege for a certificate holder terminated from a group health plan to purchase individual health insurance without providing evidence of insurability.

Health Plan means health insurance coverage offered through either individual coverage or a group health plan.

Individual market has the meaning given the term in section 2791(e)(1) of the PHS Act and section 1304(a)(2) of the

Affordable Care Act.

Large Employer has the meaning given the term in section 2791(e)(2) of the PHS Act and section 1304(b)(1) of the Affordable Care Act, except that as provided by section 1304(b)(3) of the Affordable Care Act, until 2016 a State may substitute "51" employees for "101" employees in the definition.

Large group market has the meaning given the term in section 2791(e)(3) of the PHS Act and section 1304(a)(3) of the Affordable Care Act.

MLR reporting year means a calendar year during which group or individual health insurance coverage is provided by an issuer.

Multi-State blended rate means a single rate charged for health insurance coverage provided to a single employer through two or more of an issuer's affiliated companies for employees in two or more States.

Policyholder means any entity that has entered into a contract with an issuer to receive health insurance coverage as defined in section 2791 (b) of the PHS Act.

Situs of the contract means the jurisdiction in which the contract is issued or delivered as stated in the contract.

Small Employer has the meaning given the term in section 2791(e)(4) of the PHS Act and section 1304(b)(2) of the Affordable Care Act, except that as provided by section

1304(b)(3) of the Affordable Care Act, until 2016 a State may substitute "50" employees for "100" employees in the definition.

Small group market has the meaning in section 2791(e)(5) of the PHS Act and section 1304(a)(3) of the Affordable Care Act.

Subscriber refers to both the group market and the individual market. In the group market, subscriber means the individual, generally the employee, whose eligibility is the basis for the enrollment in the group health plan and who is responsible for the payment of premiums. In the individual market, subscriber means the individual who purchases an individual policy and who is responsible for the payment of premiums.

Unearned premium means that portion of the premium paid in the MLR reporting year that is intended to provide coverage during a period which extends beyond the MLR reporting year.

Unpaid Claim Reserves means reserves and liabilities established to account for claims that were incurred during the MLR reporting year but had not been paid within 3 months of the end of the MLR reporting year.

Subpart A - Disclosure and Reporting

§158.110 Reporting requirements related to premiums and expenditures.

(a) General requirements. For each MLR reporting year, an issuer must submit to the Secretary a report which complies with

the requirements of this Part, concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued.

(b) Timing and form of report. (1) Except as provided in paragraph (b)(2) of this section, the report for each MLR reporting year must be submitted to the Secretary by June 1 of the year following the end of an MLR reporting year, on a form and in the manner prescribed by the Secretary.

(2) An issuer that reports its experience separately under §158.120(d)(3) or (4) of this subpart must submit a report for each quarter of the 2011 MLR reporting year, on the same form and in the same manner as described in paragraph (b)(1) of this section, as follows:

(i) By May 1 for the quarter ending March 31;

(ii) By August 1 for the quarter ending June 30; and

(ii) By November 1 for the quarter ending September 30.

(c) Transfer of Business. Issuers that purchase a line or block of business from another issuer during an MLR reporting year are responsible for submitting the information and reports required by this Part for the assumed business, including for that part of the MLR reporting year that was prior to the purchase.

§158.120 Aggregate reporting.

(a) General requirements. For purposes of submitting the

report required in §158.110 of this subpart, the issuer must submit a report for each State in which it is licensed to issue health insurance coverage that includes the experience of all policies issued in the State during the MLR reporting year covered by the report. The report must aggregate data for each entity licensed within a State, aggregated separately for the large group market, the small group market and the individual market. Experience with respect to each policy must be included on the report submitted with respect to the State where the contract was issued, except as specified in §158.120(d) of this subpart.

(b) Group Health Insurance Coverage in Multiple States. Group coverage issued by a single issuer that covers employees in multiple States must be attributed to the applicable State based on the situs of the contract. Group coverage issued by multiple affiliated issuers that covers employees in multiple States must be attributed by each issuer to each State based on the situs of the contract.

(c) Group Health Insurance Coverage With Dual Contracts. Where a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, solely for the purpose of providing a group health plan that offers both in-network and out-of-network benefits,

experience may be treated as if it were all related to the contract provided by the in-network issuer. However, if the issuer chooses this method of aggregation, it must apply it for a minimum of 3 MLR reporting years.

(d) Exceptions. (1) For individual market business sold through an association, the experience of the issuer must be included in the State report for the State that has jurisdiction over the certificate of coverage.

(2) For employer business issued through a group trust or multiple employer welfare association, the experience of the issuer must be included in the State report for the State where the employer or the association has its principal place of business.

(3) For the 2011 MLR reporting year, an issuer with policies that have a total annual limit of $250,000 or less must report the experience from such policies separately from other policies.

(4) For the 2011 MLR reporting year, an issuer with group policies that provide coverage for employees working outside their country of citizenship, employees working outside of their country of citizenship and outside the employer’s country of domicile, and citizens working in their home country, must aggregate the experience from these policies but report the experience from such policies separately from other policies.

§158.121 Newer experience.

If, for any aggregation as defined in §158.120, 50 percent or more of the total earned premium for an MLR reporting year is attributable to policies newly issued and with less than 12 months of experience in that MLR reporting year, then the experience of these policies may be excluded from the report required under §158.110 of this subpart for that same MLR reporting year. If an issuer chooses to defer reporting of newer business as provided in this section, then the excluded experience must be added to the experience reported in the following MLR reporting year.

§158.130 Premium revenue.

(a) General requirements. An issuer must report to the Secretary earned premium for each MLR reporting year. Earned premium means all monies paid by a policyholder or subscriber as a condition of receiving coverage from the issuer, including any fees or other contributions associated with the health plan.

(1) Earned premium is to be reported on a direct basis except as provided in paragraph (b) of this section.

(2) All earned premium for policies issued by one issuer and later assumed by another issuer must be reported by the assuming issuer for the entire MLR reporting year during which the policies were assumed and no earned premium for that MLR

reporting year must be reported by the ceding issuer.

(3) Reinsured earned premium for a block of business that was subject to indemnity reinsurance and administrative agreements effective prior to March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(b) Adjustments. Earned premium must include adjustments to:

(1) Account for assessments paid to or subsidies received from Federal and State high risk pools.

(2) Account for portions of premiums associated with group conversion charges.

(3) Account for any experience rating refunds paid or received, excluding any rebate paid based upon an issuer's MLR.

(4) Account for unearned premium.

§158.140 Reimbursement for clinical services provided to enrollees.

(a) General requirements. The report required in §158.110 of this subpart must include direct claims paid to or received by providers, including under capitation contracts with physicians, whose services are covered by the policy for clinical services or supplies covered by the policy. In

addition, the report must include claim reserves associated with claims incurred during the MLR reporting year, the change in contract reserves, reserves for contingent benefits and the claim portion of lawsuits, and any experience rating refunds paid or received. Reimbursement for clinical services as defined in this section are referred to as "incurred claims."

(1) If there are any group conversion charges for a health plan, the conversion charges must be subtracted from the incurred claims for the aggregation that includes the conversion policies and this same amount must be added to the incurred claims for the aggregation that provides coverage that is intended to be replaced by the conversion policies.

(2) Incurred claims must include changes in unpaid claims between the prior year's and the current year's unpaid claims reserves, including claims reported in the process of adjustment, percentage withholds from payments made to contracted providers, claims that are recoverable for anticipated coordination of benefits (COB), and claim recoveries received as a result of subrogation.

