

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Part 158**

[CMS-9998-FC]

RIN 0938-AQ71

Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule with comment period.

SUMMARY: This final rule with comment period revises the regulations implementing medical loss ratio (MLR) requirements for health insurance issuers under the Public Health Service Act in order to address the treatment of “mini-med” and expatriate policies under these regulations for years after 2011; modify the way the regulations treat ICD-10 conversion costs; change the rules on deducting community benefit expenditures; and revise the rules governing the distribution of rebates by issuers in group markets.

DATES: *Effective date.* This rule is effective on January 3, 2012.

Comment date. We will consider comments on § 158.150(b)(2)(i)(A)(6) and (c)(5) regarding the treatment of ICD-10 conversion costs, and § 158.242(b) and § 158.260 regarding the process for providing rebates to group enrollees and reporting of rebates that are received at one of the addresses provided in the **ADDRESSES** section of this rule no later than 5 p.m. EST on January 6, 2012.

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

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

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention: CMS-9998-FC*, P.O. Box 8010, Baltimore, MD 21244-8010.

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

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention: CMS-9998-FC*, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue 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 CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

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

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

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

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

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday

through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (800) 743-3591.

FOR FURTHER INFORMATION CONTACT:
Carol Jimenez, (301) 492-4457.

SUPPLEMENTARY INFORMATION:

Comment Subject Areas: We will consider comments on the treatment of ICD-10 conversion costs, and the process for providing rebates to group enrollees, as discussed in this final rule with comment period that are received by the date and time indicated in the **DATES** section of this final rule with comment period.

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (Pub. L. 111-152) was enacted on March 30, 2010. In this preamble, we refer to the two statutes collectively as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of Part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

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

II. Provisions of the Interim Final Rule and Responses to Comments

We received approximately 90 public comments on the December 1, 2010 interim final rule with comment period. Commenters included consumer and patient organizations, insurance regulators, health insurance issuers, provider groups, actuarial professional group, and others. In this final rule, we do not address all of the comments we received on the interim final rule, but only those comments that pertain to the provisions in this final rule: (1) Rules regarding the treatment of “mini-med” and expatriate policies; (2) rules governing how ICD-10 conversion costs, fraud reduction expenses, and community benefit expenditures are accounted for; and (3) rules regarding

the distribution of rebates in group markets. In this section of the preamble, we summarize the provisions of the interim final rule and respond to the public comments received on these subjects.

A. "Mini-med" Policies (45 CFR 158.110(b)(2), 158.120(d)(3), and 158.221(b)(3))

For purposes of the MLR requirements, the interim final rule provided separate treatment for mini-med policies with total annual benefit limits of \$250,000 or less by requiring issuers to report mini-med experience separately from other experience, by State and by market, for the 2011 MLR reporting year. Issuers of mini-med policies with total annual benefit limits of \$250,000 or less were also directed to use a special methodology for calculating the MLR numerator for calendar year 2011 reporting and rebate purposes. Specifically, incurred claims and activities that improve health care quality are multiplied by 2.00 in calculating the MLR for mini-med policies. Issuers of mini-med policies were directed to submit a report for each of the first three quarters of the 2011 MLR reporting year as provided under § 158.110(b), in addition to the annual report required of all issuers subject to MLR standards. The authority for this treatment of special circumstances is provided under section 2718(c) of the PHS Act, which directs HHS to "take into account the special circumstances of smaller plans, different types of plans, and newer plans."

The preamble to the interim final rule notes that, after reviewing the quarterly filings of the mini-med policies' 2011 experience, CMS would make a determination as to whether this treatment of special circumstances should continue and, if so, whether it should be modified beyond the 2011 MLR reporting year.

Comment: We received comments that both support and oppose an adjustment for issuers of mini-med policies. Commenters that supported a special methodology for mini-med experience generally claimed that the unique cost structure of mini-med policies make issuers unable to meet the statutory MLR without an adjustment to the reporting methodology. Specifically, issuers of mini-med policies asserted that such plans have higher administrative costs relative to benefits paid, as compared to other more comprehensive coverage, as a result of—(1) Higher enrollee turnover; (2) shorter enrollment periods; and (3) lower incurred claims due to high deductibles and limited coverage. Two commenters

asserted that an adjustment is necessary to preserve access to mini-med policies for employers and participants.

Three commenters requested that HHS extend until 2014 the 2011 special circumstances methodology of a multiplier of 2.00 for mini-med policies. These commenters stated that the unique structure of these plans would remain consistent between 2011 and 2014, after which a total prohibition on annual dollar limits under PHS Act section 2711 will be in effect, other than for grandfathered plans in the individual market. These commenters asserted that without this MLR treatment for the interim years, before new coverage options and premium tax credits are available through the Affordable Insurance Exchanges, issuers may withdraw from the market. This withdrawal could leave employers unable to afford other health care coverage for their employees, leaving some consumers without affordable health care coverage that will be available to them in 2014.

Many commenters, however, opposed any continuation of this methodology for issuers of mini-med policies. Consumer advocates, healthcare organizations, and a labor organization asserted that mini-med policies do not need a special circumstances adjustment. They noted that issuers did not request such an adjustment during the public comment period of the National Association of Insurance Commissioners (NAIC) model rule making process and that the NAIC did not recommend such an adjustment. They also asserted that issuers of mini-med policies should be required to operate with the same efficiency as more robust policies and to meet the statutory MLR standard. Two commenters did not support extending the adjustment for mini-med policies any longer than 2014.

Response: In determining the appropriate treatment for mini-med policies with total annual benefit limits of \$250,000 or less with respect to MLR, we considered commenters' concerns about loss of coverage if issuers of mini-med policies exit the market absent separate MLR treatment. We also considered commenters' concerns about the need for issuers to operate efficiently and provide valuable coverage.

In the interim final rule, we requested three quarters of data, including amount of premium spent on claims, quality improving activities, non-claims costs, and taxes. This final rule is being issued after receiving and analyzing two quarters of this data. We believe it is necessary to determine the final MLR

policy as to the treatment of mini-med policies, despite the fact that we have not yet analyzed the third quarter data, because otherwise we could not issue rules in time for the special circumstances adjustment to be effective for 2012 and to minimize the chance that issuers may withdraw these policies due to uncertainty about MLR requirements. After analyzing the first and second quarter data, seeking to strike a balance that ensures continued access for consumers while ensuring that they receive value for their premium dollar, we have determined that in 2012, the appropriate multiplier for mini-med policy experience is 1.75, in 2013, the appropriate multiplier is 1.50, and in 2014, the appropriate multiplier is 1.25.

The Department only addresses mini-med policy experience for the 2012, 2013, and 2014 MLR reporting years. Section 2711 of the PHS Act provides that for policy years beginning on and after January 1, 2014, when the Affordable Insurance Exchanges will be in place to provide consumers with better, more affordable coverage options, non-grandfathered plans in all markets and grandfathered plans in the large and small group markets will no longer be permitted to have annual dollar limits. Thus, policies with annual limits under § 158.110(d)(3) will no longer exist in those markets. We have applied a multiplier through the 2014 MLR reporting year to account for mini-med policies with a plan year that begins after January 1, 2013 and ends sometime in 2014.

Based upon the data we received from the first and second quarterly reports of 2011, without any multiplier, in 2011, seven of the 12 issuers in the individual market, and six of the 15 issuers in the large group market would not meet the MLR of 80 and 85 percent, respectively. With the multiplier of 2.00, three of the 12 issuers in the individual market would not meet the MLR standard¹, and all issuers in the small group or large group market would meet the MLR standard.

A graduated allowance for an adjustment of 1.75 in 2012, 1.50 in 2013 and 1.25 in 2014 will incentivize issuers to reduce their administrative expenses and operate more efficiently to ensure that they meet the MLR standard while minimizing issuer market withdrawal, maintaining access to coverage for consumers and ensuring that they receive greater value from these policies

¹ This analysis takes into consideration issuers that operate in States which have been granted an adjustment to the MLR standard for the individual market, pursuant to § 158.301.

until 2014. We plan on publishing the data used in this analysis in the spring of 2012.

B. "Expatriate" Policies (45 CFR 158.110(b)(2), 158.120(d)(4), and 158.221(b)(4))

The interim final rule defines expatriate policies as "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 non-U.S. citizens working in their home country * * *"² (45 CFR 158.120(d)(4)). Several public comments were received regarding the definition of expatriate policies. In this final rule, we are amending the definition of expatriate policies to read "group policies that provide coverage to employees, substantially all of whom are: Working outside their country of citizenship; working outside of their country of citizenship and outside the employer's country of domicile; or non-U.S. citizens working in their home country * * *." We add the phrase "substantially all of whom are" to ensure that issuers do not classify a policy as an expatriate policy when expatriates account for only a limited proportion of the covered population.

The preamble to the interim final rule states that expatriate policies issued by non-U.S. issuers for services rendered outside the United States are not subject to the MLR regulation, nor are expatriate policies written on a form not filed with and approved by a State insurance department. Issuers must report expatriate policy experience separately from other experience for the 2011 MLR reporting year and must aggregate that experience on a national level for the large group market and the small group market. The definition of expatriate policies does not include policies issued in the individual market.

Section 158.221(b)(4) directs issuers of expatriate policies to use a separate methodology for calculating the MLR numerator for reporting and rebate purposes for the 2011 MLR reporting year. Specifically, incurred claims and activities that improve health care quality are to be multiplied by a factor of 2.00 in calculating the MLR. The interim final rule directs issuers to submit a report for each of the first three quarters of the 2011 MLR reporting year. The preamble to the interim final rule notes that, after reviewing the quarterly filings of the expatriate policies based on 2011 experience, we will make a determination as to whether this treatment should continue or be

modified beyond the 2011 MLR reporting year.

Comment: CMS received six comments regarding the treatment of expatriate policies in the interim final rule. The majority of the commenters supported the interim final rule's treatment of expatriate policies for the 2011 MLR reporting year. Specifically, issuers and trade associations supported the special methodology for calculating the MLR numerator for expatriate policies, noting that these policies have higher administrative costs as a result of (1) Providing international access to providers; (2) maintaining emergency evacuation services; and (3) navigating health care and legal systems in different countries. These policies may also have unpredictable experience depending on the location of the enrollees. One issuer stated that a large portion of international policies are sold through brokers, and high broker fees contribute to the increased administrative cost. We received no comments opposing a special circumstances adjustment for expatriate policies.

Other issuers and commenters suggested that the interim final rule's adjustment to the MLR numerator does not do enough to relieve expatriate issuers from the MLR standards provided in the Affordable Care Act. One issuer claimed that the MLR reporting requirement creates an unlevel playing field because U.S. issuers must disclose proprietary cost structure information under the MLR reporting requirements, while foreign issuers would not be required to do so. Two commenters specifically suggested that the adjustment for expatriate policies should extend beyond the 2011 MLR reporting year, either temporarily or permanently.

Response: We recognize the unique administrative costs associated with expatriate policies as evidenced from the public comments and the first two quarterly reports of 2011.² Commenters asserted that the costs of: (1) Identifying and credentialing providers worldwide in countries with different licensing and other requirements; (2) processing claims submitted in various languages; (3) standardizing billing procedures; (4) providing translation and other services to enrollees; and (5) helping subscribers locate qualified providers internationally justify a separate methodology that takes into account these special circumstances. After reviewing the first and second quarter

data, we have determined that continuing a special circumstances adjustment of a multiplier of 2.00 to the numerator of the MLR is appropriate for expatriate policies.

According to the year-to-date second quarter data provided by issuers of expatriate policies, without applying the special circumstances adjustment provided in the interim final rule, the majority of issuers in the large group market³ reported credibility-adjusted MLRs significantly below 85 percent MLR standard. However, with the multiplier of 2.00, we estimate that issuers' credibility-adjusted MLRs will meet the MLR standards, thus ensuring that Americans working abroad will still have access to U.S.-based coverage.

