(2) Information about the enrollment process in accordance with §155.725 of this subchapter.

(f) *New employees and changes in employee eligibility.* Qualified employers participating in the SHOP must provide the SHOP with information about dependents or employees whose eligibility status for coverage purchased through the employer in the SHOP has changed, including:

(1) Newly eligible dependents and newly qualified employees. In a Federally-facilitated SHOP or in a State Exchange that uses the Federal platform for SHOP functions, a qualified employer must provide information about a newly qualified employee on or before the thirtieth day after the day that the employee becomes a newly qualified employee; and

(2) Loss of qualified employee status.

(g) *Annual employer election period.* Qualified employers must adhere to the annual employer election period to change their program participation for the next plan year described in §155.725(c) of this subchapter.

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 157.206 is applicable for plan years beginning on or after January 1, 2018.

[77 FR 18474, Mar. 27, 2012, as amended at 81 FR 94183, Dec. 22, 2016; 83 FR 17070, Apr. 17, 2018]

§157.206 Qualified employer participation process in a SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* When joining the SHOP, a qualified employer must comply with the requirements, processes, and timelines set forth by this part and must remain in compliance for the duration of the employer's participation in the SHOP.

(b) *Selecting QHPs.* During an election period, a qualified employer may make coverage in a QHP available through the SHOP in accordance with the processes developed by the SHOP in accordance with §155.706 of this subchapter.

(c) *Information dissemination to employees.* A qualified employer participating in the SHOP must disseminate information to its qualified employees about the process to enroll in a QHP through the SHOP.

(d) *Employees hired outside of the initial or annual open enrollment period.* Qualified employers must provide employees hired outside of the initial or annual open enrollment period with information about the enrollment process.

(e) *Participation in the SHOP and termination of coverage or enrollment through the SHOP.* (1) Changes affecting participation. Employers must submit a new single employer application to the SHOP or withdraw from participating in the SHOP if the employer makes a change that could end its eligibility under §155.710 of this subchapter.

(2) If an employer receives a determination of ineligibility to participate in the SHOP or the SHOP terminates its eligibility to participate in the SHOP, unless the SHOP notifies the issuer or issuers of the determination of ineligibility or termination of eligibility, the employer must notify the issuer or issuers of QHPs in which their group members are enrolled in coverage of its ineligibility or termination of eligibility within 5 business days of the end of any applicable appeal process under §155.741 of this subchapter, which could include when the time to file an appeal lapses without an appeal being filed, when the appeal is rejected or dismissed, or when the appeal process concludes with an adjudication by the appeals entity, as applicable.

(3) Employers must promptly notify the issuer or issuers of QHPs in which their group members are enrolled in coverage if it wishes to terminate coverage or enrollment through the SHOP, unless the SHOP notifies the issuer or issuers.

(f) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17070, Apr. 17, 2018]

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

Sec.

AUTHORITY: 42 U.S.C. 300gg–18.

SOURCE: 75 FR 74921, Dec. 1, 2010, unless otherwise noted.

§ 158.101 Basis and scope.

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

(b) *Scope.* Subpart A of this part establishes the requirements for health insurance issuers (''issuers'') offering group or individual health insurance coverage to report information concerning premium revenues and the use of such premium revenues for clinical

services provided to enrollees, activities that improve health care quality, and all other non-claims costs. Subpart B describes how this information will be used to determine, with respect to each medical loss ratio (MLR) reporting year, whether the ratio of the amount of adjusted premium revenue expended by the issuer on permitted costs to the total amount of adjusted premium revenue (MLR) meets or exceeds the percentages established by section 2718(b)(1) of the PHS Act. Subpart B also addresses requirements for calculating any rebate amounts that may be due in the event an issuer does not meet the applicable MLR standard. Subpart C implements the provision of section 2718(b)(1)(A)(ii) of the PHS Act allowing the Secretary to adjust the MLR standard for the individual market in a State if requiring issuers to meet that standard may destabilize the individual market. Subparts D through F provide for enforcement of this part, including requirements for issuers to maintain records and civil monetary penalties that may be assessed against issuers who violate the requirements of this part.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010]

§ 158.102 Applicability.

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

§ 158.103 Definitions.

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

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

Contract reserves means reserves that are established by an issuer which, due to the gross premium pricing structure at issue, account for the value of the future benefits that at any time exceeds the value of any appropriate future valuation of net premiums at that time. Contract reserves must not include premium deficiency reserves. Contract reserves must not include reserves for expected MLR rebates.

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

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

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

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

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

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

Large Employer has the meaning given the term in § 144.103 of this subchapter.

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

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

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

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

Small Employer has the meaning given the term in § 144.103 of this subchapter.

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

Student administrative health fee has the meaning given the term in §147.145 of this subchapter.

Student health insurance coverage has the meaning given the term in §147.145 of this subchapter.

Student market means the market for student health insurance coverage.

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

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

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

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012; 81 FR 12352, Mar. 8, 2016]

Subpart A—Disclosure and Reporting

§158.110 Reporting requirements related to premiums and expenditures.

(a) *General requirements.* For each MLR reporting year, an issuer must submit to the Secretary a report which complies with the requirements of this part, concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued. Reporting requirements of this part that apply to expenses incurred directly by the issuer also apply to expenses for functions outsourced to or services provided by other entities retained by the issuer.

(b) *Timing and form of report.* The report for each of the 2011, 2012, and 2013 MLR reporting years must be submitted to the Secretary by June 1 of the year following the end of an MLR reporting year, on a form and in the manner prescribed by the Secretary. Beginning with the 2014 MLR reporting year, the report for each MLR reporting year must be submitted to the Secretary by July 31 of the year following the end of an MLR reporting year, on a form and in the manner prescribed by the Secretary.

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

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76592, Dec. 7, 2011; 78 FR 15539, Mar. 11, 2013; 85 FR 29262, May 14, 2020]

§158.120 Aggregate reporting.

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

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

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

for the purpose of providing a group health plan that offers both in-network and out-of-network benefits, experience may be treated as if it were all related to the contract provided by the in-network issuer. However, if the issuer chooses this method of aggregation, it must apply it for a minimum of 3 MLR reporting years.

(d) *Exceptions.* (1) For individual market business sold through an association or trust, the experience of the issuer must be included in the State report for the issue State of the certificate of coverage.

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

(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.

(5) An issuer in the student market must aggregate and report the experience from these policies on a national basis, separately from other policies.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010; 76 FR 76592, Dec. 7, 2011; 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012]

§ 158.121 Newer experience.

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

[81 FR 94183, Dec. 22, 2016]

§ 158.130 Premium revenue.

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

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

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

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

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

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

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

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

(4) Account for unearned premium.

(5) Account for the net payments or receipts related to the risk adjustment, risk corridors (using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), and reinsurance programs under sections 1341, 1342, and 1343 of the Patient

Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 28790, May 16, 2012; 78 FR 15539, Mar. 11, 2013; 79 FR 13842, Mar. 11, 2014]

§ 158.140 Reimbursement for clinical services provided to enrollees.

