

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS-4173-P]

RIN 0938-AR69

Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement medical loss ratio (MLR) requirements for the Medicare Advantage Program and the Medicare Prescription Drug Benefit Program under the Patient Protection and Affordable Care Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EST on April 16, 2013.

ADDRESSES: In commenting, please refer to file code CMS-4173-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4173-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4173-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and

Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Iliina Chaudhuri, 410-786-8628 or Iliina.Chaudhuri@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111-148), was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (Pub. L.

111-152) ("Reconciliation Act"), was enacted on March 30, 2010. In this preamble we refer to the two statutes collectively as the Affordable Care Act. The Affordable Care Act includes significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act concerning the Part C Medicare Advantage (MA) and Part D Prescription Drug programs largely focus on beneficiary protections, MA payment reforms, and simplification of MA and Prescription Drug program processes for both programs. Regulations implementing most Affordable Care Act provisions pertaining to the MA and Prescription Drug Program provisions were published on April 5, 2011 (77 FR 22072) and a correction was published June 1, 2012 (77 FR 32407).

This proposed rule would implement section 1103 of Title I, Subpart B of the Reconciliation Act. This section of the Affordable Care Act amends section 1857(e) of the Social Security Act (the Act) to add new medical loss ratio (MLR) requirements. An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care, rather than for such other items as administrative expenses or profit. Because section 1860D-12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e), these new Affordable Care Act medical loss ratio requirements also apply to the Part D program. Under these new requirements, MA organizations and Part D sponsors are required to report their MLR, and are subject to financial and other penalties for a failure to meet a new statutory requirement that they have an MLR of at least 85 percent. The Affordable Care Act requires several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. This proposed rule sets forth CMS' proposed approach to implement these new MLR requirements for the MA and Part D programs.

II. Provisions of the Proposed Regulations

A. Introduction

The new minimum MLR requirement in section 1857(e)(4) of the Act is intended to create incentives for MA organizations and Part D sponsors to reduce administrative costs, and marketing, profits, and other uses of the funds earned by plan sponsors and help

to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans. Under this proposed rule, an MLR would be determined based on the percentage of contract revenue spent on clinical services, prescription drugs, quality improving activities, and direct benefits to beneficiaries in the form of reduced Part B premiums. The higher the MLR, the more the MA organization or Part D sponsor is spending on claims and quality improving activities and the less they are spending on other things. MA organizations and Part D sponsors will remit payment to CMS when their spending on clinical services, prescription drugs, quality improving activities, and Part B premium rebates, in relation to their total revenue, is less than the 85 percent MLR requirement established under section 1857(e)(4) of the Act. We believe the payment remittance of section 1857(4)(e)(A) of the Act is designed to encourage the provision of value to policyholders by creating incentives for MA organizations and Part D sponsors to become more efficient in their operations. If a plan sponsor fails to meet MLR requirements for more than 3 consecutive years, they will also be subject to enrollment sanctions and, after 5 consecutive years, to contract termination.

The Affordable Care Act also enacted a new MLR requirement under section 2718 of the Public Health Service Act (PHSA) that applies to issuers of employer group and individual market private insurance. We have already issued regulations implementing this private insurance MLR. A request for information (RFI) relating to the PHSA MLR provision was published in the April 4, 2010 (75 FR 19297) **Federal Register**. In the December 1, 2010 **Federal Register** (75 FR 74864), we published an interim final rule implementing the PHSA MLR requirements for health insurance issuers. Under this interim final rule, health insurance issuers must report an MLR and related supporting data by state and market (individual, small group or large group). If the required MLR threshold is not met in any one year, generally 85 percent in the large group market and 80 percent in the small group or individual market, health insurance issuers must provide a rebate to enrollees, which is generally done by providing it to the policyholder on behalf of the enrollees. Finally, enforcement of the reporting and rebate requirements of section 2718(a) and (b) of the PHSA are addressed, as specifically authorized in section 2718(b)(3) of the PHSA. This interim

final rule applies to covered private health insurance issuers beginning January 1, 2011.

Since then, we have made several revisions and technical corrections to 45 CFR part 158. On March 23, 2012, we also published a final rule (75 FR 17220), entitled "Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment," that establishes standards for the establishment and operation of a transitional reinsurance program, temporary risk corridors program, and a permanent risk adjustment program. These programs do not go into effect until January 1, 2014. Therefore, the commercial MLR and rebate calculations in the December 1, 2010 interim final rule do not take these programs into account. Section 2718(c) of the PHSA directs the National Association of Insurance Commissioners (NAIC), subject to certification by the Secretary, to establish uniform definitions and calculation methodologies related to MLRs. In the MLR IFR, we adopt the recommendations in the NAIC's model MLR regulations. In 45 CFR 158.221(c) of the MLR IFR allows an issuer to deduct from earned premium federal and state taxes, and assessments, and in some instances, community benefit expenditures. We interpreted the MLR IFR to mean that a tax exempt not-for-profit issuer could deduct either state premium tax or community benefit expenditures, but not both. Therefore, on December 7, 2011, we published a final rule with comment period (76 FR 76574) to revise the MLR IFR, in which we clarified that any issuer may deduct either state premium tax or community benefit expenditures, but not both. The final rule limited the community benefit expenditures deduction at the highest premium tax rate in the state. On December 7, 2012, we published a proposed rule (73 FR 73117), which discusses revising the policy of community benefit expenditures, in addition to discussion on the treatment of premium stabilization payments, timing of the annual commercial MLR reports, and distribution of rebates. We will call the body of rules on commercial MLR requirements the "commercial MLR rules."

Section 2718 of the PHSA directed the NAIC to make recommendations to the Secretary of Health and Human Services (the Secretary), subject to certification by the Secretary. NAIC's recommendations regarding definitions and methodologies for calculating MLRs were adopted in the commercial MLR rules. The NAIC, in making its recommendations, conducted a

thorough and transparent process in which the views of regulators and stakeholders were discussed, analyzed, addressed and documented in numerous open forums held by a number of stakeholders, including state insurance departments (which includes the commissioner/superintendent and directors), the NAIC, issuers, and consumer representatives. The commercial MLR rules largely adopted the NAIC recommendations.

In this proposed rule for the MA and Prescription Drug Benefit Programs, we are using the commercial MLR rules as a reference point for developing the Medicare MLR requirements. We have decided to do this for several reasons. First, the intent of the provisions to help ensure value for health coverage is comparable. Second, keeping the requirements similar will limit the burden on organizations that participate in both markets (the overwhelming majority of those offering Medicare products). Third, aligning the commercial and Medicare regulations will make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes, including by Medicare beneficiaries. We recognize that some areas of the regulation for private health insurance plans needed to be revised to fit the unique characteristics of the MA and Prescription Drug plan (PDP) markets. For example, we propose that MA and Part D PDP MLRs will be reported on a contract basis, rather than by state and market.

B. Scope, Applicability, and Definitions

As noted previously, section 1857(e)(4) of the Act, which establishes requirements for a minimum MLR directly applies to the MA program. The requirements at section 1857(e)(4) of the Act also apply to the Medicare Prescription Drug Benefit Program, because section 1860D-12(b)(3)(D) of the Act requires that the contractual requirements at section 1857(e) of the Act apply to the Part D program.

1. Scope and Applicability

Part 422 of the Code of Federal Regulations (CFR) regulates the MA Program, and Part 423 of the CFR regulates the Part D program. This proposed rule would implement sections 1857(e)(4) and 1860D-12(b)(3)(D) of the Act by adding to both Parts 422 and 423 a new Subpart X, "Requirements for a Minimum Medical Loss Ratio."

The proposed Subpart X for the MA program has the same structure as the proposed Subpart X for the Part D program. Thus, discussion in this

preamble is organized by each Subpart X section, and both MA and Part D proposals are discussed within each section. Any differences between the MA and Part D proposals are described within the relevant section.

Because section 1857(e) of the Act, where the MLR requirement appears in statute, does not directly apply to Cost HMOs/CMPs (Cost Health Maintenance Organizations/Competitive Medical Plans), HCPPs (Health Care Prepayment Plans) or PACE (Program of All-Inclusive Care for the Elderly) organizations, the proposed MLR requirements set forth in this rule generally do not apply to section 1876 Cost HMO/CMPs, section 1833 HCPPs, or to PACE organizations, which are authorized under section 1894 of the Act.

However, given the incorporation of section 1857(e)(4) by 1860–12(b)(3) of the Act, we believe that, to the extent Cost HMOs/CMPs offer Part D as an optional supplemental benefit under § 417.440(b)(2)(ii), these requirements would apply to that Part D product. While an HCPP cannot offer Part D, to the extent an employer or union offering an HCPP to its members separately offers Part D coverage as an Employer/Union Only PDP under section 1860D–22(b) of the Act, the MLR requirement does apply to these Part D programs. Therefore, for Cost HMOs/CMPs and employers or unions offering HCPPs, only those offering Part D are subject to the MLR requirements, and then only for the Part D portion of their benefit offerings. Since the MLR rule can only apply to the Part D portion of the benefits offered by Cost HMOs/CMPs and employers/unions offering HCPPs, we will treat them more like PDPs than MA–PDs for MLR purposes. Cost HMOs/CMPs and employers/unions offering HCPPs bid on Part D and receive Part D payments based on their bid. Thus, we propose to require remittances, suspend enrollment, and/or terminate such Part D contracts based on whether the cost HMOs/CMPs or employers/unions offering HCPPs meet the MLR requirement for the Part D benefits they offer under their contract with CMS. In essence, a Cost HMO/CMP or an HCPP that did not meet the minimum MLR requirement on the Part D portion of the benefits it provides to Medicare enrollees would potentially (after 3 consecutive years) be forced to stop enrolling new individuals in such Part D coverage and, after 5 consecutive years, would potentially lose the Part D portion of its contract.

For PACE organizations offering Part D, the situation is different. Similar to Cost HMOs/CMPs and HCPPs, we do

not believe that the MLR requirements at section 1857(e)(4) of the Act and this proposed rule apply to the A/B portion of a PACE organization's benefit offering. In-so-far as section 1857(e)(4) of the Act does not apply to PACE organizations directly, its application to them would be only through its application to Part D through incorporation at section 1860D–12(b)(3) of the Act. However, unlike Cost HMOs/CMPs and section 1833 HCPPs addressed in section 1876 of the Act, which are not compelled by any specific statutory or regulatory authority to offer Part D benefits, PACE organizations are required by both statute and regulation to provide drug coverage (see section 1894(b)(1)(A)(i) of the Act and § 460.92(a)). Thus, while Cost HMOs/CMPs and HCPPs could continue to operate without offering Part D coverage to their enrolled members, PACE organizations as a practical matter could not, as they would likely have to absorb the full cost of fulfilling their obligation to cover drugs. To the extent that drug coverage other than Part D drug coverage could not be offered by PACE organizations, such a result would effectively terminate not only the Part D drug plan offered by a PACE organization, but the PACE organization itself. This result would have the effect of applying a Part D penalty on Part A benefits, Part B benefits and Medicaid benefits offered to dual eligibles. The Congress did not directly apply the MLR rule directly to these benefits (as MA–PD rules only apply to the Part D component of PACE plans). We believe this result would be inconsistent with the intent of the statutory authority establishing the PACE program at section 1894 of the Act as an option for dual eligibles. We note, however, that we have the authority to waive application of Part D requirements (including the new MLR requirements) to PACE organizations as such application could potentially result in the inability of a PACE program to continue, which we do not believe the Congress intended. Specifically, section 1860D–21(c)(2) of the Act (incorporated for PACE under section 1860D–21(f)(1)) of the Act provides authority to waive provisions, such as the MLR requirement, to the extent such provisions duplicate, conflict with, or as may be necessary in order to improve coordination between Part D and PACE. We believe that application of the Part D MLR requirement to PACE organizations, even for only their Part D offering, would conflict with our understanding of the intent of the PACE statute and implementing regulations, as

it could thwart the ability of the PACE plan to serve its special needs enrollees. Therefore, we propose not to apply the Part D MLR requirements to the Part D offerings of PACE organizations.

2. Definitions

In § 422.2401 and § 423.2401, we propose certain definitions pertaining to the MLR provisions. Note that there also are terms defined in other sections of the Part 422 Subpart X and Part 423 Subpart X (for example, “incurred claims” is defined in § 422.2420(b) and § 423.2420(b), and “quality improving activities” are defined in § 422.2430 and § 423.2430.)

First, we propose that the acronym MLR be used to refer to the medical loss ratio referenced in throughout Part 422, Subpart X and Part 423, Subpart X.

We propose to define non-claims costs as those expenses for administrative services that are not: incurred claims, payments toward reducing the Part B premium for MA plan enrollees, expenditures on quality improving activities, licensing and regulatory fees, or state and federal taxes and assessments that cannot be deducted from total revenue.

C. General Requirements for MA Organizations and Part D Sponsors

Sections 1857(e)(4) and section 1860D–12 of the Act (which incorporates section 1857(e)(4) of the Act by reference) set forth a requirement that MA organizations and Part D sponsors report MLRs, and that these MLRs meet the statutory standard of 85 percent. Those organizations that do not meet this MLR requirement will be required to pay remittances. If organizations are unable to meet the minimum MLR for 3 consecutive years, they will also be subject to enrollment sanctions and for 5 consecutive years, contract termination. MA organizations and Part D sponsors will be required to submit data to CMS that will allow enrollees of health plans, consumers, regulators, and others to take into consideration MLRs as a measure of health insurers' efficiency. Similar to the intentions of section 2718 of the PHS Act, we believe that this provision is intended to provide beneficiaries both with information needed to better understand how much of plan sponsor revenue is used to pay for services, quality improving activities, and direct rebates for enrollees versus how much is used to pay for the “non-claims,” or administrative expenses, incurred by the plan sponsor as well as profits, and to provide incentives to spend more on the former group activities and less on the latter.

This section discusses two general issues regarding our proposed implementation of the MLR requirement: the level of aggregation at which MLRs must be reported, and the sanctions facing MA organizations and Part D sponsors when they do not meet the MLR requirement.

1. Aggregation of MLR to the Contract Level

Under the MA program, MA organizations offer MA plan benefit packages (MA plans, defined at § 422.2) under contracts with CMS. Plans offered under an MA contract can be MA-only plans (which only offer non-drug benefits) and/or MA-PD plans (which also offer Part D qualified prescription drug coverage). Further, under the Part D program, Part D sponsors, as defined in § 423.4, offer plan benefit packages (prescription drug plans or PDPs) under contracts with CMS. An MA organization or a Part D sponsor can have one or multiple contracts with CMS and, under each contract, the MA organization or Part D sponsor can offer one or multiple plans in which beneficiaries may enroll.

We propose at § 422.2410(a) and § 423.2410(a) that an MA organization and a Part D sponsor must report an MLR for each contract they have with CMS. We believe that the contract is the best level of aggregation for MLR reporting in Medicare. The contract provides the legal framework for our statutory and regulatory authority over MA organizations and Part D sponsors. For example, an MA organization is defined, at section 1857(a) of the Act and § 422.2, as a state-licensed entity that is certified by CMS as meeting the CMS contract requirements.

Aggregating MLRs to the contract level is an approach that closely parallels the commercial MLR approach, which aggregates the MLR to the state and market level, rather than to each specific health plan policy or benefit offering. We note that MA and PDP contracts are also often executed at the state level.

Moreover, we believe that requiring contract-level MLRs will promote program stability and the continued availability to beneficiaries of a variety of benefit structures in MA and Part D plans. Lastly, contract-level reporting is administratively less burdensome for MA organizations and Part D sponsors; for example, administrative costs will not need to be disaggregated by plan.

