January 27, 2025

*Submitted electronically via http://www.regulations.gov*

Acting Administrator Jeff Wu
U.S. Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

**RE: Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly [CMS-4208-P]**

To Acting Administrator Jeff Wu:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule titled "Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly."[1]

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans (PDPs) and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the Exchanges established by the Affordable Care Act (ACA).

We appreciate that CMS must move the program forward during a period of administration transition. However, we strongly recommend that CMS focus on statutorily required policy changes and ongoing, annual processes such as Stars updates.

In this letter, PCMA provides discussion and recommendations on the following topics following the section orders in the proposed rule:

[1] Federal Register / Vol. 89, No. 237 / Tuesday, December 10, 2024. 2024-27939.pdf

**Pharmaceutical Care Management Association**
325 7th Street, NW, 9th Floor
Washington, DC 20004
**www.pcmanet.org**

1. **Inflation Reduction Act:** We support the IRA-related policy codifications and provide some helpful considerations for future calendar years.

2. **Strengthening Current Medicare Advantage, Medicare Prescription Drug Benefit, and Medicaid Program Policies:**

   - ***Part D Coverage of Anti-Obesity Medications:*** CMS should refrain from finalizing its reinterpretation of the Part D statute to require coverage of AOMs when used to treat obesity.

   - ***Network Transparency for Pharmacies:*** CMS should not proceed with requirements that are unnecessary and duplicative.

   - ***Part D Sponsors Must Provide Network Pharmacies Reciprocal Rights to Terminate Contracts Without Cause and Request for Information on Access to Pharmacy Services and Prescription Drugs:*** CMS should not proceed with this proposal, as Part D plans and pharmacies are not in an equivalent position, and plans need greater flexibility to be able to protect enrollees from bad actors.

   - ***Request for Information on Access to Pharmacy Services and Prescription Drugs:*** CMS should provide additional data regarding its concerns so that stakeholders have a better understanding to be able to provide suggestions to address them.

   - ***Formulary Inclusion and Placement of Generics and Biosimilars:*** CMS should not further limit the formulary flexibility of Part D sponsors.

3. **Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System:** CMS should methodologically address social determinants of health and allow for continued use of guardrails to ensure the appropriateness and stability of cut-points. CMS should consider separately tracking Medicare Prescription Payment Plan–related CTMs and set a grace period to allow for implementation-related troubleshooting.

4. **Medicare Transaction Facilitator:** CMS should grant Part D plans a minimum of 14 days for Part D plan PDE submissions.

5. **Medical Loss Ratio:** PCMA opposes the proposed changes to the MLR requirements for Part D plans.

6. **CMS Request for Information on Vertical Integration:** CMS should refrain from pursuing the policies in this RFI in any future rulemaking, and to continue working with all relevant stakeholders to make improvements to the Part D program that focus on quality of care and access for Medicare beneficiaries.

Thank you for the opportunity to provide comments. We look forward to working with you on your ongoing efforts to improve Part D.

Sincerely,

*Tim Dube*

Tim Dube
Senior Vice President, Policy and Regulatory Insights

Enclosure
cc: Cheri Rice, Acting Deputy Administrator, Centers for Medicare & Medicaid Services
Debjani Mukherjee, PCMA

**I. Implementation of IRA Provisions for the Medicare Prescription Drug Benefit**

**Program**
A. Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices under Medicare Part D (§§ 423.100 and 423.120)

**Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices**

CMS proposes to codify the requirements related to $0 cost-sharing for adult vaccines recommended by ACIP under Part D for 2026 and each subsequent plan year. CMS states that utilization management (UM) strategies may be used to ensure that an enrollee meets the age or clinical requirements recommended by ACIP for a particular vaccine so as to ensure that a particular vaccine meets the definition of an ACIP-recommended adult vaccine and so qualifies for the statutory zero cost-sharing.

PCMA supports the codification of the cost-sharing requirements for ACIP-recommended adult vaccines. PCMA also asks that CMS clarify its expectations regarding the implementation of UM strategies to ensure that the zero cost-sharing is correctly applied when vaccines are administered by a physician or other health professional rather than a network pharmacy. Part D plans do not have a direct relationship with these health care providers. This causes operational barriers in imposing UM requirements in that context. We ask that CMS provide clear guidance on whether it expects Part D plans to implement UM edits to determine the appropriate cost-sharing for vaccines administered by physicians or other health professionals that do not have a direct relationship with the Part D plan.

**PCMA Recommendation: CMS should provide clear guidance regarding use of UM requirements when vaccines are administered by physicians or other health professionals that do not have a direct relationship with the Part D plan.**

B. Appropriate Cost-Sharing for Covered Insulin Products under Medicare Part D (§§ 423.100 and 423.120)

CMS proposes to codify the requirements related to appropriate cost-sharing for covered insulin products under Part D for 2026 and each subsequent plan year. CMS also proposes to add a definition of “applicable copayment amount” for covered insulin products to clarify that it is the lesser of $35, 25% of the maximum fair price (MFP), if applicable, or 25% of the negotiated price of the covered insulin product under the Part D plan.

PCMA supports the codification of the covered insulin cost-sharing requirements. We appreciate the clarification regarding appropriate cost-sharing, but note that this interpretation will further increase premiums for Part D enrollees. To ensure consistent treatment for selected and non-selected drugs, CMS should revise the definition of "applicable copayment amount" to include sales tax and dispensing fees for selected drugs subject to an MFP, since current MFP refers to the ingredient cost only. Thus, the cost-sharing could not exceed 25% of the sum of the MFP, sales tax, and dispensing fee for a selected drug. This is consistent with capping cost-sharing at 25% of the negotiated price, which also includes sales tax and the dispensing fee, in accordance with the statute, which limits the ingredient cost of a selected drug to the MFP.

***PCMA Recommendation: CMS should revise the definition of "applicable copayment amount" to include 25% of sales tax and dispensing fees for selected drugs to be consistent with the cost-sharing for other Part D drugs.***

C. Medicare Prescription Payment Plan (MPPP) (§§ 423.137, 423.2265, 423.2267, and 423.2536)

PCMA supports the codification of IRA guidance, including those for MPPP. Given that the program is new for regulators, pharmacies, plan sponsors, and PBMs, we would like to remind CMS not to make significant changes to operations for CY 2026. Major changes during the first few years of the program will only result in confusion among beneficiaries and greater need for troubleshooting.

Auto Renewal:

PCMA supports the proposal to implement an automatic renewal process by which MPPP elections will be carried forward from one year to the next for enrollees remaining in the same plan. We appreciate that this would reduce administrative burden and cost related to processing of new election forms for active program participants or conduct "likely to benefit" analyses for the upcoming plan year. We suggest that the auto-renewal notification to enrollees be streamlined by CMS and be incorporated into other annual notification documents. Separate mailings for auto-renewal would be burdensome for plans, as well as confusing for beneficiaries. With regard to effective date, CMS should clarify whether the auto-renewal policy would be applicable at the end of 2025 and carry into 2026 or start in 2026 and go into future years.

24-Hour Enrollment and Real-Time Enrollment:

PCMA supports the proposal to codify the current requirement that enrollment into M3P must be processed within 24 hours during the plan year.