Based on the reported data and on information from stakeholders concerning this unique market, we believe that a multiplier of two is appropriate to ensure that issuers remain in the expatriate market. As discussed previously, expatriate policies have significantly different and additional administrative costs than do policies that provide primarily domestic coverage. In addition, the experience of expatriate policies is subject to more variability than other types of policies, due to the fact that they primarily cover care in all parts of the world in a wide variety of health care systems, which also makes pricing to a particular MLR standard much more difficult. Due to this inherent uncertainty in pricing and their unique administrative costs, we have determined that it is appropriate to provide this special circumstances multiplier to expatriate policies. We understand that the experience of expatriate policies is significantly more variable than the experience of other types of policies, warranting a larger adjustment to account for this. This multiplier of two applies to expatriate policies beginning in the 2012 MLR reporting year, and applies indefinitely.

We believe that the MLR standards do not materially affect U.S. issuers' ability to compete with foreign issuers, in part because U.S. employers want to provide their employees who are working abroad and their dependents with comprehensive health insurance that meets the unique needs of expatriates and provides benefits that are comparable to the coverage of their U.S.-based employees. Also, U.S.-based issuers generally will not be required to disclose any proprietary financial structure information that is not already

² CMS is basing its determination on two quarters of data for the same reasons set forth above with respect to mini-med policies.

³ No issuers of expatriate policies in the small group market had credible experience in 2011. However, they may become credible in 2012, when issuers' MLRs will generally be calculated based on multiple years of experience and data.

being provided to the States through the NAIC's Supplemental Health Care Exhibit (SHCE).

C. Fraud Reduction Expenses (45 CFR 158.140(b)(2)(iv) and 158.150(c)(8))

The interim final rule describes the types of expenses that are adjustments to claims under the MLR disclosure and reporting requirements. Specifically, under § 158.140(b)(2)(iv), the amount of claim payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, can be included in incurred claims. Fraud reduction efforts include fraud prevention as well as fraud recovery. In addition, the interim final rule provides that fraud prevention activities are excluded from quality improvement activities (QIA).

Comment: We received 12 comments on the treatment of fraud prevention activities in the interim final rule. Eleven of the commenters supported the inclusion of fraud prevention activities as QIA. Specifically on this point, issuers argued that fraud prevention activities improve patient safety, and deter the use of medically unnecessary services, thus providing a higher level of health care quality. Commenters asserted that, by not including all fraud reduction efforts as QIA, issuers would reduce their fraud reduction efforts, which would decrease patient safety and quality of care. Two commenters added that by prohibiting plans from including the costs they incur for fraud prevention activities as QIA, the rule likens the costs to wages, overhead, and advertising expenses. Two trade associations asserted that HHS should be consistent with the Administration's efforts to prevent fraud in government programs, stating that excluding fraud prevention as QIA undermines the federal government's efforts to prevent, detect, and prosecute fraud. Two commenters provided information regarding the savings that fraud prevention programs can provide issuers. This information suggested that among large issuers surveyed, the net savings from anti-fraud operations were more than \$3 per enrollee in 2008, that medium sized issuers reported \$1 savings per enrollee, and that small issuers estimated \$2.70 savings per enrollee.

Not all commenters supported characterizing fraud prevention activities as QIA. A provider association expressed concerns that Pharmacy Benefit Managers may improperly try to categorize certain activities as fraud detection due to the lack of a clear definition for fraud detection and recovery. This commenter asserted that

excluding fraud prevention activities from QIA is an appropriate way to apportion medical costs versus administrative costs, and urged HHS to allow only those efforts to reduce fraud, as defined by Medicare, to be allowed to be deducted from an issuer's administrative costs.

Response: We considered the comments regarding fraud reduction expenses, and are maintaining the MLR treatment of fraud reduction expenses provided in the interim final rule. We will continue to exclude fraud prevention activities from QIA. The current treatment of fraud reduction efforts under the MLR rule is consistent with the NAIC's position and adequately addresses the concerns of issuers, while still recognizing that many fraud prevention efforts are not directly targeted towards quality improvement. We recognize the importance of fraud reduction expenses and the disincentive it could create if these expenses were treated solely as non-claims and non-quality improving expenses. Thus, allowing payments recovered through fraud reduction efforts as adjustments to incurred claims gives issuers the opportunity to recoup monies invested to deter fraud. Modifying the interim final rule to allow an unlimited adjustment would undermine the purpose of requiring issuers to meet the MLR standard in the Affordable Care Act.

We believe that issuers will continue to invest in fraud reduction, including fraud prevention, regardless of the MLR treatment and encourage issuers to do so. Issuers have incentives to reduce fraud regardless of how this expense is classified within the MLR, as demonstrated from the comments and data provided by issuers. By allowing fraud reduction expenses as an adjustment to incurred claims, up to the amount of fraudulent claims recovered, the interim final rule mitigates any disincentive issuers may have to invest in these programs. We appreciate the comments from the industry regarding the savings that result from fraud reduction efforts, which support the MLR policy in the interim final rule that the amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, should be included in incurred claims.

D. ICD-10 Conversion Expenses (45 CFR 158.150(b)(2)(i)(A)(6) and (c)(5))

Under § 158.150(a), health insurance issuers are required to submit an annual report to the Secretary documenting their expenditures for activities that improve health care quality. As

provided by § 158.150(b), in order for an activity to be considered a QIA, it must be designed, among other things, to improve health quality and increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements. In addition, the activity must be primarily designed to—(1) Improve health outcomes; (2) prevent hospital readmissions; (3) improve patient safety; or (4) implement, promote and increase wellness and health activities. Health Information Technology (HIT) expenditures that meet the requirements under § 158.150 are considered QIA. The list of activities excluded as QIA includes—(1) Those activities designed primarily to control or contain costs; and (2) those that establish or maintain a claims adjudication system, including costs directly related to upgrades in HIT 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 ICD-10 requirements). The preamble to the interim final rule stated that CMS would examine the reported conversion costs of ICD-10 to determine whether the policy to exclude these costs from QIA should be revisited. In addition, the interim final rule specifically requested comments on whether ICD-10 should be included as a QIA.

Comment: Provider associations and advocacy groups supported the interim final rule's treatment of ICD-10. Specifically, provider associations contended that ICD-10 does not have any bearing on the treatment that an enrollee receives, and that there is no direct impact on patient outcomes, even if it benefits the medical community as a whole. Commenters also noted that issuers will achieve greater administrative efficiency with ICD-10's more detailed coding, allowing claims to be paid more efficiently. For these reasons, such commenters asserted that these costs are administrative in nature and should be excluded from QIA. A consumer advocate further suggested that excluding ICD-10 costs from QIA would prevent issuers from reclassifying administrative tasks as QIAs.

Issuers opposed the interim final rule's treatment of ICD-10 conversion costs, asserting that ICD-10 costs are a QIA because they are meant to improve data collection for diagnoses and medical procedure coordination, patient

safety, health outcomes, and medical research. They also stated that ICD-10 conversion allows for alignment of quality and wellness programs, which are QIA. In support of classifying ICD-10 expenses as QIA, a health insurance issuer stated that ICD-10 coding can improve health plans' ability to share data among clinicians for the purpose of quality improvement and care coordination activities, thereby allowing for a better understanding of diagnoses and better treatment. An issuer and an industry association asserted that because ICD-10 implementation is a legal requirement, the burden of cost should not be on the issuers.

Finally, issuers acknowledged that conversion costs can be tracked and separated from maintenance costs through current accounting processes, and most supported excluding ICD-10 maintenance costs occurring after October 1, 2013 from QIA.

Response: In response to the comments highlighting the dual nature of ICD-10, we considered the impact of ICD-10 on improving data collection for diagnoses and medical procedure coordination, patient safety, health outcomes, and medical research. In addition, we consulted with the Office of E-Health Standards and Services (OESS) within CMS. OESS oversees ICD-10 and considers some of the impact of ICD-10 to be QIA, and supports the treatment of ICD-10 set forth in this final rule.

We also recognize that ICD-10 has some claims processing functions as well. This final rule recognizes the dual nature of ICD-10 and includes as QIA ICD-10 conversion costs incurred in 2012 and 2013 up to 0.3 percent of an issuer's earned premium in the relevant State market in each of those years. Analysis of the 2010 SHCE filings reveals that ICD-10 expenses, as a percent of earned premium, account for less than 0.02 percent of issuer spending in each market (individual, small group and large group). However, significant ICD-10 conversion efforts will be made in 2012 and 2013, as issuers cannot convert to ICD-10 until after January 1, 2012, when the new version 5010 standards for electronic health care transactions will be upgraded. Federal HIPAA regulations direct that the ICD-10 transition must be completed by October 2013. The industry provided a range of percentages using their projected expenditures of ICD-10 conversion costs on their MLRs, if allowed as a QIA. After reviewing the data provided by issuers and 2010 SHCE filings, we chose a cap that allows as QIA amounts that issuers projected spending on ICD-10 conversion,

without permitting issuers to include claims adjudication systems costs in QIA.

In addition, ICD-10 maintenance costs are excluded from QIA in this final rule, based on the industry's collective comments stating that separating conversion costs from maintenance costs is feasible, and based on their support for excluding ICD-10 maintenance costs from QIA.

We request further comment on the treatment of ICD-10 conversion costs adopted in this final rule. Specifically, we are soliciting comments on whether including as QIA ICD-10 conversion costs as a QIA is appropriate, and if the cap set at up to 0.3 percent of an issuer's earned premium is an appropriate amount based on past and future ICD-10 conversion expenses.

E. Community Benefit Expenditures (45 CFR 158.160(b)(2)(vi) and 158.162(b)(1)(vii), (c)(1))

In the interim final rule, we requested comment on the treatment of community benefit expenditures. The interim final rule allows a not-for-profit, tax-exempt issuer to deduct from earned premium the amount of its community benefit expenditures, limited to the State premium tax rate applicable to for-profit issuers. The interim final rule also requires a not-for-profit issuer to report community benefit expenditures "in lieu of taxes * * * but not to exceed the amount of taxes [it] would otherwise be required to pay." (45 CFR 158.162(c)(1)).

Comment: CMS received nine comments on the treatment of community benefit expenditures, including from six issuers, a labor union, a law firm, and an issuer coalition organization. Seven commenters agreed that the MLR rule should not discourage not-for-profit issuers from providing services and financial support to the community. Three commenters expressed concern that limiting community benefit expenditures deductibility would discourage community benefit expenditures and community investment. Two commenters suggested that the definition of community benefit expenditures be expanded to include expenses not specifically targeted at increasing access to health care. Another commenter suggested that community benefit expenditures be considered QIA.

Some commenters expressed concern that the treatment of community benefit expenditures in the interim final rule would result in unequal treatment among not-for-profit issuers, and between not-for-profit and for-profit issuers, for several reasons. Five

commenters noted that the community benefit expenditures deduction would not be uniformly available to a not-for-profit issuer because State premium tax rates vary by State, and within some States, vary by issuer type (for example, PPO or HMO). They also suggested that the varying premium tax rates by type of issuer within a State would result in confusion when determining which premium tax rate to apply to the community benefit expenditures limit. The commenters asserted that in States without a premium tax, a not-for-profit issuer's community benefit expenditures would not be deductible and therefore its MLR would be relatively lower than an issuer in a State with a premium tax.

Six commenters suggested that a flat national community benefit expenditures deduction limit would result in a more even playing field, as well as simplify the administrative burden in determining community benefit expenditures deduction limits. Five commenters proposed a flat deduction limit ranging from three to five percent of earned premium. Another commenter proposed allowing not-for-profit issuers to deduct all community benefit expenditures from earned premium.