(a) *General requirements.* The report required in § 158.110 must include direct claims paid to or received by providers, including under capitation contracts with physicians, whose services are covered by the policy for clinical services or supplies covered by the policy. In addition, the report must include claim reserves associated with claims incurred during the MLR reporting year, the change in contract reserves, reserves for contingent benefits and the medical claim portion of lawsuits, and any incurred experience rating refunds. Reimbursement for clinical services, as defined in this section, is referred to as ''incurred claims.'' All components of and adjustments to incurred claims, with the exception of contract reserves, must be calculated based on claims incurred only during the MLR reporting year and paid through March 31st of the following year. Contract reserves must be calculated as of December 31st of the applicable year.

(1) If there are any group conversion charges for a health plan, the conversion charges must be subtracted from the incurred claims for the aggregation that includes the conversion policies and this same amount must be added to the incurred claims for the aggregation that provides coverage that is intended to be replaced by the conversion policies. If an issuer transfers portions of earned premium associated with group conversion privileges between group and individual lines of business in its Annual Statement accounting, these amounts must be added to or subtracted from incurred claims.

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

(3) Incurred claims must include claims incurred but not reported based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

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

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

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

(i)(A) For MLR reporting years before 2022, prescription drug rebates received by the issuer;

(B) Beginning with the 2022 MLR reporting year, prescription drug rebates and other price concessions received and retained by the issuer, and prescription drug rebates and other price concessions that are received and retained by an entity providing pharmacy benefit management services to the issuer and are associated with administering the issuer's prescription drug benefits.

(ii) Overpayment recoveries received from providers.

(iii) Cost-sharing reduction payments received by the issuer to the extent not reimbursed to the provider furnishing the item or service.

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

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

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

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

(iv) The amount of claims payments recovered through fraud reduction efforts not to exceed the amount of fraud reduction expenses.

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

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

(ii) Amounts paid to third party vendors for network development, administrative fees, claims processing, and

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

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

(iv) Amounts paid to a provider for services that do not represent reimbursement for covered services provided to an enrollee and are directly covered by a student administrative health fee.

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

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

(ii) Receipts related to the transitional reinsurance program and net payments or receipts related to the risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in §153.500 of this subchapter, equal to zero percent) under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

(5) Other adjustments to incurred claims:

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

(ii) [Reserved]

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010; 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012; 78 FR 15539, Mar. 11, 2013; 79 FR 13842, Mar. 11, 2014; 80 FR 10876, Feb. 27, 2015; 85 FR 29262, May 14, 2020]

§158.150 Activities that improve health care quality.

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

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

(1) The activity must be designed to:

(i) Improve health quality.

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

(iii) Be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.

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

(2) The activity must be primarily designed to:

(i) Improve health outcomes including increasing the likelihood of desired outcomes compared to a baseline and

reduce health disparities among specified populations.

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

(*1*) Effective case management, care coordination, chronic disease management, and medication and care compliance initiatives including through the use of the medical homes model as defined in section 3502 of the Affordable Care Act.

(*2*) Identifying and addressing ethnic, cultural or racial disparities in effectiveness of identified best clinical practices and evidence based medicine.

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

(*4*) Health information technology to support these activities.

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

(*6*) Commencing with the 2012 reporting year and extending through the first reporting year in which the Secretary requires ICD–10 as the standard medical data code set, 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.

(B) [Reserved]

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

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

(B) Patient-centered education and counseling.

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

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

(E) Health information technology to support these activities.

(iii) Improve patient safety, reduce medical errors, and lower infection and mortality rates.

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

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

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

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

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

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

(*6*) Health information technology to support these activities.

(B) [Reserved]

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

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

(*1*) Wellness assessments;

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

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

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

(*5*)(*i*) For MLR reporting years before 2021, actual rewards, incentives, bonuses, and reductions in copayments (excluding administration of such programs) that are not already reflected in premiums or claims should be allowed as a quality improvement activity for the group market to the extent

permitted by section 2705 of the PHS Act;

(*ii*) Beginning with the 2021 MLR reporting year, actual rewards, incentives, bonuses, reductions in copayments (excluding administration of such programs) that are not already reflected in premiums or claims, to the extent permitted by section 2705 of the PHS Act;

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

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

(*8*) Health information technology to support these activities.

(B) [Reserved]

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

(c) *Exclusions.* Expenditures and activities that must not be included in quality improving activities are:

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

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

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

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

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims, 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.

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

(7) All retrospective and concurrent utilization review;

(8) Fraud prevention activities;

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

(10) Provider credentialing;

(11) Marketing expenses;

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

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

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

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76592, Dec. 7, 2011; 77 FR 28790, May 16, 2012; 79 FR 30352, May 27, 2014; 85 FR 29262, May 14, 2020]

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

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

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

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

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

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

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

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

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

(8) Provision of electronic health records, patient portals, and tools to facilitate patient self-management.

(b) [Reserved]

§ 158.160 Other non-claims costs.

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

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

(2) Expenses for administrative services include the following:

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

(ii) Loss adjustment expenses not classified as a cost containment expense.

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

(iv) Agents and brokers fees and commissions.

(v) General and administrative expenses.

(vi) Community benefit expenditures.

(vii) Beginning with the 2022 MLR reporting year, prescription drug rebates and other price concessions that are received and retained by an entity providing pharmacy benefit management services to the issuer and are associated with administering the issuer's prescription drug benefits.

[75 FR 74921, Dec. 1, 2010, as amended at 85 FR 29262, May 14, 2020]

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

(a) *Licensing and regulatory fees included.* The report required in §158.110 must include statutory assessments to defray operating expenses of any State

or Federal department, transitional reinsurance contributions assessed under section 1341 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, and examination fees in lieu of premium taxes as specified by State law.

(b) *Licensing and regulatory fees excluded.* The report required in §158.110 must include fines and penalties of regulatory authorities, and fees for examinations by any State or Federal departments other than as specified in §158.161(a) as other non-claims costs, but not as an adjustment to premium revenue.''

[75 FR 82279, Dec. 30, 2010, as amended at 78 FR 15539, Mar. 11, 2013]

§ 158.162 Reporting of Federal and State taxes.

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

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

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

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

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

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

(ii) Guaranty fund assessments.

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

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

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

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

(vii) Payments made by a Federal income tax exempt issuer for community benefit expenditures as defined in paragraph (c) of this section, limited to the highest of either:

(A) Three percent of earned premium; or

(B) The highest premium tax rate in the State for which the report is being submitted, multiplied by the issuer's earned premium in the applicable State market.

(viii) In lieu of reporting amounts described in paragraph (b)(1)(vi) of this section, an issuer that is not exempt from Federal income tax 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 multiplied by the issuer's earned premium in the applicable State market.

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

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

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

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

(iv) State employment and similar taxes and assessments.

(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.

[75 FR 74921, Dec. 1, 2010. Redesignated and amended at 75 FR 82279, Dec. 30, 2010; 76 FR 76593, Dec. 7, 2011; 78 FR 15540, Mar. 11, 2013; 80 FR 10876, Feb. 27, 2015]

§ 158.170 Allocation of expenses.

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

(b) *Description of the methods used to allocate expenses.* The report required in § 158.110 must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses (unless the report utilizes the percentage of premium option described in § 158.221(b)(8), in which case the allocation method description should state so), Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

(1) Allocation to each category should be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories above will generally be the most accurate method. If a specific identification is not feasible, the issuer should provide an explanation of why it believes the more accurate result will be gained from allocation of expenses based upon pertinent factors or ratios such as studies of employee activities, salary ratios or similar analyses.