However, we would like to reiterate our prior comments regarding technical barriers for moving to real-time enrollment requiring interface between different systems of plan sponsor, PBM, and pharmacy. Since real-time enrollment requires a new value in an existing National Council for Prescription Drug Programs (NCPDP) data field for the program, changing the enrollment process at this point would be premature. CMS should delay changes in administrative processes and accompanying technical changes for the M3P until after plan sponsors have at least a full year's real-world experience with the program. Moreover, NCPDP must approve and

publish new standards before any real-time enrollment change could be implemented. Given current issues with pharmacy claims processing systems software and inability to process M3P claims appropriately due to inadequate updates, this addition to the program seems premature and problematic.

Terminations:

PCMA thanks CMS for the clarity provided regarding termination time frames, including maintaining the requirement to send notice of voluntary termination within 10 calendar days. We also ask that CMS allow a 72-hour termination effectuation period instead of 24 hours. While plans are working to process voluntary terminations quickly, the flexibility built into 72-hour effectuation would greatly facilitate program functions.

Overpayment/Underpayment Adjustments and Grace Periods:

PCMA supports the proposed modifications regarding overpayment and underpayment adjustments. We appreciate the modified grace period timing requirements proposed and appreciate CMS addressing this inconsistency between Part 1 and Part 2 guidance. Streamlining implementation grace period requirements will avoid administrative confusion and facilitate programmatic efficiency.

**PCMA Recommendation: CMS should delay significant changes to M3P, such as real-time enrollment, until there is at least a full year of operational experience with the program.**

**II. Strengthening Current Medicare Advantage, Medicare Prescription Drug Benefit, and Medicaid Program Policies**

CMS proposes to reinterpret the longstanding statutory coverage exclusion for drugs used for weight loss under Medicare Part D to cover FDA-approved indications of AOMs when used for the treatment of obesity. While we acknowledge that these drugs hold promise and potentially carry significant benefits to the Medicare patient population, PCMA is deeply concerned with CMS's proposal to reverse its decades-long policy, as it is clearly contrary to the plain language of the underlying statute, the will of Congress, and the agency's own legal interpretation clarified just a few months ago. We are also deeply concerned with the fiscal impact this fundamental policy change will have on financially constrained state Medicaid programs.

A. Part D Coverage of Anti-Obesity Medications (AOMs) (§ 423.100)

Under Section 1860D-2(e)(2) of the Social Security Act, certain medications are excluded from the definition of a covered Part D drug. The list of medications includes, among other drugs, "agents when used for anorexia, weight loss, or weight gain." In this proposed rule, CMS reinterprets this reference such that AOMs would in the future be covered under Part D when used for the treatment of obesity. "Overweight" is not a recognized disease, and FDA labels do not typically specify overweight or obese as indications for these medications, making it difficult to determine whether a Part D sponsor's coverage criterion is within the label parameters. The proposed expansion of Part D to include coverage of AOMs to treat obesity would be significant, both operationally and financially, and its implementation would be fraught with

uncertainties regarding which drugs would need to be included on Part D formularies and for which members, leading to inconsistent coverage between plans and, accordingly, increased risks of adverse selection for certain plans. It is also a major change in the interpretation of the statutory language, which is straightforward and unambiguous, leaving little room for any different interpretation, let alone one so different from the current interpretation and statutory language. While we acknowledge the agency's interest in pursuing the policy from a social determinants of health perspective, we are concerned about the operational and financial implications of such a radical re-interpretation of the statute without any legislative support. The statute presently does not prohibit Part D plan sponsors from covering these products for these uses as supplemental drugs, if desired.[2] CMS should instead continue to allow plans the flexibility to determine whether to provide coverage of such optional drugs.

*CMS's proposal is contrary to the plain language of the statute and congressional intent.*

The plain language of the Medicare statute excludes AOMs from the definition of a covered Part D drug. Section 1860D-2(e)(2) of the Social Security Act (the "Act") excludes from Medicare coverage (via reference to the Medicaid statute at Section 1927(d)(2) of the Act) "agents when used for anorexia, weight loss, or weight gain." CMS proposes to extend Part D coverage to AOMs when "used for weight loss or chronic weight management for the treatment of obesity"—reversing a policy in place for nearly two decades. AOMs used for weight loss or chronic weight management are clearly "agents used for weight loss." CMS's proposal is directly at odds with the plain language of the underlying statute.

CMS's proposal is also incompatible with Congressional intent. The Medicare Part D statute established specific exclusions from the definition of a covered Part D drug by cross-referencing an existing provision in the Medicaid statute, enacted in 1993, outlining drugs that may be excluded under the Medicaid program.[3] At no point was the relevant language in the Medicaid statute interpreted as providing an exception to the "agents for weight loss" exclusion for drugs that treat obesity. Congress, by simply cross-referencing the language in section 1927(d)(2) in this context, intended for the scope of the Part D exclusion to generally mirror the scope of the Medicaid statute's exclusion of "drugs or classes of drugs, or their medical uses." When Congress wanted the scope between the two programs to differ, it did so explicitly, such as by clarifying in the Part D statute that barbiturates are covered Part D drugs only if "used in the treatment of epilepsy, cancer, or a chronic mental health disorder." Had Congress intended for an obesity carve-out to the Part D exclusion, it would have taken a similar approach. For example, Congress could have noted that the term *covered Part D drug* "does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), *other than* subparagraph (A) if used in the treatment of obesity." Congress did not take such an approach, and has not ventured to do so in the 20-plus years since it enacted the Part D statute.

---

[2] *See* Section 1860D-2(a)(2)(A)(ii) of the Act, which defines as supplemental coverage "Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A)."

[3] *See* Section 1860D-2(e)(2)(A) of the Act (excluding from the definition of covered Part D drug those "drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2)).

We also note that, following the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, courts may no longer defer to administrative agencies' statutory interpretations, and are instead tasked with determining the "single, best meaning" of a particular statutory provision, which will primarily entail interpreting the plain language of the relevant statute.[4] Here, as explained above, the plain language of the statute excludes from the definition of covered Part D drug "agents when used for weight loss," which clearly encompasses AOMs used for weight loss and weight management for individuals with obesity.

Under *Loper Bright*, courts may consider agency interpretations as *persuasive* authorities, but the strongest agency interpretations are those "issued contemporaneously with the enactment of [a] statute" and long adhered to by an agency.[5] As noted above, since its first rulemaking implementing the new Part D program, CMS interpreted Section 1860D-2(e)(2) of the Act as excluding from the definition of covered Part D drug any drug used for weight loss, and the agency has *consistently* adhered to this interpretation for close to two decades. Notably, the agency reiterated its legal interpretation of this language *just a few months* before reversing course and issuing this proposed rule.[6]

Notwithstanding the promise of these therapies, we urge CMS to avoid venturing into the legally questionable morass of reversing its long-standing interpretation of the scope of section 1860D-2(e)(2). The agency's prior interpretation is in line with the best reading of the statute, and most clearly effectuates the will of Congress. CMS's proposal will exacerbate already strained financial resources of the Medicare and state Medicaid programs.

