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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS-4173-F]

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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: Final rule.

SUMMARY: This final rule implements new medical loss ratio (MLR) requirements for the Medicare Advantage Program and the Medicare Prescription Drug Benefit Program established under the Patient Protection and Affordable Care Act.

DATES: These regulations are effective on July 22, 2013.

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

SUPPLEMENTARY INFORMATION:

I. Background

We are publishing this final rule for the Medicare Advantage (Part C) and prescription drug (Part D) programs to make changes as required by the Patient Protection and Affordable Care Act (Pub. L. 111-148) as amended by the Health Care and Education Reconciliation Act (Pub. L. 111-152) (“Reconciliation Act”), which we refer to 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 12, 2012 (77 FR 22072) and a correction was published June 1, 2012 (77 FR 32407).

This final rule implements 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) of the Act, 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 the Secretary, a prohibition on enrolling new members, and ultimately contract termination. In the February 22, 2013 **Federal Register** (78 FR 12428), we published a proposed rule with revisions to the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D). This final rule sets forth CMS’ implementation of these new MLR requirements for the MA and Part D programs.

II. Provisions of the Proposed Rule and Summary of and Responses to the Public Comments

We received approximately 51 items of timely correspondence containing comments in response to the February 22, 2013 proposed rule. These public comments addressed issues on multiple topics. Commenters included health and drug plan organizations, insurance industry trade groups, provider associations, pharmacist and pharmacy associations, beneficiary advocacy groups, private citizens, and others. Overall, commenters supported our decision to model Medicare MLR policy after the commercial MLR rules.

In this final rule, we address comments and concerns regarding the policies included in the proposed rule. We present a summary of public comments received, as well as our responses to them in the applicable section of this final rule.

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 such as marketing costs, profits, and other uses of the funds earned by MA organizations and Part D sponsors and

to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans. Under this final rule, an MLR will be determined based on the percentage of Medicare 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 an MA organization or Part D 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.

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

This section discusses the scope of the Medicare MLR requirements and the applicability to various plan types. 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 final rule implements 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.” Subpart X for the MA program has the same structure as 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 provisions are discussed within each section. Any differences between the MA and Part D provisions

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, we are finalizing that MLR requirements set forth in this final rule only apply to the Part D portion of the benefits offered by Cost HMOs/CMPs and employers/unions offering HCPPs. We are finalizing our proposal that we would treat these contracts like PDPs for MLR purposes. If a Cost HMO/CMP or an HCPP does not meet the minimum MLR requirement on the Part D portion of the benefits it provides to Medicare enrollees, for 3 consecutive years, it will be forced to stop enrolling new individuals in such Part D coverage and, after 5 consecutive years, will potentially lose the Part D portion of its contract.

As explained in the proposed rule, we believe that for PACE organizations offering Part D, the situation is different such that we should use our authority under the PACE statute to waive Medicare MLR requirements for PACE organizations. We received a comment on this proposal, which supported our proposed approach, and thus we are finalizing this proposal without modification, and are not applying the Part D MLR requirements to the Part D offerings of PACE organizations.

Comment: Several commenters supported the proposed rule and CMS's general approach of using the commercial MLR rules as a reference point for developing the Medicare MLR requirements.

Response: We appreciate the support.

Comment: Many commenters believe that CMS has the discretion to not apply the Medicare MLR requirements to the Part D program, citing what they contended was a lack of evidence of Congressional intent to do so, or noting that holding Part D stand-alone contracts to the same minimum MLR as MA contracts is unfair because of relatively low drug claims costs or more volatility compared to medical-only plans or plans with both medical and drug benefits. Several commenters pointed to the provision in section 1857(e)(3) of the Act that applies to contracts with federally qualified health centers (FQHCs) as a precedent for not applying a provision in section 1857(e) of the Act to Part D, presumably based on the belief that the FQHC provision does not apply to Part D.

Another commenter stated that, if Medicare MLR applies to Part D, we should consider a multiplier to increase Part D MLRs. Another commenter asked us to consider lowering the 85 percent requirement for Part D contracts. Some commenters argued that enforcing an MLR for Part D contracts would be unnecessary because plans are already subject to risk corridors that serve as an upper limit on net revenue. A commenter suggested that, at a minimum, CMS delay the applicability of Medicare MLR requirements to Part D until 2015. Several commenters supported applying Medicare MLR requirements to the Part D program.

Response: In the proposed rule, we explained that the statute requires us to apply all provisions in section 1857(e) of the Act to the Part D program. We disagree that the FQHC provision is relevant precedent for understanding the Medicare MLR statute. While this provision is not applicable as a practical matter, as Part D sponsors do not subcontract with FQHCs to provide FQHC services, if a Part D plan ever did so, that contract would be subject to this provision. In the case of the MLR rule, however, it clearly can be applied to drug costs, as it is under the commercial MLR rule upon which this rule is based.

With respect to the commenters seeking special treatment for Part D under the MLR rule, our analysis suggests that by including Part D reinsurance payments in the MLR calculation, meeting the minimum MLR requirement will be reasonably achievable for Part D stand-alone contracts and thus a multiplier to increase MLRs for these contracts is not necessary. We believe that the MLR requirements and risk sharing achieve different goals, though they are related. The purpose of risk sharing as part of the Part D payment reconciliation is for sponsors and the government to share in the unexpected gains or losses to a sponsor that are not already included in the reinsurance subsidy or taken into account through risk adjustment. The MLR requirement places a lower bound on the percent of total revenue that must be spent on claims and quality improving activities, which risk sharing does not. Furthermore, one objective that the MLR policy will accomplish, that risk sharing does not, is to provide beneficiaries a measure by which they can compare relative value of Medicare products.

Comment: A few commenters believe that the Medicare MLR requirements should not apply to Part D stand-alone contracts because the Medicare MLR should mirror the commercial MLR, which the commenters believe does not

require MLR reporting for drug-only coverage.

Response: As discussed in the prior response, the statute requires us to apply the Medicare MLR requirement to the Part D program. Moreover, the commercial MLR rule does apply to an insurance policy covering only drugs, as it applies to all health insurance coverage as defined by the Public Health Service Act, so the premise of the question is incorrect.

Comment: A commenter believed that applying MLR to Part D would make it difficult for beneficiaries to compare Medicare MLRs within the Medicare market and between the Medicare and commercial markets.

Response: By applying the Medicare MLRs to the Part D program, we believe that beneficiaries can meaningfully compare health insurance products between the Medicare and commercial markets. We recognize that the advantage to beneficiaries of applying the Medicare MLRs to Part D stand-alone contracts is to allow for comparison among the stand-alone contracts more so than comparison with the MA-PD contracts.

Comment: A commenter expressed concern about the MLR requirements placing Cost Plans at a competitive disadvantage. The commenter gave the example of a beneficiary comparing an MA-PD with a Cost Plan that offers Part D and concluding that the MA-PD offers better value based on the MLR even if Cost Plan is more efficient in providing drug coverage. In this situation, the commenter was concerned that it would reflect poorly on the Cost Plan as a whole and not just on the Part D portion of the plan.

Response: Because the MLR rule is applied to the Part D portion of the benefits offered by Cost Plans, we will be treating them like PDPs for MLR purposes. Thus, when we make MLR information available to the public, we plan to make clear which MLRs are associated with comprehensive benefits and which are associated only with a drug benefit.

Comment: Because beneficiary premiums fund 25 percent of the value of benefits offered under Part D plans, a commenter believes that absence of any mechanism to share the remittances with beneficiaries is further evidence that the Medicare MLR requirement is not applicable to Part D.

Response: That would not be a reason to exempt Part D coverage, as beneficiaries with Part C coverage may also have a premium.

Comment: A commenter sought clarification regarding the applicability of the rule for section 1876 Cost HMO/

CMPs and section 1833 Cost HCPPs (Health Care Prepayment Plans) that offer Part D.

Response: As the Medicare MLR rule will only apply to the Part D portion of the benefits offered by Cost HMOs/ CMPs and employers/unions offering HCPPs, we will treat them like PDPs instead of MA-PDs for MLR purposes.

Comment: A commenter stated that application of the MLR to Part D would create an uneven playing field due to the manner by which LIS beneficiaries are auto-enrolled into certain plans without sponsors paying agent and broker fees to acquire this new enrollment. Because agent and broker fees are considered administrative costs under this rule, the commenter suggests that those contracts with high levels of auto-enrolled beneficiaries would be advantaged in meeting the MLR requirements.

Response: We do not believe this introduces a systemic bias that favors particular plan sponsors. Every plan sponsor has the potential to bid below the LIS benchmark and receive auto-enrollment for its non-enhanced PDPs.

Comment: A commenter supported applying the Medicare MLR requirements to EGWPs, while another commenter requested that we waive the Medicare MLR requirements for all EGWPs. A few commenters requested clarification that the MLR applies only to the defined standard benefit for Part D EGWPs in light of CMS' policy effective as of January 2014 that supplemental benefits for Part D EGWPs will be considered non-Medicare benefits for purposes of adjudicating the benefit and populating PDE records.

Response: The MLR statutory provision does not provide for an exemption for EGWPs and thus applies to contracts offering MA and Part D plans. As a significant percentage of MA enrollees are members of EGWPs (about 20 percent), we believe that it is important not to exempt EGWPs. We expect EGWPs to report costs and revenue per § 422.2420 and § 423.2420 on the Medicare-funded portion of each contract. Additional information regarding how to determine the Medicare-funded portion of each contract will be provided in sub-regulatory guidance or in the Paperwork Reduction Act notice and comment process. We note that though we currently do not collect information on EGWP benefit packages, we have the authority to request this information if needed. For non-CY EGWPs, we expect that MLR calculations and remittances would occur on a calendar year basis, similar to how payments and most

submissions to CMS are on a calendar year basis.

Comment: A commenter supported not applying the Part D MLR requirements to the Part D offerings of PACE organizations.

Response: We appreciate the support, and as noted previously we are adopting this policy in this final rule.

Comment: A few commenters inquired how the Medicare MLR requirements will apply to private health plans participating in state demonstration to integrate care for dually eligible Medicare and Medicaid beneficiaries.