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

(3) Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses. Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.

(c) *Disclosure of allocation methods.* The issuer must identify in the report required in § 158.110 of this subpart the specific basis used to allocate expenses reported under this part to States and, within States, to lines of business including the individual market, small group market, large group market, supplemental health insurance coverage, health insurance coverage offered to beneficiaries of public programs (such as Medicare and Medicaid), and group health plans as defined in § 145.103 of this chapter and administered by the issuer.

(d) *Maintenance of records.* The issuer must maintain and make available to the Secretary upon request the data used to allocate expenses reported under this part together with all supporting information required to determine that the methods identified and reported as required under paragraph (b) of this section were accurately implemented in preparing the report required in § 158.110 of this subpart.

[75 FR 74921, Dec. 1, 2010, as amended at 83 FR 17070, Apr. 17, 2018]

Subpart B—Calculating and Providing the Rebate

§ 158.210 Minimum medical loss ratio.

Subject to the provisions of § 158.211 of this subpart:

(a) *Large group market.* For all policies issued in the large group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 85 percent, as determined in accordance with this part.

(b) *Small group market.* For all policies issued in the small group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 80 percent, as determined in accordance with this part.

(c) *Individual market.* For all policies issued in the individual market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 80 percent, as determined in accordance with this part.

(d) *Adjustment by the Secretary.* If the Secretary has adjusted the percentage that issuers in the individual market in a specific State must meet, then the adjusted percentage determined by the Secretary in accordance with § 158.301 of this part *et seq.* must be substituted for 80 percent in paragraph (c) of this section.

§ 158.211 Requirement in States with a higher medical loss ratio.

(a) *State option to set higher minimum loss ratio.* For coverage offered in a State whose law provides that issuers in the State must meet a higher MLR than that set forth in § 158.210, the State's higher percentage must be substituted for the percentage stated in § 158.210. If a State requires the small group market and individual market to be merged and also sets a higher MLR standard for the merged market, the State's higher percentage must be substituted for the percentage stated in § 158.210 for both the small group and individual markets.

(b) *Considerations in setting a higher minimum loss ratio.* In adopting a higher minimum loss ratio than that set forth in § 158.210, a State must seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State, and value for consumers so that premiums are used for clinical services and quality improvements.

[75 FR 74921, Dec. 1, 2010, as amended at 79 FR 30352, May 27, 2014]

§ 158.220 Aggregation of data in calculating an issuer's medical loss ratio.

(a) *Aggregation by State and by market.* In general, an issuer's MLR must be calculated separately for the large group market, small group market and individual market within each State. However, if a State requires the small group market and individual market to be merged, then the data reported separately under subpart A of this part for the small group and individual market in that State must be merged for purposes of calculating an issuer's MLR and any rebates owing.

(b) *Years of data to include in calculating MLR.* Subject to paragraphs (c) and (d) of this section, an issuer's MLR for an MLR reporting year is calculated according to the formula in § 158.221 of this subpart and aggregating the data reported under this part for the following 3-year period:

(1) The data for the MLR reporting year whose MLR is being calculated; and

(2) The data for the two prior MLR reporting years.

(c) *Requirements for MLR reporting years 2011 and 2012.* (1) For the 2011 MLR reporting year, an issuer's MLR is calculated using the data reported under this part for the 2011 MLR reporting year only.

(2) For the 2012 MLR reporting year—

(i) If an issuer's experience for the 2012 MLR reporting year is fully credible, as defined in § 158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2012 MLR reporting year.

(ii) If an issuer's experience for the 2012 MLR reporting year is partially credible or non-credible, as defined in § 158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2011 MLR reporting year and the 2012 MLR reporting year.

(d) *Requirements for MLR reporting years 2013 and 2014 for the student market*

only. (1) For the 2013 MLR reporting year, an issuer's MLR is calculated using the data reported under this part for the 2013 MLR reporting year only.

(2) For the 2014 MLR reporting year—

(i) If an issuer's experience for the 2014 MLR reporting year is fully credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2014 MLR reporting year.

(ii) If an issuer's experience for the 2014 MLR reporting year is partially credible or non-credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2013 MLR reporting year and the 2014 MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 16469, Mar. 21, 2012; 79 FR 30352, May 27, 2014]

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

(a) *Medical loss ratio*. (1) An issuer's MLR is the ratio of the numerator, as defined in paragraph (b) of this section, to the denominator, as defined in paragraph (c) of this section, subject to the applicable credibility adjustment, if any, as provided in §158.232 of this subpart.

(2) An issuer's MLR shall be rounded to three decimal places. For example, if an MLR is 0.7988, it shall be rounded to 0.799 or 79.9 percent. If an MLR is 0.8253 or 82.53 percent, it shall be rounded to 0.825 or 82.5 percent.

(b) *Numerator*. The numerator of an issuer's MLR for an MLR reporting year must be the issuer's incurred claims, as defined in §158.140 of this part, plus the issuer's expenditures for activities that improve health care quality, as defined in §158.150 and §158.151 of this part, that are reported for the years specified in §158.220 of this subpart.

(1) The numerator of the MLR for the 2012 MLR reporting year may include any rebate paid under §158.240 of this subpart for the 2011 MLR reporting year if the 2012 MLR reporting year experience is not fully credible as defined in §158.230 of this subpart.

(2) The numerator of the MLR for the 2013 MLR reporting year may include any rebate paid under §158.240 for the 2011 MLR reporting year or the 2012 MLR reporting year.

(3) The numerator of the MLR for policies that are reported separately under §158.120(d)(3) of this part must be the amount specified in paragraph (b) of this section, except that for the 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.

(5) The numerator of the MLR for policies that are reported separately under §158.120(d)(5) of this part must be the amount specified in paragraph (b) of this section, except that for the 2013 MLR reporting year the total of the incurred claims and expenditures for activities that improve health care quality is then multiplied by a factor of 1.15.

(6) The numerator of the MLR in the individual and small group markets in States that adopted the transitional policy outlined in the CMS letter dated November 14, 2013 must be the amount specified in paragraph (b) of this section, except that issuers that provided transitional coverage may multiply the total incurred claims and expenditures for activities that improve health care quality incurred in 2014 in the respective State and market by a factor of 1.0001.

(7) The numerator of the MLR in the individual and small group markets for issuers participating in the State and Federal Exchanges (sometimes referred to as ''Marketplaces'') must be the amount specified in paragraph (b) of

this section, except that the total incurred claims and expenditures for activities that improve health care quality incurred in 2014 in the respective State and market may be multiplied by a factor of 1.0004.

(8) Beginning with the 2017 MLR reporting year, an issuer has the option of reporting an amount equal to 0.8 percent of earned premium in the relevant State and market in lieu of reporting the issuer's actual expenditures for activities that improve health care quality, as defined in §§ 158.150 and 158.151. If an issuer chooses this method of reporting, it must apply it for a minimum of 3 consecutive MLR reporting years and for all of its individual, small group, and large group markets; and all affiliated issuers must choose the same reporting method.

(c) *Denominator.* The denominator of an issuer's MLR must equal the issuer's premium revenue, as defined in § 158.130, excluding the issuer's Federal and State taxes and licensing and regulatory fees, described in §§ 158.161(a) and 158.162(a)(1) and (b)(1), and after accounting for payments or receipts related to risk adjustment, risk corridors, and reinsurance, described in § 158.130(b)(5).