In addition to the above, we are deeply concerned with the fiscal impact this proposal would have on both the Medicare trust fund and state Medicaid programs. In the agency's regulatory impact analysis of the policy, it estimates a $24.8 billion increase in Medicare trust fund expenditures over a 10-year period if the proposal is finalized. With respect to Medicaid, CMS estimates a $14.8 billion increase in Medicaid expenditures over a 10-year period if the proposal is finalized, with the Federal government bearing $11 billion of those costs.

As discussed above, and as CMS notes in the proposed rule, CMS's proposed reinterpretation with respect to the Medicare Part D program will also necessitate a change in interpretation with respect to the originating language pertaining to "agents when used for anorexia, weight loss, or weight gain" applicable to the Medicaid program. As a result, if finalized, this policy will also *require* state Medicaid programs to cover AOMs if used to treat obesity.

---

[4] *Loper Bright Enterprises v. Raimondo,* 144 S.Ct. 2244, 2266 (2024).

[5] *Id.* at 2262.

[6] *See* HPMS Memo, Part D Coverage of Anti-Obesity Medications with Medically Accepted Indications (March 20, 2024) (CMS noting that an AOM "that receives FDA approval for chronic weight management alone would not be considered a Part D drug" and that "Part D coverage is still not available for AOMs when used for chronic weight management in patients who do not have the additional medically accepted indication" such as diabetes).

State Medicaid programs are already under enormous financial pressures.[7] Mandating coverage of AOMs in this context will only serve to further strain state Medicaid budgets, and may ultimately place states in the impossible and unenviable position of deciding which benefits to cut in order to make ends meet. We stress that this is all exacerbated by the differing effective dates for these proposals. The policy with respect to the Part D program does not become effective (if finalized) until January 2026, whereas state Medicaid programs will be required to comply *60 days* after publication of the final rule. As such, with respect to dual-eligible individuals, states will be expected to bear the greatest burden of covering these drugs for an extended period of time. PCMA is deeply concerned with the economic impact regarding the resulting burden on state budgets, and the downstream consequences this will have on the viability of state Medicaid programs in general.

CMS should defer this proposal, given that FDA has recently posted draft guidance for developing weight-loss drugs for obese or overweight patients. According to FDA, this draft specifically focuses on clinical trials and endpoints beyond Body Mass Index (BMI) given the flaws of measuring obesity with BMI. CMS efforts related to AOMs should for now be focused on liaising with FDA to address AOM label definitions of overweight and obesity. CMS should prioritize implementing changes required by the IRA first and then focus on market stabilization efforts in Medicare Part D as needed to address the impact of these significant changes, such as considering adjustments to the Premium Stabilization Demonstration for PDPs, including further Risk Corridor Adjustments. It should not pursue such a major change in coverage under Part D at the same time as the program and participants in the Part D marketplace are still absorbing and adapting to the many IRA changes, including Part D redesign, the most significant change in Part D since its inception pursuant to the Medicare Modernization Act over two decades ago. Equally if not more important, the indications for AOMs are currently in a state of flux as the FDA has recently posted draft guidance for developing weight-loss drugs for obese or overweight patients. According to FDA, this draft specifically focuses on clinical trials and endpoints beyond Body Mass Index (BMI) given the flaws of measuring obesity with BMI. CMS efforts related to AOMs should for now be focused on liaising with FDA to address AOM label definitions of overweight and obesity. For all these reasons, it is inadvisable to proceed with this proposal at this time. CMS should instead allow time for both the Part D market to stabilize and the FDA labeling changes for AOMs to be finalized before considering this proposal.

***PCMA Recommendation*: CMS should refrain from finalizing its reinterpretation of the Part D and Medicaid statutes to require coverage of AOMs when used to treat obesity. CMS's proposals are contrary to the underlying statute and the will of Congress, and would place enormous financial strain on the Medicare trust fund and state Medicaid programs, which already face difficult decisions with respect to their long-term financial viability.**

B. Network Transparency for Pharmacies

---

[7] *See* R. E. Sachs et al., *Confronting State Medicaid Drug Spending Pressures*, JAMA (Oct. 9, 2020), https://jamanetwork.com/journals/jama/fullarticle/2771844; *see also* N. Jasemi, *Top five Medicaid budget pressures for fiscal year 2025*, National Association of Medicaid Directors (April 23, 2024), https://medicaiddirectors.org/resource/top-five-medicaid-budget-pressures-for-fiscal-year-2025/.

CMS proposes to require Part D sponsors to notify network pharmacies of which plans the pharmacies will be in-network for in a given plan year by October 1 of the preceding calendar year, and to provide pharmacies with this list on request after October 1. CMS states that this is necessary to ensure that pharmacies can provide their customers with accurate information about which plans the pharmacy is participating in.

PCMA agrees that pharmacies should know which Part D plans they will be in-network for in a given plan year. This is important not only for beneficiaries, but also for plans and pharmacies themselves so that they comply with applicable plan requirements. However, we do not believe it is necessary for Part D sponsors to provide a notification to this effect to pharmacies, since pharmacies should already have this information from their contracts or be able to obtain it quickly and easily without undue burden. We also disagree with the premise that pharmacies lack negotiating leverage. Independent pharmacies are usually represented by large, national pharmacy service administrative organizations (PSAOs) and chain pharmacies are also large, often national corporate entities. As of 2024, 89% of independent pharmacies contracted with a PSAO, and the largest PSAOs are owned by the drug wholesalers.[8] Moreover, the participation of one or more of both chain and independent pharmacy is often critical in order for Part D plans to meet their network adequacy requirements and address beneficiary needs.

Requiring additional notification by Part D sponsors would add a substantial amount of unnecessary administrative burden and cost, particularly to print the information, since most Part D sponsors have thousands of pharmacies in their networks, and many have well over 50,000 network pharmacies. The costs of such notifications would ultimately be borne by beneficiaries and taxpayers in the form of higher Part D premiums. Even if pharmacies do not have the most updated information from their executed contracts, there are multiple quick and simple ways for a pharmacy to confirm whether it is in-network for a particular Part D plan when asked by an enrollee. These include checking Medicare Plan Finder (MPF) or the pharmacy directory on the Part D plan's website, both of which are intended for precisely this purpose and take only a few minutes to use.

CMS states that pharmacies report that using MPF is cumbersome in that it does not provide users a comprehensive list of all the plans in a service area that a particular pharmacy is in-network for. We note that pharmacies do not require such a list to respond to an enrollee's inquiry about a specific plan. Moreover, the proposed lists that Part D sponsors would be required to provide would also not provide pharmacies with such a comprehensive list and include individual sponsor specific information only. However, pharmacies can easily compile such pharmacy-focused lists themselves with minimal effort. Alternatively, since CMS has this information across all Part D sponsors, we recommend that CMS make the information available on its website or directly to pharmacies.

If CMS does proceed with this new requirement, we appreciate the clarification that notification may be provided electronically. We ask that CMS also clarify that it is permissible to provide global network pharmacy information showing the pharmacies in each Part D plan network, and that it is not a requirement to provide information individually tailored to each pharmacy. The latter would be prohibitively expensive for Part D sponsors and would still require pharmacies to compile their own lists of the Part D plans for which they are in-network.