(3) Incurred claims must include the change in claims incurred but not reported from the prior year to the current year. Except where inapplicable, the reserve should be based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(4) Incurred claims must include changes in other claims-related reserves.

(5) Incurred claims must include experience rating refunds and exclude rebates paid as required by §158.240 based upon prior MLR reporting year experience.

(b) Adjustments to incurred claims. (1) Adjustments that must be deducted from incurred claims:

(i) Prescription drug rebates received by the issuer.

(ii) Overpayment recoveries received from providers.

(2) Adjustments that may be included in incurred claims:

(i) Market stabilization payments or receipts by issuers that are directly tied to claims incurred and other claims based or census based assessments.

(ii) State subsidies based on a stop-loss payment methodology.

(iii) The amount of incentive and bonus payments made to providers.

(3) Adjustments that must not be included in incurred claims:

(i) Amounts paid to third party vendors for secondary network savings.

(ii) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management. For example, if an issuer contracts

with a behavioral health, chiropractic network, or high technology radiology vendor, or a pharmacy benefit manager, and the vendor reimburses the provider at one amount but bills the issuer a higher amount to cover its network development, utilization management costs, and profits, then the amount that exceeds the reimbursement to the provider must not be included in incurred claims.

(iii) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee. For example, medical record copying costs, attorneys' fees, subrogation vendor fees, compensation to paraprofessionals, janitors, quality assurance analysts, administrative supervisors, secretaries to medical personnel and medical record clerks must not be included in incurred claims.

(4) Adjustments that can be either included in or deducted from incurred claims:

(i) Payment to and from unsubsidized State programs designed to address distribution of health risks across issuers via charges to low risk issuers that are distributed to high risk issuers must be included in or deducted from incurred claims, as applicable.

(ii) [Reserved]

(5) Other adjustments to incurred claims:

(i) Affiliated issuers that offer group coverage at a blended rate may choose whether to make an adjustment to each affiliate's incurred claims and activities to improve health care quality, to reflect the experience of the issuer with respect to the employer as a whole, according to an objective formula that will be defined prior to January 1, 2011, so as to result in each affiliate having the same ratio of incurred claims to earned premium for that employer group for the MLR reporting year as the ratio of incurred claims to earned premium calculated for the employer group in the aggregate.

(ii) [Reserved]

§158.150 Activities that improve health care quality.

(a) General requirements. The report required in §158.110 of this subpart must include expenditures for activities that improve health care quality, as described in this section.

(b) Activity requirements. Activities conducted by an issuer to improve quality must meet the following requirements:

(1) The activity must be designed to:

(i) Improve health quality.

(ii) Increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

(iii) Be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide

health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.

(iv) Be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

(2) The activity must be primarily designed to:

(i) Improve health outcomes including increasing the likelihood of desired outcomes compared to a baseline and reduce health disparities among specified populations.

(A) Examples include the direct interaction of the issuer (including those services delegated by contract for which the issuer retains ultimate responsibility under the insurance policy), providers and the enrollee or the enrollee's representative (for example, face-to-face, telephonic, web-based interactions or other means of communication) to improve health outcomes, including activities such as:

(1) Effective case management, care coordination, chronic disease management, and medication and care compliance initiatives including through the use of the medical homes model as defined in section 3606 of the Affordable Care Act.

(2) Identifying and addressing ethnic, cultural or racial

disparities in effectiveness of identified best clinical practices and evidence based medicine.

(3) Quality reporting and documentation of care in non-electronic format.

(4) Health information technology to support these activities.

(5) Accreditation fees directly related to quality of care activities.

(B) [Reserved]

(ii) Prevent hospital readmissions through a comprehensive program for hospital discharge. Examples include:

(A) Comprehensive discharge planning (for example, arranging and managing transitions from one setting to another, such as hospital discharge to home or to a rehabilitation center) in order to help assure appropriate care that will, in all likelihood, avoid readmission to the hospital;

(B) Patient-centered education and counseling.

(C) Personalized post-discharge reinforcement and counseling by an appropriate health care professional.

(D) Any quality reporting and related documentation in non-electronic form for activities to prevent hospital readmission.

(E) Health information technology to support these activities.

(iii) Improve patient safety, reduce medical errors, and

lower infection and mortality rates.

(A) Examples of activities primarily designed to improve patient safety, reduce medical errors, and lower infection and mortality rates include:

(1) The appropriate identification and use of best clinical practices to avoid harm.

(2) Activities to identify and encourage evidence-based medicine in addressing independently identified and documented clinical errors or safety concerns.

(3) Activities to lower the risk of facility-acquired infections.

(4) Prospective prescription drug Utilization Review aimed at identifying potential adverse drug interactions.

(5) Any quality reporting and related documentation in non-electronic form for activities that improve patient safety and reduce medical errors.

(6) Health information technology to support these activities.

(B) [Reserved]

(iv) Implement, promote, and increase wellness and health activities:

(A) Examples of activities primarily designed to implement, promote, and increase wellness and health activities, include --

(1) Wellness assessments;

(2) Wellness/lifestyle coaching programs designed to achieve specific and measurable improvements;

(3) Coaching programs designed to educate individuals on clinically effective methods for dealing with a specific chronic disease or condition;

(4) Public health education campaigns that are performed in conjunction with State or local health departments;

(5) Actual rewards, incentives, bonuses, reductions in copayments (excluding administration of such programs), that are not already reflected in premiums or claims should be allowed as a quality improvement activity for the group market to the extent permitted by section 2705 of the PHS Act;

(6) Any quality reporting and related documentation in non-electronic form for wellness and health promotion activities;

(7) Coaching or education programs and health promotion activities designed to change member behavior and conditions (for example, smoking or obesity); and

(8) Health information technology to support these activities.

(B) [Reserved]

(v) Enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology consistent with §158.151 of this subpart.

(c) Exclusions. Expenditures and activities that must not

be included in quality improving activities are:

(1) Those that are designed primarily to control or contain costs;

(2) The pro rata share of expenses that are for lines of business or products other than those being reported, including but not limited to, those that are for or benefit self-funded plans;

(3) Those which otherwise meet the definitions for quality improvement activities but which were paid for with grant money or other funding separate from premium revenue;

(4) Those activities that can be billed or allocated by a provider for care delivery and which are, therefore, reimbursed as clinical services;

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims (for example, costs of implementing new administrative simplification standards and code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d-2, as amended, including the new ICD-10 requirements);

(6) That portion of the activities of health care professional hotlines that does not meet the definition of

activities that improve health quality;

(7) All retrospective and concurrent utilization review;

(8) Fraud prevention activities, other than fraud detection/recovery expenses up to the amount recovered that reduces incurred claims;

(9) The cost of developing and executing provider contracts and fees associated with establishing or managing a provider network, including fees paid to a vendor for the same reason;

(10) Provider credentialing;

(11) Marketing expenses;

(12) Costs associated with calculating and administering individual enrollee or employee incentives;

(13) That portion of prospective utilization that does not meet the definition of activities that improve health quality; and

(14) Any function or activity not expressly included in paragraph (c) of this section, unless otherwise approved by and within the discretion of the Secretary, upon adequate showing by the issuer that the activity's costs support the definitions and purposes in this Part or otherwise support monitoring, measuring or reporting health care quality improvement.

§158.151 Expenditures related to Health Information Technology and meaningful use requirements.