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, Dec. 7, 2011; 77 FR 16469, Mar. 21, 2012; 78 FR 15540, Mar. 11, 2013; 79 FR 30352, May 27, 2014; 83 FR 17070, Apr. 17, 2018]

§ 158.230 Credibility adjustment.

(a) *General rule.* An issuer may add to the MLR calculated under § 158.221(a) of this subpart the credibility adjustment specified by § 158.232 of this section, if such MLR is based on partially credible experience as defined in paragraph (c)(2) of this section. An issuer may not apply the credibility adjustment if the issuer's experience is fully credible, as defined in paragraph (c)(1) of this section, or non-credible, as defined in paragraph (c)(3) of this section.

(b) *Life-years.* The credibility of an issuer's experience is based upon the number of life-years covered by the issuer. Life-years means the total number of months of coverage for enrollees whose premiums and claims experience is included in the report to the Secretary required by § 158.110 of this part, divided by 12.

(c) *Credible experience.* (1) An MLR calculated under § 158.221(a) through (c) of this subpart is fully credible if it is based on the experience of 75,000 or more life-years.

(2) An MLR calculated under § 158.221(a) through (c) of this subpart is partially credible if it is based on the experience of at least 1,000 life-years and fewer than 75,000 life-years.

(3) An MLR calculated under § 158.221(a) through (c) of this subpart is non-credible if it is based on the experience of less than 1,000 life-years.

(d) If an issuer's MLR is non-credible, it is presumed to meet or exceed the minimum percentage required by § 158.210 or § 158.211 of this subpart.

§ 158.231 Life-years used to determine credible experience.

(a) The life-years used to determine the credibility of an issuer's experience are the life-years for the MLR reporting year plus the life-years for the two prior MLR reporting years. If a State requires the small group market and individual market to be merged, then life-years used to determine credibility must be the life-years from the small group market and the individual market for the MLR reporting year plus the life-years from the small group market and the individual market for the two prior MLR reporting years.

(b) For the 2011 MLR reporting year, the life-years used to determine credibility are the life-years for the 2011 MLR reporting year only.

(c) For the 2012 MLR reporting year-

(1) If an issuer's experience for the 2012 MLR reporting year is fully credible, the life-years used to determine credibility are the life-years for the 2012 MLR reporting year only;

(2) If an issuer's experience for the 2012 MLR reporting year only is partially credible or non-credible, the life-years used to determine credibility are the life-years for the 2011 MLR reporting year plus the life-years for the 2012 MLR reporting year.

(d) For the 2013 MLR reporting year for the student market only, the life-years used to determine credibility are the life-years for the 2013 MLR reporting year only.

(e) For the 2014 MLR reporting year for the student market only—

(1) If an issuer's experience for the 2014 MLR reporting year is fully credible, the life-years used to determine credibility are the life-years for the 2014 MLR reporting year only;

(2) If an issuer's experience for the 2014 MLR reporting year only is partially credible or non-credible, the life-years used to determine credibility are the life-years for the 2013 MLR reporting year plus the life-years for the 2014 MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82279, Dec. 30, 2010; 77 FR 16469, Mar. 21, 2012; 79 FR 30353, May 27, 2014]

§ 158.232 Calculating the credibility adjustment.

(a) *Formula.* An issuer's credibility adjustment, if any, is the product of the base credibility factor, as determined under paragraph (b) of this section, multiplied by the deductible factor, as determined under paragraph (c) of this section.

(b) *Base credibility factor.* (1) The base credibility factor for fully credible experience or for non-credible experience is zero.

(2) The base credibility factor for partially credible experience is determined based on the number of life-years included in the aggregation, as determined under §158.231 of this subpart, and the factors shown in Table 1. When the number of life-years used to determine credibility exactly matches a life-year category listed in Table 1, the value associated with that number of life-years is the base credibility factor. The base credibility factor for a number of life-years between the values shown in Table 1 is determined by linear interpolation.

TABLE 1 TO § 158.232: BASE CREDIBILITY FACTORS

Life-years	Base credibility factor
<1,000	No Credibility.
1,000	8.3%.
2,500	5.2%.
5,000	3.7%.
10,000	2.6%.
25,000	1.6%.
50,000	1.2%.
≥75,000	0.0% (Full Credibility).

(c) *Deductible factor.* (1) The deductible factor is based on the average per person deductible of policies whose experience is included in the aggregation, as determined under §158.231 of this subpart. When the weighted average deductible, as determined in accordance with this section, exactly matches a deductible category listed in Table 2, the value associated with that deductible is the deductible factor. The deductible factor for an average weighted deductible between the values shown in Table 2 is determined by linear interpolation.

(i) The per person deductible for a policy that covers a subscriber and the subscriber's dependents shall be the lesser of: the deductible applicable to each of the individual family members; or the overall family deductible for the subscriber and subscriber's family divided by two (regardless of the total number of individuals covered through the subscriber).

(ii) The average deductible for an aggregation is calculated weighted by the life-years of experience for each deductible level of policies included in the aggregation.

(2) An issuer may choose to use a deductible factor of 1.0 in lieu of calculating a deductible factor based on the average of policies included in the aggregation.

TABLE 2 TO § 158.232: DEDUCTIBLE FACTOR

Health plan deductible	Deductible factor
<$2,500	1.000
$2,500	1.164
$5,000	1.402
≥$10,000	1.736

(d) *No credibility adjustment.* Beginning with the 2013 MLR reporting year, the credibility adjustment for an MLR based on partially credible experience is zero if both of the following conditions are met:

(1) Each year in the aggregation included experience of at least 1,000 life-years; and

(2) The issuer's preliminary MLR, as defined under paragraph (f) of this section, for each year in the aggregation was below the applicable MLR standard, as established under §§158.210 and 158.211.

(e) *No credibility adjustment.* Beginning with the 2015 MLR reporting year

for the student market only, the credibility adjustment for an MLR based on partially credible experience is zero if both of the following conditions are met:

(1) Each year in the aggregation included experience of at least 1,000 life-years; and

(2) The issuer's preliminary MLR, as defined under paragraph (f) of this section, for each year in the aggregation was below the applicable MLR standard, as established under §§ 158.210 and 158.211.

(f) *Preliminary MLR.* Preliminary MLR means the ratio of the numerator, as defined in § 158.221(b) and calculated as of March 31st of the year following the year for which the MLR report required in § 158.110 is being submitted, to the denominator, as defined in § 158.221(c), calculated using only a single year of experience, and without applying any credibility adjustment.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82279, Dec. 30, 2010; 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012; 78 FR 15540, Mar. 11, 2013; 78 FR 66655, Nov. 6, 2013; 81 FR 94183, Dec. 22, 2016]

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

(a) *General requirement.* For each MLR reporting year, an issuer must provide a rebate to each enrollee if the issuer's MLR does not meet or exceed the minimum percentage required by §§ 158.210 and 158.211 of this subpart.

(b) *Definition of enrollee for purposes of rebate.* For the sole purpose of determining whom is entitled to receive a rebate pursuant to this part, the term ''enrollee'' means the subscriber, policyholder, and/or government entity that paid the premium for health care coverage received by an individual during the respective MLR reporting year.