Response: Unless waived, all applicable statutory and regulatory requirements of the Medicare program apply to plans participating in these demonstrations. During the demonstration development process, we will determine, in conjunction with participating states, whether and to what extent to waive the Medicare MLR requirement.

2. Definitions

In proposed § 422.2401 and § 423.2401, we stated that the acronym MLR would be used to refer to the medical loss ratio referenced in Part 422, Subpart X and Part 423, Subpart X. We also defined 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.

After consideration of the public comments received, we are finalizing these provisions as proposed.

C. General Requirements for MA Organizations and Part D Sponsors

Sections 1857(e)(4) and 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.

Comment: A few commenters requested that we deviate from requiring an 85 percent MLR for a contract year in favor of a lower MLR requirement, or that we calculate MLRs using a rolling 3-year average as required in the commercial markets.

Response: The 85 percent standard is set in statute, as is the fact that an MLR is calculated for each "contract year."

1. Aggregation of MLR to the Contract Level

We proposed 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, instead of at the MA plan level or at the MA organization level. We also proposed requiring MA organizations to report one MLR for each contract that includes MA-PD plans, instead of one for nondrug benefits and another for prescription drug benefits.

Comment: Many commenters supported reporting MLRs at a higher level than the contract level, such as at the parent organization level. The commenters noted that this approach would be preferable as there would be less claims variation, would be administratively less burdensome to report, would reflect the national character of the Medicare program, is the closest option to the commercial MLR, and would ensure a level playing field. A few commenters recommended that CMS require aggregation of the MLR for MA organizations at the contract level within a state and for Part D stand-alone contracts at the contract level by region. Another commenter suggested that the appropriate level of aggregation is aggregated to the state level by MA or Part D plan, noting that beneficiaries enroll in plans and not contracts, that a good MLR at the contract level may mask low-value plans underneath it, and that applying sanctions at plan level would cause the least beneficiary disruption. These commenters recognized the potential value of reporting plan-level MLRs and urged us to continue considering this option after the final rule is published. Several commenters suggested that sponsors be able to choose a level of aggregation when reporting MLRs similar to the manner in which they can choose the level of aggregation when determining gain/loss margins for bidding. Many commenters agreed with reporting at the contract level as proposed.

Response: We continue to believe that reporting MLRs at the contract level strikes an appropriate balance of

administrative burden, meaningful MLRs, and comparability with commercial MLR reporting. Although Medicare is a national program, beneficiaries consider the coverage options available to them in a particular geographic area, which often correlates with the state in which they live. As MA and PDP contracts are often executed at the state level and no other reporting for MA and Part D organizations is done at the state level of aggregation, we believe that reporting Medicare MLRs at the contract level is preferable. This level of aggregation parallels the commercial MLR approach, which aggregates the MLR to the state and market level, and avoids imposing administrative burden for the minority of contracts that span multiple states. Contrary to the claim that aggregating at the parent organization level is necessary to ensure a level playing field, it would in fact favor parent organizations that operate nationally by allowing claims and revenues to be shifted around to meet the MLR requirements, which a parent organization with more limited scope would be unable to do.

Though we recognize that the value of individual plans in a contract may differ from one another, we also need to keep in mind that calculating MLRs at the plan level would necessitate higher credibility adjustments due to higher random claims variation; and therefore, may not result in a better measure of value. If we allowed sponsors to choose their level of reporting, then the foremost concern is that resulting MLRs would not be comparable by beneficiaries. We presume that most MA organizations and Part D sponsors would choose to report at the highest level of parent organization, which would raise the concerns we have previously discussed of meaningfulness of the MLR and significant beneficiary disruption in the event of enrollment sanction or contract termination.

Comment: Many commenters agreed with our proposed approach of reporting one combined MLR for MA only and MA-PD contracts for clarity to beneficiaries and the public.

Response: We appreciate the support.

After consideration of the public comments received, we are finalizing the level of aggregation for reporting Medicare MLR at the contract level as proposed.

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 will not have been met and the sponsoring organization will be required to remit a payment to CMS. The amount of the remittance will 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 final rule.

Comment: Notwithstanding the statutory requirement for remittances to be paid to the Secretary, a few commenters believe that we should reimburse Medicare beneficiaries who paid premiums to plans that did not meet the 85 percent MLR during the plan year.

Response: As the commenters note, the statute expressly provides that MA organizations and Part D sponsors must remit to the Secretary when the minimum MLR is not met.

After consideration of the public comments received, we are finalizing these provisions as proposed.

3. Enrollment Sanction

As set forth in § 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, enrollment of new enrollees in plans under that contract will be prohibited. The year for which this enrollment sanction will apply will 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 will be reported in 2015 through 2017. If a contract did not meet the MLR requirement for the 2014, 2015, and 2016 contract years, new enrollment in plans under that contract will be prohibited beginning in 2018, which is the second succeeding contract year after the third consecutive year of failure (2016) to meet the MLR requirement.

Comment: A few commenters suggested establishing a special enrollment period to allow beneficiaries under MA or Part D contracts that do not meet the minimum MLR to disenroll and select a new plan.

Response: As discussed in section II.G. of this final rule, we are requiring MA organizations and Part D sponsors that fail to meet the minimum MLR 2 years in a row to report earlier the following year, such that any beneficiary would have sufficient time to select a new plan during the annual election period. Thus, we do not believe that a special enrollment period would be necessary. We note that in the

circumstance of a contract termination for failure to meet the MLR, during the special enrollment period, enrollees in the plans under that contract being terminated would be notified that they have to elect another option for the year the termination takes effect, or would be placed under original Medicare.

Comment: A commenter requested that CMS interpret the enrollment sanction required after the "second succeeding contract year" as the second succeeding contract year following submission of the report. The commenter noted that such an interpretation would avoid imposing enrollment suspensions on MA organizations and Part D sponsors after they have already submitted their bids.

Response: We believe that one purpose of the enrollment sanction is to keep beneficiaries from enrolling in low value plans. The plain reading of the statute supports this goal, whereas interpreting the enrollment sanction to apply the second succeeding contract year following submission of the report would allow new enrollment into low value plans for another year.

Comment: A commenter asked for new enrollment to be allowed for plans that meet MLR requirements in the fourth year of reporting but had failed to meet the requirements for 3 consecutive years.

Response: If a contract fails to meet the minimum MLR for contract years 2014, 2015, and 2016, the enrollment sanction for all plans under that contract will be for contract year 2018. If the contract then meets the minimum MLR for 2017, new enrollment for plans under that contract will be allowed during contract year 2019.

Comment: A commenter urged that the processes that currently apply to suspensions of enrollment imposed as an intermediate sanction should apply to prohibitions on new enrollment based on a failure to meet MLR requirements.

Response: We would not expect an MA organization or Part D sponsor to contest a suspension of enrollment since it is required by statute and would be based on an MLR that the organization itself reported. However, if an MA organization or Part D sponsor wished to argue that an enrollment sanction should not have been imposed because they did not report 3 consecutive years of below 85 percent MLRs, we would make available the processes that currently apply to suspensions of enrollment imposed as an intermediate sanction. We note that under that process, the prohibition on new enrollment would remain in place

during any appeal of the enrollment sanction.

After consideration of the public comments received, we are finalizing these provisions as proposed.

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 proposed to implement section 1857(e)(4)(C) of the Act by terminating the contract for the year following the year in which the MA organization or Part D sponsor is required to report the MLR for the fifth year. For termination, we proposed to implement the “second succeeding contract year” requirement in a manner similar to how we proposed 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 will terminate the contract in 2020.

Comment: A commenter concerned about beneficiary displacement asked how beneficiaries would be notified and transitioned in the event of a contract termination for failure to meet the MLR requirements.

Response: As discussed in section II.G. of this proposed rule, we are requiring MA organizations and Part D sponsors that fail to meet the minimum MLR 2 years in a row and onwards to report earlier the following year, such that any beneficiary would have sufficient time to select a new plan during the annual election period should the beneficiary wish to do so based on the MLR finding. As noted previously, in the case of a termination, enrollees would be informed that they needed to elect another option for the year the termination takes effect, or would be placed under original Medicare. Thus, in the event of a contract termination for failure to meet the MLR, the plans under that contract would not be available as an option for beneficiaries during the annual election period.

Comment: A commenter requested for appeal rights in the event of a contract termination due to failure to meet the MLR requirements for 5 consecutive years.

Response: We would not expect an MA organization or Part D sponsor to contest a contract termination since it is required by statute and would be based on an MLR that the organization itself reported. However, in response to this

comment we are making notice and appeal rights in § 422.510(b)(1) and (d) and § 423.509(b)(1) and (d) available in the event of a contract termination for MLR reasons. Therefore, we are not finalizing § 422.510(a)(16) as proposed and instead revising § 422.2410(d) and § 423.2410(d) to state that CMS would terminate a contract per § 422.510(b)(1) and (d) and § 423.509(b)(1) and (d).

After consideration of the public comments received, we are finalizing these provisions as proposed, with the exceptions of not finalizing § 422.510(a)(16) and instead revising § 422.2410(d) to state that “CMS terminates the contract per § 422.510(b)(1) and (d) effective as of the second succeeding contract year” and not finalizing § 423.509(a)(16) and instead revising § 423.2410(d) to state that CMS terminates the contract per § 423.509(b)(1) and (d) effective as of the second succeeding contract year.

D. Calculation of Medical Loss Ratio

1. Definition of Medical Loss Ratio

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). In general, the MA and Part C costs are in the numerator and revenues are in the denominator. A credibility adjustment is discussed in section II.F. of this final rule.

Proposed § 422.2410(a)(2) provides that the MLR for an MA contract not offering Part D prescription drug benefits will 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 the 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 specified that the MLR for a PDP contract would be required to reflect costs and revenues for standard coverage, alternative coverage, and enhanced alternative coverage.

Comment: A number of commenters commended CMS for adopting the same MLR rules that apply to commercial plans (which were based on recommendations of the National Association of Insurance Commissioners), modifying them when appropriate for the Medicare program. Commenters noted that this reduces issuer burden by avoiding needless

duplication for issuers participating in both Medicare and commercial markets, facilitating common standards allowing comparisons and evaluations, and minimizes confusion for the public.

