

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 (additional percentage 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