(c) *Amount of rebate to each enrollee.* (1) For each MLR reporting year, an issuer must rebate to the enrollee, subject to paragraph (d) of this section, the total amount of premium revenue, as defined in § 158.130, received by the issuer from the enrollee, after subtracting Federal and State taxes and licensing and regulatory fees as provided in §§ 158.161(a) and 158.162(a)(1) and (b)(1), and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance as provided in § 158.130(b)(5), multiplied by the difference between the MLR required by § 158.210 or § 158.211, and the issuer's MLR as calculated under § 158.221.

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the individual market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the individual market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting a pro rata portion of taxes and fees and accounting for payments or receipts related to the reinsurance, risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent). If the issuer's total earned premium for the MLR reporting year in the individual market in the State is $200,000, the issuer received transitional reinsurance payments of $2,500, and made net payments related to risk adjustment and risk corridors of $20,000 (calculated using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), the issuer's gross earned premium in the individual market in the State would be $200,000 plus $2,500 minus $20,000, for a total of $182,500. If the issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§ 158.161(a), 158.162(a)(1) and 158.162(b)(1), allocated to the individual market in the State are $15,000, and the net payments related to risk adjustment and risk corridors, reduced by reinsurance receipts, that must be accounted for in premium revenue as described in §§ 158.130(b)(5), 158.221, and 158.240, are $17,500 ($20,000 reduced by $2,500), then the issuer would subtract $15,000 and add $17,500 to gross premium revenue of $182,500, for a base of $185,000 in premium. The issuer would owe rebates of 5 percent of $185,000, or $9,250 in the individual market in the State.

In this example, if an enrollee of the issuer in the individual market in the State paid $2,000 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or $92.50.

(d) *Limitation on total rebate payable for each year in the aggregation.* For any State and market, an issuer may elect to limit the amount of rebate payable for the MLR reporting year to the issuer's total outstanding rebate liability with respect to all years included in the aggregation. If an issuer elects this option, the outstanding rebate liability with respect to a specific year in the aggregation must be calculated by multiplying the denominator with respect to that year, as defined in §158.221(c), by the difference between the MLR required by §158.210 or §158.211 for the MLR reporting year, and the sum of the issuer's preliminary MLR for that year, as defined under §158.232(f), and the credibility adjustment applicable to the current MLR reporting year. The outstanding rebate liability with respect to a specific year must be reduced by any rebate payments applied against it in prior MLR reporting years. A rebate paid for an MLR reporting year must be applied first to reduce the outstanding rebate liability with respect to the earliest year in the aggregation.

(e) *Timing of rebate.* For each of the 2011, 2012, and 2013 MLR reporting years, an issuer must provide any rebate owing to an enrollee no later than August 1 following the end of the MLR reporting year. Beginning with the 2014 MLR reporting year, an issuer must provide any rebate owing to an enrollee no later than September 30 following the end of the MLR reporting year.

(f) *Late payment interest.* An issuer that fails to pay any rebate owing to an enrollee or subscriber in accordance with paragraph (e) of this section or to take other required action within the time periods set forth in this part must, in addition to providing the required rebate to the enrollee, pay the enrollee interest at the current Federal Reserve Board lending rate or ten percent annually, whichever is higher, on the total amount of the rebate, accruing from the date payment was due under paragraph (e) of this section.

[75 FR 74921, Dec. 1, 2010, as amended at 78 FR 15540, Mar. 11, 2013; 79 FR 13842, Mar. 11, 2014; 81 FR 94183, Dec. 22, 2016]

§158.241 Form of rebate.

(a) *Current enrollees.* (1) An issuer may choose to provide any rebates owing to current enrollees in the form of a premium credit, lump-sum check, or, if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium.

(2) For each of the 2011, 2012, and 2013 MLR reporting years, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with the 2014 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after September 30 following the MLR reporting year. If the amount of the rebate exceeds the premium due for October, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited.

(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.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, Dec. 7, 2011; 78 FR 15540, Mar. 11, 2013]

§158.242 Recipients of rebates.

(a) *Individual market.* An issuer must meet its obligation to provide any rebate due to an enrollee in the individual market by providing it to the enrollee. For individual policies that cover more than one person, one lump-

sum rebate may be provided to the subscriber on behalf of all enrollees covered by the policy.

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

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

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

(iii) A cash refund to subscribers of the group health plan option for which the issuer is providing a rebate, who were enrolled in the group health plan option either during the MLR reporting year that resulted in the issuer providing the rebate or at the time the rebate is received by the policyholder;

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

(v) All rebate distributions made under paragraphs (b)(1)(i), (ii), or (iii) of this section must be made within 3 months of the policyholder's receipt of the rebate. Rebate distributions made after 3 months must include late payment interest at the current Federal Reserve Board lending rate or 10 percent annually, whichever is higher, on the total amount of the rebate, accruing from the date payment was due under this section.

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

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

(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.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, 76599, Dec. 7, 2011; 80 FR 10876, Feb. 27, 2015]

§ 158.243 *De minimis* rebates.

(a) *Minimum threshold.* An issuer is not required to provide a rebate to an enrollee based upon the premium that

enrollee paid, under the following circumstances:

(1) For a group policy 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.

(2) In the individual market, if the total rebated owed to the subscriber is less than $5.

(b) *Distribution.* (1) An issuer must aggregate and distribute any rebates not provided because they did not meet the minimum threshold set forth in paragraph (a) of this section by aggregating the unpaid rebates by individual market, small group market and large group market in a State and use them to increase the rebates provided to enrollees who receive rebates based upon the same MLR reporting year as the aggregated unpaid rebates. An issuer must distribute such aggregated rebates by providing additional premium credit or payment divided evenly among enrollees who are being provided a rebate.

(2) For example, an issuer in the individual market has aggregated unpaid rebates totaling $2,000, and the issuer has 10,000 enrollees who are entitled to be provided a rebate above the minimum threshold for the applicable MLR reporting year. The $2,000 must be redistributed to the 10,000 and added on to their existing rebate amounts. The $2,000 is divided evenly among the 10,000 enrollees, so the issuer increases each enrollee's rebate by $0.20.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, Dec. 7, 2011]

§158.244 Unclaimed rebates.

An issuer must make a good faith effort to locate and deliver to an enrollee any rebate required under this part. If, after making a good faith effort, an issuer is unable to locate a former enrollee, the issuer must comply with any applicable State law.

§158.250 Notice of rebates.

(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.

[76 FR 76593, Dec. 7, 2011]

§158.251 Notice of MLR information.

(a) *Notice of MLR information when the MLR standard is met or exceeded*—(1) *General requirement.* Except as provided in paragraph (b) of this section, for the 2011 MLR reporting year, an issuer whose MLR meets or exceeds the applicable MLR standard required by §158.210 or §158.211 must provide each policyholder and subscriber of a group health plan, and each subscriber in the individual market, a notice in accordance with the requirements of this section.

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

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

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

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

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

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

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

[77 FR 28797, May 16, 2012]

§ 158.260 Reporting of rebates.

(a) *General requirement.* For each MLR reporting year, an issuer must submit to the Secretary a report concerning the rebates provided to and on behalf of enrollees pursuant to this subpart.

(b) *Aggregation of information in the report.* The information in the report must be aggregated in the same manner as required by § 158.120.