Response: We appreciate the support for aligning commercial and Medicare approaches to MLR reporting.

After consideration of the public comments received, we are finalizing these provisions as proposed.

2. MLR Numerator

Proposed sections 422.2420(b) and § 423.2420(b) for MA and Part D contracts identify the elements to be included in the numerator for a contract’s MLR. Sections 422.2420(b)(1) and 423.2420(b)(1) identify two basic elements that would 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.

a. Incurred Claims

For the MA program, under the proposed rule, 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, as set forth at 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, which are net of direct or indirect remuneration from any source. “Actually paid” claims refer to those costs for which the MA organization or Part D sponsor is liable through all phases of the benefit, including the reinsurance portion of claim costs in the catastrophic phase of the benefit. MA and Part D contracts would also be required to reflect the various items under § 422.2420(b)(2)(iii) through (xi) and § 423.2420(b)(2)(ii).

Comment: A commenter inquired whether claims costs for members with end-stage renal disease (ESRD) or who have elected hospice should be included in the numerator as incurred claims.

Response: Sections 422.2420(b)(1)(i) and 423.2420(b)(1)(i) state that the MLR numerator should include incurred claims for all enrollees. Thus, claims costs for ESRD enrollees should be included in the numerator as incurred

claims, as well as claims paid by the plan (and not fee-for-service Medicare) for enrollees who have elected hospice.

Comment: A commenter argued that use of Part C rebate dollars to reduce Part D premium and cost sharing should be added to the numerator for MA–PD contracts, in the same manner that the proposed rule allows rebate dollars allocated to reduce the Part B premium to be added to the numerator, because the Part D reductions also benefit beneficiaries. The commenter noted that this approach would be especially important to SNPs, which typically use some or all of the bid savings to buy down the cost of prescription drugs.

Response: The MLR is based on actual costs and revenues for plan benefit packages under a contract. Part C rebates are revenue to the MA organization, and thus are in the MLR denominator. The numerator includes expenses for benefits. A reduced Part B premium is a plan benefit, and only accounting flows make this appear other than a benefit expense. Currently, CMS makes a monthly payment to the MA organization for each enrollee in a plan, which includes the plan-specific rebate amount minus the amount (if any) for Part B premium reduction. This is revenue. Then CMS sends the amounts allocated to reduce Part B premiums to the Social Security Administration (SSA). If CMS instead paid the MA organization the Part B premium rebate amount and then required the MA organization to pay the SSA on behalf of its enrollees, it would be more apparent that such a payment is payment for a benefit, that is, a cost in the numerator. Given existing accounting flows, we find it appropriate to add the Part B rebate amount to the numerator, as proposed at § 422.2420(b)(ii) and § 422.2420(b)(ii). In contrast, rebates used to reduce Part D premiums and cost-sharing are associated with expenditures on drugs, and these costs are included in the numerator as incurred claims. Incurred claims reflect the benefit design for each plan under the contract, including design features such as reduced cost-sharing and supplemental drug coverage (which are in the benefit design in part because of rebate revenue). In reviewing this comment, we realized that making an adjustment for Part B premiums is not applicable to stand-alone Part D contracts and we have therefore deleted proposed § 423.2420(b)(1)(ii) and renumbered accordingly.

Comment: A few commenters requested that CMS clarify whether MA organizations employing capitated provider reimbursement arrangements may consider the full capitation amount

as a benefit expense unless the provider contract specifies a distinct fee for administrative services. A commenter noted that an approach including the full capitation amount in incurred claims would mirror the commercial MLR requirements. Another commenter noted that capitated services often may include care management or disease management activities and other activities intended to improve quality.

Response: In § 422.2420(b)(2), we are following the commercial MLR approach where incurred claims are direct claims paid to providers, including under capitation contracts. Where an MA organization of Part D sponsor has arranged with a clinical provider for capitation payments rather than fee-for-service reimbursement for covered services to enrollees, and such capitation payments include reimbursement for certain provider administrative costs, then the entire per member per month capitation payment paid to the provider may be included in incurred claims. The full capitation amount paid to a provider for covered services described at § 422.2420(a)(2) could be reported as a benefit expense, unless, as the commenters noted, the provider contract specifies a distinct fee for administrative services. Note that if the capitated payment includes payment for quality-improving activities that also would meet the requirements under § 422.2430 and § 423.2430 (activities that improve health care quality), the MA organization must ensure that costs for these activities are only counted once in the numerator.

Comment: A commenter requested that CMS exclude from provider bonuses and incentive payments, which must be included in the numerator, the treatment of incentive bonuses to providers for the purposes of exclusive provider-sponsor contracting.

Response: One requirement of incentives and bonus payments to providers under § 422.2420(b)(2) and § 423.2420(b)(2) is that the payments must be “related to clinical services and prescription drug costs”, which would not include bonus payments specifically as an incentive not to contract with another organization.

Comment: A commenter stated that CMS’ proposal to include costs and revenues for optional supplemental benefits in the MLRs for MA contracts is unjustified because revenue for these benefits comes solely from beneficiary premium, and by law beneficiaries do not share in any remittances that must be made by MA organizations and Part D sponsors for contracts that fail to meet the MLR requirement. The commenter believed that the MLR should only

include benefits funded by the Medicare program.

Response: The commenter is correct that we intend for the MA MLR to include all of the MA benefits defined at § 422.100(c): Basic benefits, mandatory supplemental benefits, and optional supplemental benefits. We believe that all Medicare costs and revenues under an MA contract should be included in the MLR, and the optional supplemental benefit package is defined by law as a type of Medicare benefit under the MA program. The fact that the optional supplemental benefit is funded completely by beneficiary premiums is a reason for including these benefits in the MLR. A key goal of the MLR provision is to provide beneficiaries with information needed to better understand how much of revenue—including beneficiary premiums—is being used to pay for their Medicare services and quality-improving activities.

Comment: A commenter recommended that CMS establish a multiplier to apply to the numerator for Part D contracts in recognition of significant differences between the structure of these limited benefit policies and comprehensive medical coverage, analogous to the multiplier developed for mini-med policies under the commercial MLR rule.

Response: We do not believe that the Medicare Part D benefit package is analogous to the limited benefit packages referred to as a mini-med policies, which the commercial MLR has defined as policies that have a total annual limit of \$250,000 or less, and thus do not believe that application of an adjuster analogous to the mini-med adjuster is appropriate. Like stand-alone Part D contracts, commercial, stand-alone pharmacy policies are subject to the commercial MLR standard and do not receive an adjustment.

Comment: A few commenters requested that CMS follow the commercial rule and implement a 3-year reporting period to allow for smoothing of abatement years, thus resulting in a more accurate MLR calculation.

Response: The statutory language for the Medicare MLR requirement, unlike the commercial statute, requires that “the Secretary determines for a contract year” whether the MLR meets the threshold of 85 percent. We believe that CMS does not have the authority to implement a rolling 3-year average MLR.

Comment: A commenter determined that the proposed treatment of commercial reinsurance in the proposed rule deviated from the commercial MLR regulation. The commenter noted that

under 45 CFR 158.130(a)(3) of the commercial regulation, the only instances in which the premiums and claims associated with a “100 percent indemnity reinsurance treaty” are reported as part of the MLR calculation by the “assuming entity” instead of by the “ceding entity” are—(1) when the reinsurance treaty was in force prior to the date of enactment of the Affordable Care Act; and (2) in situations in which the assuming entity is also completely responsible for performing administrative functions.

Response: We thank the commenter for pointing out this unintended inconsistency with the commercial MLR regulation in our proposed provisions at § 422.2420(b)(1)(iv), § 422.2420(c)(4), § 423.2420(b)(1)(iv) and § 423.2420(c)(4).

Our proposed regulation would require that claims and revenue be reported on a direct basis, at § 422.2420(b)(2)(i), § 422.2420(c)(1), § 423.2420(b)(2)(i), and § 423.2420(c)(1). We agree that our proposed regulations about the exceptions to direct reporting should be corrected to mirror the commercial regulation as we intended. As we stated in the preamble to the proposed rule, we only intended to depart from the commercial MLR rule to the extent necessary and appropriate given the Medicare context. In this case, the provisions at issue do not involve Medicare. Thus, we are revising the proposed regulation text to mirror more exactly the commercial regulation at 45 CFR 158.130(a)(2) and (a)(3). We are separating provisions on assumptive and 100 percent indemnity reinsurance, and incorporating the commercial rule language at 45 CFR 158.130(a)(3), which provides that the only instance in which the premiums (revenue) and claims associated with a 100 percent indemnity reinsurance treaty are reported by the assuming entity, instead of by the ceding entity, is when the reinsurance treaty was in force prior to the date of enactment of the Affordable Care Act. In short, with this change our provisions now mirror the distinction between paragraphs § 158.130(a)(2) and (a)(3) in the commercial rule.

We are including these reinsurance provisions under § 422.2420 and § 423.2420 for both the MLR numerator (costs) and MLR denominator (revenue.) (The commercial MLR rule addresses the treatment of reinsurance for the MLR numerator at § 158.103 through a definition of direct paid claims.) Finally, we are moving the numerator provision at § 158.103 (b)(1)(iv) to (b)(5) and adding paragraph (b)(6).

Comment: A few commenters questioned whether, and how, the MLR

requirement applies to MA Medical Savings Account (MSA) plans. One of these commenters requested that MSA plans be exempted, and another commenter argued that if the requirement applies to this unique plan type, the beneficiary deposit should be included in both the numerator and denominator of the calculation.

Response: Medicare MSA plans are a type of MA plan, and they are not exempted from the MLR statutory provisions. We agree with the commenter, however, that the annual deposit into the beneficiary’s MSA should be included in both the numerator and denominator of the MLR calculation. In response to this comment, we are revising proposed § 422.2420(b)(1), to indicate that the annual deposit to the beneficiary’s medical savings account should be included in the MLR numerator.

Note that the requirement to include optional supplemental benefit costs and revenue under the contract applies to all MA plan types.