Four commenters asserted that because of the different corporate structures, business plans, missions, and tax liabilities of not-for-profit and for-profit issuers, it would be speculative and burdensome to determine what a not-for-profit issuer's hypothetical tax liability would be if it were a for-profit issuer. Finally, issuers expressed concern that not-for-profit issuers have fundamentally different missions than for-profit issuers, that tax liability is determined based on a series of credits and adjustments built into a taxable issuer's business plan, and that it would be too burdensome and speculative for a tax-exempt or not-for-profit issuer to estimate its "but for" tax liability.

Response: Although we share the concern that the MLR standard should not discourage a not-for-profit issuer from spending on community benefit expenditures, we are not persuaded that the definition of community benefit expenditures should generally be expanded and maintain the definition currently in § 158.160(c)(2). We note that existing laws pertaining to not-for-profit issuer status and the benefits associated with this status continue to apply. However, based on the comments regarding the variance of State premium tax rates by type of issuer, in this final rule the community benefit expenditures deduction is revised to

help ameliorate such disparate effects. Currently, 48 States have premium taxes, but tax rates in many States differ for different kinds of plans and in some States they differ for not-for-profit and for-profit issuers. Several States do not tax HMOs or not-for-profit issuers at all. In this final rule, we modify § 158.162(b)(1)(vii) to allow an issuer to deduct either the amount it paid in State premium taxes, or the amount of its community benefit expenditures up to a maximum of the highest State premium tax rate in the State, whichever is greater. This treatment does not create a disincentive against community benefit expenditures, while equalizing some of the disparities that were identified in comments to the interim final rule.

We also considered the comments regarding a hypothetical tax reporting requirement in § 158.162(c)(1) and agree that it is not necessary. Because of the modification to the community benefit expenditures deduction limit, it is no longer necessary for an issuer to report community benefit expenditures limited by its hypothetical tax liability, and thus this final rule removes that requirement. By removing § 158.162(c)(1) of the interim final rule, this final rule simplifies the reporting requirement.

Section 158.160(b)(2)(vi) of the interim final rule directs issuers to report non-claims costs by type, including all community benefit expenditures. This reporting standard applies regardless of whether an issuer elects to adjust earned premium for community benefit expenditures, as permitted by § 158.162(b)(1)(vii) in this final rule.

F. Rebates to Enrollees in Group Markets (45 CFR 158.241(b), 158.242(b), 158.243(a)(1), 158.250, and 158.260(c))

In § 158.242(b), the interim final rule directs issuers in the large and small group markets that have not met the applicable MLR standard to provide any owed rebate to the policyholder and each subscriber, “in amounts proportionate to the amount of premium each paid.” The interim final rule also allows an issuer to enter into an agreement with the group policyholder to distribute the rebates on behalf of the issuer if the policyholder agrees to distribute it proportionately as directed and provide detailed documentation regarding the distribution to each subscriber. However, under the interim final rule, the issuer remains liable for complying with all of its obligations under the statute and for maintaining records that demonstrate rebates were provided accurately to individual enrollees.

Comment: CMS received several comments regarding rebate distribution in the group market. Generally, commenters supported the pro rata distribution of rebates to the policyholder and each subscriber. Many commenters, however, expressed significant concern about the logistical and tax problems inherent in the interim final rule’s mechanism for providing rebates in the group markets. For example, several issuers expressed concern that the issuer lacks access to the information needed to distribute rebates to individual enrollees covered under a group policy, asserting that the policyholder (and not the issuer) has information regarding the premium contribution amount from the employer and the employee. A few commenters expressed their concern that it is unfair for issuers to remain liable under the interim final rule, even when the issuer enters into an agreement with a policyholder, since issuers are unable to monitor or control the actions of the policyholder.

Issuers, trade associations, and a State regulator recommended that issuers be allowed to distribute rebates to policyholders, and that the policyholder should become responsible for distributing rebates to enrollees. Two commenters noted that the proposed distribution treatment should be governed by the Employee Retirement Income Security Act of 1974, as amended (ERISA). However, one commenter asserted that rebates should not be considered plan assets under ERISA for which plan administrators owe a fiduciary duty.

A few commenters also recommended allowing issuers to rely on the representations made by policyholders that they calculated and disbursed rebates as required and that making a good faith effort to obtain the information from policyholders should fulfill issuers’ reporting obligations under the interim final rule.

Subsequent to the closing of the public comment period on the interim final rule, CMS received several inquiries to our public email address asking about the tax implications to issuers, employers, and consumers, as a result of the mechanism for providing rebates established in the interim final rule.

Response: In response to the comments we received and the inquiries to our public email address, we examined the issue in consultation with the Departments of Labor and Treasury. Requiring issuers to apportion and pay rebates directly to policyholders and each of their subscribers (who are generally employees) in the group

health plan context, as provided by the interim final rule, has unintended administrative consequences as well as potential tax consequences for issuers, employers, and consumers. For the portion of the premiums that were paid with pre-tax dollars (that is, through an Internal Revenue Code section 125 cafeteria plan), which is the case for a significant proportion of group enrollees, rebates paid to enrollees may be treated as wages, raising issues as to the application of employment taxes and the potential that an issuer may have to administer any applicable withholding obligations.

While the above burdens and logistical problems could be avoided by simply providing for rebates to be paid to the policyholder (for example, employer), the statute directs that enrollees receive the benefit of rebates and we are committed to ensuring that this is the case. Having considered the tax and other logistical implications of providing rebates to enrollees in a group health plan, the effect on consumers, and the burden on issuers and employers, this final rule directs issuers in the group markets to provide rebates to the group policyholder but, as discussed below, includes protections designed to satisfy, in a practical way, the objective of benefitting subscribers and their related enrollees. In providing rebates to the group policyholder, the final rule maintains the definition of enrollee for purposes of the rebate provisions, found in § 158.240(b), which states that “enrollee” means the subscriber, policyholder, and/or government entity that paid the premium for health care coverage received by an individual during the relevant MLR reporting year. Issuers must provide rebates, if any, to policyholders covered during the MLR reporting year on which the rebate is based.

The final rule establishes separate standards for ERISA-covered group health plans and plans that are neither covered by ERISA nor are governmental plans (for example, church plans). The handling of rebates by ERISA-covered plans and church plans are not subject to direct CMS regulation. Thus, the separate standards for such plans in the final rule are designed to acknowledge the different legal and regulatory frameworks that apply to those plans while still establishing, either directly or through reliance on other applicable legal standards, such as ERISA, a requirement that is consistent with the statutory directive that MLR rebates benefit enrollees. Non-Federal governmental plans are subject to direct regulation by CMS and we are issuing

an interim final rule contemporaneous with this final rule that addresses rebates to such plans.

Many group health plans are employee benefit plans that are subject to ERISA. Through consultation regarding this final rule, the Department of Labor has advised CMS that, in the context of ERISA-covered group health plan coverage, rebates paid to the policyholder in accordance with § 158.242(b) of this final rule may have plan asset, fiduciary responsibility, and prohibited transaction implications under Title I of ERISA. Distributions from insurance companies to their policyholders, including employee benefit plans, take a variety of forms, including refunds, dividends, demutualization payments and excess surplus distributions. ERISA, Department of Labor rulings, and other authority currently provide guidance on the proper handling of such distributions to employee benefit plans covered under Title I of ERISA. To the extent MLR rebates constitute plan assets of an ERISA-covered group health plan, decisions regarding the handling and allocation of the rebate would have to be made by a plan fiduciary consistent with ERISA. The Department of Labor has also advised that it is publishing guidance on its Web site at <http://www.dol.gov/ebsa/healthreform>, contemporaneously with this final rule, regarding the duties of employers/plan sponsors and other fiduciaries responsible under sections 403, 404 and 406 of ERISA for decisions relating to MLR rebates. Accordingly, rebates paid in connection with policies for ERISA-covered employee benefit plans may constitute plan assets that are required to be handled in accordance with the requirements of ERISA.

With respect to non-Federal governmental plans, there currently is no similar legal framework set forth in Federal law governing distributions from issuers to their plan policyholders. Accordingly, under the authority in section 2792 of the PHS Act to promulgate regulations determined “appropriate” to “carry out” the provisions of part A of title XXVII of the PHS Act, which include PHS Act section 2718, we are, in a separate interim final rule being published contemporaneously with this final rule, directing that the portion of rebates attributable to the amount of premium paid by subscribers of non-Federal governmental plans be used for the benefit of subscribers, which ensures that enrollees in such plans similarly receive the benefit of rebates.

With respect to rebates paid to a policyholder that is a group health plan

but is not a governmental plan and not subject to ERISA, for example a church plan, this final rule provides that an issuer may make rebate payment to the policyholder if the issuer receives written assurance from the policyholder that the rebate will be used for the benefit of current subscribers using one of the options prescribed for non-Federal governmental plans. Without such written assurance, the issuer must pay directly the policyholder's subscribers covered by the policy during the MLR reporting year on which the rebate is based.

The purpose of the MLR is to provide enrollees value for their premium dollar, and issuers must meet the applicable MLR standard or pay rebates based upon aggregated market data in each State. The law does not provide for a group health plan MLR or an individual enrollee MLR. Thus, rebates are not based upon a particular group health plan's experience or a particular subscriber's experience. We believe that distributing rebates to subscribers in the manner prescribed by this final rule and the interim final rule published contemporaneously with this final rule accomplishes the purpose of the MLR requirement, while streamlining the rebate process for consumers, employers, and issuers. Because the final rule and the interim final rule published contemporaneously with this final rule provide that rebates are to be distributed to the policyholder for subscribers of group health plans, the final rule modifies § 158.241(b) regarding rebates to former enrollees, so that § 158.241(b) now applies only to former enrollees in the individual market.

The final rule also provides that issuers must provide notice of rebates, if any, to current group health plan subscribers as well as group policyholders, and to subscribers in the individual market. The notice of rebates to policyholders and subscribers of group health plans will be prescribed by the Secretary of Health and Human Services, in consultation with the Secretary of Labor.

The notice must include information about the MLR and its purpose, the MLR standard, the issuer's MLR, and the rebate being provided. In addition, the notice to policyholders and current subscribers in plans that are not subject to ERISA must contain an explanation as to how the rebate will be handled. If the plan is subject to ERISA, the notice to policyholders and subscribers must contain an explanation that the policyholder may have obligations under ERISA's fiduciary responsibility provisions with respect to the handling

and allocation of the rebate and contact information for questions concerning the handling and allocation of the rebate under their plan. As noted above, the Department of Labor is publishing guidance on its Web site contemporaneously with the publication of this final rule that provides guidance on the duties of policyholders under ERISA with respect to the handling and allocation of rebates in the case of policies that cover an employee benefit plan subject to ERISA.

If the policyholder is a non-Federal governmental plan, the notice to the policyholder and subscribers must contain an explanation that the policyholder must use the portion of the rebate attributable to subscribers' contribution to premium in certain ways for the benefit of current subscribers. If the policyholder is not a governmental plan and not subject to ERISA, the notice must contain an explanation that the policyholder must agree to use the portion of the rebate attributable to subscribers' contribution to premium for the benefit of current subscribers or the issuer will pay the rebate directly to the policyholder's subscribers.

We believe that the above notice requirement will not only provide policyholders and subscribers with information on rebates to be paid, and how they will benefit from them, but greater transparency on how premium dollars are used by issuers, and how the issuer's MLR compares to the standard set by Congress. We believe that these latter two purposes would also be served by a notice to policyholders and subscribers with MLR information from issuers that do not owe rebates. In addition to providing policyholders and subscribers with material information on how their premium dollars are used, the provision of such a notice would create an incentive to spend as high a percentage of premium dollars on care and quality improvement as possible, rather than just enough to avoid paying rebates.