(a) General requirements. An issuer may include as

activities that improve health care quality such Health Information Technology (HIT) expenses as are required to accomplish the activities allowed in §158.150 of this subpart and that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, as well as those consistent with Medicare and/or Medicaid meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improvement or make new quality improvement initiatives possible by doing one or more of the following:

(1) Making incentive payments to health care providers for the adoption of certified electronic health record technologies and their "meaningful use" as defined by HHS to the extent such payments are not included in reimbursement for clinical services as defined in §158.140 of this subpart;

(2) Implementing systems to track and verify the adoption and meaningful use of certified electronic health records technologies by health care providers, including those not eligible for Medicare and Medicaid incentive payments;

(3) Providing technical assistance to support adoption and meaningful use of certified electronic health records technologies;

(4) Monitoring, measuring, or reporting clinical

effectiveness including reporting and analysis of costs related to maintaining accreditation by nationally recognized accrediting organizations such as NCQA or URAC, or costs for public reporting of quality of care, including costs specifically required to make accurate determinations of defined measures (for example, CAHPS surveys or chart review of HEDIS measures and costs for public reporting mandated or encouraged by law.

(5) Tracking whether a specific class of medical interventions or a bundle of related services leads to better patient outcomes.

(6) Advancing the ability of enrollees, providers, issuers or other systems to communicate patient centered clinical or medical information rapidly, accurately and efficiently to determine patient status, avoid harmful drug interactions or direct appropriate care, which may include electronic Health Records accessible by enrollees and appropriate providers to monitor and document an individual patient’s medical history and to support care management.

(7) Reformatting, transmitting or reporting data to national or international government-based health organizations for the purposes of identifying or treating specific conditions or controlling the spread of disease.

(8) Provision of electronic health records, patient

portals, and tools to facilitate patient self-management.

(b) [Reserved]

§158.160 Other non-claims costs.

(a) General requirements. The report required in §158.110 of this subpart must include non-claims costs described in paragraph (b) of this section and must provide an explanation of how premium revenue is used, other than to provide reimbursement for clinical services covered by the benefit plan, expenditures for activities that improve health care quality, and Federal and State taxes and licensing or regulatory fees as specified in this part.

(b) Non-claims costs other than taxes and regulatory fees. (1) The report required in §158.110 of this subpart must include any expenses for administrative services that do not constitute adjustments to premium revenue as provided in §158.130 of this subpart, reimbursement for clinical services to enrollees as defined in §158.140 of this subpart, or expenditures on quality improvement activities as defined in §§158.150 and 158.151 of this subpart.

(2) Expenses for administrative services include the following:

(i) Cost-containment expenses not included as an expenditure related to an activity at §158.150 of this subpart.

(ii) Loss adjustment expenses not classified as a cost

containment expense.

(iii) Direct sales salaries, workforce salaries and benefits.

(iv) Agents and brokers fees and commissions.

(v) General and administrative expenses.

(vi) Community benefit expenditures.

§158.161 Reporting of Federal and State licensing and regulatory fees.

(a) Federal taxes. The report required in §158.110 of this subpart must separately report:

(1) Federal taxes excluded from premium under subpart B which include all Federal taxes and assessments allocated to health insurance coverage reported under section 2718 of the PHS Act.

(2) Federal taxes not excluded from premium under subpart B which include Federal income taxes on investment income and capital gains as other non-claims costs.

(b) State taxes and assessments. The report required in §158.110 of this subpart must separately report:

(1) State taxes and assessments excluded from premium under subpart B which include:

(i) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly, or premium subsidies that are designed to cover the costs of

providing indigent care or other access to health care throughout the State.

(ii) Guaranty fund assessments.

(iii) Assessments of State industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(iv) Advertising required by law, regulation or ruling, except advertising associated with investments.

(v) State income, excise, and business taxes other than premium taxes.

(vi) State premium taxes plus State taxes based on policy reserves, if in lieu of premium taxes.

(vii) One of the following types of payments:

(A) Payments to a State, by not-for-profit health plans, of premium tax exemption values in lieu of State premium taxes limited to the State premium tax rate applicable to for-profit entities subject to premium tax multiplied by the allocated premiums earned for individual, small group and large group;

(B) Payment by not-for-profit health plans for community benefit expenditures as described in paragraph (c) of this section limited to the State premium tax rate applicable to for-profit entities subject to premium tax multiplied by the allocated premiums earned for individual, small group and large

group. These payments must be State based requirement to qualify for inclusion in this line item; or

(C) Payments made by (Federal income) tax exempt health plans for community benefit expenditures as defined in paragraph (c) of this section limited to the State premium tax rate applicable to for-profit entities subject to premium tax multiplied by the allocated premiums earned for individual, small group, and large group.

(2) State taxes and assessments not excluded from premium under subpart B which include:

(i) State sales taxes if the issuer does not exercise options of including such taxes with the cost of goods and services purchased.

(ii) Any portion of commissions or allowances on reinsurance assumed that represent specific reimbursement of premium taxes.

(iii) Any portion of commissions or allowances on reinsurance ceded that represents specific reimbursement of premium taxes.

(c) Community benefit expenditures. (1) A not-for-profit issuer exempt from Federal or State taxes and assessments, but required to make community benefit expenditures in lieu of taxes, must report to the Secretary such community benefit expenditures, multiplied by the allocated premiums earned for

individual, small group and large group, but not to exceed the amount of the taxes they would otherwise be required to pay. Each expenditure must not be reported more than once, but may be split between Federal and State taxes as applicable.

(2) Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden. This includes any of the following activities that:

(i) Are available broadly to the public and serve low-income consumers;

(ii) Reduce geographic, financial, or cultural barriers to accessing health services, and if ceased to exist would result in access problems (for example, longer wait times or increased travel distances);

(iii) Address Federal, State or local public health priorities such as advancing health care knowledge through education or research that benefits the public;

(iv) Leverage or enhance public health department activities such as childhood immunization efforts; and

(v) Otherwise would become the responsibility of government or another tax-exempt organization.

§158.170 Allocation of expenses.

(a) General requirements. Each expense must be reported

under only one type of expense, unless a portion of the expense fits under the definition of or criteria for one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses. Expenditures that benefit lines of business or products other than those being reported, including but not limited to those that are for or benefit self-funded plans, must be reported on a pro rata share.

(b) Description of the methods used to allocate expenses. The report required in §158.110 of this subpart must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

(1) Allocation to each category should be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories above will generally be the most accurate method. If a specific identification is not feasible, the issuer should provide an

explanation of why it believes the more accurate result will be gained from allocation of expenses based upon pertinent factors or ratios such as studies of employee activities, salary ratios or similar analyses.

(2) Many entities operate within a group where personnel and facilities are shared. Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the entities incurring the expense.

(3) Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses. Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.

(c) Disclosure of allocation methods. The issuer must identify in the report required in §158.110 of this subpart the specific basis used to allocate expenses reported under this Part to States and, within States, to lines of business including the individual market, small group market, large group market, supplemental health insurance coverage, health insurance coverage offered to beneficiaries of public programs (such as Medicare and Medicaid), and group health plans as defined in

§145.103 of this chapter and administered by the issuer.

(d) Maintenance of records. The issuer must maintain and make available to the Secretary upon request the data used to allocate expenses reported under this Part together with all supporting information required to determine that the methods identified and reported as required under paragraph (b) of this section were accurately implemented in preparing the report required in §158.110 of this subpart.

Subpart B – Calculating and Providing the Rebate

§158.210 Minimum medical loss ratio.

Subject to the provisions of §158.211 of this subpart:

(a) Large group market. For all policies issued in the large group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 85 percent, as determined in accordance with this Part.

(b) Small group market. For all policies issued in the small group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 80 percent, as determined in accordance with this Part.

(c) Individual market. For all policies issued in the individual market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an

MLR of less than 80 percent, as determined in accordance with this Part.