After consideration of the public comments received, we are finalizing these provisions as proposed, with the exception of revising the proposed § 422.2420(b)(1) to indicate that the annual deposit to the beneficiary’s medical savings account should be included in the MLR numerator, and making changes to the 100 percent indemnity and assumptive reinsurance provisions under § 422.2420 and § 423.2420.

b. Adjustments to and Exclusions From Incurred Claims

Under proposed § 422.2420(b)(3) and § 423.2420(b)(3), any amounts paid to providers that were recovered because they were overpayments would have to be deducted from incurred claims. There are also several expenditures that would not be included in incurred claims for MA and PDP contracts, as provided in § 422.2420(b)(4) and § 423.2420(b)(4). 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) are not permitted to be included in incurred claims for any contract year.

Comment: A few commenters noted that direct and indirect remuneration was inadvertently being backed out of incurred claims twice, as the definition of drug costs “actually paid” per § 423.308 is already net of DIR and then again in the section listing adjustments that must be deducted from incurred claims.

Response: We agree and are correcting this error by removing proposed § 422.2420(b)(3)(i) and renumbering § 422.2420(b)(3)(ii) accordingly, as well as removing proposed § 423.2420(b)(3)(i) and renumbering § 423.2420(b)(3)(ii) accordingly. For clarity in the regulatory text, we added a reference to direct and indirect remuneration in § 423.2420(b)(2)(i).

Comment: Several commenters recommended that all low income premium and cost sharing subsidies (LIPS and LICS) and discounts on brand drugs advanced to beneficiaries as part of the Coverage Gap Discount Program be taken into account in the numerator (and denominator), similar to the treatment of Part D reinsurance.

Response: We make LIPS payments to MA organizations and Part D sponsors to make the sponsor whole for reduced premiums that eligible beneficiaries are paying the plan. Beneficiary premiums are revenue, not costs, and thus LIPS payments are taken into account in the denominator of the MLR. We view LICS payments and coverage gap discount payments as pass-through payments, unlike federal reinsurance, which pays for a portion—but not all—of plan liability in the catastrophic phase of the benefit. Thus, LICS and CGDP amounts do not belong in the MLR numerator or the MLR calculation.

We are finalizing this provision with the following modifications. We have made changes to the regulatory text by deleting proposed § 422.2420(b)(3)(i) and renumbering § 422.2420(b)(3)(ii) accordingly, as well as deleting proposed § 423.2420(b)(3)(i) and renumbering § 423.2420(b)(3)(ii) accordingly. We inserted the reference to direct and indirect remuneration in § 423.2420(b)(2)(i). We made these changes to make clear that direct and indirect remuneration must already be netted out of drug costs that are actually paid per § 423.308 and therefore should not be deducted again.

3. MLR Denominator

We proposed 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 include our risk-adjusted payments to the MA

organization for all enrollees under a contract, reflecting final risk scores, including Part C rebate payments, 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 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 or Part D sponsor as a condition of receiving coverage under an MA or Part D plan; our payments for low income premium subsidies under § 423.780; and risk corridor payments under § 423.315(e).

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, reflecting final risk scores, 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; all changes in unearned premium reserves; and risk corridor payments under § 423.315(e).

At § 422.2420(c)(2), we proposed three categories of taxes and fees that must be deducted from total revenue: Licensing and regulatory fees, federal taxes and assessments, and state taxes and assessment. We also proposed that a fourth amount be deducted from total revenue: community benefit expenditures. We proposed to align with the commercial MLR regulations to allow a federal income tax-exempt issuer to deduct community benefit expenditures by defining them in § 422.2420(c)(2)(iv) and § 423.2420(c)(2)(iv), up to a cap 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 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.

Next, we proposed that some items not be included in total revenue. First is 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. We

proposed that HITECH, or EHR, incentive payments and payment adjustments would not be considered for purposes of the MLR calculation. Thus, neither 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), nor EHR payment adjustments for a failure to meet meaningful use requirements (as administered under Part 495 subpart C) will be in the MLR calculation. We proposed that Coverage Gap Discount Program payments under § 423.2320 would not be included in total revenue.

Finally, as explained in the preamble to the proposed rule, we did not propose an adjustment to total revenue for commercial reinsurance.

Comment: A few commenters requested clarification on the proposed regulatory requirement that total revenue must include all unpaid premium amounts that an MA organization or Part D sponsor could have collected from enrollees under a contract, but should exclude from total revenue all unpaid premium amounts for which they can demonstrate to CMS they made a reasonable effort to collect. Both commenters wanted to exclude all unpaid beneficiary premium revenue from the denominator. A commenter noted that the citations in the proposed rule to § 422.74(d)(1)(i) and § 423.44(d)(1)(i) are references to CMS' disenrollment policy, which includes the option that an MA organization or Part D sponsor may forgive unpaid amounts and not disenroll beneficiaries, and they requested clarification.

Response: We appreciate that the commenters brought to our attention that these provisions of the proposed rule are somewhat confusing because our disenrollment policy is cited. Specifically, at § 422.2420(c)(1)(v), § 422.2420(c)(3)(i), § 423.2420(c)(1)(iv), and § 423.2420(c)(3)(i), where we regulate the treatment of unpaid premium amounts, we included references to § 422.74(d)(1)(i) and § 423.44(d)(1)(i). These citations are to our policy on the conditions under which an MA organization or Part D sponsor may disenroll a beneficiary for non-payment of plan premiums. This disenrollment policy is focused on beneficiary protection by setting limits around disenrollment. We believe that these citations are confusing in the context of MLR calculation and reporting. Thus, we are revising proposed § 422.2420(c)(3)(i) and § 423.2420(c)(3)(i) to delete these citations. The policy intention remains the same: The MA organization or Part

D sponsor will include all beneficiary premium amounts under a contract in total revenue (the MLR denominator) minus any premium amounts that remain unpaid after reasonable collection efforts.

Comment: Several commenters requested that CMS allow the MLR for dual SNPs and FIDE SNPs to include Medicaid and Medicare costs and revenues.

Response: We do not believe that we have the authority to include Medicaid costs and revenues in the Medicare MLR requirement, including the authority to require payment of a remittance calculated on a combined MLR.

Comment: A number of commenters contended that there are a number of administrative costs that are in the denominator of the MLR that are barriers to contracts meeting the MLR requirement. A few commenters argued that administrative costs associated with the rules of participating in the Medicare program should specifically be excluded from the calculation of their MLRs, similar to the treatment of taxes and fees in the MA and Part D MLR calculation. Examples of these costs include provider credentialing, costs associated with meeting the annual bidding requirements, member communications, compliance activities over which MA organizations and Part D sponsors have no control, and expenses incurred for maintaining compliance and quality assurance programs in accordance with state and federal requirements, maintaining effective grievance and appeals processes, and audits that require additional investments. Other commenters argued that it is an unbalanced approach to include administrative costs associated with managing several components of the Part D program in total revenue, with no costs related to these items allowed in the numerator: low-income cost-sharing (LICS) payments, low-income subsidy payments that cover beneficiary premiums (LIPS), and discounts on brand drugs advanced to beneficiaries as part of the Coverage Gap Discount Program (CGDP). These commenters argued that LICS, LIPS, and CGDP should be treated similarly to how CMS proposed to treat Part D reinsurance payments, as allowable in both the numerator and denominator of the MLR.

Response: As the commenters noted, administrative costs are an element of doing business. A goal of the MLR is to indicate the share of medical and prescription drug costs under a contract, relative to total revenue. Total revenue includes amounts that cover administrative costs and margin. We do

not believe that excluding administrative costs from revenue (or adding such costs to the numerator) would provide an accurate representation of the MLR for a contract. This is reflected in the commercial MLR rule, which does not permit administrative expenses like provider credentialing, annual bidding, member communications, compliance, quality assurance, grievance and appeals, or audit costs to be deducted from the premium or added to the numerator. In fact, one of the key goals of the MLR is to have a measure to compare how cost-effectively MA organizations and Part D sponsors can meet their administrative requirements.

Regarding administrative costs specific to the CGDP, we believe that CMS bears most of these administrative costs, including executing agreements with manufacturers participating in the CGDP, paying monthly interim coverage gap payments, invoicing manufacturers, and conducting coverage gap discount reconciliation. We require all MA organizations and Part D sponsors to engage in certain administrative activities as a condition of participation in the MA and Part D programs, and believe that the burden of meeting these requirements is fairly distributed.

For these reasons, we do not believe it necessary or appropriate to adjust the MLR calculation for administrative costs beyond what we proposed. We will be mindful of placing additional administrative requirements on MA organizations and Part D sponsors that could have differential impacts on the MLR calculation.

LICS, LIPS, and CGDP payments are not allowable in both the numerator and denominator of the MLR, like the way Part D reinsurance payments are treated. As we make LIPS payments on behalf of eligible beneficiaries, this amount is treated as revenue just as if the beneficiary had paid these amounts directly to the plan. We view LICS and CGDP payments as pass-through payments, unlike federal reinsurance, for which MA organizations and Part D sponsors retain some plan liability in the catastrophic phase of the benefit.

Comment: One commenter requested clarification regarding the exclusion of commercial reinsurance from total revenue and inquired whether the "commercial reinsurance" exclusion means net reinsurance (that is, reinsurance premium less reinsurance recoveries) or whether both premiums and recoveries are excluded from the MLR calculation.

Response: We followed the commercial MLR approach by not allowing MA organizations and Part D

sponsors to adjust the MLR for commercial reinsurance (we note that this response is addressing commercial insurance and not the federal reinsurance provision under the Part D program). That is, both reinsurance premiums and recoveries are excluded from the MLR calculation. Both costs and revenues must be reported on a direct basis, that is, before ceded reinsurance as stated at § 422.2420(b)(2)(1) regarding incurred claims as direct claims direct drug costs that are actually paid, and § 422.2420(c)(1) and § 423.2420(c)(1) regarding total revenue reported on a direct basis.

