

(c) Any termination does not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts incurred before the effective date of the termination.

(d) Upon the effective date of termination of the Discount Program Agreement, CMS ceases releasing data to the manufacturer except as necessary to ensure that the manufacturer reimburses applicable discounts for previous time periods in which the Discount Program Agreement was in effect, and notifies the manufacturer to destroy data files provided by CMS under the Discount Program Agreement.

(e) Manufacturer reinstatement is available only upon payment of any and all outstanding applicable discounts incurred during any previous period under the Discount Program Agreement. The timing of any such reinstatement is consistent with the requirements for entering into a Discount Program Agreement under § 423.2315(c) of this subpart.

Subpart X—Requirements for a Minimum Medical Loss Ratio

SOURCE: 78 FR 31310, May 23, 2013, unless otherwise noted.

§ 423.2400 Basis and scope.

This subpart is based on sections 1857(e)(4), 1860D–12(b)(3)(D), and 1106 of the Act, and sets forth medical loss ratio requirements for Part D sponsors, financial penalties and sanctions against Part D sponsors when minimum medical loss ratios are not achieved by Part D sponsors and release of medical loss ratio data to entities outside of CMS.

[81 FR 80558, Nov. 15, 2016]

§ 423.2401 Definitions.

Non-claims costs means those expenses for administrative services that are not—

- (1) Incurred claims (as provided in § 423.2420(b)(2) through (b)(4));
- (2) Expenditures on quality improving activities (as provided in § 423.2430);
- (3) Licensing and regulatory fees (as provided in § 423.2420(c)(2)(i)); or

(4) State and Federal taxes and assessments (as provided in § 423.2420(c)(2)(ii) and (iii)).

§ 423.2410 General requirements.

(a) For contracts beginning in 2014 or subsequent contract years, a Part D sponsor (defined at § 423.4) is required to report the information required under § 423.2460 for each contract under this part for each contract year.

(b) If CMS determines for a contract year that a Part D sponsor has an MLR for a contract that is less than 0.85, the Part D sponsor must remit to CMS an amount equal to the product of the following:

(1) The total revenue of the prescription drug plan for the contract year.

(2) The difference between 0.85 and the MLR for the contract year.

(c) If CMS determines that a Part D sponsor has an MLR for a contract that is less than 0.85 for 3 or more consecutive contract years, CMS does not permit the enrollment of new enrollees under the contract for coverage during the second succeeding contract year.

(d) If CMS determines that a Part D sponsor has an MLR for a contract that is less than 0.85 for 5 consecutive contract years, CMS terminates the contract under the authority at 423.509(b)(1) and (d) effective as of the second succeeding contract year.

[78 FR 31310, May 23, 2013; 78 FR 43821, July 22, 2013; 83 FR 16756, Apr. 16, 2018]

§ 423.2420 Calculation of medical loss ratio.

(a) *Determination of the MLR.* (1) The MLR for each contract under this part 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). An MLR may be increased by a credibility adjustment according to the rules at § 423.2440, or subject to an adjustment determined by CMS to be warranted based on exceptional circumstances for areas outside the 50 states and the District of Columbia.

(2) The MLR must reflect costs and revenues for benefits described at § 423.104(d) through (f). The MLR for MA–PD plans (defined at § 422.2 of this chapter) must also reflect costs and

revenues for benefits described at § 422.100(c) of this chapter.

(b) *Determining the MLR numerator.* (1) For a contract year, the numerator of the MLR for a Part D prescription drug contract must equal the sum of paragraphs (b)(1)(i) through (iii) of this section and must be in accordance with paragraphs (b)(5) and (b)(6) of this section.

(i) Incurred claims for all enrollees, as defined in paragraphs (b)(2) through (4) of this section.

(ii) The expenditures under the contract for activities that improve health care quality, as defined in § 423.2430;

(2) *Incurred claims for prescription drug costs.* Incurred claims must include the following:

(i) Direct drug costs that are actually paid (as defined in § 423.308, which are net of prescription drug rebates and other direct or indirect remuneration as defined herein) by the Part D sponsor.

(ii) Unpaid claims reserves for the current contract year, including claims reported in the process of adjustment.

(iii) Percentage withholds from payments made to contracted providers.

(iv) Claims incurred but not reported based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(v) Changes in other claims-related reserves.

(vi) Claims that are recoverable for anticipated coordination of benefits.

(vii) Claims payments recoveries received as a result of subrogation.

(viii) [Reserved]

(ix) Reserves for contingent benefits and the Part D claim portion of lawsuits.

(3) Adjustments that must be deducted from incurred claims include the following:

(i) Overpayment recoveries received from providers.

(4) *Exclusions from incurred claims.* The following amounts must not be included in incurred claims:

(i) Non-claims costs, as defined in § 423.2401, which include the following:

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

(B) Amounts paid to third party vendors for any of the following:

(1) Network development.

(2) Administrative fees.

(3) Claims processing.

(4) Utilization management.

(C) Amounts paid, including amounts paid to a pharmacy, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee, such as the following:

(1) Medical record copying costs.

(2) Attorneys' fees.

