§ 423.2430 Activities that improve health care quality.

(a) Activity requirements. Activities conducted by a Part D sponsor to improve quality fall into one of the categories in paragraph (a)(1) of this section and meet all of the requirements in paragraph (a)(2) of this section.

(1) 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 health outcomes.
quality of care, or provide the technological infrastructure to enhance current quality improving activities or make new quality improvement initiatives possible.

(2) 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.

(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.

(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 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) Fraud prevention activities.

(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.

§ 423.2440 Credibility adjustment.

(a) A Part D sponsor may add a credibility adjustment to a contract’s MLR if the contract’s experience is partially credible, as determined by CMS.

(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 determined by CMS.

(c) For those contract years for which a contract has non-credible experience for their MLR, sanctions under § 423.2410(b) through (d) will not apply.

(d) CMS defines and publishes definitions of partial credibility, full credibility, and non-credibility and the credibility factors through the notice and comment process of publishing the Advance Notice and Final Rate Announcement.

§ 423.2450 [Reserved]

§ 423.2460 Reporting requirements.

(a) For each contract year, each Part D sponsor must submit a report to CMS, in a timeframe and manner specified by CMS, which includes but is not limited to the data needed by the Part D sponsor to calculate and verify the