Comment: Some commenters supported the alignment of the proposed rule with the commercial MLR regulations, by allowing federal income tax-exempt MA organizations and Part D sponsors to deduct community benefit expenditures from total revenue, up to a cap. In regards to contracts that span more than one state, a commenter supported the blending of the highest premium tax rates for the states in which the contract is offered. Another commenter recommended applying the state premium tax rate to the proportion of community benefit expenditures furnished by plans under the contract in that state, or allocating based on proportions of enrollment in each applicable state, then deducting the amount up to the cap. Several commenters noted that community benefit expenditures should not be considered a category of expenditures to be deducted from total revenue. Generally, commenters who did not support the deduction of community benefit expenditures argued that since MA and Part D plans do not pay state premium taxes on their Medicare revenue, the proposed rule provides an unfair advantage for federal income tax-exempt issuers and does not recognize the community benefit expenditures made by for-profit issuers.

Response: We agree that, because an MA organization or Part D sponsor that is exempt from federal income taxes must make community benefit expenditures, such an MA organization or Part D sponsor should be allowed to deduct community benefit expenditures. This final rule allows a federal income tax-exempt MA organization or Part D sponsor to deduct its community benefit expenditures in the same manner that a for-profit plan sponsor is allowed to deduct its federal income taxes. This rule explains the community benefit expenditure deduction available to an MA organization or Part D sponsor that is exempt from federal income taxes. Such

MA organizations and Part D sponsors will be allowed to deduct actual community benefit expenditures up to the higher of 3 percent of total revenue as defined for MLR purposes, or the highest premium tax rate in the state where the MA organization or Part D sponsor is licensed, multiplied by the MA organization or Part D sponsor's earned premium for the contract. We note that the amount of community benefit expenditures deducted is not allowed to exceed the amount of actual community benefit expenditures in the reporting year. In the instance where a contract spans more than one state, we will blend the highest premium tax rates for the states in which the contract is offered in a manner to be determined through sub-regulatory guidance or the Paperwork Reduction Act notice and comment process.

After consideration of the public comments received, we are finalizing these provisions with the following technical corrections. First, we are revising proposed § 422.2420(c)(3)(i) by removing the citation to § 422.74(d)(1)(i), and we are revising proposed § 423.2420(c)(3)(i) by removing the citation to § 423.44(d)(1)(i). These changes to the provisions on treatment of unpaid premiums remove a confusing reference to our disenrollment policy, which is not directly relevant to the determination of total revenue for MLR purposes. The second technical correction clarifies what is meant by total revenue under the contract, specifically, that total revenue for a contract is not simply the amount under paragraph § 422.2420(c)(1) and § 423.2420(c)(1) but is the amount under paragraph (c) that reflects (c)(1) through (c)(4). Finally, we are correcting proposed § 422.2420(c)(3) and § 423.2420(c)(3), which are provisions on amounts to be excluded from total revenue; we erroneously proposed "incurred claims," which are in the MLR numerator. We have corrected this to state "revenue."

4. Projection of Net Total Revenue

When calculating Medicare MLRs, we proposed that MA organizations 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.

Comment: Several commenters stated concerns about CMS' proposal that the MLR would be reported once, based on the Medicare revenue for the year at the time of the report, and that neither

reopening(s) of a reconciliation process nor any risk adjustment data validation (RADV) audits that could change the final revenue amount would result in a reopening of the MLR reported for a contract year. A few commenters agreed that the MLR calculation should not be reopened on a routine basis, but recommended that CMS allow the reopening of the MLR for contracts with MLRs below the threshold. Finally, some commenters requested that, at a minimum, if there is a finding from a RADV or other audit that requires an issuer to remit funds to CMS, CMS should allow recalculation of a past MLR to reflect this adjustment to revenue based on an audit finding, or alternatively allow an adjustment to revenue in the MLR reported for the year of the audit finding.

Response: We believe that the remittances owed based on a failure to meet the MLR standard should be based on the revenue figure at the time of the report, and should not be subject to change if this revenue figure is decreased or increased in a future year. First, that is the revenue that in fact was received by the MA organization or Part D sponsor at the time it made its decisions on how to apportion it between patient care and quality improvement and other costs. The remittance (and other sanctions) can be considered a penalty for plans that apportioned more than 15 percent of the revenue received to costs other than patient care or quality improvement. Presumably, the MA organization did not make those decisions based upon an assumption that its revenue would be reduced or increased in a future year as a result of an audit or reconciliation that changes the final Medicare payment amount in some future year.

Moreover, if the payment amount is adjusted downward in a future year (for example, because it is found that the organization or sponsor submitted inflated risk scores that were not justified), we do not believe it would be appropriate for the MA organization or Part D sponsor to be provided with an adjustment to its MLR that could reduce or eliminate its penalty for violating the MLR standard for the year in question. The fact that the MA organization or Part D sponsor had to refund amounts to which it should not have been entitled does not retroactively affect the value it delivered with the funds it had during the contract year at issue. Thus, if an MLR violates the 85 percent standard as reported, that MLR is final.

We are finalizing these provisions as proposed.

5. Allocation of Expenses

We proposed that MA organizations and Part D sponsors would be required to properly allocate all expenses stemming from each contract, as provided under § 422.2420(d) and § 423.2420(d). 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 will 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 under our proposal have to be reported on a pro rata share basis. This approach aligns with the commercial MLR rules.

Comment: A commenter requested clarification regarding the alignment with the commercial MLR in reference to the proposal that, MA organizations and Part D sponsors must use Statutory Accounting Principles for the purposes of MLR determination except in cases when another regulatory authority such as state insurance departments requires other reporting for a particular contract or product using Generally Accepted Accounting Principles (GAAP).

Response: We agree that use of Statutory Accounting Principles for Medicare MLR requirements would align with current practices in determining commercial MLR and minimize administrative burden on issuers. We thus are adopting this approach by requiring MA organizations and Part D sponsors to explain how revenue is used to pay for non-claims expenditures. MA organizations and Part D sponsors must allocate their non-claims and quality improving expenses by contract. If an expense is attributable to a specific activity, then MA organizations and Part D sponsors should allocate the expense to that particular activity. However, if this is not feasible, then the MA organization or Part D sponsor must apportion the costs using a generally accepted accounting method that yields the most accurate results.

After consideration of the public comments received, we are finalizing these provisions as proposed.

E. Activities That Improve Health Care Quality

We proposed to adopt definitions of activities that improve health care quality for the purposes of this MLR rule that will result in a uniform accounting of the associated costs for

MA organizations and Part D sponsors. As noted in the proposed rule, this definition of quality would apply 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. This final rule provides a set of criteria in § 422.2430 and § 423.2430 which MA organizations or Part D sponsors will be required to comply with in order for the activity in question to be treated as quality improving. In the proposed rule, we requested comment on the types of drug utilization review that should be considered a quality improving activity for Medicare MLR purposes.

Comment: A few commenters noted that concurrent and retrospective utilization reviews are often used for cost containment purposes. However, commenters generally recommended the inclusion of concurrent and retrospective reviews and remarked that the activities provide an opportunity to prevent overutilization, increase the likelihood of desired health outcomes, and improve education of providers and future patients, thereby making them quality-improving. Many commenters recommended expanding the definition under proposed § 423.2430 to allow all utilization review as a QIA. A few commenters suggested categorizing utilization management as an allowable QIA.

Response: As discussed in the proposed rule, prospective utilization is considered a QIA because it is rendered before care or services are delivered and can help ensure that the most appropriate treatment or services is given in the most appropriate setting. While concurrent and retrospective review in Part D cannot meet the “before care or services are delivered” prong, we understand that these types of utilization reviews could promote quality in certain circumstances, especially in the Part D context. In reviewing the comments received on QIA in the commercial MLR and the experience we have had in collecting commercial MLR data, which includes expenditures to provide a drug benefit, we are not persuaded that deviating from the proposed QIA definition is necessary. Thus, we believe that the interest of maintaining consistency with the definition of QIA in the commercial rule outweighs changing the treatment of utilization review in the QIA definition.

Comment: Many commenters supported the definition of QIA and our efforts to align the Medicare MLR

regulation with the commercial MLR policy. A few of these commenters particularly supported requiring QIA to be grounded in evidence-based practice that can be objectively measured. Many commenters suggested that CMS expand their interpretation of QIA for MA organizations and Part D sponsors, as well as expand the guidance on QIA.

Response: We appreciate the commenters' support. We believe it is important to maintain definitions of QIA that are consistent with the commercial MLR regulation for more accurate comparability for beneficiaries and to minimize the administrative burden on MA organizations and Part D sponsors that have both commercial and Medicare lines of business.

Comment: A number of commenters responded to the solicitation for comments regarding Medication Therapy Management (MTM) programs in a Part D context, with the recommendation that programs be considered for inclusion in the MLR as quality improving activities. Generally, commenters remarked that MTM programs required by CMS improve quality and care coordination and therefore, should be included in the MLR. In addition, commenters noted the importance of MTM programs in individualized disease management and some commenters believe the inclusion of MTM programs would further encourage and incentivize providers to strengthen their MTM programs.

Response: We appreciate the comments on this topic and will use them to inform our MTM requirements. We also agree that so long as the MTM activities meet the requirements set forth in § 422.2430 and § 423.2430, they would qualify as a QIA.

Comment: Many commenters requested that CMS consider as QIA all activities to prevent and reduce fraud, waste, and abuse, noting that CMS requires such activities as a condition of participation in the Part C and D programs. Commenters stated their concerns that by not allowing plans to count all expenses incurred in reducing fraud, waste, and abuse, it will result in a disincentive to engage in these beneficial activities.

Response: Fraud reduction efforts include both fraud prevention and fraud recovery. We are allowing 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 per § 422.240(b)(2)(ix) and § 423.240(b)(2)(xiii). Thus, even though fraud prevention is not a QIA, we believe this provides an incentive for MA organizations and Part D sponsors

to engage in fraud reduction activities. To the extent that MA organizations and Part D sponsors are engaging in other activities that meet the requirements in § 422.2430 and § 423.2430, they may be considered as quality improving activities.

Comment: A number of commenters advised caution in regards to categorizing wellness programs as QIA. They suggest that CMS only include wellness programs that have evidence to support their effectiveness, those that do not penalize beneficiaries who do not participate, and those that are at low-risk for "cherry-picking" the healthiest beneficiaries. In particular, commenters were worried about wellness programs that disproportionately penalize groups of older adults, those with disabilities, racial minority groups, and low-income individuals. Similarly, one commenter urged us to be critical of coaching programs that are not evidence-based.