(d) Adjustment by the Secretary. If the Secretary has adjusted the percentage that issuers in the individual market in a specific State must meet, then the adjusted percentage determined by the Secretary in accordance with §158.301 of this part et seq. must be substituted for 80 percent in paragraph (c) of this section.

§158.211 Requirement in States with a higher medical loss ratio.

(a) State option to set higher minimum loss ratio. For coverage offered in a State whose law provides that issuers in the State must meet a higher MLR than that set forth in §158.210, the State's higher percentage must be substituted for the percentage stated in §158.210 of this subpart.

(b) Considerations in setting a higher minimum loss ratio. In adopting a higher minimum loss ratio than that set forth in §158.210, a State must seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State, and value for consumers so that premiums are used for clinical services and quality improvements.

§158.220 Aggregation of data in calculating an issuer's medical loss ratio.

(a) Aggregation by State and by market. In general, an

issuer's MLR must be calculated separately for the large group market, small group market and individual market within each State. However, if, pursuant to section 1312(c)(3) of the Affordable Care Act, a State requires the small group market and individual market to be merged, then the data reported separately under subpart A for the small group and individual market in that State may be merged for purposes of calculating an issuer's MLR and any rebates owing.

(b) Years of data to include in calculating MLR. Subject to paragraph (c) of this section, an issuer's MLR for an MLR reporting year is calculated according to the formula in §158.221 of this subpart and aggregating the data reported under this Part for the following 3-year period:

(1) The data for the MLR reporting year whose MLR is being calculated; and

(2) The data for the two prior MLR reporting years.

(c) Requirements for MLR reporting years 2011 and 2012. (1) For the 2011 MLR reporting year, an issuer's MLR is calculated using the data reported under this Part for the 2011 MLR reporting year only.

(2) For the 2012 MLR reporting year –

(i) If an issuer's experience for the 2012 MLR reporting year is fully credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this

Part for the 2012 MLR reporting year.

(ii) If an issuer's experience for the 2012 MLR reporting year is partially credible or non-credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this Part for the 2011 MLR reporting year and the 2012 MLR reporting year.

§158.221 Formula for calculating an issuer's medical loss ratio.

(a) Medical loss ratio. (1) An issuer's MLR is the ratio of the numerator, as defined in paragraph (b) of this section, to the denominator, as defined in paragraph (c) of this section, subject to the applicable credibility adjustment, if any, as provided in §158.232 of this subpart.

(2) An issuer's MLR shall be rounded to three decimal places. For example, if an MLR is 0.7988, it shall be rounded to 0.799 or 79.9 percent. If an MLR is 0.8253 or 82.53 percent, it shall be rounded to 0.825 or 82.5 percent.

(b) Numerator. The numerator of an issuer's MLR for an MLR reporting year must be the issuer's incurred claims, as defined in §158.140 of this part, plus the issuer's expenditures for activities that improve health care quality, as defined in §158.150 and §158.151 of this part, that are reported for the years specified in §158.220 of this subpart.

(1) The numerator of the MLR for the 2012 MLR reporting

year may include any rebate paid under §158.240 of this subpart for the 2011 MLR reporting year if the 2012 MLR reporting year experience is not fully credible as defined in §158.230 of this subpart.

(2) The numerator of the MLR for the 2013 MLR reporting year may include any rebate paid under §158.240 for the 2011 MLR reporting year or the 2012 MLR reporting year.

(3) The numerator of the MLR for policies that are reported separately under §158.120(d)(3) of this part must be the amount specified in paragraph (b) of this section, except that for the 2011 MLR reporting year the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of two.

(4) The numerator of the MLR for policies that are reported separately under §158.120(d)(4) of this part must be the amount specified in paragraph (b) of this section, except that for the 2011 MLR reporting year the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of two.

(c) Denominator. The denominator of an issuer's MLR must equal the issuer's premium revenue, as defined in §158.130, minus the issuer's Federal and State taxes and licensing and regulatory fees, described in §§158.161(a) and 158.162(a)(1) and (b)(1) of this part.

§158.230 Credibility Adjustment.

(a) General rule. An issuer may add to the MLR calculated under §158.221(a) of this subpart the credibility adjustment specified by §158.232 of this section, if such MLR is based on partially credible experience as defined in paragraph (c)(2) of this section. An issuer may not apply the credibility adjustment if the issuer's experience is fully credible, as defined in paragraph (c)(1) of this section, or non-credible, as defined in paragraph (c)(3) of this section.

(b) Life-years. The credibility of an issuer's experience is based upon the number of life-years covered by the issuer. Life-years means the total number of months of coverage for enrollees whose premiums and claims experience is included in the report to the Secretary required by §158.110 of this part, divided by 12.

(c) Credible experience. (1) An MLR calculated under §158.221(a) through (c) of this subpart is fully credible if it is based on the experience of 75,000 or more life-years.

(2) An MLR calculated under §158.221(a) through (c) of this subpart is partially credible if it is based on the experience of at least 1,000 life-years and fewer than 75,000 life-years.

(3) An MLR calculated under §158.221(a) through (c) of this subpart is non-credible if it is based on the experience of less than 1,000 life-years.

(d) If an issuer's MLR is non-credible, it is presumed to meet or exceed the minimum percentage required by §158.210 or §158.211 of this subpart.

§158.231 Life-years used to determine credible experience.

(a) The life-years used to determine the credibility of an issuer's experience are the life-years for the MLR reporting year plus the life-years for the two prior MLR reporting years.

(b) For the 2011 MLR reporting year, the life-years used to determine credibility are the life-years for the 2011 MLR reporting year only.

(c) For the 2012 MLR reporting year -

(1) If an issuer's experience for the 2012 MLR reporting year is fully credible, the life-years used to determine credibility are the life-years for the 2012 MLR reporting year only;

(2) If an issuer's experience for the 2012 MLR reporting year only is partially credible, the life-years used to determine credibility are the life-years for the 2011 MLR reporting year plus the life-years for the 2012 MLR reporting year.

§158.232 Calculating the credibility adjustment.

(a) Formula. An issuer's credibility adjustment, if any, is the product of the base credibility factor, as determined under paragraph (b) of this section, multiplied by the

deductible factor, as determined under paragraph (c) of this section.

(b) Base credibility factor. (1) The base credibility factor for fully credible experience or for non-credible experience is zero.

(2) The base credibility factor for partially credible experience is determined based on the number of life-years included in the aggregation, as determined under §158.231 of this subpart, and the factors shown in Table 1. When the number of life-years used to determine credibility exactly matches a life-year category listed in Table 1, the value associated with that number of life-years is the base credibility factor. The base credibility factor for a number of life-years between the values shown in Table 1 is determined by linear interpolation.

Table 1 to §158.232: Base credibility factors

Life-Years	Base credibility Factor
<1,000	No Credibility
1,000	8.3%
2,500	5.2%
5,000	3.7%
10,000	2.6%
25,000	1.6%
50,000	1.2%
≥75,000	0.0% (Full Credibility)

(c) Deductible factor. (1) The deductible factor is based on the average per person deductible of policies whose experience is included in the aggregation, as determined under §158.231 of this subpart. When the weighted average deductible, as determined in accordance with this section, exactly matches a deductible category listed in Table 2, the value associated with that deductible is the deductible factor. The deductible factor for an average weighted deductible between the values shown in Table 2 is determined by linear interpolation.

(i) The per person deductible for a policy that covers a subscriber and the subscriber's dependents shall be calculated as follows: the lesser of the sum of the individual family members' deductibles or the overall family deductible for the subscriber and subscriber's family, shall be divided by the total number of individuals covered through the subscriber (including the subscriber).

(ii) The average deductible for an aggregation is calculated weighted by the life-years of experience for each deductible level of policies included in the aggregation.