We also considered the approach of requiring MLR reporting at the plan level, since beneficiaries enroll in a plan and experience their health care at the plan level (known as plan benefit

package level), and since CMS' bids and payments occur at this level. In addition, for a contract with a large number of plans, it arguably would be less disruptive to apply an enrollment or termination sanction at the plan level rather than the contract level. Plan-level MLRs also would be based on fewer enrollees and be more prone to random variations in claims experience. Contract-level MLRs would generally represent a more stable population and a larger claims base, resulting in more reliable and, therefore, more meaningful MLRs. In future years, we may reconsider the approach of calculating MLRs at the plan level.

Finally, we considered applying the MLR at the organization level. Because many MA organizations and Part D sponsors are national organizations, an MLR at this level of aggregation would be less meaningful, particularly for beneficiaries who are comparing plans in a specific geographic area. Because resource commitments to services offered may differ by market, due to differences in labor costs, demand, and competition, a national MLR would provide less information to consumers. In addition, we determined that the application of enrollment-related and termination action sanctions to an MA organization or Part D sponsor that is nationally representative would have a much larger enrollee impact than contract-level sanctions.

In short, we believe our proposal of contract-level aggregation for MLR calculation is both reasonable and in alignment with important goals of program stability and administrative simplification.

We note that, while the statutory language at 1857(e)(4) of the Act uses the terms "MA plan," it also uses the term "contract" six times. Further, the requirement that an MA "plan" "remit" an amount to CMS when the minimum MLR is not met clearly refers to the organization offering one or more MA plans, and not to a specific plan benefit package, which cannot take an action such as remitting an amount to CMS. We believe that the statute uses the term "plan" in the generic sense in which it is often used to refer to an organization offering products, and that CMS thus has the discretion to apply and enforce the MLR requirement at the contract level.

Note that the proposed requirement at § 422.2410(a) and § 423.2410(a) refers to "an MLR" for each contract. This proposal means that the MLR calculation for a contract that includes MA-PD plans must combine non-drug costs with prescription drug costs and non-drug revenues with prescription

drug revenues, across all plans under the contract. We also considered the approach of requiring MA organizations to report two MLRs for each contract that include MA-PD plans: one for nondrug benefits and another for prescription drug benefits. We decided to require one MLR per MA contract, as this aligns better with the commercial MLR requirements, which require one MLR per issuer regardless of plan type, and which include prescription drug costs along with other expenditures on health care services. Further, it is not clear how meaningful having two effectively partial MLRs would be to consumers.

Finally, Part C rebates often fund the Part D premiums for MA-PD plans and thus are used to provide Part D benefits. Since most MA contracts include MA-PD plans, requiring a single MLR for each MA contract is an administratively simple approach that eliminates the need for disaggregation of these rebates.

2. Remittance Requirement

Per section 1857(e)(4)(A) of the Act and as set forth in proposed § 422.2410(b) and § 423.2410(b), if we determine for a contract year that an MA organization or Part D sponsor has an MLR for a contract year that is less than 0.85 (85 percent), the MLR requirement would not have been met and the sponsoring organization would be required to remit a payment to CMS. The amount of the remittance would be equal to the product of: (1) The total revenue under the contract for the contract year; and (2) the difference between 0.85 and the contract's MLR. Total revenue is discussed later in section II.D. of this proposed rule.

In order to support the reported MLR for each contract year, and in order to further allow comparison of MLRs across product lines (for example, Medicare and commercial), MA organizations and Part D sponsors would be required to report to CMS certain data concerning the MLR. Reporting requirements are addressed in section II.G. of this proposed rule.

3. Enrollment Sanction

As set forth in proposed § 422.2410(c) and § 423.2410(c), if an MA or PDP contract fails to have an MLR of at least 0.85 for 3 or more consecutive contract years, we would not permit the enrollment of new enrollees in plans under that contract during the second succeeding contract year. We interpret this requirement to mean that, if a contract fails to have an MLR of 0.85 for 3 or more consecutive years, we would halt all new enrollment into all plans covered under that contract. The year

for which the enrollment sanction would apply would be the second succeeding year after the third consecutive year in which the MA organization or Part D sponsor fails to meet the MLR requirement. For example, the MLRs for contract years 2014 through 2016 would be reported in 2015 through 2017. If a contract did not meet the MLR requirement for the 2014, 2015, and 2016 contract years, we would not permit new enrollment in plans under that contract in 2018, which is the second succeeding contract year after the third consecutive year of failure (2016) to meet the MLR requirement.

As discussed later in this section, if an MA or PDP contract fails to meet the MLR requirement for 5 consecutive years, we are required by statute to terminate the contract. Because a contract that fails to meet the MLR requirement for 4 consecutive years has failed to meet the requirement for 3 consecutive years, we are thus proposing in § 422.2410(c) and § 423.2410(c) to clarify that an enrollment sanction would apply to contracts that fail to meet the MLR for 3 or more (that is, 4) consecutive years.

4. Termination

If the contract fails to have an MLR of at least 0.85 (85 percent) for 5 consecutive contract years, we are required under section 1857(e)(4)(C) of the Act to terminate the contract. This requirement is reflected in proposed § 422.2410(d) and § 423.2410(d). We propose to implement section 1857(e)(4)(C) of the Act by terminating the contract for the year following the year in which the plan sponsor is required to report the MLR for the fifth year. With respect to termination, we propose to implement the “second succeeding contract year” requirement in a manner similar to how we propose to implement the enrollment termination after 3 or more consecutive years of not meeting the minimum MLR requirement. Thus, for a contract that failed to meet the MLR requirement in 2014 through 2018, we would terminate the contract in 2020.

D. Calculation of Medical Loss Ratio

1. Definition of Medical Loss Ratio

In this section, we address the calculation of an MLR for MA and Part D contracts. Generally, our approach to what counts as costs and revenues (which are in the numerator and denominator, respectively) is consistent with the approach in the commercial MLR rules. Proposed § 422.2420(a) and § 423.2420(a) set forth a high-level

definition of the MLR as a ratio of the numerator defined in paragraph (b) to the denominator defined in paragraph (c). We propose to follow the commercial MLR rules by allowing MA organizations and Part D sponsors to increase the MLRs of low-enrollment contracts with a credibility adjustment. This adjustment is discussed in section F.

Proposed section § 422.2410(a)(2) provides that the MLR for an MA contract not offering Part D prescription drug benefits would only be required to reflect the costs and revenues related to the benefits defined at § 422.100(c), basic benefits, mandatory supplemental benefits, and optional supplemental benefits. If the MA contract includes MA–PD plans, the MLR would also under this proposed rule be required to reflect costs and revenues for benefits described at § 423.104(d)(e), and (f), standard coverage, alternative coverage, and enhanced alternative coverage. Proposed § 423.2410(a)(2) also specifies that the MLR for a PDP contract would be required to reflect costs and revenues for standard coverage, alternative coverage, and enhanced alternative coverage.

Details about our proposal for the calculation of the numerator and denominator for MA and PDP contracts are discussed later in this section. For MA and PDP contracts, the MLR would be calculated using the cost and revenue data for a contract year, which is a 1-year reporting period in accordance with 1857(e)(4) of the Act, in contrast to the 3-year period (starting in 2014) for the commercial MLR.

2. MLR Numerator

In proposed § 422.2420(b) and § 423.2420(b) for MA and Part D contracts, respectively, we identify the elements that we would require to be included in the numerator for a contract’s MLR. Proposed § 422.2420(b)(1) and § 423.2420(b)(1) identify two basic elements that constitute the MLR numerator: incurred claims (as defined in paragraphs (b)(2) through (b)(4) for both programs) and expenditures under the contract for activities that improve health care quality, which are referenced at paragraph (b)(1)(iii) for both programs, and described in detail at sections § 422.2430 and § 423.2430. This approach of including incurred claims and quality improving activities mirrors the commercial MLR rules.

In addition, under our proposal, the MLR numerator for MA contracts would include a third element, which is unique to MA contracts: the amount to reduce the Part B premium, if any, for

all MA plans under the contract for the contract year. The Part B premium reduction is a benefit design option available to MA organizations, and is one of five uses of Part C rebate dollars described at § 422.266(b) and in section II.D.3. of this proposed rule. Because this is an allowed benefit under MA, we are allowing the use of these dollars to pay for the Part B premium to be in the numerator.

We propose that, under an assumptive or 100 percent indemnity reinsurance agreement, the assuming MA organization or Part D sponsor be required to report incurred claims in the numerator for those contracts, and that no incurred claims for the contracts under the agreement be permitted to be reported by the ceding MA organization or Part D sponsor. This clarification would ensure that incurred claims implicated in assumptive or 100 percent indemnity agreements are neither double counted by both the assuming and ceding MA organizations and Part D sponsors nor omitted by both the assuming and ceding organizations. Instead, the incurred claims would be counted for MLR purposes only once; by the assuming MA organization or Part D sponsor.

a. Incurred Claims

We propose that incurred claims consist of several amounts. For the MA program, incurred claims would include direct claims that the MA organization pays to providers (including under capitation contracts) for covered services that are provided to all enrollees under the contract, as described at § 422.2420(b)(2)(i).

In addition, under proposed § 422.2420(b)(2)(ii) and § 423.2420(b)(2)(i), for MA contracts that include MA–PD plans and for PDP contracts, respectively, incurred claims would be required to include only drug costs that are “actually paid” by the Part D sponsor. The concept of “actually paid” is defined at in § 423.308 and refers to Part D costs that must be actually incurred by the Part D sponsor, net of any direct or indirect remuneration from any source. Prescription drug rebates are rebates that pharmaceutical companies pay to MA organizations or Part D sponsors based upon the drug utilization of the MA organization’s or Part D sponsor’s enrollees and should be deducted from incurred claims. This approach aligns with the commercial MLR rules, which require that prescription drug rebates be deducted from incurred claims. In addition, “actually paid” claims refers to those costs for which the MA organization or Part D sponsor is liable,

through all phases of the benefit. Thus, the reinsurance portion of claim costs in the catastrophic phase of the benefit is also included in the numerator of the MLR.

For both MA and Part D contracts, under proposed § 422.2420(b)(2)(iii) through (xi) and § 423.2420(b)(2)(ii) through (x), incurred claims would also be required to reflect the following: unpaid claims reserves for the current contract year, including claims reported and in the process of adjustment; percentage withholds from payments made to contracted providers; incurred but not reported claims based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity and changes in other claims-related reserves; claims that are recoverable for anticipated coordination of benefits (COB); and claims payments recoveries received as a result of subrogation; reserves for contingent benefits and the medical or Part D claim portion of lawsuits. We follow the commercial MLR rules in proposing to allow the amount of claim payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, to be included in incurred claims. Fraud reduction efforts include fraud prevention as well as fraud recovery. The preamble to the commercial MLR rule stated and we continue to believe that without such an adjustment, the recovery of paid fraudulent claims would reduce an MLR and could create a disincentive to engage in fraud reduction activities. Thus, requiring that incurred claims reflect claims payments recoveries up to a limit would help mitigate whatever disincentive might occur if fraud reduction expenses were treated solely as non-claims and non-quality improving expenses. However, allowing an unlimited adjustment for fraud reduction expenses would undermine the purpose of requiring issuers to meet the MLR standard.

For MA and MA-PD contracts, incurred claims would be required to reflect the amount of incentive and bonus payments made to providers, as set forth at § 422.2420(b)(2)(xi). Medical incentive pools are arrangements with providers and other risk sharing arrangements whereby the MA organization agrees to either share savings with or make incentive payments to providers. These payments would be required to be included under incurred claims and would not be permitted to be counted under quality improving expenditures.

b. Adjustments to and Exclusions From Incurred Claims

After proposing which elements should be included in incurred claims, we propose which elements would be deducted from incurred claims and which elements would not be included in incurred claims at all. Under proposed § 422.2420(b)(3) and § 423.2420(b)(3), two adjustments would be deducted from incurred claims for the MA and Part D programs, both of which are currently required in the commercial MLR rules. First, prescription drug rebates and other direct or indirect remuneration as defined in § 423.308 that are received by the MA organization or Part D sponsor would be required to be deducted. Second, any amounts paid to providers that were recovered because they were overpayments would have to be deducted from incurred claims.

Next, there are several expenditures that would not be included in incurred claims for MA and PDP contracts, as provided in proposed § 422.2420(b)(4) and § 423.2420(b)(4). The three types of administrative costs that would be required to be excluded from incurred claims reflect the provisions in the commercial MLR rules: (1) Amounts paid to third party vendors for secondary network savings; (2) amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management; and (3) amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee, such as medical record copying costs, attorneys' fees, subrogation vendor fees, bona fide service fees, compensation to paraprofessionals, janitors, quality assurance analysts, administrative supervisors, secretaries to medical personnel and medical record clerks would not be permitted to be included in incurred claims. Regarding item (2), for example, if an MA organization, contracts with a behavioral health, chiropractic network, or high technology radiology vendor, or if an MA organization or Part D sponsor contracts with a pharmacy benefit manager, and the vendor reimburses the provider at one amount but bills the MA organization or Part D sponsor at a higher amount to cover the vendor's network development, utilization management costs, claims processing, and profits, then the amount that exceeds the reimbursement to the provider would not under our proposal

be permitted to be included in incurred claims.

Finally, under proposed § 422.2420(b)(4)(ii) and § 423.2420(b)(4)(ii), amounts paid to CMS by an MA organization or Part D sponsor as a remittance under § 422.2410(b) or § 423.2410(b) would not be permitted to be included in incurred claims for any contract year.

3. MLR Denominator

We propose at § 422.2420(c) and § 423.2420(c) that the MLR denominator would equal the total revenue under the contract (as described in § 422.2420(c)(1) and § 423.2420(c)(1)), net of deductions set forth in § 422.2420(c)(2) and § 423.2420(c)(2), taking into account the exclusions described in § 422.2420(c)(3) and § 423.2420(c)(3), and in accordance with § 422.2420(c)(4) and § 423.2420(c)(4). Total revenue for the MA program, as defined under proposed § 422.2420(c)(1) and § 423.2420(c)(1), must be reported on a direct basis and would mean our payments to the MA organization for all enrollees under a contract, including, for MA plans under a contract that offer Part D, direct subsidy payments and reinsurance payments as reconciled per § 423.329(c)(2)(ii); all premiums paid by or on behalf of enrollees to the MA organization as a condition of receiving coverage under an MA plan; our payments for low income premium subsidies under § 423.780; all unpaid premium amounts that an MA organization or Part D sponsor could have collected from enrollees in the plan(s) under the contract; all changes in unearned premium reserves, and risk corridor payments under § 423.315(e). We note that MA organizations or Part D sponsors that volunteer to waive the portion of the monthly adjusted basic beneficiary premium that is a *de minimis* amount above the low-income benchmark for a subsidy eligible individual per section 3303(a) of the Affordable Care Act would not be permitted to consider the *de minimis* amount an unpaid premium amount that could have been collected from beneficiaries. We propose that calculation and reporting of total revenue for purposes of the Medicare MLR would include total risk-adjusted payments, and would take into account payments or receipts for risk corridors and payments under the reinsurance phase of the Part D benefit (adjusted for reconciled amounts). While this approach is generally consistent with the commercial MLR rules, it is not identical. We believe that the nature of the payment mechanisms required under these programs support this

approach. The payments which we make to MA organizations and Part D sponsors are risk-adjusted as part of the payment calculation to reflect the appropriate adjustment to revenue to reflect the risk profile of each enrolled beneficiary. Further, risk corridors and reinsurance, which are permanent features of Part D payment, are adjustments to plan payment. In the case of risk corridors, payment adjustments reflect the extent to which an MA organization or Part D sponsor over- or under-bid for their projected population. Part D reinsurance is more appropriately classified as a cost-based reimbursement methodology than reinsurance, per se, and as such is appropriately treated as revenue.