(c) *Information to report.* The report required by this section must include the total:

(1) Number 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.

(d) *Timing and form of report.* The data required by paragraphs (c)(1) through (4) of this section must be submitted with the report under § 158.110, on a form and in the manner prescribed by the Secretary. The data required by paragraph (c)(5) of this section must be submitted with the report under § 158.110 for the subsequent MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76594, Dec. 7, 2011]

§ 158.270 Effect of rebate payments on solvency.

(a) If a State's insurance commissioner, superintendent, or other responsible official determines that the payment of rebates by a domestic issuer in that State will cause the issuer's risk based capital (RBC) level to fall below the Company Action Level RBC, as defined in the NAIC's Risk Based Capital (RBC) for Insurers Model Act, the commissioner, superintendent, or other responsible official must notify the Secretary. In such a circumstance, the commissioner, superintendent, or other responsible official may request that the Secretary defer all or a portion of the rebate payments owed by the issuer.

(b) In the event an insurance commissioner, superintendent, or other responsible official makes the request set forth in paragraph (a) of this section, the following should be provided to the Secretary along with the notification:

(1) The domestic issuer's RBC reports for the current calendar year and the 2 preceding calendar years; and

(2) A calculation of the amount of rebates that would be owed by the domestic issuer pursuant to this part.

(c) Upon receipt of the notification under paragraph (a), the Secretary will examine the information provided by the insurance commissioner, superintendent, or other responsible official along with any other information the Secretary may request from the issuer, and determine whether the payment of rebates by the issuer will cause its RBC level to fall below the Company Action Level RBC.

(d) When the Secretary determines that the payment of rebates by an issuer will cause its RBC level to fall below the Company Action Level RBC, the Secretary may permit a deferral of all or a portion of the rebates owed, but only for a period determined by the Secretary in consultation with the State. The Secretary will require that the issuer must pay these rebates with interest in a future year in which payment of the rebates would not cause the issuer's RBC level to fall below the Company Action Level RBC.

Subpart C—Potential Adjustment to the MLR for a State's Individual Market

§ 158.301 Standard for adjustment to the medical loss ratio.

The Secretary may adjust the MLR standard that must be met by issuers offering coverage in the individual market in a State, as defined in section

2791 of the PHS Act, for a given MLR reporting year if, in the Secretary's discretion, the Secretary determines that there is a reasonable likelihood that an adjustment to the 80 percent MLR standard of section 2718(b)(1)(A)(ii) of the Public Health Service Act will help stabilize the individual market in that State.

[83 FR 17070, Apr. 17, 2018]

§ 158.310 Who may request adjustment to the medical loss ratio.

A request for an adjustment to the MLR standard for a State must be submitted by the State's insurance commissioner, superintendent, or comparable official of that State in order to be considered by the Secretary.

§ 158.311 Duration of adjustment to the medical loss ratio.

A State may request that an adjustment to the MLR standard be for up to three MLR reporting years.

§ 158.320 Information supporting a request for adjustment to the medical loss ratio.

A State must submit in electronic format the information required by §§ 158.321 through 158.323 of this subpart in order for the request for adjustment to the MLR standard for the State to be considered by the Secretary. A State may submit to the Secretary any additional information it determines would support its request. In the event that certain data are unavailable or that the collection of certain data is unduly burdensome, a State may provide written notice to the Secretary and the Secretary may, at her discretion, request alternative supporting data or move forward with her determination.

§ 158.321 Information regarding the State's individual health insurance market.

(a) Subject to § 158.320, the State must provide, for each issuer who actively offers coverage in the individual market in the State, the following information, in accordance with paragraph (b) of this section, for the preceding calendar year and, at the State's option, for the current year:

(1) Total earned premium and incurred claims;

(2) Total number of enrollees (life-years and covered lives);

(3) Total agents' and brokers' commission expenses;

(4) Net underwriting gain;

(5) Risk-based capital level; and

(6) Whether the issuer has provided notice to the State's insurance commissioner, superintendent, or comparable State authority that the issuer will cease or begin offering individual market coverage on the Exchange, certain geographic areas, or the entire individual market in the State.

(b) The information required in paragraphs (a)(1) through (4) and (6) of this section must be provided separately for the issuer's individual market plans grouped by the following categories, as applicable: On-Exchange, off-Exchange, grandfathered health plans as defined in § 147.140 of this subchapter, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage. The information required in paragraph (a)(5) of this section must be provided at the issuer level.

(c) The State must also provide information regarding whether any issuer other than those described in paragraph (a) of this section has provided notice to the State's insurance commissioner, superintendent, or comparable State authority that the issuer will cease or begin offering individual market coverage on the Exchange, certain geographic areas, or the entire individual market in the State.

[83 FR 17070, Apr. 17, 2018]

§ 158.322 Proposal for adjusted medical loss ratio.

A State must provide its own proposal as to the adjustment it seeks to the MLR standard. This proposal must include an explanation of how an adjustment to the MLR standard for the State's individual market will help stabilize the State's individual market.

[83 FR 17071, Apr. 17, 2018]

§ 158.323 State contact information.

A State must provide the name, telephone number, e-mail address, and

mailing address of the person the Secretary may contact regarding the request for an adjustment to the MLR standard.

§ 158.330 Criteria for assessing request for adjustment to the medical loss ratio.

The Secretary may consider the following criteria in assessing whether an adjustment to the 80 percent MLR standard, as calculated in accordance with this subpart, would be reasonably likely to help stabilize the individual market in a State that has requested such adjustment:

(a) The number and financial performance (based on data provided by a State under § 158.321) of issuers actively offering individual health insurance coverage on- and off-Exchange, grandfathered health plans as defined in § 147.140 of this subchapter, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage; the number of issuers reasonably likely to cease or begin offering individual market coverage in the State; and the likelihood that an adjustment to the 80 percent MLR standard could help increase competition in the individual market in the State, including in underserved areas.

(b) Whether an adjustment to the 80 percent MLR standard for the individual market may improve consumers' access to agents and brokers.

(c) The capacity of any new issuers or issuers remaining in the individual market to write additional business in the event one or more issuers were to cease offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State.

(d) The impact on premiums charged, and on benefits and cost sharing provided, to consumers by issuers remaining in or entering the individual market in the event one or more issuers were to cease or begin offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State.

(e) Any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

[83 FR 17071, Apr. 17, 2018]

§ 158.340 Process for submitting request for adjustment to the medical loss ratio.

(a) *Electronic submission.* A State must submit electronically, to an address and in a format prescribed by the Secretary, all of the information required by this subpart in order for its request for an adjustment to the MLR standard for its individual market to be considered by the Secretary.

(b) *Submission by mail.* A State may also submit by overnight delivery service or by U.S mail, return receipt requested, to an address and in a format prescribed by the Secretary, its request for an adjustment to the MLR standard for its individual market.

§ 158.341 Treatment as a public document.

A State's request for an adjustment to the MLR standard, and all information submitted as part of its request, will be treated as a public document. Instructions for how to access documents related to a State's request for an adjustment to the MLR standard will be made available on the Secretary's website.

[83 FR 17071, Apr. 17, 2018]

§ 158.342 Invitation for public comments.

