

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