MA organizations would also be required to account for Part C rebate payments in their total revenue. Rebates are paid for enrollees in plans with bids below the benchmark described under section 1853(a)(1)(E) of the Act, and may be allocated to one or more uses: reduction of A/B cost sharing and reduction of the premium for additional non-drug benefits, reduction of the Part B premium (mentioned previously), and reduction of the Part D basic premium and Part D supplemental premium. Essentially, the effect of rebates is that the beneficiary pays a smaller share of total plan premium (the total price of the plan benefit package) and the government pays a larger share. Thus, these funds would correctly be accounted for as revenue.

Total revenue for the Part D program, as defined at § 423.2420(c)(1), means CMS' payments to the Part D sponsor for all enrollees under a contract, including: direct subsidy payments at § 423.329(a)(1), reinsurance payments at § 423.329(a)(2), and payment adjustments resulting from reconciliation per § 423.329(c)(2)(ii); all premiums paid by or on behalf of enrollees to the Part D sponsor as a condition of receiving coverage under a plan; CMS' payments for low income premium subsidies under § 423.780; all unpaid premium amounts that a Part D sponsor could have collected from enrollees in the plan(s) under the contract; and risk corridor payments under § 423.315(e).

Adjustments to and exclusions from total revenue. After proposing which elements should be included in total revenue, we propose which elements must be deducted from and which elements should not be included in total revenue. CMS is largely following the commercial MLR rule in the treatment of adjustments and exclusions.

There are four categories of expenditures that would be required to

be deducted from total revenue for both MA and PDP contracts, as provided under proposed § 422.2420(c)(2) and § 423.2420(c)(2). Note that, unlike commercial issuers, MA organizations and Part D sponsors are exempt from state premium tax "or similar tax" on their Part C and D premium revenues, per sections 1854(g) and 1860D-12(g) of the Act.

Three of these categories that would be deducted from total revenue for a contract are taxes and fees. First, federal taxes and assessments allocated to MA plans and enrollees would be deducted from total revenue for purposes of calculating the MLR. Two examples are the "user fee" described in section 1857(e)(2) of the Act and the portion of the "annual fee on health insurance providers" attributable to Part C and D premium revenues described in section 9010 of the Affordable Care Act. Second, licensing and regulatory fees, consisting of statutory assessments to defray operating expenses of any state or federal department and examination fees in lieu of premium taxes as specified by state law, would be deducted from total revenue for purposes of calculating the MLR. Third, state taxes and assessments that would be deducted from total revenue for purposes of calculating the MLR would include: (1) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the state directly; (2) guaranty fund assessments; (3) 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; and (4) state income, excise, and business taxes other than premium taxes.

We note that there are some taxes and fees that would not be permitted to be deducted from the MLR denominator. For example, we propose that the denominator would not include fines and penalties of regulatory authorities, and fees for examinations by any state or federal departments that are not specified in § 422.2420(c)(2)(i) and § 423.2420(c)(2)(i). Fines, penalties, and fees that do not fall under § 422.2420(c)(2)(i) and § 423.2420(c)(2)(i) would be appropriately reported as non-claims costs, not as an adjustment to total revenue. Federal income taxes on investment income and capital gains would not be deducted from total revenue for purposes of calculating the MLR and would instead be considered a non-claims cost. Finally, we propose that state sales taxes may not be deducted from total revenue if the MA

organization or Part D sponsor does not exercise the options of including such taxes with the cost of goods and services purchased. Examples include any portion of commissions or allowances on reinsurance assumed that represent specific reimbursement of premium taxes and any portion of commissions or allowances on reinsurance ceded that represents specific reimbursement of premium taxes.

The fourth category of expenditures that would be deducted from total revenue under our proposal is community benefit expenditures. Federal income tax-exempt issuers are required to make community benefit expenditures to maintain their federal income tax exempt status. The commercial MLR rules allow a federal income tax-exempt issuer to deduct community benefit expenditures in the same manner that a for-profit issuer is allowed to deduct its federal income taxes. We propose to align with the commercial MLR regulations by defining community benefit expenditures, up to a cap, at § 422.2420(c)(2)(iv) and § 423.2420(c)(2)(iv) as 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.

For purposes of the commercial MLR rule, the NAIC determined that the deduction for community benefit expenditures should be limited to a reasonable amount to discourage fraud and abuse. We propose to follow the commercial MLR approach as suggested in the December 7, 2012 proposed rule (73 FR 73117) by allowing federal income tax-exempt MA organizations and Part D sponsors to deduct community benefit expenditures in the same manner that a for-profit issuer is allowed to deduct its federal income taxes, up to the limit of 3 percent of total revenue under this part or the highest premium tax rate in the state for which the MA organization or Part D sponsor is licensed. As one contract may span more than one state, we seek comment on methods to apply the limit in these circumstances, perhaps by blending the highest premium tax rates for the states in which the contract is offered. Organization-wide community benefit expenditures would be required to be allocated to a contract or multiple contracts as required under paragraph (d)(1).

Next, amounts that would not be included in total revenue under our proposal include the amount of unpaid premiums that the MA organization or Part D sponsor can demonstrate to us

that it made a reasonable effort to collect, as required under § 422.74(d)(i), and § 423.44(d)(1)(i), respectively. In addition, HITECH, or EHR, payments would not be included, specifically EHR incentive payments for meaningful use of certified electronic health records by qualifying MAOs, MA EPs and MA-affiliated eligible hospitals (as administered under Part 495 subpart C), and EHR payment adjustments for a failure to meet meaningful use requirements (as administered under Part 495 subpart C). Such incentive payments and payment adjustments would not be considered for purposes of MLR calculations to be covered under this part. Finally, Coverage Gap Discount Program payments under § 423.2320 would not be included in total revenue under our proposal. The Coverage Gap Discount amounts represent a 50 percent discount on the negotiated price of applicable (generally, brand) drugs for applicable (generally, non-low-income) beneficiaries, and is essentially an amount paid by pharmaceutical manufacturers and passed through to applicable beneficiaries and does not represent revenue to the MA organization or Part D sponsor.

Note that we are not proposing to adjust total revenue for commercial reinsurance in this proposed rule because, as stated in the preamble to the commercial MLR rules, this largely would provide a tool for issuers to manipulate reported premiums.

4. Projection of Net Total Revenue

We are proposing that, when calculating Medicare MLRs, MA organization and Part D sponsors would be required to account for all Part C and D revenue that would be paid after the final risk adjustment reconciliation occurs, and all Part D revenue that would be paid after all reinsurance and risk corridor reconciliations occur.

Risk adjustment is an adjustment to payment that reflects expected relative risk of a beneficiary. Reinsurance reconciliation is a cost-based adjustment to the Part D prospective payments made throughout the year, and the net reinsurance payments would be counted as total revenue. Risk corridors are risk-sharing arrangements around the Part D direct subsidy payments, and we are proposing to count all adjustments through the risk corridor process as adjustments to total revenue.

We propose to require MA organizations and Part D sponsors to project revenue from all expected reconciliation processes, and account for the net adjustments from all and any risk adjustment reconciliations, risk

corridor reconciliations, and reinsurance reconciliations as adjustments to total revenue. Because the same data underlies reconciliation and MLR reporting, we would not expect large discrepancies between data reported before and after reconciliation. We propose to validate that the data used in reconciliation is consistent with that used in MLR reporting, and make appropriate payment adjustments should there be irregularities in reporting. We also propose that the MLR would be reported once and that neither any reopening(s) of any reconciliation processes nor any risk adjustment data validation audits would result in a reopening of the MLR reported for a contract year.

5. Allocation of Expenses

MA organizations and Part D sponsors would, under our proposal, be required to properly allocate all expenses stemming from each contract, as provided under proposed § 422.2420(d) and § 423.2420(d). We propose that each expense would be required to be included under only one type of expense, unless a portion of the expense fits under the definition of one type of expense and the remainder fits into a different type of expense, in which case the expense would be required to be pro-rated between types of expenses. Expenditures that benefit multiple contracts, or contracts other than those being reported, including but not limited to those that are for, or benefit, commercial plans, would have to be reported on a pro rata share basis. This proposed approach aligns with the commercial MLR rules.

There are several different methods for allocating costs incurred by MA organizations and Part D sponsors that would be allowable under our interpretation of statutory accounting principles. All costs reported by MA organizations or Part D sponsors would have to be allocated according to generally accepted accounting methods that yield the most accurate results and are well-documented. An MA organization's or Part D sponsor's allocation method would be required to illustrate the costs associated with a specific activity and any resulting effect the activity has had on its MA or Part D line of business. If the expense is related to a specific activity, the allocation of such expenditure would have to be on a direct basis. If an expense is not easily attributable to a specific activity, then the expense would, under our proposal, have to be apportioned based on pertinent factors or ratios, such as studies of employment activities, salary ratios or similar

analyses. Any shared expenses between two or more affiliated entities would have to be "apportioned pro rata to the entities incurring the expense" even if the expense has been paid solely by one of the incurring entities.

We are proposing that each expense that is allocated by an MA organization or Part D sponsor to a type of expenditure would have to be appropriately attributed using a generally accepted accounting method to each contract. However, all federal and state taxes paid by an organization would be required to be attributed proportionately and appropriately to each contract. While federal taxes are not typically allocated to contracts on a state-by-state basis, for purposes of complying with the MLR requirements in this subpart, all organizations would be required to report some percentage of federal taxes paid on their behalf, along with applicable state taxes (other than premium taxes, which do not apply to the plans offered under the MA and Part D programs).

We are proposing that MA organizations and Part D sponsors would be required to allocate their non-claims and quality improving expenses on a contract basis as stated in the commercial MLR rules. If an expense is attributable to a specific activity, then the MA organization or Part D sponsor would allocate the expense to that particular activity. However, if it is not feasible to allocate such expenditure to a specific activity, then the organization would, under our proposal, be required to apportion the costs using a generally accepted accounting method that yields the most accurate results.

E. Activities That Improve Health Care Quality

We propose to adopt a definition of activities that improve health care quality for the purposes of this MLR rule that would result in a uniform accounting of the associated costs for MA organizations and Part D sponsors. This proposed definition aligns with that in the commercial MLR requirements at 45 CFR 158.150 through 45 CFR 158.151. We propose to align with the definition of activities that improve health care quality, also referred to as "quality improving activities," in the commercial MLR rules so that there is a uniform definition across lines of business. This alignment would help reduce burden on plan sponsors that also have commercial business by aligning the accounting and tracking of quality improving activities. It also allows for the comparison of quality spending across products. We note that we are proposing to adopt this

definition of quality solely for the purposes of MLR reporting and calculation, and not for other purposes, such as Medicare star ratings that determine MA quality bonus payments as authorized under the Affordable Care Act or any quality activities related to the Medicaid program. However, we anticipate large areas of overlap.

The definition of quality improving activities that was adopted for the commercial MLR, which we are proposing to adopt for the Medicare MLR, is derived from section 2717 of the PHSA. The PHSA has the goal of improving the quality of care by encouraging health care spending on the following activities that would:

- 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 Affordable Care Act, for treatment or services under the plan or coverage.

- Implement activities 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.

- Implement activities 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.

- Implement wellness and health promotion activities; or
- Enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology.

This proposed rule would allow for a non-claims expense incurred by an MA organization or Part D sponsor to be accounted for as a quality improving activity only if the activity falls into one of the categories described previously and meets all of the following requirements:

- It must be designed to improve health quality.

- It must be designed to increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

- It must 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.

- It must 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.

Examples of activities that improve health outcomes would include those that increase the likelihood of desired outcomes compared to a baseline and reduce health disparities among specified populations, and may involve the direct interaction of the MA organization or Part D sponsor (including those services delegated by contract for which the MA organization or Part D sponsor retains ultimate responsibility under the insurance policy), providers and the enrollee or the enrollee's representative (for example, face-to-face, telephonic, web-based interactions or other means of communication) to improve health outcomes. These activities would under our proposal include the following:

- 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 in section 3606 of the Affordable Care Act.

- Identifying and addressing ethnic, cultural or racial disparities in effectiveness of identified best clinical practices and evidence based medicine.

- Quality reporting and documentation of care in non-electronic format.

- Health information technology to support these activities.

- Accreditation fees directly related to quality of care activities.

Examples of activities that prevent hospital readmissions through a comprehensive program for hospital discharge would include the following:

- Comprehensive discharge planning (for example, arranging and managing transitions from one setting to another, such as hospital discharge to home or to a rehabilitation center) in order to help assure appropriate care that will, in all likelihood, avoid readmission to the hospital.

- Patient-centered education and counseling.

- Personalized post-discharge reinforcement and counseling by an appropriate health care professional.

- Any quality reporting and related documentation in non-electronic form for activities to prevent hospital readmission.

- Health information technology to support these activities.

Examples of activities that improve patient safety, reduce medical errors, and lower infection and mortality rates would include the following:

- The appropriate identification and use of best clinical practices to avoid harm.

- Activities to identify and encourage evidence-based medicine in addressing independently identified and documented clinical errors or safety concerns.

- Activities to lower the risk of facility-acquired infections.

- Prospective prescription drug Utilization Review aimed at identifying potential adverse drug interactions.

- Any quality reporting and related documentation in non-electronic form for activities that improve patient safety and reduce medical errors.

- Health information technology to support these activities.

Examples of activities that implement, promote, and increase wellness and health activities would include the following:

- Wellness assessments.

- Wellness/lifestyle coaching programs designed to achieve specific and measurable improvements.

- Coaching programs designed to educate individuals on clinically effective methods for dealing with a specific chronic disease or condition.

- Public health education campaigns that are performed in conjunction with state or local health departments.

- Actual rewards, incentives, bonuses, reductions in copayments (excluding administration of such programs), that are not already reflected in premiums or claims should be allowed as a quality improving activity for the group market to the extent permitted by section 2705 of the PHSA.

- Any quality reporting and related documentation in non-electronic form for wellness and health promotion activities.

- Coaching or education programs and health promotion activities designed to change member behavior and conditions (for example, smoking or obesity).

- Health information technology to support these activities.

Examples of activities that enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology would include activities related to health information technology (HIT). HIT offers providers, MA organizations, Part D sponsors, and beneficiaries the capability to share clinical information in a real-time

setting. Any HIT expenditure that is attributable to improving health care, preventing hospital readmissions, improving safety and reducing errors, or promoting health activities and wellness to an individual or an identified segment of the population, would under our proposal be classified as a quality improving activity. HIT resources that are designed to improve the quality of care received by an enrollee would include the provision of electronic health records and patient portals, as well as the monitoring, measuring, and reporting of clinical effectiveness measures. HIT expenses that are consistent with meaningful use requirements would be treated as expenditures to improve health care quality.

We are proposing to follow the commercial MLR rules and recognize HIT as a category of quality improving activities, provided that the use of HIT meets the criteria discussed earlier.

In this proposed rule, we recognize that some quality improving activities may be what are sometimes referred to as "population-directed" and may not involve face-to-face interaction between an employee or contractor of the MA organization or Part D sponsor and the enrollee. However, such activities would have to be directed to identified segments of the MA organization's or Part D sponsor's enrollees. The MA organization or Part D sponsor would be required to be able to measure the level of engagement with these enrollees in addition to tracking the effect(s) of these activities on health outcomes in this population through a process that is well defined, well developed, and utilized.

Any quality improving activity that results in cost savings to a contract would not, by itself, cause expenditures on that activity to be classified as non-quality improving expenditures under our proposal, if they meet the criteria set forth in this proposed rule. However, if the activity is designed primarily to control or contain costs, then expenditures for it would not be permitted to be included as a quality improving activity, as provided in proposed § 422.2430(b) and § 423.2430(b).

As many quality improving activities are fluid in nature, they may properly be classified in more than one quality improving activity category. However, the proposed rule would not permit issuers to count any occurrence of a quality improving activity more than once, as explained in § 422.2420(d) and § 423.2420(d). Moreover, shared expenses among related entities as well as expenses that are for lines of business

or products other than those being reported, including self-funded plans, would have to be apportioned among the entities and among the lines of business or products. For example, a quality improving program that is developed and implemented for commercial plans would have to be prorated among the lines of business, and the portion of expenditures for the program that are for the commercial plans may not be included in quality improving activities reported under 1857 of the Act.