(2) An issuer may choose to use a deductible factor of 1.0 in lieu of calculating a deductible factor based on the average

of policies included in the aggregation.

Table 2 to §158.232: Deductible Factor

Health Plan Deductible	Deductible Factor
<$2,500	1.000
$2,500	1.164
$5,000	1.402
≥$10,000	1.736

(d) No credibility adjustment. For the 2013 MLR reporting year, the credibility adjustment for an MLR based on partially credible experience is zero if both of the following conditions are met:

(1) The current MLR reporting year and each of the two previous MLR reporting years included experience of at least 1,000 life-years; and

(2) Without applying any credibility adjustment, the issuer's MLR for the current MLR reporting year and each of the two previous MLR reporting years were below the applicable MLR standard for each year as established under §158.210 in this subpart.

§158.240 Rebating premium if the applicable medical loss ratio standard is not met.

(a) General requirement. For each MLR reporting year, an issuer must provide a rebate to each enrollee if the issuer's MLR does not meet or exceed the minimum percentage required by

§§158.210 and 158.211 of this subpart.

(b) Definition of enrollee for purposes of rebate. For the sole purpose of determining whom is entitled to receive a rebate pursuant to this Part, the term "enrollee" means the subscriber, policyholder, and/or government entity that paid the premium for health care coverage received by an individual during the respective MLR reporting year.

(c) Amount of rebate to each enrollee. (1) For each MLR reporting year, an issuer must rebate to the enrollee the total amount of premium revenue received by the issuer from the enrollee after subtracting Federal and State taxes and licensing and regulatory fees as provided in §158.161(a), §158.162(a)(1) and §158.162(b)(1) of this part, multiplied by the difference between the MLR required by §158.210 or §158.211 of this subpart, and the issuer's MLR as calculated under §158.221 of this subpart.

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the small group market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the small group market in a State that has not set a higher MLR, the

issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting premium and subtracting taxes and fees as provided in paragraph (c) of this section. In this example, an enrollee may have paid $2,000 in premiums for the MLR reporting year. If the Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in §158.161(a), §158.161(a)(1) and §158.162(b)(1) of this subpart are $150 for a premium of $2,000, then the issuer would subtract $150 from premium revenue, for a base of $1,850 in premium. The enrollee would be entitled to a rebate of 5 percent of $1,850, or $92.50.

(d) Timing of rebate. An issuer must provide any rebate owing to an enrollee no later than August 1 following the end of the MLR reporting year.

(e) Late Payment Interest. An issuer that fails to pay any rebate owing to an enrollee or subscriber in accordance with paragraph (d) of this section or to take other required action within the time periods set forth in this Part must, in addition to providing the required rebate to the enrollee, pay the enrollee interest at the current Federal Reserve Board lending rate or ten percent annually, whichever is higher, on the total

amount of the rebate, accruing from the date payment was due under paragraph (d) of this section.

§158.241 Form of rebate.

(a) Current enrollees. (1) An issuer may choose to provide any rebates owing to current enrollees in the form of a premium credit, lump-sum check, or, if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium.

(2) Any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR Reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited.

(b) Former enrollees. Rebates owing to former enrollees must be paid in the form of lump-sum check or lump-sum reimbursement using the same method that was used for payment, such as credit card or direct debit.

§158.242 Recipients of rebates.

(a) Individual market. An issuer must meet its obligation

to provide any rebate due to an enrollee in the individual market by providing it to the enrollee. For individual policies that cover more than one person, one lump-sum rebate may be provided to the subscriber on behalf of all enrollees covered by the policy.

(b) Large group and small group markets. An issuer must meet its obligation to provide any rebate to persons covered under a group health plan by providing it to the enrollee, in amounts proportionate to the amount of premium the policyholder and each subscriber paid.

(1) Arrangement with policyholder to distribute rebates. An issuer may meet its obligation to provide any rebate owing to a large group or small group enrollee by entering into an agreement with the group policyholder to distribute the rebate on behalf of the issuer, subject to all of the following conditions:

(i) The issuer must remain liable for complying with all of its obligations under this Part.

(ii) The issuer must obtain and retain records and documentation evidencing accurate distribution of any rebate owing, sufficient to demonstrate compliance with its obligations

under this subpart, subpart D, and subpart E. Such records and documentation include:

(A) The amount of the premium paid by each subscriber;

(B) The amount of the premium paid by the group policyholder;

(C) The amount of the rebate provided to each subscriber;

(D) The amount of the rebate retained by the group policyholder; and

(E) The amount of any unclaimed rebate and how and when it was distributed.

(2) [Reserved]

§158.243 *De minimis* rebates.

(a) Minimum threshold. An issuer is not required to provide a rebate to an enrollee based upon the premium that enrollee paid, under the following circumstances:

(1) For a group policy, if the total rebate owed to the policyholder and the subscribers is less than $5 per subscriber covered by the policy for a given MLR reporting year.

(2) In the individual market, if the total rebated owed to the subscriber is less than $5.

(b) Distribution. (1) An issuer must aggregate and distribute any rebates not provided because they did not meet the minimum threshold set forth in paragraph (a) of this section

by aggregating the unpaid rebates by individual market, small group market and large group market in a State and use them to increase the rebates provided to enrollees who receive rebates based upon the same MLR reporting year as the aggregated unpaid rebates. An issuer must distribute such aggregated rebates by providing additional premium credit or payment divided evenly among enrollees who are being provided a rebate.

(2) For example, an issuer in the individual market has aggregated unpaid rebates totaling $2,000, and the issuer has 10,000 enrollees who are entitled to be provided a rebate above the minimum threshold for the applicable MLR reporting year. The $2,000 must be redistributed to the 10,000 and added on to their existing rebate amounts. The $2,000 is divided evenly among the 10,000 enrollees, so the issuer increases each enrollee’s rebate by $0.20.

§158.244 Unclaimed rebates.

An issuer must make a good faith effort to locate and deliver to an enrollee any rebate required under this Part. If, after making a good faith effort, an issuer is unable to locate a former enrollee, the issuer must comply with any applicable State law.

§158.250 Notice of rebates.

For each MLR reporting year, at the time any rebate of premium is provided in accordance with this Part, an issuer must

provide each enrollee who receives a rebate the following information in a form prescribed by the Secretary:

(a) A general description of the concept of an MLR;

(b) The purpose of setting a MLR standard;

(c) The applicable MLR standard;

(d) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(e) The issuer's aggregate premium revenue as reported in accordance with §158.130, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in §§158.161(a) and 158.162(a)(1) and (b)(1); and

(f) The rebate percentage and amount owed to enrollees based upon the difference between the issuer's MLR and the applicable MLR standard.

§158.260 Reporting of rebates.

(a) General requirement. For each MLR reporting year, an issuer must submit to the Secretary a report concerning the rebates provided to and on behalf of enrollees pursuant to this subpart.

(b) Aggregation of information in the report. The information in the report must be aggregated in the same manner as required by §158.120.

(c) Information to report. The report required by this

section must include the total:

(1) Number and percentage of enrollees who received a rebate;

(2) Number and amount of rebates provided:

(i) As premium credit; and

(ii) As lump sum check or lump-sum reimbursement to a subscriber's credit card or direct payment to a subscriber's bank account;

(3) Amount of rebates that were provided to enrollees, including a breakdown of the amounts provided based upon the portion of premiums paid by group policyholders and amounts provided based upon the portion of premium paid by subscribers;

(4) Amount of rebates that were de minimis, as provided in §158.243, and a detailed description of how these rebates were disbursed; and

(5) Amount of unclaimed rebates, a description of the methods used to locate the applicable enrollees, and a detailed description of how the unclaimed rebates were disbursed.