The Secretary will invite public comment regarding a State's request for an adjustment to the MLR standard. All public comments must be submitted in writing within 10 days of the posting of the request, and must be submitted in the manner prescribed by the Secretary. The Secretary will consider timely public comments in assessing a State's request for an adjustment to the MLR standard.

§ 158.343 Optional State hearing.

Any State that submits a request for adjustment to the MLR standard may, at its option, hold a public hearing and create an evidentiary record with respect to its application. If a State does so, the Secretary will take the evidentiary record of the hearing into

consideration in making her determination.

§ 158.344 Secretary's discretion to hold a hearing.

The Secretary may, at her discretion, conduct a public hearing with respect to a State's request for an adjustment to the MLR standard. All testimony and materials received in connection with any public hearing will be made part of the public record, and shall be considered by the Secretary in assessing a State's request for an adjustment to the MLR standard.

§ 158.345 Determination on a State's request for adjustment to the medical loss ratio.

(a) *General time frame.* The Secretary will make a determination as to whether to grant a State's request for an adjustment to the MLR standard within 30 days after determining that the information required by this subpart has been received.

(b) *Extension at the discretion of the Secretary.* The Secretary may, in her discretion, extend the 30 day time period in paragraph (a) of this section for as long a time as necessary not to exceed 30 days.

§ 158.346 Request for reconsideration.

(a) *Requesting reconsideration.* A State whose request for adjustment to the MLR standard has been denied by the Secretary may request reconsideration of that determination. A request for reconsideration must be submitted in writing to the Secretary within 10 days of her decision to deny the State's request for an adjustment, and may include any additional information in support of its request.

(b) *Reconsideration determination.* The Secretary will issue her determination on a State's request for reconsideration within 20 days of receiving the reconsideration request.

§ 158.350 Subsequent requests for adjustment to the medical loss ratio.

A State that has made a previous request for an adjustment to the MLR standard must, in addition to the other information required by this subpart, submit information as to what steps the State has taken since its prior requests, if any, to improve the stability of the State's individual market.

[83 FR 17071, Apr. 17, 2018]

Subpart D—HHS Enforcement

§ 158.401 HHS enforcement.

HHS enforces the reporting and rebate requirements described in subparts A and B, including but not limited to:

(a) The requirement that such reports be submitted timely.

(b) The requirement that the data reported complies with the definitions and criteria set forth in this part.

(c) The requirement that rebates be paid timely and accurately.

§ 158.402 Audits.

(a) *Notice of Audit.* HHS will provide 30 days advance notice of its intent to conduct an audit of an issuer.

(b) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(c) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, which will then have 30 days to respond to such findings. HHS may extend, for good cause, the time for an issuer to submit such a response.

(d) *Final Audit Findings.* If the issuer does not dispute the preliminary findings, the audit findings will become final. Alternatively, if the issuer responds to the preliminary findings, HHS will review and consider such response and finalize the audit findings.

(e) *Corrective actions.* HHS will send a copy of the final audit findings to the issuer as well as any corrective actions that issuer must undertake as a result of the audit findings.

(f) *Order to pay rebates.* If HHS determines as the result of an audit that an issuer has failed to pay rebates it is obligated to pay pursuant to this part, it may order the issuer to pay those rebates, together with interest from the date the rebates were due, in accordance with § 158.240(d) of this part.

§ 158.403 Circumstances in which a State is conducting audits of issuers.

(a) If a State conducts an audit of an issuer's MLR reporting and rebate obligations, HHS may, in the exercise of its discretion, accept the findings of that audit if HHS determines the following:

(1) The laws of the State permit public release of the findings of audits of issuers;

(2) The State's audit reports on the validity of the data regarding expenses and premiums that the issuer reported to the Secretary, including the appropriateness of the allocations of expenses used in such reporting and whether the activities associated with the issuer's reported expenditures for quality improving activities meet the definition of such activities;

(3) The State's audit reports on the accuracy of rebate calculations and the timeliness and accuracy of rebate payments;

(4) The State submits final audit reports to HHS within 30 days of finalization; and

(5) The State submits preliminary or draft audit reports to HHS within 6 months of the completion of audit field work unless they have already been finalized and reported under paragraph (a)(4) of this section.

(b) If HHS accepts an audit conducted by a State, and if the issuer makes additional rebate payments as a result of the audit, then HHS shall accept those payments as satisfying the issuer's obligation to pay rebates pursuant to this part.

Subpart E—Additional Requirements on Issuers

§ 158.501 Access to facilities and records.

(a) Each issuer subject to the reporting requirement of this part must allow access and entry to its premises, facilities and records, including computer and other electronic systems, to HHS, the Comptroller General, or their designees to evaluate, through inspection, audit, or other means, compliance with the requirements for reporting and calculation of data submitted to HHS, and the timeliness and accuracy of rebate payments made under this part.

(b) Each issuer must also allow access and entry to the facilities and records, including computer and other electronic systems, of its parent organization, subsidiaries, related entities, contractors, subcontractors, agents, or a transferee that pertain to any aspect of the data reported to HHS or to rebate payments calculated and made under this part. To the extent that the issuer does not control access to the facilities and records of its parent organization, related entities, or third parties, it will be the responsibility of the issuer to contractually obligate any such parent organization, related entities, or third parties to grant said access.

(c) The Comptroller General, HHS, or their designees may inspect, evaluate, and audit through 6 years from the date of the filing of a report required by this part or through 3 years after the completion of the audit and for such longer period set forth below provided that any of the following occur:

(1) HHS determines there is a special need to retain a particular record or group of records for a longer period and notifies the issuer at least 30 days before the disposition date.

(2) There has been a dispute, or allegation of fraud or similar fault by the issuer, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the dispute, fraud, or similar fault.

(3) HHS determines that there is a reasonable possibility of fraud or similar fault, in which case HHS may inspect, evaluate, and audit the issuer at any time.

§ 158.502 Maintenance of records.

(a) *Basic rule.* Each issuer subject to the requirements of this part must maintain all documents and other evidence necessary to enable HHS to verify that the data required to be submitted in accordance with this part comply with the definitions and criteria set forth in this part, and that the MLR is calculated and any rebates owing are calculated and provided in accordance with this part. This includes but is not limited to all administrative and financial books and

records used in compiling data reported and rebates provided under this part and in determining what data to report and rebates to provide under this part, electronically stored information, and evidence of accounting procedures and practices. This also includes all administrative and financial books and records used by others in assisting an issuer with its obligations under this part.

(b) *Length of time information must be maintained.* All of the documents and other evidence required by this part must be maintained for the current year and six prior years, unless a longer time is required under §158.501 of this subpart.

Subpart F—Federal Civil Penalties

§158.601 General rule regarding the imposition of civil penalties.

If any issuer fails to comply with the requirements of this part, civil penalties, as described in this subpart, may be imposed.

§158.602 Basis for imposing civil penalties.

Civil penalties. For the violations listed in this paragraph, HHS may impose civil penalties in the amounts specified in §158.606 of this subpart on any issuer who fails to do the following:

(a) Submit to HHS a report concerning the data required under this part by the deadline established by HHS.

(b) Submit to HHS a substantially complete or accurate report concerning the data required under this part.

(c) Timely and accurately pay rebates owing pursuant to this part.

(d) Respond to HHS inquiries as part of an investigation of issuer non-compliance.