[8] PSAOs | PCMA

***PCMA Recommendation: CMS should not proceed with this requirement, as it is unnecessary and duplicative of information already known or easily available to pharmacies with minimal effort.***

D. Part D Sponsors Must Provide Network Pharmacies Reciprocal Rights to Terminate Contracts Without Cause and Request for Information on Access to Pharmacy Services and Prescription Drugs.

CMS proposes to require Part D sponsors to allow pharmacies to terminate their network contracts without cause after the same notice period that the sponsor is allowed to terminate network pharmacy contracts without cause, if any. CMS states that it believes this change provides greater fairness in contracting terms and is necessary to protect beneficiaries from disruptions in receiving Part D benefits that would occur if network pharmacies stop providing services before formally terminating their contracts.

PCMA opposes the requirement to provide network pharmacies with reciprocal rights of termination without cause. We disagree with CMS that pharmacies may engage in ad hoc refusal to fill prescriptions as a substitute for contract termination, since this would likely violate their contract obligations. We also disagree with the premise that Part D sponsors and pharmacies are in the equivalent position, mandating identical termination rights.

For those Part D sponsors and their PBMs that do have contract rights of termination without cause, this is to reflect the legitimate need for more flexibility on the Part D sponsor's behalf to terminate pharmacy contracts than is needed by pharmacies. For example, there may be instances where pharmacy fraud, waste, or abuse (FWA) or other misconduct has occurred, where plans may not yet have fully gathered sufficient evidence that would justify a "with cause" termination. Unless Part D sponsors and/or their PBMs have without-cause termination rights, they will be unable to terminate the pharmacy contract for fear of becoming involved in a legal dispute as to whether sufficient cause has been shown for termination. As a result, bad actor pharmacies will remain in the network to the detriment of beneficiaries and the Part D program. Part D sponsors need the right to be able to act swiftly to protect beneficiaries and taxpayers.

Another concern is that some pharmacies could threaten to terminate their network contracts as a negotiating tactic, causing plans to have to notify beneficiaries only to have the pharmacy remain in the network once demands have been met. Allowing pharmacies to terminate contracts and enter and exit networks at will would lead to considerably more, rather than less, beneficiary disruption and confusion.

Finally, we note that it is not in the interests of Part D sponsors or their PBMs to exercise their contract rights of termination without cause unless they have good reason to do so. This is not only because of access requirements and the desire to have broad networks for their enrollees, but also because unless there is ultimately good cause shown for termination, the pharmacies have the right to rejoin the network at any time under the Part D "any willing provider" requirement. Terminations without cause would thus result in costly, potentially redundant, and burdensome paperwork without any benefit.

If CMS proceeds with the proposal to allow mutual rights of termination without cause, we ask that CMS require that pharmacies provide at least six months' notice to the Part D sponsor to allow Part D sponsors and their PBMs sufficient time to notify beneficiaries and find an alternative pharmacy.

***PCMA Recommendation: CMS should not proceed with this proposal, as Part D plans and pharmacies are not in equivalent positions, and plans need greater flexibility to be able to protect enrollees from bad actors.***

Request for Information on Access to Pharmacy Services and Prescription Drugs:

CMS states that it is concerned about the sustainability of pharmacies, especially small and independent pharmacies, and their potential closures that may leave Part D beneficiaries without convenient access to pharmacy services—especially in rural and underserved areas. CMS seeks comment on what additional data or information to consider—such as reimbursement rates, underlying costs, steering, contracting terms, and other elements which may affect pharmacies' ability to continue providing Part D drugs to beneficiaries—to improve CMS's ability to protect beneficiaries' convenient access to Part D drugs consistent with current access standards in Part D.

We share CMS's goal of ensuring adequate access to pharmacy services for Part D beneficiaries and are interested in further understanding the data underlying CMS's concerns about small and independent pharmacies and potential closures. Most Part D sponsors currently exceed Part D pharmacy access requirements, and our member companies have not reported experiencing difficulty contracting with a sufficient number and distribution of pharmacies to ensure sufficient access for their Part D enrollees. Furthermore, the number of independent pharmacies has remained stable over the last several years.[9]

We encourage CMS to consider the market forces impacting pharmacies unrelated to Part D reimbursement, such as shrinking population in rural areas and associated reduced volume, differentials in services offered across type and size of pharmacy, etc.[10] CMS should also consider offering incentives to Part D sponsors to contract with pharmacies in areas where there is a paucity of pharmacies when doing so is not required to meet access standards, and allowing Part D sponsors in turn to offer incentives to pharmacies to operate or offer services in rural or underserved areas.

**PCMA Recommendation: CMS should provide additional data regarding its concerns so that stakeholders have a better understanding to be able to provide suggestions to address them.**

E. Formulary Inclusion and Placement of Generics and Biosimilars

---

[9] NCPA 2024: In Spite of Challenges, Independent Pharmacies Are Continuing to Serve Patients

[10] Will PBM reform save pharmacies from closing? T. Joseph Mattingly II and Kelly E. Anderson. Jan. 15, 2025. Link: What is the real relationship between PBMs and pharmacy closures? | STAT

CMS states that it is considering including an additional step in the formulary review process to check that Part D sponsors provide broad access to generics, biosimilars, and other lower-cost drugs. CMS states that this review would encompass an evaluation of whether the formulary includes generics, biosimilars, and other lower-cost drugs, and whether these drugs are placed on a lower formulary tier than the brand drugs or reference products. CMS states that it would also review whether a formulary incorporates fewer utilization controls on brand drugs and reference products than on lower-cost alternatives.

PCMA has several concerns with this proposal and the assumptions on which it is based. As CMS acknowledges, there are robust formulary review processes in place already to ensure that Part D plans' formularies meet regulatory and statutory requirements, including comprehensive checks to ensure that the formulary does not discourage the enrollment of certain beneficiaries and that utilization management (UM) requirements are appropriate. This review is over and above the review conducted by the plan's own pharmacy and therapeutics (P&T) committee, which must itself meet extensive requirements regarding its composition, qualifications, and duties with respect to formulary development. Importantly, P&T committees must consider scientific evidence and a drug's safety and efficacy first and foremost in their decision making. Given the extensive multilayered formulary review process already in place, it is not clear what the proposed additional step would contribute, particularly since it is not clear exactly what it would deem impermissible that has not already been identified in the process. We are concerned that the additional step could instead become a stumbling block for Part D sponsors as they try to meet unclear standards regarding generics and biosimilar inclusion and placement on their formularies.

CMS's discussion appears to focus exclusively on the cost of generics and biosimilars, whereas Part D plans' formulary decisions include many factors, only one of which is cost. Clinical factors such as safety and efficacy always come first, as is required by the Part D regulation and CMS guidance. In addition, plans and their PBMs must consider product availability, dosage forms, and other factors that will impact beneficiary access and choice before including or favoring a drug on its formulary through tier placement. We note that Part D plans are heavily incentivized to manage drug utilization and costs, while always ensuring clinically appropriate utilization. UM edits are used to ensure that a drug is clinically appropriate and only then, to promote more cost-effective choices, which is never at the expense of a more appropriate clinical option. Formulary placement and UM policies allow for this evidence-based care management.

