

the dispute to the TPA in a manner specified by CMS within 60 days of receipt of the information that is the subject of the dispute.

(2) Such notice must be accompanied by supporting evidence that is material, specific, and related to the dispute in a manner specified by CMS.

(3) The manufacturer must not withhold any invoiced discount payments pending dispute resolution with the sole exception of invoiced amounts for applicable drugs that do not have labeler codes provided by the manufacturer to CMS in accordance with § 423.2315(b)(4). If payment is withheld in accordance with this paragraph, the manufacturer must notify the TPA and applicable Part D sponsors within 38 days of receipt of the applicable invoice that payment is being withheld for this reason.

(4) If the manufacturer receives an unfavorable determination from the TPA, or the dispute is not resolved within 60 calendar days of the TPA's receipt of the notice of dispute, the manufacturer may request review by the independent review entity contracted by CMS within—

(i) Thirty calendar days of the unfavorable determination; or

(ii) Ninety calendar days after the TPA's receipt of the notice of dispute if dispute is not resolved within 60 days, whichever is earlier.

(5) The independent review entity must make a determination within 90 calendar days of receipt of the manufacturer's request for review.

(6)(i) CMS or a manufacturer that receives an unfavorable determination from the independent review entity 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.

(7) CMS adjusts future invoices (or implements an alternative reimbursement process if determined necessary by CMS) if the dispute is resolved in favor of the manufacturer.

[77 FR 22172, Apr. 12, 2012, as amended at 85 FR 72909, Nov. 16, 2020]

#### **§ 423.2335 Beneficiary dispute resolution.**

The Part D coverage determination and appeals process as described in §§ 423.558 through 423.638 applies to beneficiary disputes involving the availability and amount of applicable discounts under the Discount Program.

#### **§ 423.2340 Compliance monitoring and civil money penalties.**

(a) *General rule.* CMS monitors compliance by a manufacturer with the terms of the Discount Program Agreement.

(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

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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 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

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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 de-

finied 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]

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(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 paragraph (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 administra-

tion 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 practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

(4)(i) Medication Therapy Management Programs meeting the requirements of § 423.153(d).

(ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

(b) *Exclusions.* Expenditures and activities that must not be included in quality improving activities include, but are not limited to, the following:

(1) Those that are designed primarily to control or contain costs other than those that are related to fraud reduction.

(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 improving 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 pharmacy for care delivery and that are 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 (and that are not related to fraud reduction activities under paragraph (a)(4)(ii) of this section) or to meet regulatory requirements for processing claims, including ICD–10 implementation costs in

excess of 0.3 percent of total revenue under this part, and maintenance of ICD-10 code sets adopted in accordance with 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) [Reserved]

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

(10) Pharmacy network credentialing.

(11) Marketing expenses.

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

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

(14) Any function or activity not expressly permitted by CMS under this part.

[78 FR 31310, May 23, 2013, as amended at 83 FR 16756, Apr. 16, 2018]

#### § 423.2440 Credibility adjustment.

(a) A Part D sponsor may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) A Part D sponsor may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 423.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 4,800 member months and fewer than or equal to 360,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 360,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 4,800 member months.

(e) The credibility adjustment for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the credibility adjustment. The credibility adjustment for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

TABLE 1 TO § 423.2440—CREDIBILITY ADJUSTMENTS FOR PART D CONTRACTS

| Member months  | Credibility adjustment<br>(additional<br>percentage<br>points) |
|----------------|--|
| <4,800 .....   | N/A (Non-credible).  |
| 4,800 .....    | 8.4%.  |
| 12,000 .....   | 5.3%.  |
| 24,000 .....   | 3.7%.  |
| 48,000 .....   | 2.6%.  |
| 120,000 .....  | 1.7%.  |
| 240,000 .....  | 1.2%.  |
| 360,000 .....  | 1.0%.  |
| >360,000 ..... | 0.0% (Fully credible).   |

[85 FR 33911, June 2, 2020]

#### § 423.2450 [Reserved]

#### § 423.2460 Reporting requirements.

(a) Except as provided in paragraph (b) of this section, for each contract year, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, a report that includes the data needed by the Part D sponsor to calculate and verify the medical loss ratio (MLR) and remittance amount, if any, for each contract under this part, including the amount of incurred claims for prescription drugs, supplemental benefits, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 423.2410.

(b) For contract years 2018 through 2022, each Part D sponsor must submit to CMS, in a timeframe and manner

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specified by CMS, the following information:

(1) *Fully credible and partially credible contracts.* For each contract under this part that has fully credible or partially credible experience, as determined in accordance with § 423.2440(d), the Part D sponsor must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under § 423.2410.

(2) *Non-credible contracts.* For each contract under this part that has non-credible experience, as determined in accordance with § 423.2440(d), the Part D sponsor must report to CMS that the contract is non-credible.

(c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.

(d) Subject to paragraph (e) of this section, the MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

(e) With respect to a Part D sponsor that has already submitted to CMS the MLR report or MLR data required under paragraph (a) or (b) of this section, respectively, for a contract for a contract year, paragraph (d) of this section does not prohibit resubmission of the MLR report or MLR data for the purpose of correcting the prior MLR report or data submission. Such resubmission must be authorized or directed by CMS, and upon receipt and acceptance by CMS, is regarded as the contract's MLR report or data submission for the contract year for purposes of this subpart.

[83 FR 16756, Apr. 16, 2018, as amended at 87 FR 27902, May 9, 2022]

#### **§ 423.2470 Remittance to CMS if the applicable MLR requirement is not met.**

(a) *General requirement.* For each contract year, a Part D sponsor must provide a remittance to CMS if the contract's MLR does not meet the minimum percentage required by § 423.2410(b).

(b) *Amount of remittance.* For each contract that does not meet MLR requirement for a contract year, the Part D sponsor must remit to CMS the amount by which the MLR requirement exceeds the contract's actual MLR multiplied by the total revenue of

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the contract, as provided in § 423.2420(c), for the contract year.

(c) *Timing of remittance.* CMS will deduct the remittance from plan payments in a timely manner after the MLR is reported, on a schedule determined by CMS.

(d) *Treatment of remittance.* Payment to CMS must not be included in the numerator or denominator of any year's MLR.

#### **§ 423.2480 MLR review and non-compliance.**

To ensure the accuracy of MLR reporting, CMS conducts selected review of data submitted under § 423.2460 to determine that the MLRs and remittance amounts under § 423.2410(b) and sanctions under § 423.2410(c) and (d), were accurately calculated, reported, and applied.

(a) The reviews will include a validation of amounts included in both the numerator and denominator of the MLR calculation reported to CMS.

(b) Part D sponsors are required to maintain evidence of the amounts reported to CMS and to validate all data necessary to calculate MLRs.

(c)(1) Documents and records must be maintained for 10 years from the date such calculations were reported to CMS with respect to a given contract year.

(2) Part D sponsors must require any third party vendor supplying drug cost contracting and claim adjudication services to the Part D sponsors to provide all underlying data associated with MLR reporting to that Part D sponsor in a timely manner, when requested by the Part D sponsor, regardless of current contractual limitations, in order to validate the accuracy of MLR reporting.

(d) Data submitted under § 423.2460, calculations, or any other MLR submission required by this subpart found to be materially incorrect or fraudulent—

(1) Are noted by CMS;

(2) Appropriate remittance amounts are recouped by CMS; and

(3) Sanctions may be imposed by CMS as provided in § 423.752.

[78 FR 31310, May 23, 2013, as amended at 83 FR 16756, Apr. 16, 2018]