Because the interim final rule did not discuss the possibility of a notice requirement for issuers that do not owe rebates, and the public has not had an opportunity to comment on such a requirement, we have not included it in this final rule but intend to amend this rule pursuant to comments. We invite comment on the fact that the current notice requirement only applies to issuers that owe rebates, and that as a result, policyholders and subscribers of issuers not owing rebates would not receive MLR information. We also invite comment on the idea of the provision of notices to subscribers and policyholders not receiving rebates at the same time

that subscribers and policyholders receiving notices of rebates get theirs in 2012 and beyond.

We also are considering whether it would be useful to include information in notices about the issuer's prior year MLR, so that enrollees could see whether the issuer is doing a better or worse job than the year before of efficiently using premium revenue. Information showing a less favorable MLR in the current year than that from the year before could be useful to policyholders and subscribers in predicting what might be expected to happen the next year, and thus in making plan choices. Again, because we did not discuss or seek comment on such a requirement in the interim final rule, we invite public comment on whether we should impose a requirement that it be included for all MLR notices in 2012 and/or subsequent years.

Under § 158.242(b)(4) of the final rule, if a group health plan, regardless of whether it is subject to ERISA, has been terminated at the time of rebate payment and the issuer cannot, despite reasonable efforts, locate the policyholder or employer whose employees were enrolled in the group health plan, the issuer must distribute the entire rebate (both the policyholder and subscriber's portions of the rebate) to the subscribers of the group health plan enrolled during the MLR reporting year on which the rebate was calculated by dividing the rebate equally among all subscribers entitled to a rebate. Since issuers do not know how much of a group health plan premium was paid by the policyholder and how much each subscriber contributed, issuers would not be able to divide rebates based upon each subscriber's contribution.

The final rule also modifies the minimum threshold for issuer payments of rebates in the group market from \$5.00 per subscriber to a total of \$20.00 for the policyholder portion and subscriber portion of the rebate combined when the rebate is paid directly to the policyholder. When an issuer pays the rebate directly to each subscriber in a group health plan, as provided in § 158.242(b)(3) and (4), or pays rebates in the individual market, the minimum rebate threshold remains at \$5.00 per subscriber. Finally, in § 158.260(c), the final rule modifies issuers' rebate reporting requirements to conform to changes in how rebates are provided in group markets, which we believe also simplifies the reporting requirements.

We request comment on the treatment of rebates in group markets. We request comments specifically on whether the

mechanism provided in this final rule solves or meaningfully reduces the logistical challenges of providing rebates to group health plans and their subscribers and on other potential solutions to these challenges while ensuring that enrollees benefit when rebates are paid.

III. Provisions of the Final Rule

Those provisions of this final rule that differ from the interim final rule are:

- *Mini-med Plans.* Issuers of policies with total annual benefit limits of \$250,000 or less must continue for 2012, 2013 and 2014 to report mini-med experience separately from other experience and must continue to aggregate it by State and by (individual, small group, or large group) market. Issuers of mini-med policies must apply a special circumstances adjustment to the numerator of their MLR by multiplying the total of the incurred claims plus expenditures for activities that improve health care quality by a factor of 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year. For the 2012, 2013 and 2014 MLR reporting years, mini-med experience will be reported annually, but not quarterly.

- *Expatriate Plans.* Issuers of expatriate plans must continue to aggregate and report the experience from these policies on a national basis, separately for the large group market and small group market, and separately from other policies. Issuers of expatriate policies must apply a special circumstances adjustment to the numerator of their MLR by multiplying the total of the incurred claims plus expenditures for activities that improve health care quality by a factor of 2.0 beginning with the 2012 MLR reporting year. This applies indefinitely. Expatriate experience will be reported annually, but not quarterly. The definition of expatriate policies is amended to read "group policies that provide coverage to employees, substantially all of whom are: Working outside their country of citizenship; working outside of their country of citizenship and outside the employer's country of domicile; or non-U.S. citizens working in their home country."

- *ICD-10 Conversion Expenses.* Activities that are considered quality improvement activities (QIA) include, for each of the 2012 and 2013 MLR reporting years, ICD-10 conversion costs up to 0.3 percent of an issuer's earned premium in the relevant State market. Comments are solicited on this issue.

- *Community Benefit Expenditures.* The amount an issuer may deduct from earned premium is the higher of either the total amount paid in State premium tax, or actual community benefit expenditures up to the highest premium tax rate in the State. In addition, not-for-profit issuers are no longer required to estimate the amount of taxes they would have paid if they were for-profit.

- *Recipients of Rebates.* The rebate distribution process for group markets provides that issuers generally distribute rebates to group policyholders. Comments are solicited on this issue. With respect to policyholders that are a group health plan but not a governmental plan or subject to ERISA, issuers must obtain written assurance from the policyholder that rebates will be used for the benefit of current subscribers or otherwise must pay the rebates directly to subscribers covered by the policy during the MLR reporting year on which the rebate is based. Issuers must distribute the entire rebate directly to subscribers if the group health plan has been terminated. In addition, the amount for a *de minimis* rebate in the group market is less than \$20.00 per group health plan for rebates that are distributed to the policyholder. There are conforming changes made to the reporting requirements. Enrollees are required to receive a rebate notification.

IV. 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; and
- 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):

ICRs Regarding MLR and Rebate Reporting and Notice Requirement (§ 158.101 Through § 158.170, and § 158.250)

For purposes of MLR and rebate reporting under Part 158, this final rule does not impose any new reporting requirements and generally conforms to the requirements under the interim final regulation. However, CMS plans to publish for public comment, in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the annual MLR reporting form that issuers will be required to submit to CMS starting in June 2012 for the 2011 reporting year as well as the notice of rebates that issuers will be required to send to policyholders and subscribers starting in August 2012 for the 2011 report year, in the near future.

One exception is that mini-med and expatriate issuers are no longer required to submit quarterly reports, beginning in MLR reporting year 2012. The quarterly report information collection requirements are currently approved under OMB control number 0938-1132. Due to the elimination of the quarterly reporting requirement for mini-med and expatriate issuers, it is estimated that annual reporting costs for such issuers will be reduced by a total of approximately \$2.8 million.

CMS has submitted a copy of these 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 final rule with comment period; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention: CMS Desk Officer, 9998-FC, Fax: (202) 395-6974; or Email: OIRA_submission@omb.eop.gov.*

V. Response to Comments

Because of the large number of public comments CMS receives on **Federal Register** documents, CMS is not able to acknowledge or respond to them individually. A discussion of the comments CMS received is included in the preamble of this document.

VI. Regulatory Impact Statement

A. Summary

This final rule is designed to address several specific issues that have arisen regarding section 2718 of the PHS Act, which sets forth standards for reporting

of certain medical loss ratio (MLR) related data to the Secretary on an annual basis by issuers offering coverage in the individual and group markets, and calculating and providing rebates to policyholders in the event that an issuer's MLR fails to meet or exceed the statutory standard. This final rule establishes standardized methodologies designed to take into account the special circumstances of mini-med policies and expatriate policies in the methodologies for calculating measures of the activities that are used to calculate an issuer's MLR. This final rule also addresses ICD-10 conversion costs, expenses related to fraud reduction activities, community benefit expenditures and the distribution of rebates in the group market. These provisions are generally effective beginning January 1, 2012.

CMS is publishing this final rule to implement the protections intended by Congress in the most economically efficient manner possible. CMS has examined the effects of this rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), 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, CMS 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 final rule.

B. Executive Orders 12866 and 13563

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or

communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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

1. Need for Regulatory Action

Consistent with the provisions in Section 2718 of the PHS Act, this final rule establishes methodologies for calculating the MLR to accommodate the special circumstances of two different types of plans, mini-med policies and expatriate policies, and a mechanism for providing rebates to enrollees in group health plans when the MLR standard is not met by an issuer. This final rule also addresses ICD-10 conversion costs, expenses related to fraud reduction activities and community benefit expenditures. Section 2718(b) of the PHS Act (captioned "ensuring that consumers receive value for their premium payments") requires issuers to provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended on reimbursement for clinical services and activities that improve quality is less than the applicable minimum standard and specifies how the rebate is to be calculated.

2. Summary of Impacts

In accordance with OMB Circular A-4, Table VI.1 below depicts an accounting statement summarizing CMS's assessment of the benefits, costs, and transfers associated with this regulatory action. Tables VI.1.1–VI.1.5 list benefits, costs and transfers for each individual provision. For purposes of this regulatory impact analysis, CMS has updated relevant information that

was presented in the December 1, 2010 MLR interim final rule (75 FR 74892) based on the provisions of this final rule. CMS has limited the period covered by this regulatory impact analysis (RIA) to 2012–2013. Estimates are not provided for subsequent years because there will be significant changes in the marketplace in 2014 related to the offering of new individual and small group plans through the Affordable Insurance Exchanges. In addition, this RIA focuses only on the modifications to the provisions in the interim final rule and estimates the effects of those modifications relative to a baseline of no modifications. As discussed earlier, CMS anticipates that the adjustments to the MLR methodology in this final regulation will help ensure that consumers receive value for their premium dollars, have continued access to insurance coverage

options, and encourage efficiency in the disbursement of rebates to group health plan enrollees. Additionally, CMS believes that allowing issuers of group health plans to distribute all rebates to the policyholder for the benefit of subscribers will avoid any increase in tax and administrative burdens for consumers and issuers. Elimination of quarterly reporting requirements for mini-med and expatriate policies will reduce related reporting costs for issuers of those policies. Allowing for inclusion of community benefit expenditures in the MLR calculation for issuers without requiring not-for-profit issuers to calculate hypothetical tax liability will also reduce reporting costs for issuers. Executive Order 12866 also requires consideration of the “distributive impacts” and “equity” of a regulation. As described in this RIA, the adjustment in the MLR methodology for mini-med

policies will result in an increase in rebate payments to enrollees in those policies, while the adjustments in MLR methodology to account for costs related to ICD–10 conversion and community benefit expenditures in some States will result in reduced rebate payments to affected enrollees. Distributing group health plan rebates to the policyholders for the benefit of subscribers will also transfer the benefits of those rebates from enrollees who leave the plan to new enrollees in the plan. In accordance with Executive Order 12866, CMS believes that the benefits of this regulatory action justify the costs. The regulatory impact analysis does not include estimates related to fraud reduction activities since this final rule does not change the policy or treatment of fraud reduction expenses.

TABLE VI.1—ACCOUNTING TABLE: SUMMARY

Benefits:

Qualitative:

- * Increase in quality of medical care as a result of increased spending on quality improving activities by issuers of mini-med policies.
- * Improved health as a result of increased spending on medical care by issuers of mini-med policies.
- * Continued access to mini-med and expatriate health policies for consumers.
- * Benefits to consumers by encouraging issuers to undertake community benefit expenditures.

Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	(\$4.2 million)	2011	7	2012–2013
	(\$4.4 million)	2011	3	2012–2013

Annual reduction in costs for issuers of mini-med and expatriate policies due to elimination of requirement to file quarterly reports and change in method of disbursement of rebates for group health plans.

Qualitative:

- * Increased spending on quality-improving activities by issuers of mini-med policies.
- * Increased spending on medical care by issuers of mini-med policies.
- * Reduced administrative burden for not-for-profit issuers since they will no longer need to calculate and report hypothetical tax liabilities.
- * Reduced tax burden for group health plan enrollees relating to the change in the method of disbursement of rebate payments.
- * Increased administrative costs for policyholders that disburse rebates to group health plan subscribers.