(d) Timing and form of report. The data required by paragraphs (c)(1) through (4) of this section must be submitted with the report under §158.110, on a form and in the manner prescribed by the Secretary. The data required by paragraph (c)(5) of this section must be submitted with the report under §158.110 for the subsequent MLR reporting year.

§158.270 Effect of rebate payments on solvency.

(a) If a State's insurance commissioner, superintendent, or other responsible official determines that the payment of rebates by a domestic issuer in that State will cause the issuer's risk based capital (RBC) level to fall below the Company Action Level RBC, as defined in the NAIC's Risk Based Capital (RBC) for Insurers Model Act, the commissioner, superintendent, or other responsible official must notify the Secretary. In such a circumstance, the commissioner, superintendent, or other responsible official may request that the Secretary defer all or a portion of the rebate payments owed by the issuer.

(b) In the event an insurance commissioner, superintendent, or other responsible official makes the request set forth in paragraph (a) of this section, the following should be provided to the Secretary along with the notification:

(1) The domestic issuer's RBC reports for the current calendar year and the 2 preceding calendar years; and

(2) A calculation of the amount of rebates that would be owed by the domestic issuer pursuant to this Part.

(c) Upon receipt of the notification under paragraph (a), the Secretary will examine the information provided by the insurance commissioner, superintendent, or other responsible official along with any other information the Secretary may

request from the issuer, and determine whether the payment of rebates by the issuer will cause its RBC level to fall below the Company Action Level RBC.

(d) When the Secretary determines that the payment of rebates by an issuer will cause its RBC level to fall below the Company Action Level RBC, the Secretary may permit a deferral of all or a portion of the rebates owed, but only for a period determined by the Secretary in consultation with the State. The Secretary will require that the issuer must pay these rebates with interest in a future year in which payment of the rebates would not cause the issuer's RBC level to fall below the Company Action Level RBC.

Subpart C – Potential Adjustment to the MLR for a State's Individual Market

§158.301 Standard for adjustment to the medical loss ratio.

The Secretary may adjust the MLR standard that must be met by issuers offering coverage in the individual market in a State, as defined in section 2791 of the PHS Act, for a given MLR reporting year if, in her discretion, she determines that application of the 80 percent MLR standard of section 2718(b)(1)(A)(ii) of the Public Health Service Act may destabilize the individual market in that State. Application of the 80 percent MLR standard may destabilize the individual market in a State only if there is a reasonable likelihood that

application of the requirement will do so.

§158.310 Who may request adjustment to the medical loss ratio.

A request for an adjustment to the MLR standard for a State must be submitted by the State's insurance commissioner, superintendent, or comparable official of that State in order to be considered by the Secretary.

§158.311 Duration of adjustment to the medical loss ratio.

A State may request that an adjustment to the MLR standard be for up to three MLR reporting years.

§158.320 Information supporting a request for adjustment to the medical loss ratio.

A State must submit in electronic format the information required by §§158.321 through 158.323 of this subpart in order for the request for adjustment to the MLR standard for the State to be considered by the Secretary. A State may submit to the Secretary any additional information it determines would support its request. In the event that certain data are unavailable or that the collection of certain data is unduly burdensome, a State may provide written notice to the Secretary and the Secretary may, at her discretion, request alternative supporting data or move forward with her determination.

§158.321 Information regarding the State's individual health insurance market.

(a) State MLR standard. The State must describe its

current MLR standard for the individual market, if any, and the formula used to assess compliance with such standard.

(b) State market withdrawal requirements. The State must describe any requirements it has with respect to withdrawals from the State's individual health insurance market. Such requirements include, but are not limited to, any notice that must be provided and any authority the State regulator may have to approve a withdrawal plan or ensure that enrollees of the exiting issuer have continuing coverage, as well as any penalties or sanctions that may be levied upon exit or limitations on re-entry.

(c) Mechanisms to provide options to consumers. The State must describe the mechanisms available to the State to provide consumers with options in the event an issuer withdraws from the individual market. Such mechanisms include, but are not limited to, a guaranteed issue requirement, limits on health status rating, an issuer of last resort, or a State-operated high risk pool. A description of each mechanism should include detail on the issuers participating in and products available under such mechanism, as well as any limitations with respect to eligibility, enrollment period, total enrollment, and coverage for pre-existing conditions.

(d) Issuers in the State's individual market. Subject to §158.320 of this subpart, the State must provide:

(1) For each issuer who offers coverage in the individual market in the State its number of individual enrollees by product, available individual premium data by product, and individual health insurance market share within the State; and

(2) For each issuer who offers coverage in the individual market in the State to more than 1,000 enrollees, the following additional information:

(i) Total earned premium on individual market health insurance products in the State;

(ii) Reported MLR pursuant to State law for the individual market business in the State;

(iii) Estimated MLR for the individual market business in the State, as determined in accordance with §158.221 of this part;

(iv) Total agents' and brokers' commission expenses on individual health insurance products;

(v) Estimated rebate for the individual market business in the State, as determined in accordance with §158.221 and §158.240 of this part;

(vi) Net underwriting profit for the individual market business and consolidated business in the State;

(vii) After-tax profit and profit margin for the individual market business and consolidated business in the State;

(viii) Risk-based capital level; and

(ix) Whether the issuer has provided notice of exit to the State's insurance commissioner, superintendent, or comparable State authority.

§158.322 Proposal for adjusted medical loss ratio.

A State must provide its own proposal as to the adjustment it seeks to the MLR standard. This proposal must include:

(a) An explanation and justification of how the proposed adjustment to the MLR was determined;

(b) An explanation of how an adjustment to the MLR standard for the State's individual market will permit issuers to adjust current business models and practices in order to meet an 80 percent MLR as soon as is practicable;

(c) An estimate of the rebates that would be paid if the issuers offering coverage in the individual market in the State must meet an 80 percent MLR for the applicable MLR reporting years; and

(d) An estimate of the rebates that would be paid if the issuers offering coverage in the individual market in the State must meet the adjusted MLR proposed by the State for the applicable MLR reporting years.

§158.323 State contact information.

A State must provide the name, telephone number, e-mail address, and mailing address of the person the Secretary may contact regarding the request for an adjustment to the MLR

standard.

§158.330 Criteria for assessing request for adjustment to the medical loss ratio.

The Secretary may consider the following criteria in assessing whether application of an 80 percent MLR, as calculated in accordance with this subpart, may destabilize the individual market in a State that has requested an adjustment to the 80 percent MLR:

(a) The number of issuers reasonably likely to exit the State or to cease offering coverage in the State absent an adjustment to the 80 percent MLR and the resulting impact on competition in the State. In making this determination the Secretary may consider as to each issuer that is reasonably likely to exit the State:

(1) Each issuer's MLR relative to an 80 percent MLR;

(2) Each issuer's solvency and profitability, as measured by factors such as surplus level, risked-based capital ratio, net income, and operating or underwriting gain;

(3) The requirements and limitations within the State with respect to market withdrawals; and

(4) Whether each issuer covers less than 1,000 life-years in the State's individual insurance market.

(b) The number of individual market enrollees covered by issuers that are reasonably likely to exit the State absent an

adjustment to the 80 percent MLR.

(c) Whether absent an adjustment to the 80 percent MLR standard consumers may be unable to access agents and brokers.