(e) Maintain records as required under this part for the periodic auditing of books and records used in compiling data reported to HHS and in calculating and paying rebates pursuant to this part.

(f) Allow access and entry to premises, facilities and records that pertain to any aspect of the data reported to HHS or to rebates calculated and paid pursuant to this part.

(g) Comply with corrective actions resulting from audit findings.

(h) Accurately and truthfully represent data, reports or other information that it furnishes to a State or HHS.

§158.603 Notice to responsible entities.

If HHS learns of a potential violation described in §158.602 of this subpart or if a State informs HHS of a potential violation prior to imposing any civil monetary penalty HHS must provide written notice to the issuer, to include the following:

(a) Describe the potential violation.

(b) Provide 30 days from the date of the notice for the responsible entity to respond and to provide additional information to refute an alleged violation.

(c) State that a civil monetary penalty may be assessed if the allegations are not, as determined by HHS, refuted.

§158.604 Request for extension.

In circumstances in which an entity cannot prepare a response to HHS within the 30 days provided in the notice, the entity may make a written request for an extension from HHS detailing the reason for the extension request and showing good cause. If HHS grants the extension, the responsible entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in HHS's imposition of a civil monetary penalty based upon its determination of a potential violation described in §158.602 of this subpart.

§158.605 Responses to allegations of noncompliance.

In determining whether to impose a civil monetary penalty, HHS may review and consider documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with Affordable Care Act requirements. The following are examples of documentation that a potential responsible entity may submit for HHS's consideration in determining whether a

civil monetary penalty should be assessed and the amount of any civil monetary penalty:

(a) Any evidence that refutes an alleged noncompliance.

(b) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(c) Evidence documenting the development and implementation of internal policies and procedures by an issuer to ensure compliance with the Affordable Care Act requirements regarding MLR. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with Affordable Care Act requirements regarding MLRs and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(d) Evidence documenting the entity's record of previous compliance with Affordable Care Act requirements regarding MLRs.

§ 158.606 Amount of penalty—general.

A civil monetary penalty for each violation of § 158.602 of this subpart may not exceed $100 as adjusted annually under 45 CFR part 102 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this part are in addition to any other penalties prescribed or allowed by law.

[75 FR 74921, Dec. 1, 2010, as amended at 81 FR 61581, Sept. 6, 2016]

§ 158.607 Factors HHS uses to determine the amount of penalty.

In determining the amount of any penalty, HHS may take into account the following:

(a) *The entity's previous record of compliance.* This may include any of the following:

(1) Any history of prior violations by the responsible entity, including whether, at any time before determination of the current violation(s), HHS or any State found the responsible entity liable for civil or administrative sanctions in connection with a violation of Affordable Care Act requirements regarding minimum loss ratios.

(2) Evidence that the responsible entity has never had a complaint for noncompliance with Affordable Care Act requirements regarding MLRs filed with a State or HHS.

(3) Such other factors as justice may require.

(b) *The gravity of the violation.* This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

§ 158.608 Determining the amount of the penalty—mitigating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by § 158.606 of this subpart to reflect that fact. As guidelines for taking into account the factors listed in § 158.607 of this subpart, HHS considers the following:

(a) *Record of prior compliance.* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under § 158.603 of this subpart, implemented and followed a compliance plan as described in § 158.605(c) of this subpart.

(2) Had no previous complaints against it for noncompliance.

(b) *Gravity of the violation(s).* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Made adjustments to its business practices to come into compliance with the requirements of this part so that the following occur:

(i) Each enrollee adversely affected by the violation has been paid any amount of rebate owed so that, to the extent practicable, that enrollee is in the same position that he, she, or it would have been in had the violation not occurred.

(ii) The rebate payments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from HHS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

§ 158.609 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several aggravating circumstances, HHS may set the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by § 158.606 of this subpart to reflect that fact. HHS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§ 158.610 Determining the amount of penalty—other matters as justice may require.

HHS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§ 158.611 Settlement authority.

Nothing in § 158.606 through § 158.610 of this subpart limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with § 158.603 of this subpart or to compromise on any penalty provided for in §§ 158.606 through 158.610 of this subpart.

§ 158.612 Limitations on penalties.

(a) *Circumstances under which a civil monetary penalty is not imposed.* HHS does not impose any civil monetary penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. HHS also may not impose a civil monetary penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to HHS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 158.613 Notice of proposed penalty.

(a) *Contents of notice.* If HHS proposes to assess a penalty in accordance with this part, it must provide the issuer written notice of its intent to assess a penalty, which includes the following:

(1) A description of the requirements under this part that HHS has determined the issuer violated.

(2) A description of the information upon which HHS based its determination, including the basis for determining the number of affected individuals and the number of days or weeks for which the violations occurred.

(3) The amount of the proposed penalty as of the date of the notice.

(4) Any considerations described in §158.607 through §158.610 of this subpart that were taken into account in determining the amount of the proposed penalty.

(5) A specific statement of the issuer's right to a hearing.

(6) A statement that failure to request a hearing within 30 days after the date of the notice permits the assessment of the proposed penalty without right of appeal in accordance with §158.615 of this subpart.

(b) *Delivery of notice.* This notice must be either hand delivered, sent by certified mail, return receipt requested, or sent by overnight delivery service with signature upon delivery required.

§158.614 Appeal of proposed penalty.

Any issuer against which HHS has assessed a penalty under this part may appeal that penalty in accordance with §150.400 *et seq.*

§158.615 Failure to request a hearing.

If the issuer does not request a hearing within 30 days of the issuance of the notice described in §158.613 of this subpart, HHS may assess the proposed civil monetary penalty indicated in such notice and may impose additional penalties as described in §158.606 of this subpart. HHS must notify the issuer in writing of any penalty that has been assessed and of the means by which the issuer may satisfy the penalty. The issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with §150.405 of this subchapter, unless the responsible entity can show good cause, as determined at §150.405(b) of this subchapter, for failing to timely exercise its right to a hearing.

PART 159—HEALTH CARE REFORM INSURANCE WEB PORTAL

Sec.

AUTHORITY: Section 1103 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

SOURCE: 75 FR 24482, May 5, 2010, unless otherwise noted.

§159.100 Basis and scope.

This part establishes provisions governing a Web portal that will provide information on health insurance coverage options in each of the 50 States and the District of Columbia. It sets forth data submission requirements for health insurance issuers. It covers the individual market and the small group market.

§159.110 Definitions.

For purposes of part 159, the following definitions apply unless otherwise provided:

Health Insurance Coverage: We adopt the Public Health Service Act (PHSA) definition of ''health insurance coverage'' found at section 2791(b)(1) of the Public Health Service Act (PHSA).

Health Insurance Issuer: We adopt the PHSA definition of ''health insurance issuer'' found at section 2791(b)(2) of the PHSA.

Health Insurance Product: Means a package of benefits that an issuer offers that is reported to State regulators in an insurance filing.

Individual Health Insurance Coverage: We adopt the PHSA definition of ''individual health insurance coverage'' found at section 2791(b)(5) of the PHSA.

Individual Market: We adopt the Affordable Care Act definition of ''individual market'' found at section 1304(a)(2) of the Affordable Care Act and 2791(e)(1)(A) of the PHSA.

Portal Plan: Means the discrete pairing of a package of benefits and a particular cost sharing option (not including premium rates or premium quotes).