Transfers:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	\$2.4 million	2011	7	2012–2013
	\$2.6 million	2011	3	2012–2013

Annual transfer of rebate dollars to enrollees from shareholders or nonprofit stakeholders of mini-med policies, resulting from adjustment in MLR methodology for mini-med policies.

Qualitative:

- * Savings for consumers and reduced profit for issuers of mini-med policies.
- * Transfer from enrollees to shareholders or nonprofit stakeholders in individual, small and large group markets, resulting from adjustment in MLR methodology to account for community benefit expenditures and ICD–10 conversion costs.
- * Transfer of benefits of rebate dollars disbursed to the group health plan from enrollees who leave the group health plan to enrollees new to the group health plan.

TABLE VI.1.1—ACCOUNTING TABLE: MINI-MED POLICIES

Benefits:

Qualitative:

- * Increase in quality of medical care as a result of increased spending on quality improving activities by issuers of mini-med policies.
- * Improved health as a result of increased spending on medical care by issuers of mini-med policies.

TABLE VI.1.1—ACCOUNTING TABLE: MINI-MED POLICIES—Continued

* Continued access to mini-med health policies for consumers.				
Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	(\$2.5 million)	2011	7	2012–2013
	(\$2.6 million)	2011	3	2012–2013

Annual reduction in costs for issuers of mini-med policies due to elimination of requirement to file quarterly reports.

Qualitative:

- * Increased spending on quality-improving activities by issuers of mini-med policies.
- * Increased spending on medical care by issuers of mini-med policies.

Transfers:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	\$2.4 million	2011	7	2012–2013
	\$2.6 million	2011	3	2012–2013

Annual transfer of rebate dollars to enrollees from shareholders or nonprofit stakeholders of mini-med policies, resulting from adjustment in MLR methodology for mini-med policies.

Qualitative:

- * Savings for consumers and reduced profit for issuers of mini-med policies.

TABLE VI.1.2—ACCOUNTING TABLE: EXPATRIATE POLICIES

Benefits:

Qualitative:

- * Continued access to expatriate health policies for consumers.

Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	(\$80,000)	2011	7	2012–2013
	(\$85,000)	2011	3	2012–2013

Annual reduction in costs for issuers of expatriate policies due to elimination of requirement to file quarterly reports.

TABLE VI.1.3—ACCOUNTING TABLE: ICD–10 COSTS

Transfers:

Qualitative:

- * Transfer from enrollees to shareholders or nonprofit stakeholders in individual, small and large group markets, resulting from adjustment in MLR methodology to account for ICD–10 conversion costs.

TABLE VI.1.4—ACCOUNTING TABLE: COMMUNITY BENEFIT EXPENDITURES

Benefits:

Qualitative:

- * Benefits to consumers by encouraging issuers to undertake community benefit expenditures.

Costs:

- * Reduced administrative burden for not-for-profit issuers since they will no longer need to calculate and report hypothetical tax liabilities.

Transfers:

Qualitative:

- * Transfer from enrollees to shareholders or nonprofit stakeholders in individual, small and large group markets resulting from adjustment in MLR methodology to account for community benefit expenditures.

TABLE VI.1.5—ACCOUNTING TABLE: DISTRIBUTION OF REBATES IN GROUP MARKETS

Costs:	Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized (\$millions/year)	(\$1.6 million) (\$1.7 million)	2011 2011	7 3	2012–2013 2012–2013
Annual reduction in costs due to change in method of disbursement of rebates for group health plans.				

Qualitative:

- * Reduced tax burden for group health plan subscribers relating to the change in the method of disbursement of rebate payments.
- * Increased administrative costs for policyholders that disburse rebates to group health plan enrollees.

Transfers:

Qualitative:

- * Transfer of benefits of rebate dollars disbursed to the group health plan from subscribers who leave the group health plan to subscribers new to the group health plan.

3. Qualitative Discussion of Anticipated Benefits, Costs and Transfers

The medical loss ratio (MLR) is a measurement 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. The MLR interim final rule (75 FR 74892) provided an overall discussion of the anticipated benefits, costs and transfers associated with the MLR provisions. In the following sections, we discuss some of the anticipated benefits, costs and transfers associated with the adjustment of the MLR methodology for mini-med and expatriate policies, accounting of ICD-10 conversion costs and community benefit expenditures in the MLR, and change in the process for disbursement of rebates for enrollees in group health plans.

a. Benefits

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

Mini-med and expatriate policies tend to have relatively higher administrative costs compared to other types of policies due to their special circumstances. As discussed earlier in the preamble, commenters claimed that mini-med issuers have a unique cost structure—low premiums, high administrative costs (for example, as a result of high turnover) and low incurred claims (because of high deductibles and limited coverage)—that make some issuers unable to meet the statutory MLR without any adjustment to the claim reporting methodology.

Under the interim final rule, for the MLR reporting year 2011, the total of the incurred claims and expenditures for activities that improve healthcare quality for mini-med issuers with total annual benefit limits of \$250,000 or less is multiplied by a factor of 2.00. The level of the adjustment is changed from a multiplier of 2.00 under the interim final rule to a multiplier of 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year under the final rule. We have applied a multiplier through the 2014 MLR reporting year to account for mini-med policies with a plan year that begins after January 1, 2013 and ends sometime in 2014. Based on analysis of 2011 quarterly data submitted by mini-med issuers, CMS anticipates that with the adjustment to MLR methodology provided in this final rule, a majority of issuers in this market would reach the applicable MLR standard, and that all issuers who would be subject to rebates will remain profitable in the markets in which they would be paying rebates. The adjustment minimizes potential market withdrawal by issuers and preserves access to benefits for individuals served by these policies. Issuers that do not otherwise meet the MLR standard may attempt to do so by increasing quality promoting activities, expanding covered benefits or reducing cost sharing, and reducing administrative costs. Increased spending on quality improving activities and medical care would result in better quality of medical care and better health for enrollees in these plans. There are 25 issuers of mini-med policies with approximately 932,000 enrollees collectively and we expect that this rule should not have an effect on mini-med issuers' participation in the market.

As discussed earlier in the preamble, expatriate policies have unique administrative costs, as evidenced from

public comments and the first two quarterly reports submitted by issuers of expatriate policies. These unique costs arise from factors such as identifying and credentialing international providers, processing claims in different languages, standardizing billing procedures and providing translation and other services to enrollees. Under the interim final rule, for the MLR reporting year 2011, the total of the incurred claims and expenditures for activities that improve healthcare quality for expatriate experience is multiplied by a factor of 2.00. The level of the adjustment remains at a multiplier of 2.00 under this final rule. The reasons for this level of adjustment are discussed earlier in Section II.B., which include the volatility of the expatriate experience. Based on analysis of 2011 quarterly data submitted by issuers of expatriate policies, CMS anticipates that with the adjustments to MLR methodology provided in this final rule, all issuers in this market would reach the applicable MLR standard. Maintaining the multiplier of 2.00 would not result in any change in rebates being paid to enrollees, but should help ensure that issuers of expatriate policies generally are able to meet the requirements of section 2718 as well as help ensure that the MLR standard does not cause issuers to leave the market. There are eight issuers of expatriate policies that submitted quarterly reports, with approximately 288,000 enrollees.

Under the interim final rule, a not-for-profit issuer could deduct from earned premium community benefit expenditures, limited to the amount of State premium taxes the issuer would otherwise pay if it were a for-profit issuer. A not-for-profit issuer was also required to report community benefit expenditures up to the amount of taxes it would have paid if it were a for-profit

issuer. As discussed earlier in the preamble, commenters expressed concern that variations in State premium tax rates, by State and by type of issuer and the fact that some States do not have a premium tax, created an uneven playing field. Commenters also expressed concern about the difficulties and burden in calculating hypothetical tax liability. The final rule provides that an issuer will be able to deduct from earned premium the greater of the amount actually spent on community benefit expenditures limited to the State's highest premium tax rate, or the amount it pays in State premium tax. Issuers that otherwise do not meet the MLR standard may increase community benefit expenditures if their current expenditure levels or premium taxes are lower than the maximum amount they would be able to deduct under the final rule. CMS anticipates that this may encourage community benefit expenditures and allow for more equitable treatment of issuers and eliminate the reporting burden inherent in not-for-profit issuers calculating a hypothetical tax liability.

b. Costs

Under the final rule, the multiplier for the numerator of the MLR for mini-med policies has been lowered from 2.00 to 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year. Based on analysis of 2011 quarterly data submitted by mini-med issuers, CMS anticipates that most issuers in this market would reach the applicable MLR standard. Issuers that do not otherwise meet the MLR standard may attempt to do so by increasing spending on quality improving activities and by increasing covered benefits or lowering consumers' cost-sharing, which would increase issuer spending on medical care.

There are some cost savings as a result of this final rule.

Issuers of mini-med and expatriate policies were directed to submit a report for each of the first three quarters of the 2011 MLR reporting year as provided under § 158.110(b), in addition to the annual report required of all issuers. Beginning in MLR reporting year 2012, these issuers will no longer submit quarterly reports. The elimination of this requirement will reduce these issuers' administrative burden related to reporting, approximately \$2.8 million dollars annually.

This final rule also provides standardized ways to account for community benefit expenditures in the MLR methodology. Not-for-profit issuers will no longer need to calculate and

report hypothetical tax liability and this will reduce administrative burdens related to reporting for these issuers.

Finally, this rule provides for a more efficient and cost effective way for issuers in group markets to disburse rebate payments to enrollees by allowing issuers in group markets to provide rebates to the policyholders for distribution. This provision will lower administrative costs related to rebate disbursement for issuers of group health plans by approximately \$1.8 million annually, and will largely eliminate the tax burden on employers and consumers inherent in the prior rebate mechanism. Policyholders will experience an increase in administrative costs related to the disbursement of rebates, although these administrative costs will be offset by eliminating the administrative burden and tax consequences inherent in the prior rebate mechanism.

c. Transfers

To the extent that issuers' MLR experience falls short of the minimum MLR standard, they must provide rebates to enrollees. These rebates would reflect transfer of income from the issuers or their shareholders to the policyholders.

Under the interim final rule, for the 2011 MLR reporting year, the total of the incurred claims and expenditures for activities that improve healthcare quality for mini-med experience is multiplied by a factor of 2.00. The level of the adjustment is changed from a multiplier of 2.00 under the interim final rule to a multiplier of 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year under the final rule. The adjustment of the MLR methodology for mini-med policies will result in higher rebate payments to enrollees, estimated to be approximately \$1.3 million in 2012 and \$4.1 million in 2013, assuming the spending patterns included in the 2011 quarterly data do not change. However, the final rule also allows issuers to account for ICD-10 conversion costs and community benefit expenditures in the MLR, both up to a specified cap, which will lower rebate payments. In addition, issuers of mini-med policies that do not otherwise meet the MLR standard may attempt to do so by increasing spending on quality promoting activities and medical care, which would result in savings for consumers and reduced profits for issuers.

In addition, this final rule allows issuers in group markets to disburse rebate payments to enrollees by allowing issuers to provide rebates to the policyholder for distribution. This

change in the process for disbursement of rebate payments for enrollees in group health plans may result in a transfer of benefits from enrollees who have left the group health plan to enrollees new to the group health plan.