(3) Subrogation vendor fees.

(4) Bona fide service fees.

(5) Compensation to any of the following:

(i) Paraprofessionals.

(ii) Janitors.

(iii) Quality assurance analysts.

(iv) Administrative supervisors.

(v) Secretaries to medical personnel.

(vi) Medical record clerks.

(ii) Amounts paid to CMS as a remittance under § 423.2410(b).

(5) Incurred claims under this part for policies issued by one Part D sponsor and later assumed by another entity must be reported by the assuming organization for the entire MLR reporting year during which the policies were assumed and no incurred claims under this part for that contract year must be reported by the ceding Part D sponsor.

(6) Reinsured incurred claims for a block of business that was subject to indemnity reinsurance and administrative agreements effective before 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.

(c) *Determining the MLR denominator.* For a contract year, the denominator of the MLR for a Part D prescription drug contract must equal the total revenue under the contract. Total revenue under the contract is as described in paragraph (c)(1) of this section, net of deductions described in paragraph (c)(2) of this section, taking into account the exclusions described in and paragraph (c)(3) of this section, and be in accordance with paragraphs (c)(4) and (5) of this section.

(1) CMS' payments to the Part D sponsor for all enrollees under a contract, reported on a direct basis, including the following:

(i) Payments under § 423.329(a)(1) and (2).

(ii) Payment adjustments resulting from reconciliation per § 423.329(c)(2)(ii).

(iii) All premiums paid by or on behalf of enrollees to the Part D sponsor as a condition of receiving coverage under a Part D plan, including CMS' payments for low income premium subsidies under § 422.304(b)(2) of this chapter.

(iv) All unpaid premium amounts that a Part D sponsor could have collected from enrollees in the Part D plan(s) under the contract.

(v) All changes in unearned premium reserves.

(vi) Payments under § 423.315(e).

(2) The following amounts must be deducted from total revenue in calculating the MLR:

(i) *Licensing and regulatory fees.* Statutory assessments to defray operating expenses of any State or Federal department, such as the "user fee" described in section 1857(e)(2) of the Act, and examination fees in lieu of premium taxes as specified by State law.

(ii) *Federal taxes and assessments.* All Federal taxes and assessments allocated to health insurance coverage.

(iii) *State taxes and assessments.* State taxes and assessments, such as the following:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly.

(B) Guaranty fund assessments.

(C) 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.

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

(iv) *Community benefit expenditures.* Community benefit expenditures are payments made by a Federal income tax-exempt Part D sponsor for community benefit expenditures as defined in paragraph (c)(2)(iii)(A) of this section, limited to the amount defined in para-

graph (c)(2)(iii)(B) of this section, and allocated to a contract as required under paragraph (d)(1) of this section.

(A) 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.

(B) Such payment may be deducted up to the limit of either 3 percent of total revenue under this part or the highest premium tax rate in the State for which the Part D sponsor is licensed, multiplied by the Part D sponsor's earned premium for the contract.

(3) The following amounts must not be included in total revenue:

(i) The amount of unpaid premiums for which the Part D sponsor can demonstrate to CMS that it made a reasonable effort to collect.

(ii) Coverage Gap Discount Program payments under § 423.2320.

(4) Total revenue (as defined at § 423.2420(c)) of this chapter for policies issued by one Part D sponsor and later assumed by another entity must be reported by the assuming entity for the entire MLR reporting year during which the policies were assumed and no revenue under this part for that contract year must be reported by the ceding Part D sponsor.

(5) Total revenue (as defined at § 423.2420(c) of this chapter) that is reinsured for a block of business that was subject to indemnity reinsurance and administrative agreements effective before 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.

(d) *Allocation of expenses—(1) General requirements.* (i) Each expense must be included 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 prorated between types of expenses.

(ii) Expenditures that benefit multiple contracts, or contracts 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.

(2) *Description of the methods used to allocate expenses.* (i) Allocation to each category must 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 in paragraph (b) or (c) of this section will generally be the most accurate method.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the entities incurring the expense.

(iii)(A) 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.

(B) 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.

[78 FR 31310, May 23, 2013; 78 FR 43821, July 22, 2013; 83 FR 16756, Apr. 16, 2018]

§ 423.2430 Activities that improve health care quality.

(a) *Activity requirements.* (1) Activities conducted by a Part D sponsor to improve quality must either—

(i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or

(ii) Be listed in paragraph (a)(4) of this section.

(2) *Categories of quality improving activities.* The activity must be designed to achieve one or more of the following:

(i) To improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient

Protection and Affordable Care Act, for treatment or services under the plan or coverage.

(ii) To prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post-discharge reinforcement by an appropriate health care professional.

(iii) To improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology under the plan or coverage.

(iv) To promote health and wellness.

(v) To enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology. Activities, such as Health Information Technology (HIT) expenses, are required to accomplish the activities that improve health care quality 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, and are consistent with meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improving activities or make new quality improvement initiatives possible.

(3) The activity must be designed for all of the following:

(i) To improve health quality.

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

(iii) To 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) To be grounded in evidence-based medicine, widely accepted best clinical