Access to generics and biosimilars improves each year in the Part D market, which is the strongest evidence that Part D plans do not seek to favor higher-cost brand and biologics. Plans have every incentive to seek the lowest-cost products, and when generics and biosimilars are the lowest cost, plans will reflect this in their formulary placement, UM edits, and other programs. Thus, we strongly support recent policy changes in the CY2025 MA & Part D final rule[11] that allow mid-year formulary substitutions of generics and biosimilars for brand and biologic reference products. This allows plans the flexibility to substitute more cost-effective products when they become available (although in some instances the timing parameters limit application of the new policy).

[11] Federal Register / Vol. 89, No. 79 / Tuesday, April 23, 2024. 2024-07105.pdf

However, generics and biosimilars are not always the lowest-net-cost products. This is especially the case for products new to market. Thus, in some instances, it may be more cost effective for a plan to place brands and generics on the same tier, especially when there is another more cost-effective and/or more clinically appropriate product in the class that is on a lower tier. CMS's focus on cost-sharing to the exclusion of other enrollee costs is puzzling, as CMS itself urges enrollees to consider not only the cost of a drug when choosing a Part D plan, but also the premiums. The lower the net cost of a drug, the lower the plan premiums, and the appropriate focus should be on total enrollee costs, i.e., the combination of cost-sharing and premiums that an enrollee pays under a plan. This is especially the case under Part D redesign, where enrollees' out-of-pocket costs are capped but premium costs are not. As such, enrollees are more adversely impacted by high-net-cost drugs. Finally, lower-net-cost drugs benefit the Part D program and thus taxpayers, since the most significant Part D subsidies are premium subsidies.

CMS also asks for comments on the role of rebates in formulary decisions and the extent to which these reduce Part D beneficiaries' access to lower-cost drugs, and whether CMS needs to make changes to prevent Part D formularies from excluding or disfavoring coverage of generics. First and foremost, it should be noted that the price of drugs is set by manufacturers, and manufacturers hold the power to set and lower their list prices if they choose to do so instead of providing rebates. However, many manufacturers choose to provide rebates as a mechanism to promote the use of their products. Part D sponsors and their PBMs therefore use formulary inclusion and tier placement as leverage to negotiate lower drug costs from manufacturers, whether in the form of lower list prices or higher rebates to reach the lowest net cost, which ultimately benefits all enrollees and the Part D program as a whole.

We are concerned that CMS's focus on the list price of drugs and proposal to further limit the formulary decision-making of Part D sponsors and their PBMs will hurt enrollees and benefit manufacturers by limiting the negotiating leverage of Part D sponsors and their PBMs to extract lower drug prices from manufacturers. Specifically, if Part D sponsors are required to cover most or all generics or biosimilars or always favor them on their formularies, the manufacturers of these drugs will have little incentive to price them appropriately. It is no coincidence that manufacturers are amongst the most vocal proponents of measures to limit formulary flexibility and disregard the net drug costs to enrollees, since they would be the primary beneficiaries of these proposals at the expense of enrollees and taxpayers.

If CMS nevertheless proceeds with future guidance or rulemaking that implements requirements related to formulary placement for generic or biosimilar drugs, we ask that CMS avoid coverage mandates and consider the potential market distortions that could be created by such a requirement. We also ask that CMS be clear and explicit regarding the criteria it will use for any additional steps in its formulary review process so that Part D sponsors and their PBMs fully understand CMS's expectations when designing their formularies.

***PCMA Recommendation: CMS should not further limit the formulary flexibility of Part D sponsors by imposing additional requirements regarding formulary inclusion or tier placement of generics and biosimilars, since this will decrease the negotiating leverage of Part D sponsors and benefit only manufacturers.***

- ***It is important to recognize and appreciate that many other factors beyond cost inform formulary decisions, including safety, efficacy, availability, and choice.***

**III. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.166 and 423.186)**

PCMA acknowledges the need for quality assessment, given that it ensures the quality of clinical care for the beneficiary while also monitoring aspects of care delivery. Given the value of these assessments, we encourage addition of robustly tested measures with appropriate adjustments for social determinants of health. To be successful, measure mechanics—as in numerators, denominators, and exclusion factors—must be appropriate, data to calculate a measure must be readily accessible, and measure impact must be validated.

A. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

Initial Opioid Prescribing for Long Duration (IOP-LD) Measure Addition

CMS proposes to add the Initial Opioid Prescribing for Long Duration (IOP-LD) measure for the 2028 Star Ratings covering the 2026 measurement year. It is important to note that this is a difficult measure for a plan to influence. Prescribing is the function of providers, and an appropriate measure to assess opioid prescriptions needs to be focused on providers. The rationale for opioid controls and limitations cited in the proposed rule is commonly accepted, notably the citations from the 2022 CDC guidelines. So too is the acceptance of the CDC's assertion that pain is complex and influenced by a number of factors, and that prescribing authority and oversight need to remain with providers who know the individual needs of their patients. Moreover, the existing measure and the sufficiency of current measure exclusions have not been evaluated.

To increase the impact of the measure, we recommend that CMS include denominator exclusions for beneficiaries who may be frail or include a risk adjustment or stratification for age and disability. This adjustment for beneficiary-level sociodemographic status (SDS) characteristics will adequately reflect differences in patient populations that may otherwise skew the data. The measure review committee concerns that adequate exclusions could use further review is shared by clinical professionals closest to the programs serving these populations. First, the added exclusion to drug management programs to exclude cancer survivors experiencing pain post treatment but not actively being treated for cancer is appropriate, but has not been adopted by the measure steward. Second, special consideration should be given to members in long-term care facilities, since they are closely monitored by care teams and have complex needs.

We also suggest adding a requirement for documentation or rationale when a provider extends an opioid prescription beyond seven days to increase measure efficacy and avoid the potential for abuse. Furthermore, we would like CMS to include exclusion reporting as part of the monthly Patient Safety reports.

While it is understood that CMS intends for these measures to be a retrospective performance measurement and not guide clinical decision-making, the nature of the Star Ratings program drives outcomes based on industry performance. If a plan serves a population characteristically

different than the average, resulting in an appropriately higher opioid dispensing rate, that plan will be pressured to adjust their programs to bring that number down, closer to the average. If CMS's intent is merely to measure the complementary oversight functions already in place, of which there are many, that is already accomplished with measure monitoring on the display page. Oversight is already in place through concurrent Drug Utilization Review submissions, program audits, data validation audits, and annual reporting. Moreover, CMS has the authority to sanction plans it believes do not have appropriate controls in place for safe opioid dispensing.

***PCMA Recommendation*: CMS should include denominator exclusions for beneficiaries who may be frail or include a risk adjustment or stratification for age and disability and require documentation when a provider extends an opioid prescription beyond seven days for efficacy and potential for abuse.**

Methodological Considerations: Removing Star Ratings Guardrails

In the proposed rule, CMS is notifying plans of its intent to finalize the CY24 MAPD rule[12] proposal to remove guardrails when determining measure-specific thresholds, as in cut-points for non–Consumer Assessment of Healthcare Providers and Systems (non-CAHPS) measures. PCMA opposes the removal of the guardrails policy, since it provides known data elements from prior performance years, which improves the overall predictability of cut-points. We strongly recommend continuation of guardrails to ensure that cut-points do not shift by more than 5% each year, since cut-points have yet to be stable and predictable since the addition of Tukey.