Response: Our longstanding policy is that a plan benefit design cannot offer differential benefits to its enrollees, and that an MA organization or Part D sponsor may not deny, limit, or condition enrollment to individuals eligible to enroll in an MA plan offered by the organization on the basis of any factor that is related to health status, including medical history, disability, race, or age. Moreover, MA organizations and Part D sponsors must have procedures in place to ensure that members are not discriminated against in the delivery of health care services, consistent with the benefits covered in their policy, based on race, ethnicity, national origin, religion, gender, age, mental or physical disability, genetic information, or source of payment. With regard to comments that we only include wellness programs that have evidence to support their effectiveness, we developed subregulatory recommendations of acceptable evidence-based criteria which may be found in section 90.5 of Chapter 4 of the Managed Care manual. The suggestions for evidence-based approaches include: "(i) Studies from government agencies (for example, the FDA); (ii) Evaluations performed by independent technology assessment groups (for example, BCBSA); and (iii) Well-designed controlled clinical studies that have appeared in peer review journals. Chapter 4 of the managed care manual (Section 10.5.3) outlines general criteria, additional to the federal anti-discrimination laws, that plans are required to follow when designing benefits. These criteria are applicable to wellness programs. We would note that these criteria also include a prohibition against steerage: "An MAO may not

design a plan with supplemental benefits that only appeal to healthier beneficiaries." We believe it is important to provide plans the flexibility needed to design wellness programs that maximize the potential for improved health outcomes for their enrolled populations. We see this as both an opportunity to prevent the onset of chronic illness and to improve the health status of chronically ill enrollees. Therefore, for MLR purposes, these programs are appropriately considered a QIA subject to the requirements in § 422.2430 and § 423.2430.

Comment: A few commenters agreed that marketing expenses should not be included in QIA and asked us to clarify that fees paid to brokers and agents are included within the term "marketing expenses."

Response: Like the commercial MLR, we consider agents and brokers fees as non-claims costs and therefore impermissible as being considered included as incurred claims. We also exclude marketing as a quality improving activity. Though MA organizations and Part D sponsors are responsible for applying the QIA criteria to determine if a particular activity is permissible to be reported as QIA, we take this opportunity to note that our subregulatory guidance discusses agent and broker compensation in Manual chapters titled "Medicare Marketing Guidelines."

Comment: A few commenters requested including statutorily required quality-related activities that are specific to SNPs in the definition of QIA.

Response: To the extent that SNPs' quality activities meet the criteria of sections § 422.2430 and § 423.2430, they may be considered QIA.

After consideration of the public comments received, we are finalizing these provisions as proposed.

F. Credibility Adjustment

As noted in section II.A. of this final rule, we are using the commercial MLR rules as a reference point for developing the Medicare MLR. We proposed that the methodology for the Medicare MLR calculation take into account the special circumstances of contracts with lower enrollment by applying credibility adjustment factors to smaller enrollment contracts that are designed to reduce the probability that an issuer with smaller enrollment has to pay a remittance in a given year to 25 percent of the time or less. Unlike the commercial rule, we did not propose including a deductible factor.

The Office of the Actuary derived the proposed MA-PD and Part D stand-

alone credibility adjustments based on the variability of expected claims, assuming plans are priced exactly at an 85 percent MLR. The target failure rate is 25 percent for contracts priced at an 85 percent MLR. We followed 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 is partially credible, as defined by CMS. Fully-credible contracts are not eligible for a credibility adjustment. Finally, we proposed that for contract years when a contract has non-credible experience, the sanctions specified in the statute for having an MLR that does not meet the minimum requirement of 85 percent would not apply.

We defined 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 defined partially-credible experience for Part D stand-alone 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, non-credible MA contracts would have annual enrollment of less than 2,400 member months, and non-credible Part D stand-alone contracts would have annual enrollment of less than 4,800 member months. Further, fully-credible MA contracts would have an enrollment greater than 180,000 member months, and fully-credible Part D stand-alone contracts would have an enrollment greater than 360,000 member months.

Tables 1A and 1B provide the proposed credibility adjustments for partially-credible MA-PD contracts and Part D stand-alone contracts beginning in 2014. Credibility adjustments for contracts with enrollment sizes that fall between the categories of member months displayed in the tables would be determined using linear interpolation. We proposed to use member months (instead of life years, which is used in the commercial MLR credibility adjustment) to describe the enrollment thresholds pertinent to application of the Medicare credibility adjustments, such that 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.

TABLE 1A—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.

Comment: Several commenters supported CMS' proposal to apply credibility adjustments to low enrollment contracts, to best balance the goals of providing value to beneficiaries and ensuring that contracts with relatively low enrollment would be able to function effectively.

Response: We appreciate the commenters' support.

Comment: A commenter expressed concern that proposed text at § 423.2440 on credibility adjustments could be interpreted in future years to allow CMS the option of eliminating credibility adjustments for a year. The commenter confirmed the importance of credibility adjustments and requested that the regulation be amended to state that in no case can CMS eliminate a credibility adjustment.

Response: At § 422.2440 and § 423.2440, the regulation text states that we will define and publish definitions of partial, full, and non-credibility through the annual Advance Notice and Rate Announcement process. We agree that credibility adjustments are important for small enrollment contracts, which we described at length in the proposed rule. Moreover, we would not be able to completely eliminate the credibility adjustment for MLR purposes without notice and comment rulemaking outside of the Advance Notice/Rate Announcement process.

Comment: A commenter recommended that CMS consider broadening further the enrollment thresholds for a Part D credibility adjustment to provide an additional element to improve compatibility of the 85 percent MLR threshold with Part D. Another commenter requested that CMS establish full credibility thresholds at 700,000 member months for MA-PD and 1.4 million member months for Part D stand-alone contracts.

Response: We are mirroring the commercial MLR rule's approach, where credibility adjustments are designed to reduce the probability that an issuer with smaller enrollment has to pay a rebate in a given year to 25 percent of the time or less. Establishing full credibility thresholds at greater than 700,000 member months for MA-PD contracts and greater than 1.4 million member months for Part D stand-alone contracts would be approximately equivalent to using a 10 percent target failure rate. As we discussed in the proposed rule, the National Association of Insurance Commissioners (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 that setting credibility adjustments based on a 25 percent probability of paying a rebate struck a more equitable balance of consumer and issuer interests.

Comment: A few commenters questioned that the threshold for fully-credible enrollment is set at 1 percent and not zero percent. The commercial MLR regulation sets the fully-credible threshold at 0 percent. One of these commenters also requested CMS to confirm that there is a lower coefficient of variation for MA-PD claims than for Part D stand-alone claims; this commenter expected the full-credibility threshold for MA-PD contracts to be higher than that for Part D stand-alone contracts.

Response: We mirrored the commercial approach of setting 25 percent as the target failure rate for partially credible contracts. Our policy for transitioning from partial to full credibility is to maintain the 25 percent target failure rate for all partially credible contracts, up to (but excluding) the full credibility threshold. Thus, we are finalizing the credibility adjustment factors published in the proposed rule.

Regarding full credibility thresholds, it is correct that MA-PD contracts have a lower coefficient of variation (less variation around the mean) than Part D stand-alone contracts. Thus, the full credibility threshold for MA-PD contracts is set at fewer member months

than the threshold for Part D stand-alone contracts.

After consideration of the public comments received, we are finalizing our proposals for the credibility adjustments, and will apply the factors listed in Tables 1A and 1B as described.

G. Reporting Requirements

Consistent with existing reporting requirements at § 422.504(f)(2) and § 423.505(f)(2), we proposed that MA organizations and Part D sponsors be required to submit an MLR report in a timeframe and manner specified by CMS, and that the organizations be required to calculate MLRs and remittance as part of their report submission. In addition, we proposed that the reports will include, but not be 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.

The proposed rule also described three options for reporting dates after the end of the contract year, and requested comment on these options: July, September (after the risk score reconciliation), and December (after the Part D reconciliation and calculation of risk corridor payments). We noted that we must balance any preference for a later reporting date with disruption that beneficiaries will experience if we halted new enrollment or terminated a contract after open enrollment has begun.

Comment: Many commenters were concerned about the timeframe for MLR reporting. None supported MLR reporting before September and almost all recommended December reporting to reduce the extent to which MLRs are based on projections of costs and revenues. One commenter recommended against December reporting because of the disruption it could cause beneficiaries who might be enrolled in plans about to be terminated. Several commenters suggested that in the event an MA organization or Part D sponsor fails to meet the MLR threshold for 2 consecutive years, in the third year the MA organizations or Part D sponsor should be required to meet an earlier MLR reporting deadline to avoid disruptions to beneficiaries enrolled in plans that would become subject to enrollment sanctions or termination.

Response: We agree with the commenters that the best balance between beneficiary protection and calculating MLRs based on the most complete data is to require that, in general, MLR reporting for a contract year will occur in the December

following the contract year, on a date and in a manner specified by CMS. The exception will be for contracts that fail to meet the MLR threshold for 2 consecutive years. For these contracts, MLR reporting will occur in the following contract year prior to December, in a month that will be specified by us. This reporting deadline will allow time for us to implement, prior to the open enrollment period, an enrollment sanction for any contract that fails to meet the MLR threshold for 3 or more consecutive years and contract termination for any contract that fails to meet the MLR threshold for 5 consecutive years. We will specify this early reporting date for contracts that failed to meet the MLR threshold for 2 consecutive years in forthcoming guidance on MLR reporting requirements.

After consideration of the public comments received, we are finalizing these provisions with the following clarification in the preamble: in general, MLR reporting for a contract year will occur in December following the contract year, on a date and in a manner specified by us. The exception will be for contracts that fail to meet the MLR threshold for 2 consecutive years; MLR reporting will occur in the following contract year prior to December, in a month that will be specified by us and that will allow time for us to implement, prior to the open enrollment period, an enrollment sanction for any contract that fails to meet the MLR threshold for 3 or more consecutive years and contract termination for any contract that fails to meet the MLR threshold for 5 consecutive years.

H. Remittances if Applicable MLR Requirement Is Not Met

Sections 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, the timeframe 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, § 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 MA organization or Part D sponsor will remit payment to CMS as calculated under this final rule.