4. Overview of Data Sources, Methods, and Limitations

As discussed in the MLR interim final regulation, the most complete source of data on the number of licensed entities offering fully insured, private comprehensive major medical coverage in the individual and group markets is the National Association of Insurance Commissioners' (NAIC) Annual Financial Statements and Policy Experience Exhibits database. These data contain multiple years of information on issuers' revenues, expenses, and enrollment, collected on various NAIC financial exhibits (commonly referred to as "Blanks") including Supplemental Health Care Exhibits (SHCEs) that issuers submit to State insurance regulators through the NAIC. The NAIC has four different Blanks for different types of issuers: Health; Life; Property & Casualty; and Fraternal issuers.⁴

In the interim final rule, our analysis relied on 2009 data from the NAIC database. A total of 618 issuers offering comprehensive major medical coverage filed annual financial statements in 2009, with the Health and Life Blank filers accounting for approximately 99 percent of all comprehensive major medical premiums earned. For this reason we restricted our analysis to Health and Life Blank companies. Comprehensive major medical coverage⁵—including coverage offered in the individual and group markets that is subject to this 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

⁴If a company's premiums and reserve ratios for its health insurance products equals 95 percent or more of their total business for both the current and prior reporting years, a company files its annual statement using the Health Blank. Otherwise, a company files the annual statement associated with the type of license held in its domiciliary State, for example, the Life, Property & Casualty, or Fraternal Blank.

⁵Comprehensive major medical coverage sold to associations and trusts has been included in individual comprehensive major medical coverage for purposes of the RIA. CMS's estimates exclude Medigap coverage, which in the NAIC data is reported separately from comprehensive major medical coverage offered in the individual and group markets. The 2009 NAIC data does not allow us to identify mini-med policies or expatriate policies separately.

contain certain limitations; we developed imputation methods to account for these limitations and we made several additional data edits that led us to exclude 176 companies from the analysis. We used the remaining 442 companies to estimate the regulatory impacts that were discussed in the interim final rule, as well as the regulatory impacts that are discussed below. Please see the regulatory impact analysis of the interim final rule (75 FR 74892) for additional methodological information.

Although the 2009 NAIC data do not allow us to identify mini-med policies or expatriate policies separately, under the interim final rule, for the 2011 MLR reporting year issuers of mini-med and expatriate policies were required to report MLR data on a quarterly schedule under § 158.110(b). CMS has received, to date, two quarterly reports from these issuers. These quarterly reports are the best source of data for the experience of these policies.

In addition, data from NAIC's 2010 SHCE has recently become available, and we are in the process of reviewing this information.⁶ We have reported some preliminary estimates from this data in this impact analysis.

5. MLR and Rebate Estimation Methodology

Consistent with the methodology that was used in the RIA for the interim final rule, the following formula has been used for estimating companies' adjusted MLRs for the mini-med, expatriate markets, rounded to the nearest thousandth decimal place as dictated in the regulation:

$$\text{Adjusted MLR} = (i + q/p - t - f) + c + u$$

Where i = incurred claims

q = expenditures on quality improving activities

p = earned premiums
 t = Federal and State taxes
 f = licensing and regulatory fees
 c = credibility adjustment, if any
 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 (or on a national basis for expatriate policies) falls below the minimum MLR standard in a given market using the following formulas:

$$\text{Rebates} = [(m - a) * (p - t - f)]$$

Where m = the applicable minimum MLR standard for a particular market

a = an issuer's adjusted MLR for a particular State and market.

Finally, to estimate impacts under the final rule, for each year, we assume that the number of issuers, enrollment, and experience are stable over time.

6. "Mini-med" Policies

The term "mini-med" policy is used here to generally refer to policies that often cover the same types of medical services as comprehensive medical policies, but have annual benefit limits at or below \$250,000. We therefore have been using this figure as a proxy for capturing this type of policy. Under the interim final rule, for the 2011 MLR reporting year, HHS allowed a methodological change to address the special circumstances of mini-med policies. Mini-med policy issuers applied an adjustment to their reported experience to address the unusual expense and premium structure of these policies. Specifically, in the case of a policy 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 was multiplied by a

factor of 2.00. Under this final rule, this factor will be 1.75 for the 2012 MLR reporting year, 1.50 for the 2013 MLR reporting year and 1.25 for the 2014 MLR reporting year. A graduated allowance for the adjustment of 1.75 in 2012, 1.50 in 2013 and 1.25 in 2014 will incentivize issuers to reduce their administrative expenses and operate more efficiently to ensure that they meet the MLR standard while minimizing issuer market withdrawal, maintaining access to coverage for consumers and ensuring that they receive greater value from these policies until 2014. We have applied a multiplier through the 2014 MLR reporting year to account for mini-med policies with a plan year that begins after January 1, 2013 and ends sometime in 2014.

Under the interim final rule, for the 2011 MLR reporting year, issuers of mini-med policies were required to report three quarters of MLR data on a schedule specified under § 158.110(b), in addition to the annual report required of all issuers. Issuers of mini-med policies have submitted two quarterly reports thus far based on 2011 data. Table VI.2 shows the estimated distribution of issuers offering coverage in the mini-med market. Based on the reports that have been submitted, there are 25 issuers offering mini-med policies in 2011, including 12 issuers in the individual market, four issuers in the small group market and 15 issuers in the large group market, which cover more than 300 life-years each in a given State.⁷ Only five mini-med issuers offer policies in multiple markets, and of those five only one issuer offers such policies in all three markets. In addition, 11 issuers offer mini-med policies in only one State, while 14 offer policies in multiple States. There are 277 issuer/State/market combinations.

TABLE VI.2—ESTIMATED NUMBER OF MINI-MED POLICY ISSUERS SUBJECT TO MEDICAL LOSS RATIOS BY MARKET

Description	Number of issuers		Enrollment	
	Number	Percentage of total	Number	Percent of total
Total # of Issuers	25	100	931,866	100
By Market:				
Individual	12	48	234,859	25
Small Group	4	16	18,770	2
Large Group	15	60	678,237	73

Notes: (1) Source: CMS analysis of annualized 2011 quarterly data submitted by issuers of mini-med policies, each with more than 300 life-years of experience. (2) Enrollment represents "life-years" (life-years are the total number of months of enrollees' coverage during the MLR reporting year, divided by 12 if based upon a full year of reporting).

⁶ The 2010 SHCE data includes data for each issuer by market (individual, small and large group) and by State. It also includes data such as QIA

expenses, ICD-10 implementation costs, underwriting gain/loss and taxes and fees.

⁷ Not all issuers have 1,000 or more life-years and thus are not credible in each State in which they

have mini-med business, but may become partially credible in the 2012 or 2013 reporting year when issuers combine two or three years of experience, respectively.

Analysis of data shows that in the absence of any recognition of special circumstances, the 2011 credibility-adjusted MLRs for issuers of mini-med policies range from six⁸ percent to 134 percent in the individual market, with a mean of 67 percent and a median of 66 percent; 62 percent to 96 percent in the small group market, with a mean of 70 percent and a median of 73 percent; and 62 percent to 105 percent in the large group market, with a mean of 75 percent and a median of 71 percent. The large variations in the MLRs may be explained by variations in products, deductibles and premiums. For example, a plan with a low premium but a very high deductible will have very few claims, resulting in a very low

MLR, while a plan with a higher premium but lower deductible would have more claims and would have a higher MLR. For the 2011 MLR reporting year, based on multiplying total incurred claims and expenditures for activities that improve health care quality by a factor of 2.00 (consistent with the provisions in the interim final rule), it is estimated that three issuers of mini-med policies will pay rebates of approximately \$1.1 million in the individual market while no mini-med issuers will pay rebates in the small or large group markets.⁹

We use 2011 data to estimate the effects of the change in MLR methodology and assume no changes in issuers' behavior or quality improvement activities beyond what

was reported in the quarterly filing. As shown in Table VI.3, it is estimated that with a multiplier of 1.75, four of the 25 issuers will pay rebates of \$2.4 million to 45,838 enrollees. With a multiplier of 1.50, six of the 25 issuers would pay rebates of \$5.2 million to 73,427 enrollees. Therefore, a reduction in the multiplier from 2.00 to 1.75 in the 2012 MLR reporting year and a further reduction to 1.50 in the 2013 MLR reporting year will result in higher rebates being paid to enrollees, with more issuers affected and more enrollees receiving rebates. It is important to note, however, that issuers can change their spending targets to adjust to meet MLR targets moving forward.

TABLE VI.3—ESTIMATED ANNUAL REBATE PAYMENTS BY MINI-MED POLICY ISSUERS BY MARKET, 2011

Market	Multiplier = 1 (no adjustment)			Multiplier = 2			Multiplier = 1.75			Multiplier = 1.50		
	Number of affected issuers	Number of enrollees receiving rebates	Estimated rebate (\$ million)	Number of affected issuers	Number of enrollees receiving rebates	Estimated rebate (\$ million)	Number of affected issuers	Number of enrollees receiving rebates	Estimated rebate (\$ million)	Number of affected issuers	Number of enrollees receiving rebates	Estimated rebate (\$ million)
Individual Market	7	176,204	\$53.0	3	43,463	\$1.1	4	45,838	\$2.4	5	62,699	\$5.0
Small Group Market	0	0	0.0	0	0	0	0	0	0.0	0	0	0.0
Large Group Market	6	575,786	120.4	0	0	0.0	0	0	0.0	1	10,728	0.2
Total	13	751,990	173.4	3	43,463	1.1	4	45,838	2.4	6	73,427	5.2

Source: CMS analysis of annualized 2011 quarterly data submitted by issuers of mini-med policies with more than 300 life-years of experience in at least one State.

Beginning in MLR reporting year 2012, issuers of mini-med policies will only submit an annual report and will no longer be required to submit quarterly reports. Therefore, this will significantly reduce the annual costs related to MLR reporting for issuers. Issuers of mini-med policies were required to submit a report for each of the first three quarters of the 2011 MLR reporting year as provided under § 158.110(b) for each large group market, small group market, and individual market within each State in which the issuer conducts business. Therefore, in addition to the annual report which is required of all issuers, mini-med issuers were required to submit a total of 277 reports three times a year. The burden estimates included in the information collection requirement for the quarterly reports estimated that each quarterly report would require 62.4 hours with an hourly labor cost of \$52.46; therefore the estimated total annual administrative cost for all mini-med issuers for all

quarterly reports would be approximately \$2.7 million. Each year, the cost reduction associated with eliminating the quarterly reporting requirement will be approximately \$2.7 million for all issuers of mini-med policies. CMS anticipates that the adjustment in MLR methodology and reduction in reporting costs will allow issuers to remain profitable and ensure continued access to coverage for enrollees in this market, while bringing increased value to consumers.

7. Expatriate Policies

Expatriate policies provide coverage for employees, substantially all of whom are: working outside of their country of citizenship; working outside of their country of citizenship and outside the employer's country of domicile; or non-U.S. citizens working in their home country. As discussed earlier in the preamble, based on public comments and review of data submitted by expatriate policy issuers, the unique

nature of these policies results in a higher percentage of administrative costs in relation to premiums than policies that provide coverage primarily within the United States. Under the interim final rule, for the 2011 MLR reporting year, issuers were required to report the experience of these expatriate policies separately from other coverage, as provided in § 158.120(d)(4), and the calculation of claims and quality improving activities for these policies was to be multiplied by a factor of 2.00, as provided in § 158.221(b). Under this final rule, beginning in MLR reporting year 2012, this factor will remain 2.00.

Issuers of expatriate policies were required in 2011 to report three quarters of MLR data on a quarterly schedule specified under § 158.110(b), in addition to the annual report required of all issuers. Issuers of expatriate policies have submitted two quarterly reports thus far based on 2011 data. Table VI.4 shows the estimated distribution of issuers offering coverage in the

⁸ This six percent MLR is for an issuer that sells a policy with a \$50,000 deductible and thus has very low claims.

⁹ In the absence of any recognition of any special circumstances adjustment, CMS estimates that seven mini-med issuers would have paid rebates of approximately \$53 million in the individual market

and six mini-med issuers would have paid rebates of approximately \$120 million in the large group market.

expatriate market. Based on the reports that have been submitted, there are eight issuers in offering expatriate coverage in

2011—two issuers in the small group market and seven issuers in the large group market. Only one issuer offers

policies in both markets. There are nine issuer/market combinations.

