

(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