(d) The alternate coverage options within the State available to individual market enrollees in the event an issuer exits the market, including:

(1) Any requirement that issuers who exit the State's individual market must have their block(s) of business assumed by another issuer;

(2) The issuers that may remain in the State subsequent to the implementation of the 80 percent MLR, as calculated in accordance with this Part, and the nature, terms, and price of the products offered by such issuers;

(3) The capacity of remaining issuers to write additional business, as measured by their risk based capital ratios;

(4) The mechanisms, such as guaranteed issue products, an issuer of last resort, or a State high risk pool, available to the State to provide coverage to consumers in the event of an issuer withdrawing from the market, and the affordability of these options compared to the coverage provided by exiting or potentially exiting issuers; and

(5) Any authority the State's insurance commissioner, superintendent, or comparable official may exercise with respect to stabilization of the individual insurance market.

(e) The impact on premiums charged, and on benefits and cost-sharing provided, to consumers by issuers remaining in the market in the event one or more issuers were to withdraw from the market.

(f) Any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

§158.340 Process for submitting request for adjustment to the medical loss ratio.

(a) Electronic submission. A State must submit electronically, to an address and in a format prescribed by the Secretary, all of the information required by this subpart in order for its request for an adjustment to the MLR standard for its individual market to be considered by the Secretary.

(b) Submission by mail. A State may also submit by overnight delivery service or by U.S mail, return receipt requested, to an address and in a format prescribed by the Secretary, its request for an adjustment to the MLR standard for its individual market.

§158.341 Treatment as a public document.

A State's request for an adjustment to the MLR standard, and all information submitted as part of its request, will be treated as a public document and will be posted promptly on the Secretary's Internet website devoted to health care coverage.

§158.342 Invitation for public comments.

The Secretary will invite public comment regarding a State's request for an adjustment to the MLR standard. All public comments must be submitted in writing within 10 days of the posting of the request, and must be submitted in the manner prescribed by the Secretary. The Secretary will consider timely public comments in assessing a State's request for an adjustment to the MLR standard.

§158.343 Optional State hearing.

Any State that submits a request for adjustment to the MLR standard may, at its option, hold a public hearing and create an evidentiary record with respect to its application. If a State does so, the Secretary will take the evidentiary record of the hearing into consideration in making her determination.

§158.344 Secretary's discretion to hold a hearing.

The Secretary may, at her discretion, conduct a public hearing with respect to a State's request for an adjustment to the MLR standard. All testimony and materials received in connection with any public hearing will be made part of the public record, and shall be considered by the Secretary in assessing a State's request for an adjustment to the MLR standard.

§158.345 Determination on a State's request for adjustment to the medical loss ratio.

(a) General time frame. The Secretary will make a determination as to whether to grant a State's request for an adjustment to the MLR standard within 30 days after determining that the information required by this subpart has been received.

(b) Extension at the discretion of the Secretary. The Secretary may, in her discretion, extend the 30 day time period in paragraph (a) of this section for as long a time as necessary not to exceed 30 days.

§158.346 Request for reconsideration.

(a) Requesting reconsideration. A State whose request for adjustment to the MLR standard has been denied by the Secretary may request reconsideration of that determination. A request for reconsideration must be submitted in writing to the Secretary within 10 days of her decision to deny the State's request for an adjustment, and may include any additional information in support of its request.

(b) Reconsideration determination. The Secretary will issue her determination on a State's request for reconsideration within 20 days of receiving the reconsideration request.

§158.350 Subsequent requests for adjustment to the medical loss ratio.

A State that has made a previous request for an adjustment to the MLR standard must, in addition to the other information required by this subpart, submit information as to what steps

the State has taken since its initial and other prior requests, if any, to increase the likelihood that enrollees who have health coverage through issuers that are considered likely to exit the State's individual market will receive coverage at a comparable price and with comparable benefits if the issuer does exit the market.

Subpart D – HHS Enforcement

§158.401 HHS enforcement.

HHS enforces the reporting and rebate requirements described in subparts A and B, including but not limited to:

(a) The requirement that such reports be submitted timely.

(b) The requirement that the data reported complies with the definitions and criteria set forth in this Part.

(c) The requirement that rebates be paid timely and accurately.

§158.402 Audits.

(a) Notice of Audit. HHS will provide 30 days advance notice of its intent to conduct an audit of an issuer.

(b) Conferences. All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(c) Preliminary Audit Findings. HHS will share its preliminary audit findings with the issuer, which will then have

30 days to respond to such findings. HHS may extend, for good cause, the time for an issuer to submit such a response.

(d) Final Audit Findings. If the issuer does not dispute the preliminary findings, the audit findings will become final. Alternatively, if the issuer responds to the preliminary findings, HHS will review and consider such response and finalize the audit findings.

(e) Corrective actions. HHS will send a copy of the final audit findings to the issuer as well as any corrective actions that issuer must undertake as a result of the audit findings.

(f) Order to pay rebates. If HHS determines as the result of an audit that an issuer has failed to pay rebates it is obligated to pay pursuant to this Part, it may order the issuer to pay those rebates, together with interest from the date the rebates were due, in accordance with §158.240(d) of this part.

§158.403 Circumstances in which a State is conducting audits of issuers.

(a) If a State conducts an audit of an issuer's MLR reporting and rebate obligations, HHS may, in the exercise of its discretion, accept the findings of that audit if HHS determines the following:

(1) The laws of the State permit public release of the findings of audits of issuers;

(2) The State's audit reports on the validity of the data

regarding expenses and premiums that the issuer reported to the Secretary, including the appropriateness of the allocations of expenses used in such reporting and whether the activities associated with the issuer's reported expenditures for quality improving activities meet the definition of such activities;

(3) The State's audit reports on the accuracy of rebate calculations and the timeliness and accuracy of rebate payments;

(4) The State submits final audit reports to HHS within 30 days of finalization; and

(5) The State submits preliminary or draft audit reports to HHS within 6 months of the completion of audit field work unless they have already been finalized and reported under paragraph (a)(4) of this section.

(b) If HHS accepts an audit conducted by a State, and if the issuer makes additional rebate payments as a result of the audit, then HHS shall accept those payments as satisfying the issuer's obligation to pay rebates pursuant to this part.

Subpart E – Additional Requirements on Issuers

§158.501 Access to facilities and records.

(a) Each issuer subject to the reporting requirement of this part must allow access and entry to its premises, facilities and records, including computer and other electronic systems, to HHS, the Comptroller General, or their designees to evaluate, through inspection, audit, or other means, compliance

with the requirements for reporting and calculation of data submitted to HHS, and the timeliness and accuracy of rebate payments made under this Part.

(b) Each issuer must also allow access and entry to the facilities and records, including computer and other electronic systems, of its parent organization, subsidiaries, related entities, contractors, subcontractors, agents, or a transferee that pertain to any aspect of the data reported to HHS or to rebate payments calculated and made under this part. To the extent that the issuer does not control access to the facilities and records of its parent organization, related entities, or third parties, it will be the responsibility of the issuer to contractually obligate any such parent organization, related entities, or third parties to grant said access.

(c) The Comptroller General, HHS, or their designees may inspect, evaluate, and audit through 6 years from the date of the filing of a report required by this Part or through 3 years after the completion of the audit and for such longer period set forth below provided that any of the following occur:

(1) HHS determines there is a special need to retain a particular record or group of records for a longer period and notifies the issuer at least 30 days before the disposition date.

(2) There has been a dispute, or allegation of fraud or

similar fault by the issuer, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the dispute, fraud, or similar fault.

(3) HHS determines that there is a reasonable possibility of fraud or similar fault, in which case HHS may inspect, evaluate, and audit the issuer at any time.

§158.502 Maintenance of records.