We propose to adopt at § 422.2430(b) and § 423.2430(b) the list of activities in its entirety that are not to be reported as a quality improving activity under the commercial MLR rules at 45 CFR 158.150(c). These include the following:

- Those that are designed primarily to control or contain costs.
- 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.
- 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.
- Those activities that can be billed or allocated by a provider for care delivery and which are, therefore, reimbursed as clinical services.
- 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 maintenance of ICD-10 code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d-2, as amended, and ICD-10 implementation costs in excess of 0.3 percent of a MA organization or Part D sponsor's total revenue.
- That portion of the activities of health care professional hotlines that does not meet the definition of activities that improve health quality.
- All retrospective and concurrent utilization review.
- Fraud prevention activities.
- The cost of developing and executing provider or pharmacy contracts and fees associated with establishing or managing a provider or pharmacy network, including fees paid to a vendor for the same reason.
- Provider credentialing and pharmacy network credentialing.
- Marketing expenses.

- Costs associated with calculating and administering individual enrollee or employee incentives.

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

- Any function or activity not expressly permitted as a quality improving activity in this rule.

This proposed rule provides a set of criteria in § 422.2430 and § 423.2430 which MA organizations or Part D sponsors would be required to comply with in order for the activity in question to be treated as improving quality. The definition, or foundational criteria, of a quality improving activity would have to be specific enough so as to provide clear guidance without overly prescribing acceptable activities and possibly stifling future innovative quality improving activities. We believe that the definition used in the commercial MLR rules, which we have proposed to adopt, would achieve these goals.

A quality improving activity would have to be grounded in evidence-based practice, widely accepted best clinical practice, or criteria issued by recognized medical associations, accreditation bodies, government agencies, or other nationally recognized health care quality organizations. Any proposed quality improving activities would be required to be designed to improve the quality of care received by an enrollee and capable of being objectively measured (taking into account the individual needs of the beneficiary) and of producing verifiable results and achievements. While an MA organization or Part D sponsor would not have to present initial evidence proving the effectiveness of a quality improving activity, the MA organization or Part D sponsor would have to show measurable results stemming from the executed quality improving activity.

While administrative expenses such as network fees would not be counted as quality improving, some traditional administrative activities could under our proposal qualify as quality improving if they met the criteria set forth in proposed § 422.2430 and § 423.2430. For example, expenses for prospective utilization review could under our proposal be classified as expenses for quality improving activities. Prospective utilization review would be considered a quality improving activity because it is rendered before care or services are delivered and can help ensure that the most appropriate treatment or service is given in the most appropriate setting. In contrast, the network fees associated

with third party provider networks do not stem from a quality improving activity and therefore would only count as an administrative expense.

We also propose to limit the amount spent converting from International Classification of Disease code set ICD–9 to ICD–10 that may be counted as a quality improving activity, in line with the commercial rules approach. As a general matter, the development and maintenance of claims adjudication systems are not designed primarily to improve the quality of care received by an individual and, therefore, are not classified as a quality improving activity. However, there is general recognition that the conversion to ICD–10 will enhance the provision of quality care through the collection of better and more refined data. The difficulty is in parsing expenses associated with ICD–10 conversions that may be solely “development and maintenance of claims adjudication systems” as opposed to those that are uniquely conversion costs. As with some other cost categories defined in this proposed rule, little public data currently exist to guide decision making regarding this distinction. For the commercial MLR rules, we considered the impacts of ICD–10 on improving data collection for diagnoses and medical procedure coordination, patient safety, health outcomes, and medical research. In addition, we consulted with our Office of E-Health Standards and Services (OESS). OESS oversees ICD–10 and considers some of the impact of ICD–10 to be quality improving activities, and supports the treatment of ICD–10 set forth in this proposed rule. We recognize that ICD–10 has some claims processing functions as well. Recognizing the dual nature of ICD–10, we propose to include as a quality improving activity those ICD–10 conversion costs incurred in 2014 (or until the deadline for converting to ICD–10) up to 0.3 percent of an MA organization’s or Part D sponsor’s total revenue under this part in 2014, which would be reported on a direct basis. We chose this proposed cap to be consistent with the approach in the commercial MLR rules, which allows as quality improving activity amounts that issuers projected spending on ICD–10 conversion, without permitting issuers to include claims adjudication systems costs in quality improving activities. In addition, ICD–10 maintenance costs are excluded from quality improving activities in this proposed rule, based on the industry’s collective comments on the commercial MLR rules, stating that separating conversion costs from

maintenance costs is feasible, and based on their support for excluding ICD–10 maintenance costs from quality improving activities. Similarly, we propose excluding any ICD–10 implementation costs in excess of the 0.3 percent limitation from quality improving activities in this proposed rule.

We recognize that there may be certain quality improving activities that are unique to a Part D context, and we seek comment as to whether modifications to our proposed definition in § 423.2430 are needed. In particular, we are interested to consider whether the concepts of prospective, concurrent, and retrospective utilization review apply in a Part D context. Whereas beneficiaries receive medical services at the time they are rendered, a safety-related review of a beneficiary’s chronic or recurring use of medications, such as opiates or other high risk medications, could result in a prospective change to the beneficiary’s drug regimen and a resulting improvement to his or her health and safety. However, we hesitate to define all utilization review, without any bounds, as a quality improving activity. Further, we solicit comment on whether Medication Therapy Management requirements for the Part D program would be considered to qualify as a health care improving activity under § 423.2430.

F. Credibility Adjustment

As noted in section II.A. of this proposed rule, we are using the commercial MLR rules as a reference point for developing the Medicare MLR. We propose that the methodology for the Medicare MLR calculation take into account the special circumstances of contracts with lower enrollment. Proposed § 422.2440 and § 423.2440 set forth a credibility adjustment that would be designed to meet the same goals as the commercial MLR requirements in 45 CFR 158.230.

A credibility adjustment is a method that can be used to address the impact of claims variability on the MLR for smaller contracts. All MA organizations and Part D sponsors experience some random claims variability, where actual claims experience deviates from expected claims experience. In a contract with a large enrollment, the predictability of expected claims experience is more reliable than in a contract with fewer members. One source of variability is the impact of outlier claims, which can be infrequent and in either direction. For smaller contracts, these random variations in the claims experience for enrollees

could cause a contract’s reported MLR to be considerably below or above the statutory requirement in any particular year, even though the MA organization or Part D sponsor estimated in good faith that the combination of the projected premium and projected claims would produce an MLR that meets the statutory requirement. The credibility adjustment is a method to address the effect of this random variation. A credibility adjustment serves to increase the MLR of a contract, thereby reducing the probability that a contract will fail to meet the statutory requirement simply because of random claims variability.

In evaluating the desirability of including a credibility adjustment, it is important to emphasize that MA organizations and Part D sponsors bid prospectively, based on trends, assumptions and estimates from previous claims experience. When an actuary estimates that a plan bid will produce an 85 percent MLR in the upcoming year, whether or not that 85 percent MLR materializes depends on how closely members’ actual use of health care services aligns with the assumptions the actuary has made, including estimates of the mix of enrollees the plans under the contract will attract, the intensity and frequency with which its enrollees will use health care services, and unit costs for payments to providers. All things being equal, it is more likely that those assumptions driving the level of the bid and estimated claims costs will align with actual experience when a contract enrolls a large number of members rather than a small number.

To avoid requiring MA organizations and Part D sponsors to pay remittances due to random claim variation, rather than due to their underlying pricing and benefits structure, it is necessary to assess MLRs on sufficient numbers of member months for statistical credibility. Requiring MA organizations and Part D sponsors to pay remittances when random variation leads to surpluses (low MLRs), while requiring issuers to absorb losses when random variation leads to losses (high MLRs), could lead to product volatility, market exit, and inadequate levels of surplus to ensure solvency. We agree that remittance amounts should be based on the underlying premium pricing, rather than chance variation in claims experience. However, any credibility adjustment could also serve to deprive the federal government (and, thus, taxpayers and Medicare beneficiaries) of remittance amounts that they would otherwise be paid under the Affordable Care Act.

For the commercial MLR rules, we adopted a credibility adjustment methodology developed from statistical analysis conducted for the NAIC by an independent actuarial consulting firm, using historical claims data for commercial insurers.

After extensive analysis and public discussion, the methodology that we adopted to adjust the commercial MLR in instances of partial credibility was designed to reduce the probability that an issuer with smaller enrollment had to pay a rebate in a given year to 25 percent of the time or less. As discussed in the proposed commercial MLR rule, NAIC did consider setting the commercial base credibility adjustments so that such an issuer would be required to pay a rebate less than 10 percent of the time. The NAIC concluded, and we agreed, that setting credibility adjustments based on a 25 percent probability of paying a rebate struck a more equitable balance of consumer and issuer interests.

For the MA and Part D prescription drug programs, we propose to mirror the commercial approach by designing credibility adjustment factors for smaller enrollment contracts that result in a 25 percent chance of having to pay a remittance for contracts priced at an 85 percent MLR. We believe that this approach provides an acceptable balance between the interests that MA organizations and Part D sponsors have in not paying remittance when a low

MLR is the result of ordinary variation in claims experience, and the interests of Medicare beneficiaries in having plan benefits at prices that provide value and the government receiving remittances, as required by the Affordable Care Act. One difference from the approach in the commercial MLR rules is that we do not propose to include a deductible factor, because Medicare deductibles are more confined than in the commercial market. Thus, the limited range of Medicare cost sharing does not prompt the need for such an adjustment.

Our proposal for calculation of the probability of a remittance is based solely on the variability of expected claims, assuming plans are priced exactly at an 85 percent MLR. In order to estimate the variability of expected MA-PD claims, we analyzed 4 years of fee-for-service (FFS) claims data for medical claims and 4 years of prescription drug event claims and reconciliation data for the Part D benefit under MA-PD contracts (2008 to 2011). In order to estimate the variability of expected claims for Part D stand-alone contracts, we analyzed 4 years of prescription drug event claims and reconciliation data (2008 to 2011).

Generally, Medicare claims vary less than commercial claims around the average per person claim amount (in statistical terms, the coefficient of variation of claims costs (standard deviation of claims costs relative to the mean claims cost) is lower for Medicare

than commercial business relative to the mean claim cost). As a result, the threshold for full-credibility falls at a lower level of enrollment for MA-PD and Part D stand-alone contracts compared to commercial insurers. Further, claims for MA-PD contracts have a lower coefficient of less variation around the average than do claims for Part D stand-alone contracts, thus the full-credibility threshold for MA-PD contracts is lower than for Part D stand-alone contracts.

The Office of the Actuary (OACT), Centers for Medicare and Medicaid Services, derived the MA-PD and Part D stand-alone credibility adjustments using the following methodology. The credibility adjustment is intended to reduce the probability that a contract will fail to meet the MLR requirement due to random variation in claims experience. The target failure rate is 25 percent for contracts priced at an 85 percent MLR. The adjustments only account for variation in the claim experience, as related to the numerator of the MLR. Variations due to other risks and other components of the MLR formula are not considered. This approach is equivalent to the approach used in developing the commercial MLR credibility adjustments.

OACT modeled the distribution of the MLR using the following statistical formula by applying the Central Limit Theorem:

$$MLR_n = \frac{\sum_{i=1}^n X_i}{n\mu / 0.85} \xrightarrow{d} \left(0.85, \frac{0.85^2 \sigma^2}{n\mu^2} \right)$$

Where

X_i is the annual claim amount with mean (μ) and variance (σ^2) for an individual. X_i is assumed to be independently and identically distributed for each individual. OACT calculated the mean and variance from historical claim experience from Medicare Parts A and B (as a proxy for Part C) and Medicare Part D. Claims were tabulated consistent with the definitions used to define the MLR. We reviewed four calendar years of experience from 2008 through 2011 for consistency and trends over time;

n is the number of individuals in the group; and

N

$$\left(0.85, \frac{0.85^2 \sigma^2}{n\mu^2} \right)$$

denotes the Normal distribution with mean, 0.85, and variance,

$$\frac{0.85^2 \sigma^2}{n\mu^2}$$

The numerator of the formula represents the aggregate claims (a variable), and the denominator represents the aggregate premium. The denominator is modeled as a single point equal to the expected premium because we are not evaluating the variability in the denominator.

The credibility adjustment equals the expected value of the MLR less the 25th percentile (25 percent target failure rate). This difference can be calculated by multiplying the z-score for the standard Normal distribution by the standard deviation for the MLR. The credibility adjustment equals,

$$\left| -0.6745 \frac{0.85\sigma}{\sqrt{n\mu}} \right|$$

where -0.6745 is the z-score for the 25th percentile of the standard normal distribution.

We propose to use member months (instead of life years, used in the commercial MLR credibility adjustment) to describe the enrollment thresholds pertinent to application of the Medicare credibility adjustments, because member months are consistently and predominantly used in other reporting requirements for Medicare Advantage organizations and Part D sponsors. Member months for a contract year equal the sum across the 12 months of a year of the total number of enrollees for each month. This includes enrollees who are in ESRD and hospice status for a month. As with the commercial rule,

we intend to evaluate the credibility adjustments and update them, if necessary.

In proposed § 422.2440(a) and § 423.2440(a), we follow the commercial MLR rule by proposing that an MA organization and a Part D sponsor may add a credibility adjustment to a contract's MLR if the contract's experience (level of enrollment) is partially credible, as determined by us. In § 422.2440(b) and § 423.2440(b), we note that an MA organization and Part D sponsor would not be permitted to add a credibility adjustment if the contract's experience is fully-credible, as determined by us. In § 422.2440(c) and § 423.2440(c), we propose that for contract years when a contract has non-credible experience, as determined by us, the sanctions specified in statute (and implemented at § 422.2410(b), (c), and (d) and § 423.2410(b) through (d)) for having an MLR that does not meet the minimum requirement of 85 percent would not apply. Finally, in § 422.2440(d) and § 423.2440(d), we state that we will propose updates to the credibility adjustments, solicit comments, and finalize any updates through the Advance Notice and Final Rate Announcement process.

Credibility adjustments would be applied to contracts with partially-credible experience. We propose to define partially-credible experience for MA contracts as enrollment that is greater than or equal to 2,400 member months and no greater than 180,000 member months of enrollment for a contract year. We propose to define partially-credible experience for Part D standalone contracts as enrollment that is greater than or equal to 4,800 member months and no greater than 360,000 member months of enrollment for a contract year.

Accordingly, we propose that non-credible MA contracts would have annual enrollment of less than 2,400 member months, and non-credible Part D "standalone" contracts would have annual enrollment of less than 4,800 member months. Further, we propose that a fully-credible MA contract would have an enrollment greater than 180,000 member months, and a fully-credible Part D "standalone" contract would have an enrollment greater than 360,000 member months.

Table 1a provides the proposed credibility adjustments for partially-credible MA-PD contracts, and Table 1B provides the proposed credibility adjustments for partially-credible Part D stand-alone contracts. We propose that the credibility adjustments in these tables will be effective for 2014 and subsequent years. We propose that the

credibility adjustments for the contracts with enrollment sizes that fall between the categories of member months displayed in Tables 1a and 1b would be determined using linear interpolation. (For example, an MA-PD contract with 75,000 member months would have a credibility adjustment of 1.575, calculated as $1.7 \times (120,000 - 75,000) \div (120,000 - 60,000) + 1.2 \times (75,000 - 60,000) \div (120,000 - 60,000)$.)