Sections 422.2470(b) and 423.2470(b) explain the amount of the payment that will be due to CMS. Consistent with the remittance provisions in the Affordable Care Act in this final rule, we propose

that MA organizations and Part D sponsors be required to remit to CMS 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 will subtract remittances from plan payment amounts in a timely manner after the MLR is reported, on a schedule determined by CMS. Remittances by MA and Part D organizations will occur as part of regular monthly payments that CMS makes to MA organizations and Part D sponsors. Sections 422.2470(d) and 423.2470(d) specify that remittances paid in any 1 year will not be included in the numerator or denominator of the next year's or any year's MLR.

Comment: Several commenters commented on the special circumstances of MA organizations and Part D sponsors in Puerto Rico with respect to the Medicare MLR requirement. The commenters requested that Medicaid and Medicare benefits be combined when calculating the contract's MLR because expenses for Platino benefits, relative to revenue, are truly medical losses. In addition, commenters noted the unique circumstances facing plan sponsors serving Puerto Rico, where Part D low-income subsidy funding does not apply.

Response: The Medicare MLR requirement, including calculation of a remittance amount, applies to Medicare benefits and not to Medicaid benefits. However, we have added language to § 422.2420(a) and § 423.2420(a) authorizing us to make adjustments to the MLR produced by the standard formula to address exceptional circumstances for areas outside the 50 states and the District of Columbia that we determine would warrant an adjustment. We will explore whether or how to adjust the MLR calculation under this language to take into account the unique circumstances of these areas.

After consideration of the public comments received, with the exception of the new language in § 422.2420(a) and § 423.2420(a) permitting us to make adjustments warranted by exceptional circumstances for areas outside the 50 states and the District of Columbia, we are finalizing these provisions as proposed.

I. MLR Review and Non-Compliance

We proposed that 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 under this proposal 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 were 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 proposed § 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 CMS.

In addition, we proposed 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 would 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 sponsor to provide timely and accurate MLR data. Further, we proposed that 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.

Comment: A commenter supported the requirement for third party vendors to disclose claims data to MA organizations and Part D sponsors by request and suggested that we require third party electronic audit for 100 percent of paid claims, clarify what “all underlying data” means, and require a PBM to link claims to the underlying retail contract.

Response: By “all underlying data,” we mean complete claim detail. This would include, at a minimum, individual claim transaction file layout records, relevant pharmacy contractual terms and rate schedules dictating payment terms for purposes of claim detail comparison, and a similar level of detail on rebates and any other price concessions received. We decline to require third party auditing for 100 percent of paid claims, as we believe this would be an overly onerous requirement on MA organizations and Part D sponsors.

After consideration of the public comments received, we are finalizing these provisions as proposed.

III. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

- Stating in preamble that in general, MLR reporting for a contract year will occur in December following the contract year, on a date and in a manner specified by us. The exception will be for contracts that fail to meet the MLR threshold for 2 consecutive years; MLR reporting will occur in the following contract year prior to December, in a month that will be specified by us and that will allow time for us to implement, prior to the open enrollment period, an enrollment sanction for any contract that fails to meet the MLR threshold for 3 or more consecutive years and contract termination for any contract that fails to meet the MLR threshold for 5 consecutive years.

- Not finalizing proposed § 422.510(a)(16) and instead revising § 422.2410(d) to state that “CMS terminates the contract per § 422.510(b)(1) and (d) effective as of the second succeeding contract year”

- Not finalizing proposed § 423.510(a)(16) and instead revising § 423.2410(d) to state that “CMS terminates the contract per § 423.509(b)(1) and (d) effective as of the second succeeding contract year.”

- Making changes to the 100 percent indemnity and assumptive reinsurance provisions under § 422.2420 and § 423.2420 to conform with the commercial MLR rule.

- Adding new language in § 422.2420(a) and § 423.2420(a), permitting CMS to make adjustments warranted by exceptional circumstances for areas outside the 50 states and the District of Columbia.

- Revising the proposed § 422.2420(b)(1) to indicate that the annual deposit to the beneficiary’s

medical savings account should be included in the MLR numerator.

- Deleting proposed § 422.2420(b)(3)(i) and renumbering § 422.2420(b)(3)(ii) accordingly.

- Deleting proposed § 423.2420(b)(3)(i), renumbering § 423.2420(b)(3)(ii) accordingly, and inserting a reference to direct and indirect remuneration in § 423.2420(b)(2)(i)

- Revising proposed § 422.2420(c)(3)(i) by removing the citation to § 422.74(d)(1)(i), and we are revising proposed § 423.2420(c)(3)(i) by removing the citation to § 423.44(d)(1)(i).

- In proposed § 422.2420(c)(3) and § 423.2420(c)(3), revising the term “revenue” to read “incurred claims.”

- Correcting proposed § 422.2420(c)(3) and § 423.2420(c)(3).

IV. 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 final rule describes the information that will be reported by MA organizations and Part D sponsors on an annual basis to the Secretary starting in 2014. We proposed 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 will be required to calculate MLRs and remittance as part of their submission to the Secretary.

At this time, we have not developed the MLR reporting instructions and forms that MA organizations and Part D sponsors will 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 proposed 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 final 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.

Comment: One commenter requested the format for the MLR report in draft with sufficient time for stakeholder comments, including specification of which information in the report will be made public.

Response: There will be two opportunities for public comment on the draft reporting form and instructions as is required by the PRA.

We are finalizing these provisions as proposed.

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

Subpart I of the final 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 final rule, and that the MLR is calculated and any remittances owed are calculated and provided in accordance with this final rule. The proposed § 422.2480(c) and § 423.2480(c) will require MA organizations and Part D sponsors to maintain all of the documents and other evidence for 10 years.

We expect that all MA organizations and Part D sponsors will have to retain data relating to the calculation of MLRs; those who have owed remittances will 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 final 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 will 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 a 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 the proposed MLR remittance reporting requirements discussed in § 422.2470 and § 423.2470.

V. Regulatory Impact Analysis

A. Introduction

This final 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 stated 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 will remit a payment to CMS. If the

contract continues to fall below the minimum MLR standard, the contract will be subject to enrollment sanctions and possibly termination. This final rule sets forth 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 final 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 final rule. Accordingly, OMB has reviewed this final rule pursuant to the Executive Order.

We did not receive any comments on the RIA and are therefore finalizing the analysis as proposed.

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 final 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 in this final rule, 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 final 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 final rule will 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 incent 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, which we characterize in this RIA as remittances to CMS could be substantial. Estimates for CY 2014 remittances are \$717 million for MA–PD contracts and \$141 million for Part D stand-alone contracts. As discussed in section V.D.4, these estimates do not account for potential plan sponsor behavioral changes. (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 will 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 MA organizations or Part D sponsor behavioral changes.

D. Detailed Economic Analysis

1. Benefits

In developing this final 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 final rule is greater market transparency and

improved ability of beneficiaries to make informed insurance choices. The uniform reporting required under this final 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 will not otherwise meet the MLR minimum defined by this final 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 will 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 final rule could result in improved beneficiary health outcomes, thereby creating a societal benefit.

2. Costs

We have identified the direct costs associated with this final rule as the costs associated with reporting, recordkeeping, remittance payments, enrollment sanctions and termination, and other costs.

a. Direct Costs

We estimate that each MA organization and Part D sponsor will incur approximately \$16,000 in 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 final 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 final 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 products offered as a result of this final 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 final 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 will 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 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 final rule, individual enrollees in the plans under 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 will 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 will 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 proposed 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 final rule, we expect that MA organization and Part D sponsor behavior will change as a result of this final rule, which will impact the MLRs and remittances due. Because we are limited in our ability to predict behavioral changes, we do not explicitly model these behavioral changes in our estimates. We asked for 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 final rule.

4. Number of Affected Entities Subject to the MLR Provisions

We proposed 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 will be affected by the requirements of this final rule at the contract level because this is the level at which we proposed 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 will 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 CMS 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.

We note that the estimates in Table 3 will be used to estimate potential CY 2014 remittances and therefore exclude non-credible contracts, which are not subject to the remittance requirements. This RIA does not account for the changes to remittance amounts if the distributions of credibility status changes. If more contracts become partially or fully credible, then remittance amounts would increase. Conversely, if more contracts become non-credible, then remittances amounts would decrease.

5. MLR Remittance Payments

a. Data Limitations and Modeling Assumptions

As described in the commercial MLR rule, we expect that as a result of this final rule, MA organization and Part D sponsor behavior will 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 MA organization or Part D 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 final rule are as follows:

- Pricing Policy—MA organizations and Part D sponsors will 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 modify existing activities to meet the QIA definition, 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 final 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 final rule, we proposed 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 proposed 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 proposed 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 proposed 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 will not reflect a credibility adjustment. Finally, we proposed 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 will 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 final 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)).

We did not receive any comments and we are finalizing these analyses as proposed.

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 will be designated as “partially-credible” according to the standards of this final 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) will be partially-credible, and about 43 percent of Part D stand-alone contracts (representing about 1 percent of projected total stand-alone enrollment) will 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 final rule, contracts with non-credible experience during a given contract year that do not meet the minimum MLR requirement will not be required to provide any remittance to CMS nor be subject to enrollment sanctions or termination because the contract will 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 MA organization or Part D 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-credible 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 contracts that do not meet the minimum MLR requirement, as shown in Table 5.

For the purpose of this RIA (and not the actual MLR calculation), 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.

For the purpose of this RIA (and not the actual MLR calculation), 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 of 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 MA organization or Part D 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 will be categorized as partially-credible, 68 will 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 will pass the MLR requirement, and 34 will 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 will 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 will pass the requirement, and 9 will 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) will 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 final 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 final 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.

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 final 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 final 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 final 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 final rule and in a time and manner that the Secretary determines. For purposes of these impact estimates, we assume that this report will 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 final 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 used the commercial MLR RIA as a basis for estimating the total hours of administrative work related to the Medicare MLR 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 will 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 final 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	101,000	\$94.88	\$9,600,000	\$16,000
Ongoing Costs	616	616	29,000	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 will incur annual ongoing costs relating to the MLR reporting requirements in this final 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 rate 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 CMS are expected to be relatively negligible, in particular because we proposed 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 considered a variety of regulatory alternatives to the

policies proposed thus far, and solicited comments on these alternatives.