In addition, we encourage CMS to consider the need for flexibility and exceptions in instances with unforeseen consequences, such as natural disasters or another pandemic. In these situations, it may be important to account for the volatility in cut-points, as these policies could have a negative impact on beneficiaries' access to high-quality plans.

***PCMA Recommendation*: CMS should allow for continued use of guardrails to ensure the appropriateness and stability of cut-points.**

Health Equity Index

From a broad measurement policy perspective, PCMA suggests that CMS adopt a simple transition policy that applies to as few years as possible, and calculate independent HEI scores as soon as possible for each calendar year. CMS should apply the HEI calculation rules once the contract is stable enough that all data to inform the calculation comes from that singular contract, rather than transitioning contracts.

***PCMA Recommendation*: CMS should implement a transition policy that is simple.**

Medicare Prescription Payment Plan and CTMs

As part of quality assessment and Stars ratings, we are expressing some concerns and providing context with respect to recent increases in beneficiary complaints related to the Medicare Prescription Payment Plan (MPPP, also referred to in this section as Program). In the

[12] Federal Register / Vol. 88, No. 70 / Wednesday, April 12, 2023. 2023-07115.pdf

final part one MPPP guidance, CMS had stated that it would track complaints using the Complaints Tracking Module (CTM) related to the Program and consider creating a separate subcategory. As an industry, we had requested a grace period and reiterate our request again. This grace period would allow all parties (providers, pharmacies, PBMs, and payers) time to address administrative, process, and technical issues. Most beneficiary complaints result from issues at the pharmacy counter, which is beyond the purview of PBMs and payors. All segments of retail (independent and chain) pharmacies are having issues. Based on member feedback, chain pharmacies are experiencing software issues and working with IT vendors to address software needs. Legacy pharmacy systems have had to implement new software programs. Some of these new system enhancements for the Program had defects or were not working as expected. On the other hand, some pharmacies did not build an automated process to add MPPP participation to the member's profile. Therefore, they have to manually add for both new prescriptions and refills. Some pharmacies did not expect the number of opt-ins prior to January 1, and the refills created a backlog.

Our concern is that despite information dissemination by CMS and PCMA members, pharmacies are currently unprepared or uneducated. PCMA members continue to provide updated education based on pharmacy challenges and providing targeted assistance. Pharmacy account managers' PBMs are working with their network pharmacies to help resolve some of the challenges and/or answer questions. As members call into PBM customer care centers, PBMs are trying to work with the pharmacies in real time to help the pharmacy with the proper submission process. For example, if a member calls in to a PBM customer care center advising that their pharmacy is struggling, the beneficiary is put on hold as the problem is solved in real time and the pharmacy is walked through the proper submission process. Moreover, since October 2025, PBMs have:

- produced and disseminated pharmacy communications to their network pharmacies, and
- updated payer sheets with all the proper MPPP BIN/PCN/RxGroup details.

**PCMA Recommendation: CMS should consider separately tracking MPPP-related CTMs and set a grace period to allow for implementation-related, pharmacy-focused adequate training and troubleshooting.**

**IV. Medicare Transaction Facilitator**

A. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements
To facilitate the effectuation of negotiated MFPs under the IRA, CMS is proposing to codify changing the required deadline for Part D plans to submit PDE data for selected drugs to seven days. CMS claims this will shorten the time for payment of retrospective rebates to dispensing entities.

PCMA supports CMS's efforts to establish a data-sharing process between manufacturers and dispensing entities for IPAY 2026 and 2027, as managed by the MTF. We agree that the data exchange is crucial for ensuring that manufacturers provide the MFP payment to dispensing entities within the required prompt pay 14-day time frame. However, we are very concerned about the proposed shortened time frame requirement for Part D plans to submit PDE records within seven days of the date of dispensing of selected drugs. We believe this would impose significant operational and administrative burdens on Part D plans, especially for claims

requiring coordination of benefits, prior authorization, or other complex processing. A shortened time frame requirement would lead to potentially inaccurate information being transmitted to manufacturers, post-seven-day PDE reversals, and manufacturer MFP payment delays, heightening the administrative burden on all parties.

CMS previously stated in its draft guidance that its analysis of PDE record submissions shows that over 80% of PDE records are submitted within seven days of receipt from Part D plans. Our members have reported that while over 80% of PDE records are submitted within seven days, a not insignificant portion of these PDEs are reversed for multiple reasons, including when an enrollee does not pick up their medication within 14 days at the pharmacy. These post-seven-day PDE reversals represent a real financial risk to dispensing pharmacies for retroactive repayment and adjudication requests by manufacturers. As of today, there is no defined process for dispensing entities to submit PDE reversals or request adjudication through the MTF. We strongly believe it would be premature for CMS to arbitrarily make potentially significant regulatory changes to operating procedures before the Negotiation Program's initial start date of January 1, 2026. We recommend that CMS assess PDE submission timelines after at least one year of implementation of the Negotiation Program.

Additionally, if CMS codifies the proposed seven-day PDE submission timeline and Part D plans cannot meet the submission date, manufacturers may use the absence of a PDE on day 7 to delay payment of the MFP within the statutory prompt pay framework requirement. For Part D plan PDEs submitted after seven days, the manufacturer could take the position that the prompt payment clock does not commence until they receive the PDE from the MTF, even though the statute's use of the word "claim" does not condition the provision of the MFP on the PDE record. Therefore, we are concerned that CMS's reliance on a shortened PDE submission may delay payments to pharmacies and make such claims "off-cycle" relative to the payments that pharmacies receive from Part D sponsors.

While we appreciate the agency's efforts to ensure that dispensing entities receive timely payment for MFP-selected drugs, shortening the PDE submission time frame to seven days will result in administrative and financial burdens for dispensing entities due to the potential volume of post-seven-day PDE reversals and additional operational processes for payment adjudications. As stated above, a shortened time frame would lead to potentially inaccurate information being transmitted to manufacturers, yield numerous post-seven-day PDE reversals that the MTF DM process has not anticipated, and allow for manufacturer MFP reimbursement delays, heightening the administrative burden on all parties.

***PCMA Recommendation***: **We strongly urge CMS to grant Part D plans a minimum of 14 days for Part D plan PDE submissions.**

**V. Medical Loss Ratio (MLR)**

A. Proposed Regulatory Changes to Medicare Advantage (MA) and Part D Medical Loss Ratio (MLR) Standards (§§ 422.2401, 422.2420, 422.2430, 422.2450, 422.2452, 422.2454, 422.2460, 422.2480, 422.2490, 423.2401, 423.2420, 423.2430, 423.2450, 423.2452, 423.2454, 423.2480, 423.2490)

To more closely align MA/Part D medical loss ratio (MLR) rules with those it oversees in the commercial and Medicaid markets, CMS proposes several changes relating to increased oversight, reporting, and audit requirements. PCMA is concerned that some of these proposals will create additional burden and significantly increase costs for Part D plans, without any corresponding benefits to the Part D program or Medicare enrollees. We are also concerned that CMS, in its efforts to align Part D MLR rules with MLR rules in the commercial and Medicaid markets, is taking a one-size-fits-all approach that ignores the unique features of the Part D program that obviate the need for these proposed changes.