TABLE 1A.—PROPOSED MLR CREDIBILITY ADJUSTMENTS FOR MA-PD*CONTRACTS

Member months	Credibility adjustment
≤2,400	Non-credible
2,400	8.4%
6,000	5.3%
12,000	3.7%
24,000	2.6%
60,000	1.7%
120,000	1.2%
180,000	1.0%
>180,000	Fully-credible

* MA-PD combined with MA-only

TABLE 1B.—PROPOSED MLR CREDIBILITY ADJUSTMENTS FOR PART D STAND-ALONE CONTRACTS

Member months	Credibility adjustment
<4,800	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	Fully-credible

For years after 2014, we propose that any updates to the enrollment thresholds demarcating partial credibility and updates to the credibility adjustments be proposed in the annual Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, also known as the Advance Notice. After the comment period for the Advance Notice ends, the updates would be finalized in the annual Announcement of Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, otherwise known as the Final Rate Announcement. We do not envision that it will be necessary to make annual updates to the credibility adjustments, but should the need arise to make any updates in future years (for example, due to changes in payment policies that would require changes to

the variables included in the MLR numerator and/or denominator), we propose to use the Advance Notices as a vehicle for additional opportunity for notice and comment.

G. Reporting Requirements

Consistent with already established reporting requirements in § 422.504(f)(2) and § 423.505(f)(2), we are proposing that MA organizations and Part D sponsors be required to submit a report to us. For each contract year, each MA organization and Part D sponsor would submit a report to us, in a timeframe and manner specified by us. We propose that MA organizations and Part D sponsors' submissions will include information that includes, but is not limited to the data needed by the MA organization and Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract. This information may include reimbursement for clinical services and prescription drugs, total revenue, expenditures on quality improving activities, non-claim costs, taxes, licensing and regulatory fees, and any remittance owed to us under § 422.2410 and § 423.2410. MA organizations and Part D sponsors would be required to calculate MLRs and remittance as part of their submission to the Secretary.

At a later date, we will provide information on the nature of this report, when it will be due, and how and where on the internet the information will be made available to the public, in a time and manner that we determine.

We are requesting comment on when the MLR should be reported. While it is arguably preferable to set a reporting date after the payment reconciliations are complete, there are at least two reasons why this may not be feasible. First, there are occasional reopenings of reconciliations that occur after the year immediately following the contract year, and it seems unreasonable to wait until all reopenings have been completed. Second, we are statutorily required to halt new enrollment the second succeeding year after a contract has an MLR of less than the MLR required at § 422.2410(b) and § 423.2410(b) for 3 or more consecutive years, and to terminate a contract after that contract has had an MLR of less than the required MLR for 5 consecutive years. We are proposing to apply the termination sanction the second succeeding year after the fifth consecutive year that a contract does not meet the required MLR. We must balance any preference for a later reporting date with disruption that beneficiaries would experience if we halted new enrollment or terminated a

contract after open enrollment has begun.

We are considering several options. First, we are considering requiring the reporting of Medicare MLRs data in July, even before risk adjustment reconciliation is complete. MA organizations and Part D sponsors must submit their bids by the first Monday in June and the base year for the bids is the same year as the contract year for MLR reporting. We typically provide nearly complete risk scores to MA organizations and Part D sponsors to support this bidding process, and base year costs must be developed by this time. The cutoff for PDEs to be reported for reinsurance and risk corridor reconciliation is June 30th after the contract year, and MA organizations and Part D sponsors, which report the prescription drug events (PDEs) themselves, should be able to project their final risk corridor and reinsurance reconciled amounts by this time. A July 31 reporting date would provide time for MA organizations and Part D sponsors to project their final costs and revenues for the contract year, and allow us time to apply new enrollment and termination sanctions.

Another option we are considering is to require reporting of a contract year MLR data in September, after risk adjustment reconciliation, but before Part D reinsurance and risk corridor reconciliation. This would better inform the calculation of the total revenue for the contract year, and still permit us sufficient time to apply enrollment and termination sanctions, and also to adjust Part D reassignments for low-income beneficiaries.

A further option we are considering is setting a reporting date in December, after Part D reconciliation of risk corridors and reinsurance. While MA organizations and Part D sponsors would still need to project any future reconciliations, this approach would provide more information for MA organizations' and Part D sponsors' total revenue calculations. However, we have concerns about this timing since it would mean that we would not receive reported MLRs data until after open season has started, and the enforcement of enrollment and termination sanctions would create disruptions for beneficiaries who are newly enrolled in plans under a contract (for enrollment sanctions) or all beneficiaries enrolled in plans under a contract (for termination sanctions).

We reiterate that, regardless of when a contract's MLR is actually reported, we are proposing that the MA organization or Part D sponsor must project future run-out of all payments

and receipts as a result of the reconciliation of risk adjustment, reinsurance, or risk corridors. Because of the need to prevent disruption to beneficiaries who are choosing health plans for the coming year, and the necessity of projecting all future run-out, we are proposing a July 31 reporting date and request comment on this proposal.

H. Remittances to CMS if Applicable MLR Requirement Is Not Met

Proposed § 422.2470 and § 423.2470, paragraphs (a), (b), (c), and (d), delineate the proposed general requirements regarding sanctions, the calculation of the amount to be remitted to us, the time frame for payment of any amount that may be due, and the treatment of remittances in future years' numerator and denominator. In accordance with section 1857(e)(4) of the Act, proposed § 422.2470(a) and § 423.2470(a) simply provide that if a contract is partially or fully-credible and does not meet the applicable MLR standard set forth in § 422.2410(b) and § 423.2410(b), then the plan sponsor would remit payment to CMS as calculated under this proposed rule. As discussed earlier, because an MA-PD or Part D stand-alone contract that has fewer than 2,400 or 4,800 member months, respectively, does not have sufficiently credible data to determine whether the minimum MLR standard has not been met, we are proposing that an MA organization or Part D sponsor would not be required to remit any payment to us for non-credible contracts.

Proposed § 422.2470(b) and § 423.2470(b) explain the amount of the payment that would be due to CMS. The Affordable Care Act provides that MA organizations and Part D sponsors must remit to CMS the amount by which the MLR requirement exceeds the contract's actual MLR, multiplied by total revenue under this part. In this proposed rule, we specifically propose that MA organizations and Part D sponsors be required to remit to us the amount by which the applicable MLR requirement in § 422.2410(b) and § 423.2410(b) exceeds the contract's actual MLR, multiplied by the total revenue of the contract, as provided under proposed § 422.2420(c) and § 423.2420(c).

Sections 422.2470(c) and 423.2470(c) specify that we would subtract remittances from plan payment amounts in a timely manner after the MLR is reported, on a schedule determined by us. Remittances by MA and Part D organizations would occur as part of regular monthly payments that we make to plan sponsors. In § 422.2470(d) and § 423.2470(d), we specify that

remittances paid in any 1 year would not be included in the numerator or denominator of the next year's or any year's MLR.

We request comment on the special circumstances of certain MA organizations in Puerto Rico with respect to the Medicare MLR requirement. MA organizations in Puerto Rico that have Platino agreements with the Commonwealth of Puerto Rico tend to have higher Part C profit margins than other MA organizations and are thus less likely to meet the 85 percent MLR requirement.

I. MLR Review and Non-Compliance

Under this proposed rule, we would conduct selected reviews of reports submitted under § 422.2460 and § 423.2460 to determine that remittance amounts under § 422.2410(b) and § 423.2410(b) and sanctions under §§ 422.2410(c), 422.2410(d), 423.2410(c), and 423.2410(d) were accurately calculated, reported, and applied.

MA organizations and Part D sponsors would be required to retain documentation relating to the data reported, and provide access to that data to CMS, HHS, the Comptroller General, or their designees, in accordance with proposed § 422.504 and § 423.505. These proposed provisions are intended to give CMS or its designees access to information needed to determine whether the reports and amounts submitted with respect to the MLR are accurate and valid. Sanctions would be imposed for non-compliance with the MLR requirements. Furthermore, under § 422.2480(c) and § 423.2480(c), MA organizations and Part D sponsors with third party vendors would be required to have or be able to obtain and validate, in a timely manner, all underlying data associated with their services prior to the preparation and submission of MLR reporting to CMS. This includes all claims data paid on behalf of the MA organization or Part D sponsor, direct and indirect remuneration data and supporting materials, and all pricing components and utilization data that were used or rendered to substantiate invoices submitted to sponsors or financial data submitted to us.

In addition, we propose to add a failure to provide accurate and timely MLR data to the list of items in § 422.510(a) and § 423.509(a) that constitute grounds for termination, and for intermediate sanctions and civil money penalties, by adding a paragraph (15) related to MLR reporting. Such an addition will provide CMS authority to invoke the contract termination procedures in § 422.510(b) through (d)

and § 423.509(b) through (d) for failure by an MA organization or Part D plan sponsor to provide timely and accurate MLR data. Further, intermediate sanctions at § 422.752(b) and (c) and § 423.752(b) and (c) would also be available, as well as civil monetary penalties at § 422.760 and § 423.760.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

A. ICRs Regarding MLR and Remittance Reporting Requirement (§ 422.2470 and § 423.2470)

This proposed rule describes the information that would be reported by MA organizations and Part D sponsors on an annual basis to the Secretary starting in 2014. We propose that MA organizations and Part D sponsors' submissions will include information regarding reimbursement for clinical services, expenditures for activities that improve health care quality, other non-claim costs, total revenue, and federal and state taxes and regulatory fees, among other data elements. MA organizations and Part D sponsors would be required to calculate MLRs and remittance as part of their submission to the Secretary.

At this time, CMS has not developed the MLR reporting instructions and forms that MA organizations and Part D sponsors would have to complete on an annual basis beginning for contract years starting January 1, 2014. We expect the first year of MLR reporting for MA organizations and Part D sponsors to occur in 2015 for the 2014

contract year, and we propose to continue collecting MLR data for the foreseeable future. We plan to publish the instructions and forms that issuers must file for all plans in future guidance. At that time, we will solicit public comments on both the forms and the estimated burden imposed on health insurance issuers for complying with the provisions of this proposed rule. We will publish the required 60-day and 30-day notices in the **Federal Register** notifying the public of OMB approval as required by the PRA.

B. ICRs Regarding Retention of Records (§ 422.2480(b) and (c) and § 423.2480(b) and (c))

Subpart I of the proposed rule establishes our enforcement authority regarding the reporting requirements under section 1857(e) of the Act. MA organizations and Part D sponsors must maintain all documents and other evidence necessary to enable us to verify that the data required to be submitted comply with the definitions and criteria set forth in this proposed rule, and that the MLR is calculated and any remittances owed are calculated and provided in accordance with this proposed rule. The proposed rule at § 422.2480(c) and § 423.2480(c) would require plan sponsors to maintain all of the documents and other evidence for 10 years.

We expect all MA organizations and Part D sponsors will have to retain data relating to the calculation of MLRs; those who have owed remittances would also have to retain information regarding the payment of remittances. We believe that the burden associated with our record retention requirements does not exceed standard record retention practices because MA organizations and Part D sponsors are already required to retain the records and information required by this proposed rule in order to comply with the legal requirements of their states' departments of insurance. For that reason, we are assigning a lesser burden to these requirements as compared with the commercial MLR requirements. We estimate that about 616 contracts would be subject to the aforementioned requirements. (The 616 contracts are comprised of 605 contracts subject to the remittance requirement plus 11 non-credible contracts that are subject to reporting requirements). We further estimate that it will take MA organizations and Part D sponsors about 28 hours in total to meet the record retention requirements, at a cost of about \$4.00 per report. The total estimated annual burden associated with the requirements in § 422.2480(b)

and (c) and § 423.2480(b) and (c) is shown in the regulatory impact analysis.

While we have developed preliminary burden estimate, we are not seeking OMB approval at this time. We will seek OMB approval for the aforementioned recordkeeping requirements at the same time we seek OMB approval for the information collection requirements associated with proposed MLR remittance reporting requirements discussed in § 422.2470 and § 423.2470.

We welcome comments regarding the burden associated with maintaining the information described in subpart I of this proposed rule.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: William Parham (CMS-4173-P), Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850; and
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: CMS Desk Officer, (CMS-4173-P), Fax (202) 395-6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Introduction

This proposed rule implements section 1857(e)(4) of the Act, which sets forth requirements for a medical loss ratio (MLR) for MA organizations and Part D sponsors. The MLR is an accounting statistic that, stated simply, measures the percentage of total revenue that MA organizations and Part D sponsors spend on health care and quality initiatives (and, under this rule, amounts spent to reduce Part B premiums), versus what they spend on such other items as administration, marketing and profit. The higher the MLR, the more the MA organization or Part D sponsor is spending on claims and quality improving activities and the less they are spending on other items

and retaining as profit. As proposed earlier, MA organizations and Part D sponsors must submit MLR-related data to the Secretary on an annual basis, and in the event that a contract's MLR fails to meet the minimum statutory requirement, MA organizations and Part D sponsors would remit a payment to CMS. If the contract continues to fall below the minimum MLR standard, the contract would be subject to enrollment sanctions and possibly termination. This proposed regulation also proposes uniform definitions and standardized methodologies for calculating the MLR and addresses enforcement of the reporting requirements. These provisions are generally effective for contract years beginning on or after January 1, 2014.

We have examined the effects of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 (58 FR 51735) and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3)

materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB). This proposed rule is likely to have economic impacts of \$100 million or more in any 1 year, and therefore has been designated an "economically significant" rule under section 3(f)(1) of Executive Order 12866. Therefore, we have prepared an RIA that details the anticipated effects (costs, savings, and expected benefits), and alternatives considered in this proposed rule. Accordingly, OMB has reviewed this proposed rule pursuant to the Executive Order.

B. Statement of Need

Consistent with the provisions in section 1857(e)(4) of the Act, which are incorporated by reference in section 1860D-12(b)(3)(D) of the Act, this proposed rule requires MA organizations and Part D sponsors to meet the minimum MLR requirement of 85 percent. If this requirement is not met at the contract level, which is the level of aggregation proposed in this notice, MA organizations and Part D sponsors are subject to penalties. Section 1857(e)(4) of the Act requires MA organizations and Part D sponsors to "remit to the Secretary an amount equal to the product of the total revenue of the MA plan under this part for the contract year and the difference between 0.85 and the medical loss ratio." Section 1857(e)(4) of the Act also provides that the Secretary shall not permit enrollment of new enrollees if the plan does not meet the MLR requirement of 85 percent for 3 or more consecutive years and shall terminate the contract if the plan (contract) fails to have such a medical loss ratio for 5 consecutive contract years.

C. Summary of Impacts

We limited the period covered by the regulatory impact analysis (RIA) to calendar year (CY) 2014 (with the exception of section V.D.5. of this proposed rule, which presents estimates for ongoing annual administrative costs for 2014 and subsequent years). We anticipate that the transparency and standardization of MLR reporting in this

proposed rule would help ensure that taxpayers, the federal government, and enrolled beneficiaries receive value from Medicare health plans. Additionally, including in the MLR calculation those costs related to quality-improving activities could help to increase the level of investment in and implementation of effective quality improving activities, which could result in improved quality outcomes and lead to a healthier beneficiary population.

Executive Order 12866 also requires consideration of the "distributive impacts" and "equity" of a rule. As described in this RIA, this regulatory action will help ensure that MA organizations and Part D sponsors spend at least a specified portion of total revenue on reimbursement for clinical services, prescription drugs, quality improving activities, and direct benefits to beneficiaries in the form of reduced Part B premiums, and will result in a decrease in the proportion of health insurance revenue spent on administration and profit. It will require MA organizations and Part D sponsors to remit payment to CMS if this standard is not met. MA organizations and Part D sponsors may also experience sanctions if this standard is not met over a period of 3 to 5 consecutive years. The remittance will help incentivize MA organizations and Part D sponsors to price their benefit packages such that a specified portion of premium income is likely to be spent on reimbursement for clinical services and quality improving activities, resulting in increased value to beneficiaries enrolled in MA and Part D. In accordance with Executive Order 12866, we believe that the benefits of this regulatory action justify the costs.