TABLE: VI.4—ESTIMATED NUMBER OF EXPATRIATE POLICY ISSUERS SUBJECT TO MEDICAL LOSS RATIOS BY MARKET

Description	Number of issuers		Enrollment	
	Number	Percentage of total	Number	Percent of total
Total # of Issuers	8	100	287,789	100
By Market:				
Small Group	2	25	903	0.3
Large Group	7	87.5	286,887	99.7

Notes: (1) Source: CMS analysis of annualized 2011 quarterly data submitted by issuers of expatriate policies, each with more than 300 life-years of experience. (2) Enrollment represents "life-years".

Analysis of data shows that in the 2011 MLR reporting year, in the absence of any recognition of special circumstances, issuers of expatriate policies had adjusted MLRs that range from 32 percent to 61 percent in the small group market and from 49 percent to 85 percent, with a mean of 69 percent and median of 72 percent, in the large group market. For 2011, based on multiplying total incurred claims and expenditures for activities that improve health care quality by a factor of 2.00 (consistent with the provisions in the interim final rule), it is estimated that no issuer of expatriate policies will pay any rebates.¹⁰

We use 2011 data to estimate the effects of maintaining the multiplier of 2.00 and assume no changes in issuers' behavior and quality improvement activities beyond what was reported in the quarterly filing. It is estimated that with a multiplier of 2.00, no issuer will likely have an MLR below the threshold in 2012 and 2013, consistent with the policy in the first year. This should help ensure that the MLR standard does not cause issuers to leave the market.

Beginning in MLR reporting year 2012, expatriate policy issuers will submit only an annual report and will no longer be required to submit quarterly reports. The interim final rule required issuers of mini-med policies to submit a report for each of the first three quarters of the 2011 MLR reporting year as provided under § 158.110(b) for each large group market, small group market, and individual market, combining data from all states in which the issuer conducts business. Therefore, in addition to the annual report required of all issuers, expatriate issuers were required to submit a total of nine reports

three times a year. The burden estimates included in the information collection requirement for the quarterly reports estimated that each quarterly report would require 62.4 hours with an hourly labor cost of \$52.46. Therefore, estimated total annual cost for all expatriate policy issuers for all quarterly reports would be approximately \$88,000. The provisions in this final rule will reduce the annual costs related to MLR reporting for issuers. This cost reduction will be approximately \$88,000 for all expatriate policy issuers per year. CMS anticipates that the adjustment in MLR methodology and reduction in reporting costs will allow issuers to remain viable and ensure continued access to coverage for enrollees in this market.

8. ICD-10 Conversion Costs

In the interim final rule, HHS adopted the NAIC's recommendation to exclude the conversion of International Classification of Disease (ICD) code sets from ICD-9 to ICD-10 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. As discussed earlier in the preamble, some believe that ICD-10 coding can improve health plans' ability to share data among clinicians for quality improvement and care coordination activities, thereby allowing for a better understanding of diagnoses and better treatment. This final rule provides that for each of the MLR reporting years 2012 and 2013, issuers may account for ICD-10 conversion costs of up to 0.3 percent of earned premiums in the relevant State market as a quality improving activity in their MLR calculation. In addition, ICD-10 maintenance costs will continue to be excluded from QIA in the final rule, based on the industry's comments that separating conversion costs from maintenance costs is feasible. The

industry provided a range of percentages using their projected expenditures of ICD-10 conversion costs on their MLRs, if allowed as a QIA. After reviewing the data provided by issuers and 2010 SHCE filings, CMS chose a cap that allows as QIA amounts that issuers projected spending on ICD-10 conversion, without permitting issuers to include claims adjudication systems costs in QIA.

Preliminary analysis of 2010 SHCE data indicates that issuers reported ICD-10 conversion costs as representing less than 0.02 percent of earned premiums for individual, small group and large group comprehensive major medical coverage. However, ICD-10 conversion costs are expected to be higher for 2011 through 2013 since implementation efforts had only begun in 2010 but conversion to ICD-10 must be completed by October 2013. As stated earlier in the preamble, one issuer estimated that ICD-10 implementation will cost the entire industry between \$50–70 million each year for 2011 through 2013. Another issuer anticipated spending \$9.4 million in 2011 on ICD-10 implementation. An industry association commented that a study of 20 health insurance plans found that the costs averaged about \$12 per member, with small health plans paying around \$38 per member and large health plans paying around \$11 per member. However, none of these comments indicate whether these estimates apply to issuers subject to the MLR requirements, Medicare, Medicaid, self-insured, or other types of plans or the time frame spanned by these estimates. In the absence of data on actual costs related to ICD-10 conversion that will be included in the 2012 and 2013 MLR calculations, it is difficult to estimate the effect of this provision on issuers and rebates. Even so, we expect that accounting for these costs in MLR calculation will only have a small effect on MLRs and rebates.

¹⁰In the absence of any recognition of any special circumstances adjustment, CMS estimates that four issuers in the large group market would have paid rebates of approximately \$145 million, while no issuer would have paid rebates in the small group market.

9. Community Benefit Expenditures

In the interim final rule, HHS adopted the NAIC's recommendation to allow community benefit expenditures (as defined in § 158.162(c)(2)) by not-for-profit plans to be excluded from premium revenue up to the State premium tax rate, and requiring that not-for-profit issuers report their actual community benefit expenditures up to the amount they would have paid in Federal and State taxes if they had been for-profit. As discussed elsewhere in the preamble, this final rule provides that issuers will be able to deduct either the amount it paid in State premium taxes or the amount of its community benefit expenditures up to a maximum of the highest State premium tax rate in the State, whichever is greater. This creates a level playing field among issuers in States that have different premium tax rates for different types of plans, for example, PPOs and HMOs.

In the absence of reliable data on the total number of not-for-profit issuers offering major medical coverage and on community benefit expenditures, we are unable to quantify the effect of this provision. Five commenters proposed a flat deduction limit ranging between 3 to 5 percent of earned premium. Currently, 48 States have premium taxes, but tax rates in many States differ for different kinds of plans and in some States they differ for not-for-profit and for-profit issuers. Several States do not tax HMOs or not-for-profit issuers at all. State premium taxes range between 0.4 percent and 4.265 percent, according to data provided by the NAIC, and these taxes have been accounted for in the MLR and rebate calculations in the interim final rule. It is not known how many issuers will include community benefit expenditures or State premium tax liability in their MLR calculation, or how much community benefit expenditures will be included in the MLR calculation. Rebates may be reduced for issuers in States with a higher maximum premium tax rate than they are required to pay (for example, an issuer is an HMO and the State has a higher premium tax rate for PPOs) and who have higher community benefit expenditures than the applicable premium tax rate.

As discussed earlier in the preamble, CMS anticipates that this treatment will encourage community benefit expenditures. Issuers that otherwise do not meet the MLR standard may increase community benefit expenditures if their current expenditure levels or premium taxes are lower than the maximum amount they would be able to deduct under the final

rule. This provision will also allow more equitable treatment of issuers, and reduce significantly the reporting burden related to community benefit expenditures, as not-for-profit issuers no longer need to calculate and report hypothetical tax liabilities.

10. Distribution of Rebates to Enrollees in Group Markets

Section 2718(b)(1)(A) of the PHS Act requires an issuer to provide "an annual rebate to each enrollee" if the issuer does not meet the applicable MLR standard. The interim final rule directs issuers of group coverage to provide rebates to the policyholder and each subscriber in amounts proportionate to the amount of premium each paid. The interim final rule also allows an issuer to delegate its rebate disbursement obligation to group policyholders, though the issuer remains liable for complying with all its obligations under the statute and for maintaining records that demonstrated rebates were provided accurately. As discussed elsewhere in this preamble, commenters expressed concern that the issuer lacks access to the information needed to distribute rebates, asserting that the policyholder, and not the issuer, has information regarding the premium contribution amount from the employer and the employee.

This final rule provides that issuers will distribute rebates to the policyholder to be used for the benefit of subscribers. For policyholders that are a group health plan but are not a governmental plan or subject to ERISA, an issuer must obtain written assurance from the policyholder that rebates will be used for the benefit of current subscribers using one of the options permitted for non-Federal governmental plans as described in the interim final rule issued contemporaneously with this final rule; otherwise, the issuer must evenly distribute the rebate directly to the policyholder's subscribers covered by the policy during the MLR reporting year on which the rebate is based.

Disbursing rebates directly to subscribers would result in a tax burden for consumers and also a tax-administration burden for the issuers making the payment, as most premiums are paid with pre-tax dollars and thus the rebates may be wages subject to withholding obligations. Because issuers would not otherwise be paying wages to these individuals, the administrative burden of administering any applicable withholding obligations could be significant in total. If the rebates are disbursed to the policyholder (generally the employer)

for the benefit of subscribers (generally the employees), they must be used in a way that benefits subscribers (in the case of ERISA plans, consistent with their fiduciary obligations) but minimizes any tax administration issues for employers and enrollees, while consumers would still receive the benefit of the rebates. Subscribers who no longer are covered under the group health plan, however, generally would not receive the benefits from the rebates distributed through the policyholder. Therefore, there would be a transfer of benefits from enrollees who leave the plan to new enrollees in the same plan. We expect this transfer to be small since persistence rates in group health plans tend to be high.

Group health plan issuers will also experience savings due to the fact that rebate payments will no longer be required to be sent to a large number of individuals. In the interim final rule, the average cost of sending rebate payments was estimated to be \$1 per check. For the years 2012 and 2013, it was estimated that each year 0.8 million enrollees in the small group market and 1 million enrollees in the large group market would receive rebates and 50 percent of these enrollees would receive rebate checks. Assuming that all issuers of group coverage distribute rebates to policyholders, we estimate that this will lead to an annual reduction in administrative costs of approximately \$1.8 million for these issuers. However, policyholders will experience an increase in administrative costs related to the disbursement of rebates. The actual cost would depend on whether the policyholders send rebate checks or whether the rebates are disbursed through future premium reductions or through payroll. These costs will also be offset by eliminating the administrative burden and tax consequences inherent in the prior rebate mechanism.

C. Regulatory Alternatives

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

1. Mini-Med and Expatriate Policies

One alternative to the MLR methodology set forth in this final rule is to provide no adjustments in the MLR calculation for the experience of these policies. Without any adjustments to the MLR methodology for issuers of mini-med policies with total annual benefit limits of \$250,000 or less, CMS estimates that in 2011, seven issuers would have paid rebates of approximately \$53 million in the

individual market and six issuers would pay approximately \$120 million in the large group market. Without any adjustments to MLR methodology for issuers of expatriate policies, CMS estimates that in 2011, four issuers in the large group market would have paid rebates of approximately \$145 million.

Another alternative was to maintain the multiplier of 2.00 provided in the interim final rule, for mini-med policies with total annual benefit limits of \$250,000 or less. Based on 2011 data, with a multiplier of 2.00, three issuers of mini-med policies in the individual market would have paid an estimated \$1.1 million in rebates while no issuers in the small or large group markets would have paid rebates. As described elsewhere in this preamble, CMS has concluded that the MLR methodology set forth in the final rule will best balance the goals of providing value to consumers and ensuring that consumers have continued access to coverage in these markets.

2. Distribution of Rebates in the Group Market

One alternative to the MLR methodology set forth in this final rule is to require issuers to send rebate payments directly to subscribers in group health plans. As described previously, this would result in increased tax burden for consumers with group coverage and for their employers, as well as increased administrative costs for issuers associated with rebate payments. As discussed earlier, the average annual cost per issuer of sending rebate checks was estimated to be between \$43,962 and \$71,467 in the interim final rule.