(a) Basic rule. Each issuer subject to the requirements of this Part must maintain all documents and other evidence necessary to enable HHS to verify that the data required to be submitted in accordance with this Part comply with the definitions and criteria set forth in this Part, and that the MLR is calculated and any rebates owing are calculated and provided in accordance with this part. This includes but is not limited to all administrative and financial books and records used in compiling data reported and rebates provided under this Part and in determining what data to report and rebates to provide under this Part, electronically stored information, and evidence of accounting procedures and practices. This also includes all administrative and financial books and records used by others in assisting an issuer with its obligations under this Part.

(b) Length of time information must be maintained. All of the documents and other evidence required by this Part must be

maintained for the current year and six prior years, unless a longer time is required under §158.501 of this subpart.

Subpart F – Federal Civil Penalties

§158.601 General rule regarding the imposition of civil penalties.

If any issuer fails to comply with the requirements of this Part, civil penalties, as described in this subpart, may be imposed.

§158.602 Basis for imposing civil penalties.

Civil Penalties. For the violations listed in this paragraph, HHS may impose civil penalties in the amounts specified in §158.606 of this subpart on any issuer who fails to do the following:

(a) Submit to HHS a report concerning the data required under this part by the deadline established by HHS.

(b) Submit to HHS a substantially complete or accurate report concerning the data required under this part.

(c) Timely and accurately pay rebates owing pursuant to this part.

(d) Respond to HHS inquiries as part of an investigation of issuer non-compliance.

(e) Maintain records as required under this part for the periodic auditing of books and records used in compiling data reported to HHS and in calculating and paying rebates pursuant

to this Part.

(f) Allow access and entry to premises, facilities and records that pertain to any aspect of the data reported to HHS or to rebates calculated and paid pursuant to this part.

(g) Comply with corrective actions resulting from audit findings.

(h) Accurately and truthfully represent data, reports or other information that it furnishes to a State or HHS.

§158.603 Notice to responsible entities.

If HHS learns of a potential violation described in §158.602 of this subpart or if a State informs HHS of a potential violation prior to imposing any civil monetary penalty HHS must provide written notice to the issuer, to include the following:

(a) Describe the potential violation.

(b) Provide 30 days from the date of the notice for the responsible entity to respond and to provide additional information to refute an alleged violation.

(c) State that a civil monetary penalty may be assessed if the allegations are not, as determined by HHS, refuted.

§158.604 Request for extension.

In circumstances in which an entity cannot prepare a response to HHS within the 30 days provided in the notice, the entity may make a written request for an extension from HHS

detailing the reason for the extension request and showing good cause. If HHS grants the extension, the responsible entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in HHS's imposition of a civil monetary penalty based upon its determination of a potential violation described in §158.602 of this subpart.

§158.605 Responses to allegations of noncompliance.

In determining whether to impose a civil monetary penalty, HHS may review and consider documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with Affordable Care Act requirements. The following are examples of documentation that a potential responsible entity may submit for HHS's consideration in determining whether a civil monetary penalty should be assessed and the amount of any civil monetary penalty:

(a) Any evidence that refutes an alleged noncompliance.

(b) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(c) Evidence documenting the development and implementation of internal policies and procedures by an issuer to ensure compliance with the Affordable Care Act requirements regarding

MLR. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with Affordable Care Act requirements regarding MLRs and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(d) Evidence documenting the entity's record of previous compliance with Affordable Care Act requirements regarding MLRs.

§158.606 Amount of penalty—general.

A civil monetary penalty for each violation of §158.602 of this subpart may not exceed $100 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this Part are in addition to any other penalties prescribed or allowed by law.

§158.607 Factors HHS uses to determine the amount of penalty.

In determining the amount of any penalty, HHS may take into account the following:

(a) The entity's previous record of compliance. This may include any of the following:

(1) Any history of prior violations by the responsible entity, including whether, at any time before determination of the current violation(s), HHS or any State found the responsible entity liable for civil or administrative sanctions in connection with a violation of Affordable Care Act requirements regarding minimum loss ratios.

(2) Evidence that the responsible entity has never had a complaint for noncompliance with Affordable Care Act requirements regarding MLRs filed with a State or HHS.

(3) Such other factors as justice may require.

(b) The gravity of the violation. This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

§158.608 Determining the amount of the penalty—mitigating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by §158.606 of this subpart to reflect that fact. As guidelines for taking into account the factors listed in §158.607 of this subpart, HHS considers the following:

(a) Record of prior compliance. It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under §158.603 of this subpart, implemented and followed a compliance plan as described in §158.605(c) of this subpart.

(2) Had no previous complaints against it for noncompliance.

(b) Gravity of the violation(s). It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Made adjustments to its business practices to come into compliance with the requirements of this Part so that the following occur:

(i) Each enrollee adversely affected by the violation has been paid any amount of rebate owed so that, to the extent practicable, that enrollee is in the same position that he, she,

or it would have been in had the violation not occurred.

(ii) The rebate payments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from HHS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

§158.609 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several aggravating circumstances, HHS may set the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by §158.606 of this subpart to reflect that fact. HHS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§158.610 Determining the amount of penalty—other matters as justice may require.

HHS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this Part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§158.611 Settlement authority.

Nothing in §158.606 through §158.610 of this subpart limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with §158.603 of this subpart or to compromise on any penalty provided for in §§158.606 through 158.610 of this subpart.

§158.612 Limitations on penalties.

(a) Circumstances under which a civil monetary penalty is not imposed. HHS does not impose any civil monetary penalty on any failure for the period of time during which none of the

responsible entities knew, or exercising reasonable diligence would have known, of the failure. HHS also may not impose a civil monetary penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) Burden of establishing knowledge. The burden is on the responsible entity or entities to establish to HHS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§158.613 Notice of proposed penalty.

(a) Contents of Notice. If HHS proposes to assess a penalty in accordance with this Part, it must provide the issuer written notice of its intent to assess a penalty, which includes the following:

(1) A description of the requirements under this Part that HHS has determined the issuer violated.

(2) A description of the information upon which HHS based its determination, including the basis for determining the number of affected individuals and the number of days or weeks

for which the violations occurred.

(3) The amount of the proposed penalty as of the date of the notice.

(4) Any considerations described in §158.607 through §158.610 of this subpart that were taken into account in determining the amount of the proposed penalty.

(5) A specific statement of the issuer's right to a hearing.

(6) A statement that failure to request a hearing within 30 days after the date of the notice permits the assessment of the proposed penalty without right of appeal in accordance with §158.615 of this subpart.

(b) Delivery of Notice. This notice must be either hand delivered, sent by certified mail, return receipt requested, or sent by overnight delivery service with signature upon delivery required.

§158.614 Appeal of proposed penalty.

Any issuer against which HHS has assessed a penalty under this Part may appeal that penalty in accordance with §150.400 *et seq.*

§158.615 Failure to request a hearing.

If the issuer does not request a hearing within 30 days of the issuance of the notice described in §158.613 of this subpart, HHS may assess the proposed civil monetary penalty

indicated in such notice and may impose additional penalties as described in §158.606 of this subpart. HHS must notify the issuer in writing of any penalty that has been assessed and of the means by which the issuer may satisfy the penalty. The issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with §150.405 of this subchapter, unless the responsible entity can show good cause, as determined at §150.405(b) of this subchapter, for failing to timely exercise its right to a hearing.

Dated: ____November 18, 2010_____

_____

Jay Angoff,

Director,

Office of Consumer Information and

Insurance Oversight.

Dated: __November 18, 2010_____

_____

Kathleen Sebelius,

Secretary.

BILLING CODE 4150-03-P

[FR Doc. 2010-29596 Filed 11/22/2010 at 8:45 am; Publication Date: 12/01/2010]