Although we are unable to quantify benefits, Table 2 shows that the estimated transfer amounts due to failure to meet the minimum MLR requirement (that is, remittances to the HHS Secretary) could be substantial. Estimates for CY 2014 remittances are \$717 million for MA-PD contracts and \$141 million for Part D stand-alone contracts. (Note that the estimates in Tables 2 through 5 are based on CY 2013 bid data, which are a proxy for actual CY 2014 costs and revenues that will be used in actual MLR calculations.) Additional details relating to these estimates are discussed later in this regulatory impact analysis. We also estimate that administrative costs of the rule would be approximately \$9.6 million upfront and \$2.8 million in subsequent years.

TABLE 2—ESTIMATED REMITTANCE FOR CY 2014
[With Credibility Adjustment]

Contract type	Remittance estimates (in millions)		
	Contracts with MLRs < 80%	Contracts with MLRs from 80% to 84.99%	All Contracts Below MLR Requirement of 85% [Total Remittance]
MA-PD	\$293	\$424	\$717
Part D Stand-alone	5	136	141
Total	298	560	858

Source: 2013 approved bids.

Notes: Estimates reflect application of the credibility adjustment to MLRs for partially-credible contracts. The remittance for a contract is the product of the difference between 0.85 and the contract's MLR and the total revenue of the contract, as provided in §422.2420(c) and §423.2420(c). All MA contracts include at least one MA-PD plan, so are labeled MA-PD. This analysis does not explicitly model the impact of potential plan sponsor behavioral changes.

D. Detailed Economic Analysis

1. Benefits

In developing this proposed rule, we carefully considered its potential effects including both costs and benefits. We identify several potential benefits which are discussed later in this section.

A potential benefit of this proposed rule is greater market transparency and improved ability of beneficiaries to make informed insurance choices. The uniform reporting required under this proposed rule, along with other programs such as *www.Medicare.gov*, a Web site with plan-level information, will mean that beneficiaries will have better data to inform their choices, enabling the market to operate more efficiently.

In addition, contracts that would not otherwise meet the MLR minimum defined by this proposed rule may opt to increase spending on quality-promoting activities. These programs, which include case management, care coordination, chronic disease management and medication compliance, have the potential to create a societal benefit by improving outcomes and beneficiary population health.

MA organizations and Part D sponsors that would not otherwise meet the MLR minimum may also expand covered benefits or reduce cost sharing for beneficiaries. To the extent that these changes result in increased consumption of effective health services, the proposed rule could result in improved beneficiary health outcomes, thereby creating a societal benefit.

2. Costs

We have identified the direct costs associated with this proposed rule as the costs associated with reporting, recordkeeping, remittance payments,

enrollment and termination sanctions, and other costs.

a. Direct Costs

We estimate that each MA organizations and Part D sponsor would incur approximately \$16,000 one-time administrative costs (per report), and about \$5,000 in annual ongoing administrative costs (per report) related to complying with the requirements of this proposed rule. Additional details relating to these costs are discussed later in this RIA.

b. Other Costs

Additionally, there are three other potential types of costs associated with this proposed rule: costs of potential increases in medical care use, the cost of additional quality-improving activities, and costs to beneficiaries if MA organizations and Part D sponsors decide to limit offered products as a result of this proposed rule.

As discussed in the benefits section, there may be increases in quality-improving activities, provision of medical services, and Part D covered items due to this proposed rule. This is likely have some benefit to beneficiaries but also potentially represents an additional cost to MA organizations, Part D sponsors, and the federal government.

It is also possible that some MA organizations and Part D sponsors in particular areas or markets would not be able to operate profitably when required to comply with the proposed requirements. They may respond by changing or reducing the number of products they offer. MA organizations and Part D sponsors are likely to consider whether they expect to be successful competitors in a given market. Entire contracts or subsets of plans under contracts with low MLRs contracts may be withdrawn from a

given market entirely, while MA organizations and Part D sponsors with low MLR contracts (particularly those that are subsidiaries of larger organizations) may find ways to achieve higher MLRs through increased efficiencies.

To the extent that MA organizations and Part D sponsors decide to limit product offerings in response to this proposed rule, individual enrollees in these contracts may bear some costs associated with searching for and enrolling in a new Medicare health plan. For Medicare beneficiaries, this may also lead to reduced choice, the inability to purchase similar coverage, and higher search costs related to finding affordable insurance coverage.

c. Transfers

To the extent that MA organizations and Part D sponsors have contracts with MLRs that fall short of the minimum requirement, they must remit payment to the Secretary. These remittances would reflect transfers from the MA organizations or Part D sponsors to the Secretary. Using 2013 approved bid data, we have estimated remittances for CY 2014, which are presented in Table 2.

d. Additional Sanctions

To the extent that MA organizations' and Part D sponsors' MLRs fall short of the minimum MLR requirements for a period of 3 or 5 consecutive years, they will undergo additional sanctions. If an MA organization's or Part D sponsor's MLR falls below 85 percent for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the contract for coverage. If the MLR falls below 85 percent for 5 consecutive contract years, the Secretary shall terminate the contract. To the extent that enrollment sanctions are issued, this may lead to

reduced choice for Medicare beneficiaries. To the extent that contracts are terminated, individual enrollees in these contracts may bear some costs associated with searching for and enrolling in a new Medicare health or drug plan. One benefit of enrollment sanctions would be the movement of beneficiaries into contracts with a more efficient operating cost structure.

3. Overview of Data Sources, Methods, and Limitations

The most recent data on the number of licensed entities offering Medicare coverage through MA or Part D prescription drug plans are the 2013 approved bids. These bid data contain information on MA organizations' and Part D sponsors' projected revenues, expenses, and enrollment. Generally, these projections are based on actual plan experience from previous years. CY 2013 bid data are a proxy for actual CY 2014 costs and revenues that will be used in actual MLR calculations.

We used 2013 approved plan bid data, aggregated to the contract level. An MA organization or Part D sponsor can have one or multiple contracts with CMS and, under each contract, the MA organization or Part D sponsor can offer one or multiple plans (plan benefit packages) in which beneficiaries may enroll. Although these data represent the most recent data source with which to estimate impacts of the MLR regulations, there are limitations that should be noted. For example, plan bids are projected estimates of per person per month revenue needed to offer a benefit package, where required revenue is the sum of direct medical costs or

prescription drug costs, administrative costs and margin. Member month projections may differ from actual enrollment, and revenue projections in the bid may differ from the actual revenue MA organizations and Part D sponsors truly require given actual claims experience in a year.

Moreover, we propose to follow the commercial MLR regulations by including expenditures on quality improving activities in the numerator of the MLR (and, under this rule, amounts spent to reduce Part B premiums), and allowing certain amounts to be subtracted from the denominator of the MLR, such as licensing and regulatory fees; federal and state taxes and assessments; and community benefit expenditures. Some data for this RIA was collected in the bid pricing tool for the first time in 2013, such as reported estimates by MA organizations and Part D sponsors of expenditures on quality and levels of taxes and fees. Part D employer-group waiver plans are not required to submit bids, and therefore they are not included in the data analysis. Therefore, these plans are excluded from the analysis of Part D stand-alone contracts. Employer group waiver plans offered under MA-PD contracts are included in the RIA, although the bid data available for these plans are only from the MA portions of the bids.

As discussed at greater length in section V.D.4 of this proposed rule, we expect that MA organization and Part D sponsor behavior would change as a result of this proposed rule, which would impact the MLRs and remittances calculated. Because we are limited in

our ability to predict behavioral changes, we do not explicitly model these behavioral changes in our estimates. We seek comment on our methods and limitations presented in this regulatory impact analysis, anticipated impacts of behavioral changes, and additional ideas for quantifying the costs and benefits of this proposed rule.

4. Number of Affected Entities Subject to the MLR Provisions

We are proposing that the MLR provisions will apply to all MA organizations and Part D sponsors offering Part C or D coverage (except for the proposed exclusion of PACE organizations, and the proposed inclusion of cost plans' Part D coverage). For purposes of the RIA, we have estimated the total number of entities that would be affected by the requirements of this proposed rule at the contract level because this is the level at which we propose to apply the MLR. We believe that this is the best read of the statute at 1857(e) of the Act and that applying the MLR adjustment at the contract level would promote program stability and a variety of benefit structures.

Table 3 shows the estimated distribution of entities offering Part C and D contracts subject to MLR remittance requirements. Note that section 1876 Cost HMO/CMPs and section 1833 Cost HCPPs (Health Care Prepayment Plans) are excluded from this MLR analysis, as they do not submit Part C bids and only a few Part D bids for 2013 were submitted for section 1876 cost plans.

TABLE 3—ESTIMATED NUMBER OF CONTRACTS SUBJECT TO MLR REMITTANCE REQUIREMENTS

Contract type	Contract count	Estimated number of beneficiaries (in millions)
MA-PD*	544	14.3
Part D Stand-alone**	61	19.3
Total	605	33.6

* All MA contracts include at least one MA-PD plan, so are labeled MA-PD. Non-credible contracts, of which there are 11, are not displayed or included in this table as they are not subject to the remittance requirements.

** PACE and costs contracts are excluded.

Source: CMS administrative data on MA and Part D contracts, based on 2013 accepted bids. Beneficiary counts are bid projections.

Of the 605 MA-PD and Part D stand-alone contracts subject to the remittance requirement, we estimate that only 14 percent of these contracts will be required to pay an MLR related remittance to the Secretary in 2014. (see Table 5). This RIA provides estimates only for CY 2014, and, as a result, does not estimate the number of contracts that could undergo MLR-related

enrollment suspensions or terminations in subsequent years.

5. MLR Remittance Payments

a. Data Limitations and Modeling Assumptions

As described in the commercial MLR rules, we expect that as a result of this proposed rule, MA organization and

Part D sponsor behavior would change. Even if the 2013 bid data were a precise indication of actual claims costs and revenue for 2013, MLRs in 2014 may well be different as a result of plan sponsor behavioral change. However, for purposes of this analysis, we do not explicitly model these behavioral changes in our estimates. Potential behavioral changes as a result of this

proposed rule and the anticipated impact on our estimates are as follows:

- **Pricing Policy**—MA organizations and Part D sponsors would likely consider a number of responses in 2014 to minimize or avoid remittance (for example, reducing premium increases, or paying providers bonuses if incurred claims fall short of a certain threshold).

- **Activities That Improve Quality**—MA organizations and Part D sponsors may increase their quality-improving activities given the financial incentive to do so, or newly describe existing activities as such, and spending on these activities may change and vary significantly by MA organization or Part D sponsor.

- **Other Changes**—MA organizations and Part D sponsors are expected to carefully scrutinize all of their expenditures to determine whether some could legitimately be categorized as expenditures for clinical services, prescription drugs, or quality improving activities based on the definitions implemented by this regulation. Further, it is unclear to what extent companies may make other behavioral changes that could affect MLR remittances (for example, expanding coverage to increase medical claims, consolidation, requesting permission to split contracts into smaller contracts in order to receive credibility adjustments, etc.).

b. Methods for Estimating MLR Remittances

The analysis includes estimates that are based on both unadjusted and adjusted MLRs. An “adjusted MLR” refers to the MLR for a contract to which a credibility adjustment has been added, as described in section II.F. of this proposed rule. Accordingly, an unadjusted MLR is calculated without any credibility adjustment. Comparisons of unadjusted and adjusted MLRs are provided to assess the impact of the proposed credibility adjustments on partially-credible contracts. All MLRs reported in this analysis have denominators net of estimated federal and state taxes and licensing and regulatory fees, using data reported by MA organizations and Part D sponsors in their 2013 bids. Because the definitions of these taxes and fees are new to this rule, the estimates from the 2013 bid data may differ from how much they will actually spend on taxes and fees in 2014. Similarly, all estimated MLRs reported in this

analysis also incorporate 2013 bid estimates of expenses for quality improving activities, as reported by MA organizations and Part D sponsors. Because the definitions of quality improving activities are new to this rule, the estimates from the 2013 bid data may differ from how much they will actually spend on these activities in 2014.

The adjusted MLRs reflect application of the credibility adjustments for contracts that have partially credible experience. As described in section II.F. of this proposed rule, we propose that an MA–PD contract be defined as partially-credible when the enrollment is greater than or equal to 2,400 member months and no greater than 180,000 member months for a contract year. We propose that a Part D stand-alone contract be defined as partially-credible when the enrollment is greater than or equal to 4,800 member months and no greater than 360,000 member months for a contract year. We propose that these contracts receive a credibility adjustment to their MLRs to account for statistical variability in their claims experience that is inherent in contracts with smaller enrollment. We propose that MA–PD contracts are defined as fully-credible when the enrollment is greater than 180,000 member months and Part D stand-alone contracts are defined as fully-credible when the enrollment is greater than 360,000 member months. Reported MLR values for fully-credible contracts would not reflect a credibility adjustment. Finally, we propose that contracts are defined as having non-credible experience if the enrollment for a year is less than 2,400 member months for MA–PD contracts and less than 4,800 member months for Part D stand-alone contracts. Non-credible contracts would not be subject to the remittance requirements or other MLR-related sanctions specified in statute (and implemented in the regulations at § 422.2410(b), (c), and (d) and § 423.2410(b) through (d)). Section II.F. of the proposed rule describes the rationale and method for calculating credibility adjustments.

First, the unadjusted MLR for a contract is calculated as follows. Each component of the MLR numerator (incurred claims, expenditures for quality activities, Part B premium rebates amount, and Part D reinsurance) is summed across all plans under the contract for all projected enrollees and the contract-level components are then

summed. Next, each component of the MLR denominator (revenue net of taxes and fees, and Part D reinsurance) is summed across all plans under the contract for all projected enrollees, and the contract-level components are then summed. The ratio is then calculated to determine the unadjusted MLR. Finally, for contracts that are partially-credible and thus eligible for a credibility adjustment, and have an MLR below 85 percent prior to application of a credibility adjustment, we calculate an adjusted MLR for the contract by adding the applicable percentage points.

To estimate a remittance for a contract whose MLR falls below the minimum MLR requirement of 85 percent, we multiply the contract’s difference between the minimum MLR requirement of 85 percent and the contract’s MLR by the contract’s total revenue (as provided at § 422.2430(c) and § 423.2420(c).

c. Numbers and Enrollment of MA Organizations and Part D Sponsors Affected by the MLR Requirements and Associated MLR Remittance Payments

As shown in Table 4, we estimate that 336 MA–PD contracts and 26 Part D stand-alone contracts would be designated as “partially-credible” according to the standards of this proposed rule, and thus eligible for a credibility adjustment. That is, about 62 percent of MA–PD contracts (representing about 13 percent of projected total MA–PD enrollment) would be partially-credible, and about 43 percent of Part D stand-alone contracts (representing about 1 percent of projected total stand-alone enrollment) would be eligible for a credibility adjustment if the MLR falls below 85 percent. (Many MLRs for partially-credible contracts are estimated to meet the minimum MLR requirement, as shown in Table 5.)

A total of 208 MA–PD contracts and 35 Part D stand-alone contracts are estimated to be fully-credible, so are not eligible for a credibility adjustment. As discussed elsewhere in this proposed rule, contracts with non-credible experience during a given contract year that do not meet the minimum MLR requirement would not be required to provide any remittance to the Secretary nor be subject to enrollment or termination sanctions because the contract would not have a sufficiently large number of member months to yield a statistically valid MLR.

TABLE 4—ESTIMATED ENROLLMENT, REVENUE, AND AVERAGE MLR BY CREDIBILITY STATUS

Contract type	Credibility status	Contract count	Number of beneficiaries (in millions)	Total revenue (in billions)	Avg MLR* percent
MA–PD	Partial	336	1.8	\$20.8	89.6
	Full	208	12.5	135.8	88.9
Part D Stand-alone	Partial	26	0.2	0.4	86.7
	Full	35	19	31.3	88.4

Notes: The table excludes 9 MA–PD contracts and 2 Part D stand-alone contracts that are non-credible. Employer group waiver plans do not submit Part D bids, so are absent from the Part D stand-alone analysis, and only their MA bid data are included in the MA–PD analysis. This analysis does not explicitly model the impact of potential plan sponsor behavioral changes.