CMS seems to concede the materiality of these differences in at least one of its proposals. For example, CMS proposes to clarify that MLR calculations for MA plans can include provider incentives and bonus payments only if they are tied to clearly defined, measurable, and well-documented clinical or quality improvement standards. Notably, CMS states that this policy would *not* apply to Part D plans, as it "believe[s] that certain unique characteristics of the Part D program may counsel against a similar change for that program at this time." Specifically, CMS correctly notes that for Part D plans, incurred claims include only drug costs that are "actually paid" by the Part D sponsor. Under the existing framework, Part D rules already require that the amount reported in the MLR numerator as direct drug costs incurred must be net of all DIR (e.g., discounts and rebates). Existing rules also require that the MLR numerator reflect *negative* DIR (defined to include incentive and bonus payments made to pharmacies and other Part D providers). Thus, because incentive and bonus payments are already accounted for as DIR that must be included in MLR calculations, there isn't a need to impose a separate requirement in this context. Furthermore, and more importantly, given the Part D framework's existing definition of drug costs that are "actually paid," and the applicability of this definition to various other aspects of the Part D program, making any sort of changes in the MLR context would require a more significant overhaul of the relevant definition for these other aspects of the Part D program as well.

CMS clarification here is vitally important, as this is just one of many nuances that as a whole make the Part D program different in this context, and make general alignment with MLR rules for other insurance products inappropriate. As discussed in more detail below, the realm of potential costs and claims in the Part D framework is naturally much more limited than other insurance contexts. Whereas insurance for comprehensive health care services leaves open more room for a wide range and variety of potential costs and associated ambiguity with respect to the allowability of those costs, the Part D program is narrowly limited to incurred drug costs. Thus, any purported rationale for increased reporting and transparency requirements supporting greater alignment with MLR rules in the commercial market is less salient in the Part D context. As explained in further detail below with respect to our comments on CMS's request for information on vertical integration, there already exists significant transparency with respect to DIR and related data, including through the Part D bidding process, obviating the need for additional MLR transparency or oversight for Part D plans.

The Part D program is different in kind relative to the other types of plans for which CMS wishes to apply uniform, increased MLR requirements. Our concerns are heightened by the fact that Part D plans are already operating under enormous financial pressures, in part due to changes resulting from the Inflation Reduction Act (IRA), including the Part D Redesign. Policies that will increase administrative burden and cost, and which do not impact quality of care and access for Medicare beneficiaries, will serve only to place further strain on Part D plans during this period

of transition and flux.

***PCMA Recommendation:*** **PCMA opposes the proposed changes to the MLR requirements for Part D plans.**

**Comments on Specific Proposals**

Notwithstanding the above, should CMS proceed with including Part D plans in its general alignment of MLR rules across various insurance types, we outline our concerns and provide recommendations with respect to CMS's specific proposals below:

a. *Proposal to prohibit administration costs from being included as quality improving activities in the MLR numerator.*

CMS proposes to specify that only expenditures "directly related" to activities that improve health care quality may be included as "quality improve activity" (QIA) expenses for purposes of MLR reporting. In the proposed rule, CMS notes that it previously made this change for commercial plan MLR reporting, in part out of a concern that commercial plans were reporting as QIA expenses certain "indirect expenses" such as "overhead," employee salaries, and IT infrastructure.

As a threshold matter, we note that CMS points to issues it discovered with *commercial* plan QIA expense reporting as support for its decision to apply greater scrutiny to commercial plan MLR reporting, but does not provide any examples or analysis of similar behavior by Part D plans that would support extending these requirement to the Part D program. On this note, the agency simply makes a conclusory statement that "we believe that the concerns identified are also applicable to the MA and Part D markets" without explaining why that would be the case. PCMA is also concerned that CMS's proposal and discussion in the proposed rule is too vague for Part D plans to appropriately operationalize. For example, CMS seems to cast a wide net in characterizing expenses such as "overhead" as an "indirect cost," but does not delineate or acknowledge the types of "overhead" that would appropriately count as a QIA expense, such as, for example, the salary of individuals in a plan's department that focuses on QIA activities, or the office space for these individuals and associated computer maintenance costs. Put differently, under CMS's proposed governing standard, the only appropriate expenditures in this context are those that are "directly related to activities that improve health care quality." However, CMS does not elaborate on what exactly this would mean in practice, including for Part D plans.

***PCMA Recommendation:*** **In order for plans to implement and operationalize these new requirements, we urge CMS to better define what it means for something to be "directly related" to qualifying QIA activities, and to provide additional guidance to plans to operationalize these requirements, if finalized.**

b. *Proposal to establish standards for MA and Part D MLR audit examinations*.

CMS also proposes to require MA and Part D plans to be subject to audit examinations, under which selected plans would be required to provide detailed MLR data and underlying records that can be used to substantiate amounts included in the calculation of each contract's MLR, and proposes to establish certain time frames for plans to respond to CMS requests and file

appeals. As discussed above, PCMA is concerned with the additional administrative burden this new requirement would place on Part D plans, especially given the unique characteristics of Part D plans and the prescription drug benefit.

Furthermore, we are concerned that some of CMS's proposed time frames for plan responses are too short for plans to adequately review pertinent data and respond to CMS's actions. For example, CMS proposes to provide plans only "15 calendar days advance notice of its intent to conduct an audit of an" MA or Part D plan. Moreover, CMS proposes to allow plans only 15 calendar days from receiving a final audit report and remittance request from CMS to file a request for reconsideration. Given the amount and complexity of data involved, 15 calendar days is simply not long enough for plans to prepare for an audit, review CMS's audit report and remittance request, and comprehensively respond with a request for reconsideration. We urge CMS to provide at least 30 calendar days for each of these instances.

CMS also proposes to outline the material that plans can include in a reconsideration request, as well as the matters that are subject to subsequent appeal. Specifically, CMS states that a reconsideration request must include 1) the calculation with which the plan disagrees; and 2) evidence supporting the assertion that the CMS calculation of the MLR audit remittance is incorrect. Furthermore, CMS proposes to establish that a plan appeal "would be limited to CMS's *calculation* of the MLR audit remittance."

PCMA is concerned that, as currently drafted, the proposed framework would allow plans to contest only CMS's *calculation* of the MLR audit remittance, but not the evidence or methodology used by CMS in such calculations. This is problematic, as it limits the ability of plans to challenge how CMS categorized certain costs that should, or should not, be part of the calculation. This is especially salient with respect to the existing ambiguity surrounding CMS's proposal on QIA expenditures, and exactly what costs are "directly related to activities that improve health care quality." If CMS moves forward with this proposal, we urge CMS to broaden its proposed language governing the audit remittance reconsideration and appeal processes, to ensure that plans are able to challenge CMS determination regarding the evidence and methodology selected for its MLR and remittance calculations.

