

(b) *Basis for imposing civil money penalties.* CMS imposes a civil money penalty (CMP) on a manufacturer that fails to provide applicable beneficiaries applicable discounts for applicable drugs of the manufacturer in accordance with the Discount Program Agreement.

(c) *Determination of the civil money penalty amounts.* CMS imposes a CMP for each failure by a manufacturer to provide an applicable discount in accordance with the Discount Program Agreement equal to the sum of the following:

(1) The amount of applicable discount the manufacturer would have paid under the Discount Program Agreement, which will then be used to pay the applicable discount that the manufacturer had failed to provide.

(2) Twenty-five percent of such amount.

(d) *Procedures for imposing civil money penalties.* If CMS makes a determination to impose a CMP described in paragraph (c) of this section, CMS sends a written notice of its decision to impose a CMP to include the following:

(1) A description of the basis for the determination.

(2) The basis for the penalty.

(3) The amount of the penalty.

(4) The date the penalty is due.

(5) The manufacturer's right to a hearing (as specified in § 423.1006).

(6) Information about where to file the request for hearing.

(e) *Collection of civil money penalties imposed by CMS.* (1) When a manufacturer does not request a hearing, CMS initiates the collection of the CMP following the expiration of the timeframe for requesting an ALJ hearing as specified in § 423.1020.

(2) If a manufacturer requests a hearing and the Administrator upholds CMS' decision to impose a CMP, CMS may initiate collection of the CMP once the Administrator's decision is final.

(f) *Other applicable provisions.* The provisions of section 1128A of the Act (except subsections (a) and (b) of section of 1128A of the Act) apply to CMPs under this section to the same extent that they apply to a CMP or procedure under section 1128A(a) of the Act.

§ 423.2345 Termination of Discount Program Agreement.

(a)(1) CMS may terminate the Discount Program Agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown in relation to the manufacturer's participation in the Discount Program.

(2) The termination must not be effective earlier than 30 days after the date of notice to the manufacturer of such termination and must not be effective prior to resolution of timely appeal requests received in accordance with paragraphs (a)(4) and (5) of this section.

(3)(i) CMS provides the manufacturer with an opportunity to cure any ground for termination for cause or to show the manufacturer is in compliance with the Discount Program Agreement within 30 calendar days of receipt of the written termination notice.

(ii) If the manufacturer cures the violation, or establishes that it was in compliance within the cure period, CMS repeals the termination notice by written notice.

(4) CMS provides upon request a manufacturer with a hearing with the hearing officer concerning such termination if requested in writing within 15 calendar days of receiving notice of the termination. The hearing takes place prior to the effective date of the termination with sufficient time for such effective date to be repealed if CMS determines appropriate.

(5)(i) CMS or a manufacturer that has received an unfavorable determination from the hearing officer may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination.

(ii) The decision of the CMS Administrator is final and binding.

(b)(1) The manufacturer may terminate the Discount Program Agreement for any reason.

(2) Such termination is effective as of the day after the end of the calendar year if the termination occurs before January 30 of a calendar year, or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year.

(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