* Average MLRs reflect adjusted MLRs for those partially-credible contracts with MLRs below 85% prior to application of a credibility adjustment. Averages are enrollment-weighted. The average MLR for partially-credible contracts uses the MLR with credibility adjustment. Enrollment and total revenue are projections from the 2013 approved bids.

Source: CMS analysis of administrative data on MA and Part D contracts, based on 2013 accepted bids.

Finally, Table 4 shows average MLRs for the subgroups of MA–PD and Part D stand-alone partially- and fully-credible contracts. (The average MLRs for partially-credible contracts reflect the MLRs after application of a credibility adjustment for those partially-credible contracts with an MLR below 85 percent prior to application of a credibility adjustment.) On average, each of these four subgroups of contracts is estimated to meet the minimum MLR requirement, with average MLRs ranging from 86.7 percent to 89.6 percent. However, there are contracts within both subgroups of partially-credible and fully-credible that

do not meet the minimum MLR requirement, as shown in Table 5.

Total revenue for MA–PD contracts is the total MA revenue requirement + MA optional supplemental benefit premium (if any) + Part D basic bid + Part D reinsurance—Parts C and D taxes and fees.

Total revenue for Part D stand-alone contracts is the sum of the basic bid and Part D reinsurance, minus taxes and fees. Low-income cost sharing (LICS) payments are excluded.

Table 5 shows the number of MA–PD and Part D stand-alone contracts estimated to owe a remittance payment, before and after application of a

credibility adjustment to eligible partially-credible contracts. The figures in Table 5 were determined as follows. First, we used enrollment projections to determine which contracts are fully-credible and which are partially-credible. Next we calculated the MLRs with the credibility adjustment added for those partially-credible contracts with MLRs below 85 percent. Finally, to show the overall program impact of credibility adjustments, we calculated the estimated remittances for partially-credible and fully-credible contracts before and after application of credibility adjustments.

TABLE 5—ESTIMATED IMPACT OF CREDIBILITY ADJUSTMENT ON ESTIMATED MLR REMITTANCE PAYMENTS FOR CY 2014

Contract type	Credibility status	Number contracts	Number of contracts below 85% MLR before credibility adjustment	Estimated remittance without credibility adjustment (in millions)	Number of contracts below 85% after credibility adjustment	Estimated remittance with credibility adjustment (in millions)
MA–PD	Partial	336	68	\$109	34	\$55
	Full	208	37	662	37	662
	Total	544	105	771	71	717
Part D stand-alone	Partial	26	12	11	9	8
	Full	35	2	133	2	133
	Total	61	14	144	11	141

*Partially-credible contracts are those with enrollment levels that make them eligible for a credibility adjustment.

This analysis does not explicitly model the impact of potential plan sponsor behavioral changes.

Source: CMS analysis of administrative data on MA and Part D contracts, based on 2013 accepted bids.

Of the 336 MA–PD contracts that would be categorized as partially-credible, 68 would fail to meet the MLR minimum requirement of 85 percent in the absence of a credibility adjustment. The average MLR for this group of 68 contracts, prior to adding a credibility adjustment, is 82.6 percent. Upon application of the credibility adjustment, 34 of these 68 would pass the MLR requirement, and 34 would still have MLRs below 85 percent. The subset of 34 contracts that passes with application of the credibility adjustment has an average MLR of 85.7 percent. As

a result, the credibility adjustment decreases the estimated remittance amount by about \$54 million (from \$771 to \$717 million). However, it should be noted that the majority of the estimated remittance of \$717 million, that is, \$662 million, is owed by fully-credible contracts.

For Part D stand-alone contracts, 12 of the 26 partially-credible contracts would fail to meet the MLR minimum requirement in the absence of a credibility adjustment. The average MLR for this group of 12 contracts, prior to adding a credibility adjustment, is

80.4 percent. Upon application of the credibility adjustment, 3 of these 12 contracts would pass the requirement, and 9 would still have MLRs below 85 percent. The subset of 3 contracts that passes with application of the credibility adjustment has an average MLR of 86.8 percent. As a result, the credibility adjustment decreases the estimated remittance amount by about \$3 million (from \$144 to \$141 million). However, it should be noted that the majority of the estimated remittance of \$141 million, that is \$133 million, is owed by fully-credible contracts. Non-

credible contracts were excluded from this analysis because no sanctions under § 422.2410(b) through (d) would apply to these contracts; as these contracts will not have remittances, they do not factor into the analysis of the estimated impacts.

6. Administrative Costs Related to MLR Provisions

As stated previously this proposed rule implements the reporting requirements of section 1857(e)(4) of the Act, describing the medical loss ratio requirements and sanctions for not meeting those requirements, including a remittance payment of the difference to the Secretary and enrollment suspensions and contract termination for those who do not meet the requirements. Implementation of these requirements necessitates that a report be submitted to the Secretary and that MLR information be made available to the public in a time and manner that we determine, as well as the remittance calculation, payment and enforcement provisions of section 1857(e)(4) of the Act. We have quantified the primary sources of start-up costs that MA organizations and Part D sponsors will incur to bring themselves into compliance with this proposed rule, as well as the ongoing annual costs that they will incur related to these requirements. These costs and the methodology used to estimate them are discussed later in this section, on which we welcome comment.

a. Methodology and Assumptions for Estimating Administrative Costs

Many MA organizations and Part D sponsors already report to CMS several elements needed for the MLR calculation, for example, certain fields in the Part D prescription drug events records, and some information in the annual Part C and Part D Technical Reporting. This proposed rule includes requirements related to additional data elements. As discussed earlier in this

impact analysis, in order to assess the potential administrative burden relating to the requirements in this proposed rule, we drew on the regulatory impact analysis from the commercial MLR rules to gain insight into the tasks and level of effort required, and modified these estimated impacts for Medicare. Based on this review, we estimate that MA organizations and Part D sponsors will incur one-time start-up costs associated with developing teams to review the requirements in this proposed rule, and with developing processes for capturing the necessary data (for example, automating systems, writing new policies for tracking expenses in the general ledger, and developing methodologies for allocating expenses by lines of business and by contract). We estimate that MA organizations and Part D sponsors will also incur ongoing annual costs relating to data collection, populating the MLR reporting forms, conducting a final internal review, submitting the reports to the Secretary, conducting internal audits, record retention, preparing and submitting remittances, suspending enrollment (where appropriate), modifying marketing, and/or terminating contracts (where appropriate).

We anticipate that the level of effort relating to these activities will vary depending on the scope of an MA organization or Part D sponsor's operations. The complexity of each MA organization or Part D sponsor's estimated reporting burden is likely to be affected by a variety of factors, including the number of contracts it offers, enrollment size, the degree to which it currently captures relevant data, whether it is a subsidiary of a larger carrier, and whether it currently offers coverage in the commercial market (and is therefore subject to the commercial MLR requirements).

b. Costs Related to MLR Reporting

For each contract year, MA organizations or Part D sponsors must

submit a report to the Secretary that complies with the requirements of this proposed rule and in a time and manner that the Secretary determines. For purposes of these impact estimates, we assume that this report would include data relating to both the amounts expended on reimbursement for clinical services and prescription drugs, activities that improve quality and other non-clinical costs, as well as information relating to remittance payments.

The estimated total number of MLR data reports that MA organizations and Part D sponsors will be required to submit to the Secretary under the provisions of this proposed rule depends on the number of contracts held. We anticipate one report per contract. Our analysis here is based on 553 MA contracts and 63 Part D stand-alone contracts, for a total of 616 reports. The 616 contracts are comprised of 605 contracts subject to the remittance requirement plus 11 non-credible contracts that are subject to reporting requirements. We estimated the average cost per hour to be \$94.88. This figure was derived by using the May 2011 mean hourly wage of \$60.41 for computer and information systems managers from the Department of Labor's Bureau of Labor Statistics. This rate was increased by 48 percent to account for fringe benefits and overhead (36 percent for fringe benefits and 12 percent for overhead). This figure was then converted to 2014 dollars using an average annual growth rate derived from the changes to the Consumer Price Index. This is an upper-bound estimate that assumes all MA organizations and Part D sponsors would be submitting a separate MLR report for each contract. Table 6 shows our estimates that MA organizations and Part D sponsors will incur one-time costs in 2014 and ongoing costs thereafter, relating to the MLR reporting requirements in this proposed rule of approximately \$16,000 per contract on average in 2014.

TABLE 6—ESTIMATED ADMINISTRATIVE COSTS RELATED TO MEDICAL LOSS RATIO (MLR) REPORTING REQUIREMENTS

Type of administrative cost	Total number of contracts	Total number of reports	Estimated total hours	Estimated average cost per hour	Estimated total cost	Estimated average cost per report
One-Time Costs	616	616	90,000	\$94.88	\$9,600,000	\$16,000
Ongoing Costs	616	616	26,000	94.88	2,800,000	5,000

Notes: Total number of reports represents the estimated total number of MLR reports that will be submitted to the Secretary. The source data has been modified to reflect estimated costs for MA organizations and Part D sponsors. Values may not be exact due to rounding. Estimates reflect 2011 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

c. Costs Related to MLR Record Retention Requirements

Consistent with the assumptions discussed earlier, MLR record retention costs are assumed to be relatively negligible, since MA organizations and Part D sponsors already retain similar data for general MA and Prescription Drug audits and per the established requirements in § 422.504(f)(2) and § 423.505(f)(2). Therefore, to arrive at an

estimate for MA organizations and Part D sponsors, we adjusted downward the 3.5 minute-per-report estimate that appears in the RIA for the commercial MLR rule. Table 7 shows that we estimate that MA organizations and Part D sponsors would incur annual ongoing costs relating to the MLR reporting requirements in this proposed rule of approximately \$4.00 per report on average. We estimated the average cost per hour to be \$94.88. This figure was

derived by using the May 2011 mean hourly wage of \$60.41 for computer and information systems managers from the Department of Labor's Bureau of Labor Statistics. This rate was increased by 48 percent to account for fringe benefits and overhead (36 percent for fringe benefits and 12 percent for overhead). This figure was then converted to 2014 dollars using an average annual growth rated derived from the changes to the Consumer Price Index.

TABLE 7—MLR RECORD RETENTION REQUIREMENTS—ESTIMATED ONGOING ADMINISTRATIVE COSTS

Description	Total number of contracts	Total number of reports	Estimated total hours	Estimated average cost per hour	Estimated total cost	Estimated average cost per report
Ongoing Costs	616	616	28	\$94.88	\$2,600	\$4

Notes: Total number of reports represents the estimated total number of MLR reports that will be submitted to the Secretary. The source data has been modified to reflect estimated costs for MA organization and Part D sponsors. Values may not be exact due to rounding. Estimates reflect 2011 wage data from the U.S. Department of Labor, Bureau of Labor Statistics.

d. Costs Related to MLR Remittance Payments

Consistent with the assumptions discussed earlier, costs around submitting remittances to the Secretary are expected to be relatively negligible, in particular because we propose to implement payment of remittances using a standard payment adjustment procedure in our payment system, which is a routine systems interface for the industry.

E. Alternatives Considered

Under the Executive Order, we are required to consider alternatives to issuing regulations and alternative regulatory approaches. We consider a variety of regulatory alternatives to the policies proposed thus far, and solicit comments on these alternatives.

1. Credibility Adjustment

One alternative to the credibility adjustment in this proposed rule would be to not make any adjustment for credibility, and to require smaller plans to make remittance payments on the same terms as larger plans. If we do not adopt a credibility adjustment, the estimated remittance in 2014 would be approximately \$915 million for MA-PD and Part D stand-alone contracts, or approximately \$57 million larger, as shown in Table 5. As described elsewhere in this preamble, we believe that the credibility adjustment as proposed would best balance the goals of providing value to beneficiaries and assuring that contracts with relatively low enrollment would be able to function effectively.

2. Aggregation of MLR to the Contract Level

We considered two alternatives to aggregating MLRs to the contract level. Determining MLRs at the level of plan benefit package would increase the burden on MA organizations and Part D sponsors and the size of many plan benefit packages is too small for an MLR to reasonably represent the MA organization's or Part D sponsor's approach to resource allocation. We also considered calculating MLRs at the parent organization level, but we believe that this high level of aggregation would obscure local variation in resource allocation that would be important to enrollees. As described elsewhere in this proposed rule, we believe that the contract-level of aggregation is closest to the commercial MLR regulations of state-level aggregation and best promotes program stability.

3. Quality Improving Activities

After considering the commercial MLR regulations' approach to defining quality improving activities, we decided to propose aligning our definition of quality improving activities with the commercial MLR rule's approach. As discussed elsewhere in this proposed rule, potential alternatives would be to adopt narrower or broader definitions of quality improving activities. These distinctions could be made based on the criteria for selecting quality improving activities and/or the specific types of activities included in the definition.

This proposed rule defines quality-improving activities as being grounded in evidence-based medicine, designed to improve the quality of care received by an enrollee, and capable of being

objectively measured and producing verifiable results and achievements. A narrower definition might include only evidence-based quality improving initiatives, while excluding activities that have not been demonstrated to improve quality. Similarly, a narrower definition would not allow for inclusion of future innovations before data are available demonstrating their effectiveness.

Conversely, a broader definition might allow additional types of administrative expenses to be counted as activities that improve quality, such as network fees associated with third party provider networks or costs associated with converting International Classification of Disease (ICD) code sets from ICD-9 to ICD-10 that are in excess of 0.3 percent of a MA organization or Part D sponsor's total revenue. As discussed elsewhere in this proposed rule, while we agree that certain administrative expenses should not be counted as expenditures on quality improving activities, some traditional administrative activities could qualify as expenditures on quality improving activities if they meet the criteria set forth in this proposed rule.

We do not have data available to estimate the effects of alternative definitions of quality improving activities on MLRs, although it should be clear that if a broader definition of quality improving activities were adopted, then estimated remittances would be smaller, and if a narrower definition were adopted, estimated remittances would be larger.

F. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) (RFA) requires

agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The Act generally defines a "small entity" as (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of "small entity.") HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed earlier, in general, health insurance issuers offering Part C and D coverage, including MA organizations, Part D sponsors, 1876 Cost HMO/CMPs, and section 1833 HCCPs (Health Care Prepayment Plans), would be affected by the proposed rule. We believe that health insurers would be classified under the North American Industry Classification System (NAICS) Code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$7 million or less would be considered small entities for this NAICS code. Health issuers could possibly also be classified in NAICS Code 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$10 million or less.

As discussed in the Web Portal interim final rule (75 FR 24481), HHS examined the health insurance industry in depth in the RIA we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis we determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the relevant size thresholds for "small" business established by the SBA.

Similarly, MA organizations and Part D sponsors, the entities that will largely be affected by the provisions of this proposed rule, are not generally considered small business entities. They must follow minimum enrollment requirements (5,000 in urban areas and 1,500 in nonurban areas) and because of the revenue from such enrollments, these entities are generally above the revenue threshold required for analysis under the RFA. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. Additionally, a

fraction of MA organizations and sponsors could be considered small businesses because of their non-profit status and lack of dominance in their field. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule because very few small entities are subject to the provisions in this proposed rule, the estimated administrative costs associated with reporting MLR data to the Secretary are very low (see section V.D.6. of this proposed rule), and the credibility adjustment addresses the special circumstances of contracts with lower enrollment. For these reasons, we believe this proposed rule would have minimal impact on small entities. As a result, the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small entities. We welcome comment on the analysis described in this section and on HHS' conclusion.

G. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any 1 year by state, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2013, that threshold level is approximately \$141 million.

UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those "federal mandate" costs resulting from: (1) Imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

Consistent with policy embodied in UMRA, this proposed regulation has been designed to a low-burden alternative for state, local and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

This proposed rule contains reporting requirements and data retention requirements for MA organizations and Part D sponsors. We estimate that administrative costs related to MLR reporting requirements would be \$9.6 million in total one-time costs in 2014 and \$2.8 million per year in ongoing

costs. We estimate that ongoing costs per year for record retention requirements will be \$2,600. This proposed rule also contains requirements related to remittance payments paid by MA organizations and Part D sponsors that do not meet the minimum MLR standards. We estimate approximately \$858 million in remittance payments to the Secretary in 2014, contingent upon certain changes in bidding and payment behavior. It includes no mandates on state, local, or tribal governments.

H. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications.

States generally regulate health insurance coverage. However in 2003, section 232(a) of the MMA amended section 1856 for MA plans by eliminating the general and specific preemption distinctions from section 1856 and expanded federal preemption of state standards to broadly apply preemption to all state law or regulation (other than state licensing laws or state laws relating to plan solvency). In our view, while this proposed rule does not impose substantial direct requirement costs on state and local governments, this proposed rule has minimal Federalism implications due to direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining and enforcing minimum MLR standards, reporting and remittance requirements relating to coverage that MA organizations and Part D sponsors offer.

We anticipate that the federalism implications (if any) are substantially mitigated because the Affordable Care Act does not provide any role for the states in terms of receiving or analyzing the data or enforcing the requirements of section 1857(e)(4) of the Act. The enforcement provisions of this proposed rule state that the Secretary has enforcement authority and does not require the states to do anything.

As discussed earlier, in developing this proposed rule for the Medicare Advantage and the Medicare Prescription Drug Benefit programs, HHS used the commercial MLR regulations as a reference point for developing the Medicare MLR requirements. In compliance with the requirement of Executive Order 13132 that agencies examine closely any

policies that may have federalism implications or limit the policymaking discretion of the states, HHS made efforts to consult with and work cooperatively with states during the development of the commercial MLR regulation, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis. Throughout the process of developing the commercial MLR regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Department attempted to balance the states' interests in regulating health insurance issuers,

and Congress' intent to provide uniform minimum protections to consumers in every state.

By doing so, it is the Department's view that we have complied with the requirements of Executive Order 13132. Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that we have complied with the requirements of Executive Order 13132 for the attached proposed rule in a meaningful and timely manner.

I. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory

Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

J. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), we have prepared an accounting statement in Table 8 showing the classification of the transfers and costs associated with the provisions of this proposed rule for CY 2014.

TABLE 8—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE MA-PD AND PART D STAND-ALONE MLR REMITTANCE PAYMENTS FOR CY 2014
[In millions of 2013 dollars]

Category	Transfers	
	Discount Rate	Period Covered
Annualized monetized transfers	7%	3% CY 2014
Primary Estimate	\$802	\$833
From/To	From MA Organizations and Part D Sponsors/To Federal Government	
Category	Costs	
	Discount Rate	Period Covered
Annualized Costs to MA Organizations and Part D Sponsors	7%	3% CY 2014
Primary Estimate	\$9.0	\$9.3

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR parts 422 and 423 as set forth below:

PART 422 MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 422.510 is amended by adding paragraphs (a)(15) and (16) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(15) Has failed to report MLR data in a timely and accurate manner in accordance with § 422.2460.

(16) Has failed to have a minimum MLR per § 422.2410(d) for 5 consecutive contract years.

* * * * *

Subpart U—[Reserved]

Subpart W—[Reserved]

- 3. Add reserved subparts U and W.
- 4. Add subpart X to read as follows:

Subpart X—Requirement for a Minimum Medical Loss Ratio

- Sec. 422.2400 Basis and scope.
- 422.2401 Definitions.
- 422.2410 General requirements.
- 422.2420 Calculation of the medical loss ratio.
- 422.2430 Activities that improve health care quality.
- 422.2440 Credibility adjustment.
- 422.2450 [Reserved].
- 422.2460 Reporting requirements.
- 422.2470 Remittance to CMS if the applicable MLR requirement is not met.
- 422.2480 MLR review and non-compliance.

§ 422.2400 Basis and scope.

This subpart is based on section 1857(e)(4) of the Act, and sets forth

medical loss ratio requirements for Medicare Advantage organizations, and financial penalties and sanctions against MA organizations when minimum medical loss ratios are not achieved by MA organizations.

§ 422.2401 Definitions.

Non-claims costs means those expenses for administrative services that are not—

- (1) Incurred claims (as provided in § 422.2420(b)(2) through (4));
- (2) Expenditures on quality improving activities (as provided in § 422.2430);
- (3) Licensing and regulatory fees (as provided in § 422.2420(c)(2)(ii));
- (4) State and federal taxes and assessments (as provided in § 422.2420(c)(2)(i) and (iii)).

§ 422.2410 General requirements.

(a) For contracts beginning in 2014 or later, an MA organization (defined at § 422.2) is required to report an MLR for each contract under this part for each contract year.

(b) *MLR requirement.* If CMS determines for a contract year that an MA organization has an MLR for a contract that is less than 0.85, the MA organization has not met the MLR requirement and must remit to CMS an amount equal to the product of the following:

- (1) The total revenue of the MA contract for the contract year.
- (2) The difference between 0.85 and the MLR for the contract year.

(c) If CMS determines that an MA organization 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 an MA organization 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 § 422.510(a)(12) and (15) effective as of the second succeeding contract year.

§ 422.2420 Calculation of the medical loss ratio.

(a) *Determination of 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 § 422.2440.

(2) The MLR for an MA contract not offering Medicare prescription drug benefits must only reflect costs and revenues related to the benefits defined

at § 422.100(c). The MLR for an MA contract that includes MA–PD plans (defined at § 422.2) must also reflect costs and revenues for benefits described at § 423.104(d) through (f).

(b) *Determining the MLR numerator.*

(1) For a contract year, the numerator of the MLR for an MA contract must equal the sum of paragraphs (b)(1)(i) through (iii) of this section and be in accordance with paragraph (b)(1)(iv) of this section.

(i) Incurred claims for all enrollees, as defined in paragraphs (b)(2) through (4) of this section.

(ii) The amount of the reduction, if any, in the Part B premium for all MA plan enrollees under the contract for the contract year.

(iii) The expenditures under the contract for activities that improve health care quality, as defined in § 422.2430.

(iv) Incurred claims under this part for policies issued by one MA organization and later assumed by another MA organization under an assumptive or 100 percent indemnity reinsurance must be reported by the assuming organizations 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 MA organization.

(2) *Incurred claims for clinical services and prescription drug costs.*

Incurred claims must include the following:

(i) Direct claims that the MA organization pays to providers (including under capitation contracts with physicians) for covered services described at paragraph (a)(2) of this section provided to all enrollees under the contract.

(ii) For an MA contract that includes MA–PD plans (described in paragraph (a)(2) of this section), drug costs provided to all enrollees under the contract, as defined at § 423.2420(b)(2)(i).

(iii) Unpaid claims reserves for the current contract year, including claims reported in the process of adjustment.

(iv) Percentage withholds from payments made to contracted providers.

(v) Incurred but not reported claims based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(vi) Changes in other claims-related reserves.

(vii) Claims that are recoverable for anticipated coordination of benefits.

(viii) Claims payments recoveries received as a result of subrogation.

(ix) Claims payments recoveries as a result of fraud reduction efforts not to

exceed the amount of fraud reduction expenses.

(x) Reserves for contingent benefits and the medical claim portion of lawsuits.

(xi) The amount of incentive and bonus payments made to providers.

(3) Adjustments that must be deducted from incurred claims include the following:

(i) Prescription drug rebates and other direct or indirect remuneration as defined in § 423.308 received by the MA organization under the contract.

(ii) 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 § 422.2401, which include the following:

(A) Amounts paid to third party vendors for secondary network savings.

(B) Amounts paid to third party vendors for all of the following:

- (1) Network development.
- (2) Administrative fees.
- (3) Claims processing.
- (4) Utilization management.

(C) Amounts paid, including amounts paid to a provider, 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 § 422.2410(b).

(c) *Determining the MLR denominator.* For a contract year, the denominator of the MLR for an MA contract must equal the total revenue under the contract, 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 paragraph (c)(3) of this section, and be in accordance with paragraph (c)(4) of this section.

(1) *Total revenue* must be reported on a direct basis and means CMS' payments to the MA organization for all enrollees under a contract, including the following:

(i) Payments under § 422.304(a) through (3) and (c).

(ii) The amount applied to reduce the Part B premium, as provided under § 422.266(b)(3).

(iii) Payments under § 422.304(b)(1), as reconciled per § 423.329(c)(2)(ii).

(iv) All premiums paid by or on behalf of enrollees to the MA organization as a condition of receiving coverage under an MA plan, including CMS' payments for low income premium subsidies under § 422.304(b)(2).

(v) All unpaid premium amounts that an MA organization could have collected from enrollees in the MA plan(s) under the contract.

(vi) All changes in unearned premium reserves.

(vii) Payments under § 423.315(e).

(2) The following amounts must be deducted from total revenue in calculating the MLR:

(i) *Licensing and regulatory fees.* (A) 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.

(B) 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* are payments made by a federal income tax-exempt MA organization for community benefit expenditures as defined in paragraph (c)(2)(iv)(A) of this section, limited to the amount defined in paragraph (c)(2)(iv)(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 MA organization can demonstrate to CMS that it made a reasonable effort to collect, as required under § 422.74(d)(i).

(ii) The following EHR payments and adjustments:

(A) EHR incentive payments for meaningful use of certified electronic health records by qualifying MAOs, MA EPs and MA-affiliated eligible hospitals that are administered under Part 495 subpart C.

(B) EHR payment adjustments for a failure to meet meaningful use requirements that are administered under Part 495 subpart C.

(iii) Coverage Gap Discount Program payments under § 423.2320.

(4) All incurred claims under this part for policies issued by one MA organization and later assumed by another MA organization under an assumptive or 100 percent indemnity reinsurance must be reported by the assuming organizations 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 MA organization.

(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 § 422.2420(b) or (c) 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 contracts 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.

§ 422.2430 Activities that improve health care quality.

(a) *Activity requirements.* Activities conducted by an MA organization to improve quality must 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. Such 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.

(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 provider 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 to 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 provider contracts and fees associated with establishing or managing a provider network, including

fees paid to a vendor for the same reason.

- (10) Provider 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.

§ 422.2440 Credibility adjustment.

- (a) An MA organization may add a credibility adjustment to a contract's MLR if the contract's experience is partially credible, as determined by CMS.
- (b) An MA organization 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 § 422.2410(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.

§ 422.2450 [Reserved].

§ 422.2460 Reporting requirements.

For each contract year, each MA organization 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 MA organization to calculate and verify the MLR and remittance amount, if any, for each contract, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 422.2410.

§ 422.2470 Remittance to CMS if the applicable MLR requirement is not met.

- (a) *General requirement.* For each contract year, an MA organization must provide a remittance to CMS if the contract's MLR does not meet the minimum MLR requirement required by § 422.2410(b) of this subpart.
- (b) *Amount of remittance.* For each contract that does not meet the MLR requirement for a contract year, the MA organization must remit to CMS the amount by which the MLR requirement exceeds the contract's actual MLR multiplied by the total revenue of the

contract, as provided in § 422.2420(c), for the contract year.

(c) *Timing of remittance.* CMS deducts 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.

§ 422.2480 MLR review and non-compliance.

To ensure the accuracy of MLR reporting, CMS conducts selected reviews of reports submitted under § 422.2460 to determine that that the MLRs and remittance amounts under § 422.2410(b) and sanctions under § 422.2410(c) and (d), were accurately calculated, reported, and applied.

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

(b) MA organizations 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 MLR reporting year.

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

(d) Reports submitted under § 422.2460, calculations, or any other MLR submission required by this subpart found to be materially incorrect or fraudulent—

- (1) Is noted by CMS;
- (2) Appropriate remittance amounts are recouped by CMS; and
- (3) Sanctions may be imposed by CMS as provided in § 422.752.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 5. The authority for part 423 continues to read as follows:

Authority: Secs. Sections 1102, 1106, 1860D-1 through 1860D-42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh).

■ 6. Section 423.509 is amended by adding paragraphs (a)(15) and (16) to read as follows:

§ 423.509 Termination of contract by CMS.

(a) * * *

(15) Has failed to report MLR data in a timely and accurate manner in accordance with § 423.2460.

(16) Has failed to have a minimum MLR per § 423.2410(d) for 5 consecutive contract years.

* * * * *

■ 7. Add subpart X to read as follows:

Subpart X—Requirements for a Minimum Medical Loss Ratio

Sec.

423.2300 Basis and scope.

423.2401 Definitions.

423.2410 General requirements.

423.2420 Calculation of medical loss ratio.

423.2430 Activities that improve health care quality.

423.2440 Credibility adjustment.

422.2450 [Reserved]

423.2460 Reporting requirements.

423.2470 Remittance to CMS if the

applicable MLR requirement is not met.

423.2480 MLR review and non-compliance.

§ 423.2400 Basis and scope.

This subpart is based on section 1857(e)(4) of the Act, and sets forth medical loss ratio requirements for Part D sponsors, and financial penalties and sanctions against Part D sponsors when minimum medical loss ratios are not achieved by Part D sponsors.

§ 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 an MLR 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 does terminate the contract under the authority at § 423.509(a)(11) and (14) effective as of the second succeeding contract year.

§ 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.

(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) must also reflect costs and revenues for benefits described at § 422.100(c).

(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 paragraph (b)(1)(iv) of this section.

(i) Incurred claims for all enrollees, as defined in paragraphs (b)(2) through (4) of this section.

(ii) The amount of the reduction, if any, in the Part B premium for all MA plan enrollees under the contract for the contract year.

(iii) The expenditures under the contract for activities that improve health care quality, as defined in § 423.2430;

(iv) Incurred claims under this part for policies issued by one Part D sponsor and later assumed by another Part D sponsor under an assumptive or 100 percent indemnity reinsurance must be reported by the assuming organizations 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.

(2) *Incurred claims for prescription drug costs.* Incurred claims must include the following:

(i) Drug costs that are actually paid (as defined in § 423.308) 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) Claims payments recoveries received as a result of fraud reduction efforts not to exceed the amount of fraud reduction expenses.

(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) Prescription drug rebates and other direct or indirect remuneration as defined in § 423.308 received by the Part D sponsor under the contract.

(ii) 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).

(c) *Determining the MLR denominator.* For a contract year, the denominator of the MLR for a Part D prescription drug contract must be in accordance with (c)(4) and equal the total revenue under the contract, 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 paragraph (c)(3) of this section, and be in accordance with (c)(4) of this section.

(1) *Total revenue* must be reported on a direct basis and means CMS' payments to the Part D sponsor for all enrollees under a contract, 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).

(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, as required under § 423.44(d)(1)(i).

(ii) Coverage Gap Discount Program payments under § 423.2320.

(4) All incurred claims under this part for policies issued by one Part D sponsor and later assumed by another Part D sponsor under an assumptive or 100 percent indemnity reinsurance must be reported by the assuming organizations 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.

(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.

(ii) Specific identification of an expense with an activity that is represented by one of the categories in § 423.2420(b) or (c) will generally be the most accurate method.

(iii) 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.

§ 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 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 MLR and remittance amount, if any, for each contract, such as incurred claims, total revenue, costs for quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 423.2410.

(b) Total revenue reported as part of the MLR report must be net of all projected reconciliations.

(c) The MLR will be reported once, and will not be reopened as a result of any payment reconciliation processes.

§ 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 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 reviews of reports 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) Reports 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 § 422.752.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 28, 2012.

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*Acting Administrator, Centers for Medicare
& Medicaid Services.*

Approved: February 14, 2013.

Kathleen Sebelius,

*Secretary, Department of Health and Human
Services.*

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