CMS also proposes that if an audit examination finds inaccurate MLR data was reported but the MLR remains greater than 85% when recalculated based on the audit findings, the agency would issue "progressive noncompliance actions" depending on the plan's previous record of compliance and the "gravity of the violation (for example, violation frequency, level of financial impact)." PCMA asks that CMS clarify in the final rule that inaccurate MLR data resulting from minor errors would be exempt from the progressive noncompliance actions outlined herein. CMS is proposing significant changes to MLR reporting and calculation standards in this proposed rule. The agency should not penalize well-meaning stakeholders who submit MLR data that an audit finds to be inaccurate but where such inaccuracy is the result of a minor or technical error, especially in this context where the recalculated MLR remains greater than 85%. Last, CMS proposes to establish that if the agency finds MLR data to be reported in an untimely and inaccurate manner, it may pursue intermediate sanctions. We ask that CMS consider reserving the pursuit of intermediate sanctions for instances of knowing or egregious errors. The imposition of intermediate sanctions should be reserved for flagrant violators, and not stakeholders acting in good faith.

***PCMA Recommendation:*** **Should CMS move forward with its proposal to establish standards for MA and Part D MLR audit examinations, it should do so in a way that minimizes that administrative burden on plans and avoids penalizing plans for minor or technical errors.**

c. *Proposal to exclude Medicare Prescription Payment Plan unsettled balances from the MLR.*

CMS proposes to codify in regulation its existing policy that unsettled balances from the Medicare Prescription Payment Plan are treated as administrative expenses and thus must be excluded from a plan's MLR numerator. In support for this proposal, CMS points to Section 1860D-2(b)(2)(E)(v)(VI) of the Social Security Act, which specifies that any unsettled balances with respect to amounts owed under the Medicare Prescription Payment Plan "shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids." PCMA understands that CMS interprets the underlying statute as requiring this policy, but does not believe that this interpretation is mandated by the statute. On the contrary, the statute is solely addressing liability for the losses, and making clear that plans are required to bear these costs, rather than CMS. It does not mention the MLR or even suggest the appropriate treatment of these costs for MLR purposes. It is CMS's own interpretation in the Medicare Prescription Payment Plan Part Two final guidance that because these costs are "plan losses" for purposes of the bid, they are "administrative expenses" and therefore it would be inconsistent to treat them as incurred claims for MLR purposes. However, this interpretation ignores that these costs are plain and simple drug costs, which in any other context would unquestionably be treated as incurred claims. It also flies in the face of the intent of MLR, which is to encourage Part D sponsors to control their administrative costs and devote more of their resources to covering prescription drug costs and quality improvement activities. In the case of MPPP unsettled costs, the plan has no control over these and they are in fact payments to cover drug costs. Given the reality of what these costs represent and the fact that the statute does not address the MLR, we urge the agency to work with stakeholders to find an alternative approach consistent with a broader interpretation of the statute that does not penalize Part D plans for covering the drug costs of MPPP participants by treating what are clearly drug costs as plan administrative costs for MLR purposes. Treating unsettled balances as plan losses/administrative expenses is inconsistent with the program as a whole, as unsettled balances are unlike other categories that are typically classified as plan losses, such as uncollected premiums. Unsettled balances are instead specifically related to claims that were paid in full by the plan, and are thus clearly drug costs that should be included as part of incurred claims in the MLR calculations.

***PCMA Recommendation:*** **PCMA urges CMS to interpret the statute in a manner more consistent with the MLR requirements and intent, and to work with stakeholders to find an alternative approach that allows Part D plans to treat unsettled balances from the Medicare Prescription Payment Plan as the drug costs they are.**

## VI. CMS Request for Information on Vertical Integration

In the proposed rule, CMS also solicits information from stakeholders with respect to the impact of MLR on vertical integration, and requests comments on several potential policies. We provide input on each of the potential policies below, but generally note that CMS's proposed policies

indicate an outdated conception and fundamental misunderstanding of vertical integration and the impact of policies such as DIR, Part D bidding processes, and IRA reforms. We urge CMS to refrain from pursuing these policies in any future rulemaking, and to instead continue working with all relevant stakeholders to make improvements to the Part D program that focus on quality of care and access for Medicare beneficiaries, and ensure that its rulemaking does not penalize an entity simply because of its organizational structure.

Health plans participating in Medicare are organized in a variety of ways, each intended to enhance efficiency and streamline operations. One common type is the integration between PBMs and various pharmacy services, including retail, mail order, and specialty pharmacies. This integration allows for better coordination of drug distribution and management, potentially lowering costs and improving service delivery for beneficiaries. These types of integration create synergies that aim to deliver cost-effective and high-quality care to Medicare beneficiaries. As CMS seeks to collect data, it should be aware that each targeted plan is organized differently, and there is no "magic sauce" that CMS can point to or solve for in this highly dynamic and competitive market.

A. Establish parameters in MLR reporting that limit the amount of transfer payments that are incurred between related parties that can be included in the numerator, such as by limiting the amount for any service included in the numerator to be under a relative benchmark.

PCMA notes that this approach would not ensure accurate reporting of MLR, and would only serve to penalize entities that are vertically integrated. Related-party arrangements are already thoroughly reviewed and approved by CMS through the bid process. This proposal would conflict with the existing structure of the bid approval process in that Part D plans would be allowed to justify payments to a related party as "comparable" to an open market arrangement on the one hand, but then prohibit the plan from including the accurate amount of such approved payments as numerator expenses on the other. We are also concerned that even the term "transfer payments" presupposes without any basis that payments between related parties are not for services, but simply a "transfer" of funds to a related entity.

B. Revise definition of incurred claims to include profits earned by related parties as indirect remuneration to a Part D sponsor or MA organization and not allowable for inclusion in the MLR numerator.

PCMA stresses that this approach would also serve only to penalize vertical integration and would not result in more accurate MLR reporting. This potential policy is akin to the "actual cost" bidding method that has treated any profit of a related party as profit of the relevant plan. However, the current Part D bidding framework, which includes the comparability method mentioned above, generally obviates the need for this approach.

C. Revise definition of incurred claims to include payments that are net of direct or indirect remuneration by or to the Parent Organization, in addition to the Part D sponsor.

PCMA notes that this potential policy is somewhat ambiguous, but would primarily serve to penalize vertical integration, without any corresponding benefit, such as increased accuracy of MLR reporting. As previously mentioned, payments to related parties and non-related parties

are generally knowable through PDE data, and the payments are also outlined and approved through the bidding process's comparability method.

D. Establish a framework for assessing transfer payments made to or by related parties by expanding related-party reporting requirements in the MLR. CMS specifically invites comment on the kind of information CMS could collect about transfer payments to be able to assess what portions of such payments should be reported in the MLR numerator.

PCMA is greatly concerned with any additional reporting requirements imposed on Part D plans, especially in light of the precarious financial condition of the Part D market following implementation of the IRA. We also reiterate that any payments made to or by related parties are already known or ascertainable through PDE data.

***PCMA Recommendation:*** **PCMA asks that CMS refrain from pursuing the policies in this RFI in any future rulemaking, and to continue working with all relevant stakeholders to make improvements to the Part D program that focus on quality of care and access for Medicare beneficiaries.**