1. Credibility Adjustment

One alternative to the credibility adjustment in this final rule will 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 will 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 will best balance the goals of providing value to beneficiaries and assuring that contracts with relatively low enrollment will 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 will 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 will obscure local variation in resource allocation that will be important to enrollees. As described elsewhere in this final 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 that in the commercial MLR rule. As discussed elsewhere in this final 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 or the specific types of activities included in the definition.

This final rule defines quality-improving activities as being those that are 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 that demonstrate 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 final 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 final rule.

We do not have data available to estimate the effects of alternative definitions of quality improving activities on MLRs, but a broader definition of quality improving activities would produce smaller estimated remittances, and a narrower definition would result in larger estimated remittances.

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 for 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 HCPPs (Health Care Prepayment Plans), will be affected by the final rule. We believe that health insurers will 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 will 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 will 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, issuers underwriting health insurance coverage (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 final 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 final rule because very few small entities are subject to the provisions in this final rule, the estimated administrative costs associated with reporting MLR data to the Secretary are very low (see section V.D.6. of this final rule), and the credibility adjustment addresses the special circumstances of contracts with lower enrollment. For these reasons, we believe this final rule will have minimal impact on small entities. As a result, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

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 final 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 will 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 final 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 final rule does not impose substantial direct requirement costs on state and local governments, this final 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 final rule state that the Secretary has enforcement authority and does not require the states to do anything.

As discussed earlier, in developing this final rule for the Medicare Advantage and the Medicare Prescription Drug Benefit programs, HHS used the commercial MLR regulation 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 regulation, 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 final rule in a meaningful and timely manner.

I. Congressional Review Act

This final 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 final 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 final 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
	7%	3%	
Annualized Monetized Transfers: Primary Estimate	\$802	\$833	CY 2014
From/To	From MA Organizations and Part D Sponsors / To Federal Government		
Category	Costs		
	Discount rate		Period covered
	7%	3%	
Annualized Costs to MA Organizations and Part D Sponsors: Primary Estimate	\$9.0	\$9.3	CY 2014

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 amends 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 paragraph (a)(15) 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.

* * * * *

Subpart U—[Reserved]

Subpart W—[Reserved]

■ 3. Remove and reserve 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.

Subpart X—Requirement for a Minimum Medical Loss Ratio

§ 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 per § 422.510(b)(1) and (d) 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, or subject to an adjustment determined by CMS to be warranted based on

exceptional circumstances for areas outside the 50 states and the District of Columbia.

(2) The MLR for an MA contract—

(i) Not offering Medicare prescription drug benefits must only reflect costs and revenues related to the benefits defined at § 422.100(c); and

(ii) That includes MA–PD plans (defined at § 422.2) must also reflect costs and revenues for benefits described at § 423.104(d) through (f) of this chapter.

(b) Determining the *MLR numerator*.

(1) For a contract year, the numerator of the MLR for an MA contract (other than an MSA contract) must equal the sum of paragraphs (b)(1)(i) through (iii) of this section, and the numerator of the MLR for an MSA contract must equal the sum of paragraphs (b)(1)(i), (iii), and (iv) of this section. The numerator must be determined in accordance with paragraphs (b)(5) and (6) 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) The amount of the annual deposit into the medical savings account described at § 422.4(a)(2).

(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) of this chapter.

(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) 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 any 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).

(5) Incurred claims under this part for policies issued by one MA organization and later assumed by another entity 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.

(6) Reinsured incurred claims for a block of business that was subject to indemnity reinsurance and administrative agreements effective before March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the

administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(c) *Determining the MLR*

denominator. For a contract year, the denominator of the MLR for an MA contract must equal the total revenue under the contract. Total revenue under the contract is as described in paragraph (c)(1) of this section, net of deductions described in paragraph (c)(2) of this section, taking into account the exclusions described in paragraph (c)(3) of this section, and in accordance with paragraph (c)(4) of this section.

(1) CMS' payments to the MA organization for all enrollees under a contract, reported on a direct basis, including the following:

(i) Payments under § 422.304(a)(1) 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) of this chapter.

(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) of this chapter.

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

(i) *Licensing and regulatory fees.* (A) Statutory assessments to defray the 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.* 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.

(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 42 CFR part 495 subpart C.

(B) EHR payment adjustments for a failure to meet meaningful use requirements that are administered under 42 CFR part 495 subpart C.

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

(4) Total revenue (as defined at § 422.2420(c)) for policies issued by one MA organization and later assumed by another entity must be reported by the assuming entity for the entire MLR reporting year during which the policies were assumed and no revenue under this part for that contract year must be reported by the ceding MA organization.

(5) Total revenue (as defined at § 422.2420(c)) that is reinsured for a block of business that was subject to indemnity reinsurance and administrative agreements effective prior to March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and

must not be reported by the ceding issuer.

(d) *Allocation of expense*—(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 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 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 paragraph (a)(14) to read as follows:

§ 423.509 Termination of contract by CMS.

(a) * * *

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

* * * * *

■ 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.

423.2450 [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.

Subpart X—Requirements for a Minimum Medical Loss Ratio

§ 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, or subject to an adjustment determined by CMS to be warranted based on exceptional circumstances for areas outside the 50 states and the District of Columbia.

(2) The MLR must reflect costs and revenues for benefits described at § 423.104(d) through (f). The MLR for MA-PD plans (defined at § 422.2 of this chapter) must also reflect costs and revenues for benefits described at § 422.100(c) of this chapter.

(b) *Determining the MLR numerator.*

(1) For a contract year, the numerator of the MLR for a Part D prescription drug contract must equal the sum of paragraphs (b)(1)(i) through (iii) of this section and must be in accordance with 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 expenditures under the contract for activities that improve health care quality, as defined in § 423.2430;

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

(i) Direct drug costs that are actually paid (as defined in § 423.308, which are net of prescription drug rebates and other direct or indirect remuneration as defined herein) by the Part D sponsor.

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

(iii) Percentage withholdings 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) Overpayment recoveries received from providers.

(4) *Exclusions from incurred claims.* The following amounts must not be included in incurred claims:

(i) Non-claims costs, as defined in § 423.2401, which include the following:

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

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

(1) Network development.

(2) Administrative fees.

(3) Claims processing.

(4) Utilization management.

(C) Amounts paid, including amounts paid to a pharmacy, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee, such as the following:

(1) Medical record copying costs.

(2) Attorneys' fees.

(3) Subrogation vendor fees.

(4) Bona fide service fees.

(5) Compensation to any of the following:

(i) Paraprofessionals.

(ii) Janitors.

(iii) Quality assurance analysts.

(iv) Administrative supervisors.

(v) Secretaries to medical personnel.

(vi) Medical record clerks.

(ii) Amounts paid to CMS as a remittance under § 423.2410(b).

(5) Incurred claims under this part for policies issued by one Part D sponsor and later assumed by another entity must be reported by the assuming organization for the entire MLR reporting year during which the policies were assumed and no incurred claims under this part for that contract year must be reported by the ceding Part D sponsor.

(6) Reinsured incurred claims for a block of business that was subject to indemnity reinsurance and administrative agreements effective before March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(c) *Determining the MLR denominator.* For a contract year, the denominator of the MLR for a Part D prescription drug contract must be in accordance with paragraph (c)(4) of this section and equal the total revenue under the contract. Total revenue is as described in paragraph (c)(1) of this section, net of deductions described in paragraph (c)(2) of this section, taking into account the exclusions described in paragraph (c)(3) of this section, and be in accordance with (c)(4) of this section.

(1) CMS' payments to the Part D sponsor for all enrollees under a contract, reported on a direct basis, including the following:

(i) Payments under § 423.329(a)(1) and (2).

(ii) Payment adjustments resulting from reconciliation per § 423.329(c)(2)(ii).

(iii) All premiums paid by or on behalf of enrollees to the Part D sponsor as a condition of receiving coverage under a Part D plan, including CMS' payments for low income premium subsidies under § 422.304(b)(2) of this chapter.

(iv) All unpaid premium amounts that a Part D sponsor could have collected from enrollees in the Part D plan(s) under the contract.

(v) All changes in unearned premium reserves.

(vi) Payments under § 423.315(e).

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

(i) *Licensing and regulatory fees.*

Statutory assessments to defray operating expenses of any State or Federal department, such as the “user fee” described in section 1857(e)(2) of the Act, and examination fees in lieu of premium taxes as specified by State law.

(ii) *Federal taxes and assessments.* All Federal taxes and assessments allocated to health insurance coverage.

(iii) *State taxes and assessments.*

State taxes and assessments, such as the following:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly.

(B) Guaranty fund assessments.

(C) Assessments of State industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(D) State income, excise, and business taxes other than premium taxes.

(iv) *Community benefit expenditures.*

Community benefit expenditures are payments made by a Federal income tax-exempt Part D sponsor for community benefit expenditures as defined in paragraph (c)(2)(iii)(A) of this section, limited to the amount defined in paragraph (c)(2)(iii)(B) of this section, and allocated to a contract as required under paragraph (d)(1) of this section.

(A) Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden.

(B) Such payment may be deducted up to the limit of either 3 percent of total revenue under this part or the highest premium tax rate in the State for which the Part D sponsor is licensed, multiplied by the Part D sponsor’s earned premium for the contract.

(3) The following amounts must not be included in total revenue:

(i) The amount of unpaid premiums for which the Part D sponsor can demonstrate to CMS that it made a reasonable effort to collect.

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

(4) Total revenue (as defined at § 422.2420(c)) of this chapter) for policies issued by one Part D sponsor and later assumed by another entity must be reported by the assuming entity for the entire MLR reporting year during

which the policies were assumed and revenue under this part for that contract year must be reported by the ceding Part D sponsor.

(5) Total revenue (as defined at § 422.2420(c) of this chapter) that is reinsured for a block of business that was subject to indemnity reinsurance and administrative agreements effective before March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity’s financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(d) *Allocation of expenses—(1) General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of or criteria for one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated 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 to 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 § 423.752.

(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: May 15, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 15, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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