3. ICD-10 Conversion Expenses and Community Benefit Expenditures

With respect to ICD-10 conversion costs, one alternative to the MLR methodology set forth in this final rule was to exclude these costs from QIA. As discussed previously, this would result in slightly lower MLRs for issuers and therefore higher rebate payments for issuers that fail to meet the MLR standard.

With respect to community benefit expenditures, one alternative to the MLR methodology set forth in this final rule was to allow only a not-for-profit, tax-exempt issuer to deduct from earned premium the amount of its community benefit expenditures, limited to the State premium tax rate applicable to for-profit issuers and also require a not-for-profit issuer to report community benefit expenditures “in lieu of taxes * * * but not to exceed the amount of taxes [it] would otherwise be required to

pay.” As discussed previously, this would result in lower MLRs for some issuers and therefore higher rebate payments for issuers that fail to meet the MLR standard.

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 final rule. However, CMS has considered the likely impact of this final rule on small entities.

As discussed in the Web Portal final rule published on May 5, 2010 (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 issuers).¹¹

For the MLR interim final rule, the Department 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 used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. These estimates may overstate the actual number of small health insurance issuers that would be affected, since they do not include receipts from these companies’ other lines of business.

In the MLR interim final rule (75 FR 74892), the Department estimated that there are 28 small entities with less than \$7 million in A&H earned premiums that offer individual or group comprehensive major medical coverage, and would therefore be subject to the requirements of this final regulation. These small entities accounted for 6 percent of the estimated 442 total issuers that the Department estimated would be affected by the MLR requirements. The Department estimated that 86 percent of these small issuers are subsidiaries of larger carriers, 75 percent only offer coverage in a single State, 68 percent only offer individual or group comprehensive coverage in a single market, 46 percent also offer other types of A&H coverage, and 29 percent are Life Blank filers.

CMS has estimated that the provisions of the final rule do not impose any additional costs on small entities. There are, however, some cost savings as a result of this final rule. There will be an increase in rebates for some issuers of mini-med policies with total annual benefit limits of \$250,000 or less, though no small entities are affected. The changes in MLR methodology to account for inclusion of ICD-10 costs and community benefit expenditures will also lead to reduction in rebates and will therefore, not affect any small entities adversely.

CMS believes that these estimates overstate the number of small entities that will be affected by the requirements in this 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 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 final rule would not affect small rural hospitals. Therefore, the Secretary has determined that this rule would not have a significant impact on the

¹¹ “Table of Size Standards Matched to North American Industry Classification System Codes,” effective November 5, 2010, U.S. Small Business Administration, available at <http://www.sba.gov>.

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 2011, that threshold level is approximately \$136 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.

Consistent with policy embodied in UMRA, this 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 final regulation contains MLR methodology adjustments and rebate payment requirements for private sector firms (for example, health insurance issuers offering coverage in the mini-med, expatriate, individual and group markets). CMS estimates that none of these provisions impose additional costs on consumers or private sector firms, and will lead to reduced administrative costs to issuers. There will be a reduction in rebates paid by issuers in individual, small and group markets due to inclusion of ICD-10 conversion costs and community benefit expenditures. Rebates paid by issuers of mini-med policies will increase by an estimated \$59 million annually. It includes no mandates on State, local, or Tribal governments.

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 CMS’s view, while this final rule does not impose substantial direct requirement costs on State and local governments, this 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 and rebate requirements relating to coverage that State-licensed health insurance issuers offer in the individual and group markets.

However, CMS 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.

As discussed in the MLR interim final rule, 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 to be preempted.

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 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 Centers for Medicare & Medicaid Services has complied with the requirements of Executive Order 13132 for the attached final regulation in a meaningful and timely manner.

G. Congressional Review Act

This final regulation is not subject to the Congressional Review Act provisions of the Small Business

Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*).

List of Subjects in 45 CFR Part 158

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

Accordingly, the interim final rule amending 45 CFR part 158, which was published at 75 FR 74864 on December 1, 2010, and further amended by a correction on December 30, 2010, is adopted as final with the following changes:

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

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

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

§ 158.110 [Amended]

- 2. Section 158.110 is amended by—
 - a. Removing in paragraph (b)(1) the phrase “Except as provided in paragraph (b)(2) of this section, the” and adding “The” in its place.
 - b. Removing paragraph (b)(2).
 - c. Removing the paragraph designation for paragraph (b)(1).
- 3. Section 158.120 is amended by revising paragraphs (d)(3) and (4) to read as follows:

§ 158.120 Aggregate reporting.

- * * * * *
- (d) * * *
- (3) 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) An issuer with group policies that provide coverage to employees, substantially all of whom are: Working outside their country of citizenship; working outside of their country of citizenship and outside the employer’s country of domicile; or non-U.S. citizens working in their home country, must aggregate and report the experience from these policies on a national basis, separately for the large group market and small group market, and separately from other policies.

- 4. Section 158.150 is amended by—
 - a. Adding paragraph (b)(2)(i)(A)(6).
 - b. Revising paragraph (c)(5).

The addition and revision read as follows:

§ 158.150 Activities that improve health care quality.

- * * * * *

(b) * * *
 (2) * * *
 (i) * * *
 (A) * * *

(6) For each of the 2012 and 2013 MLR reporting years, implementing ICD-10 code sets that are designed to improve quality and are adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d-2, as amended, limited to 0.3 percent of an issuer's earned premium as defined in § 158.130 of this subpart.

* * * * *

(c) * * *

(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, including maintenance of ICD-10 code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d-2, as amended.

* * * * *

■ 5. Section 158.162 is amended by—
 ■ a. Revising paragraph (b)(1)(vii).
 ■ b. Revising paragraph (c).

The revisions read as follows:

§ 158.162 Reporting of Federal and State taxes.

* * * * *

(b) * * *

(1) * * *

(vii) In lieu of reporting amounts described in paragraph (b)(1)(vi) of this section, an issuer may choose to report payment for community benefit expenditures as described in paragraph (c) of this section, limited to the highest premium tax rate in the State for which the report is being submitted.

* * * * *

(c) *Community benefit expenditures.* 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:

(1) Are available broadly to the public and serve low-income consumers;
 (2) 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);

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

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

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

■ 6. Section 158.221 is amended by revising paragraphs (b)(3) and (4) to read as follows:

§ 158.221 Formula for calculating an issuer's medical loss ratio.

* * * * *

(b) * * *

(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 2012 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 1.75, for the 2013 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 1.50, and for the 2014 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 1.25.

(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 the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 2.00.

* * * * *

■ 7. Section 158.241 is amended by revising paragraph (b) to read as follows:

§ 158.241 Form of rebate.

* * * * *

(b) *Former enrollees in the individual market.* Rebates owing to former enrollees in the individual market 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.

■ 8. Section 158.242 is amended by revising paragraph (b) to read as follows:

§ 158.242 Recipients of rebates.

* * * * *

(b) *Large group and small group markets.* Except as provided in paragraphs (b)(3) and (4) of this section, an issuer must meet its obligation to provide any rebate to persons covered under a group health plan by providing it to the policyholder.

(1) [Reserved.]

(2) [Reserved.]

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

(4) If the group health plan has been terminated at the time of rebate payment and the issuer cannot, despite reasonable efforts, locate the policyholder whose plan participants or employees were enrolled in the group health plan, the issuer must distribute the rebate directly to the subscribers of the terminated group health plan by dividing the entire rebate, including the amount proportionate to the amount of premium paid by the policyholder, in equal amounts to all subscribers entitled to a rebate without regard to how much each subscriber actually paid toward premiums.

■ 9. Section 158.243 is amended by revising paragraph (a)(1) to read as follows:

§ 158.243 De minimis rebates.

(a) * * *

(1) For a group policy for which the issuer distributes the rebate to the policyholder, if the total rebate owed to the policyholder and the subscribers combined is less than \$20 for a given MLR reporting year; or for a group policy for which the issuer distributes the rebate directly to the subscribers, as provided in § 158.242(a)(3) and (4) of this subpart, if the total rebate owed to each subscriber is less than \$5.

* * * * *

■ 10. Section 158.250 is revised to read as follows:

§ 158.250 Notice of rebates.

(a) *Notice of rebates to policyholders and subscribers of group health plans.* For each MLR reporting year, at the time any rebate of premium is provided to a policyholder of a group health plan in accordance with this part, an issuer must provide each policyholder who receives a rebate and subscribers whose

policyholder receives a rebate, or each subscriber who receives a rebate directly from an issuer, the following information in a form prescribed by the Secretary:

- (1) A general description of the concept of an MLR;
- (2) The purpose of setting an MLR standard;
- (3) The applicable MLR standard;
- (4) The issuer's MLR, adjusted in accordance with the provisions of this subpart;
- (5) The issuer's aggregate premium revenue as reported in accordance with § 158.130 of this part, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in § 158.162(a)(1) and (b)(1) of this part;
- (6) The rebate percentage and the amount owed to enrollees, as defined in section 158.240(b), based upon the difference between the issuer's MLR and the applicable MLR standard; and
- (7) The fact that, as provided by this subpart, the total aggregated rebate for the group health plan is being provided to the policyholder:
 - (i) If the policy provides benefits for a plan subject to ERISA, a statement that the policyholder may have additional obligations under ERISA's fiduciary responsibility provisions with respect to the handling of rebates and contact information for questions regarding the rebate;
 - (ii) If the policyholder is a non-Federal governmental plan, the proportion of the rebate attributable to subscribers' contribution to premium must be used for the benefit of subscribers, using one of the methods

set forth in § 158.242(b)(1) of this subpart; and

(iii) If the policyholder is a group health plan that is not a governmental plan and is not subject to ERISA,

(A) The policyholder has provided written assurance that the proportion of the rebate attributable to subscribers' contribution to premium will be used for the benefit of current subscribers, using one of the methods set forth in § 158.242(b)(1) of this subpart, or

(B) If the policyholder did not provide such written assurance, the issuer must distribute the rebate evenly among the policyholder's subscribers covered by the policy during the MLR reporting year on which the rebate is based.

(b) *Notice of rebates to subscribers in the individual market.* For each MLR reporting year, at the time any rebate of premium is provided to a subscriber in the individual market in accordance with this part, an issuer must provide each subscriber that is receiving the rebate the following information in a form prescribed by the Secretary:

(1) A general description of the concept of an MLR;

(2) The purpose of setting an MLR standard;

(3) The applicable MLR standard;

(4) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(5) The issuer's aggregate premium revenue as reported in accordance with § 158.130 of this part, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in § 158.162(a)(1) and (b)(1) of this part; and

(6) The rebate percentage and amount owed to enrollees based upon the

difference between the issuer's MLR and the applicable MLR standard.

■ 11. Section 158.260 is amended by revising paragraphs (c)(1) through (5) to read as follows:

§ 158.260 Reporting of rebates.

* * * * *

(c) * * *

(1) Number of subscribers in the individual, small group and large group markets to whom the issuer paid a rebate directly, and number of small group and large group policyholders receiving a rebate on behalf of enrollees;

(2) Amount of rebates provided as premium credit;

(3) Amount of rebates provided as lump sum payment regardless of whether in cash, reimbursement to an enrollee's credit card, or direct payment to an enrollee's bank account;

(4) Amount of rebates that were de minimis as provided in § 158.243 of this subpart and the number of enrollees who did not receive a rebate because it was de minimis; and

(5) Amount of unclaimed rebates, a description of the methods used to locate the applicable enrollees, and a description of how the unclaimed rebates were disbursed.

Dated: November 2, 2011.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

Approved: November 29, 2011.

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

[FR Doc. 2011-31289 Filed 12-2-11; 11:15 am]

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