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CY 2023 Part C and D Policy and Technical Changes Proposed Rule

Summary

January 7, 2022

On January 6, 2022, the Centers for Medicare & Medicaid Services (CMS) published for public inspection the CY 2023 Part C and D Policy and Technical Changes Proposed Rule (Proposed Rule). The Proposed Rule does not contain any notable drug pricing provisions. The Proposed Rule, however, does contain a notable proposal to require *pharmacy* price concessions be passed at the point-of-sale (POS), new requirements related to marketing and communications, and the reinstatement of detailed MLR reporting requirements. These provisions are summarized below. **Comments in response to the Proposed Rule must be submitted by March 7, 2022.**

Requiring Pharmacy Price Concessions Be Applied at the Point-of-Sale (POS)

Background

PBMs often receive compensation after the point-of-sale that lowers the final net amount paid by the sponsor to the pharmacy for a particular drug—this is called direct and indirect remuneration (DIR). DIR has been growing significantly in recent years, and pharmacy price concessions specifically (referring to all forms of discounts, direct or indirect subsidies, or rebates that a pharmacy pays to a Part D sponsor to reduce the costs incurred under Part D plans by Part D sponsors) have grown faster than all other DIR—they have grown by more than 107,400 percent between 2010 and 2020.

While manufacturer rebates, which are a "non-pharmacy price concession", account for the largest category of DIR, CMS indicates that the growth in DIR for pharmacy price concessions warrants the agency's focus on pharmacy price concessions and as opposed to non-pharmacy price concessions. CMS also cites the OIG Rebate Rule and section 90006 of the Infrastructure Investment and Jobs Act which prohibits HHS from implementing the rule as another reason why it is not electing to address non-pharmacy price concessions as part of this rulemaking.

CMS states that in 2005 it believed that market competition would encourage Part D sponsors to pass through to beneficiaries at the POS a high percentage of the price concessions they received, and that establishing a minimum threshold at that time for the price concessions to be applied at the point-of-sale would only serve to undercut these market forces. According to CMS, however, this has not happened and "less than 2 percent of plans have passed through any price concessions to beneficiaries at the POS."

Problem

CMS expresses concern that pharmacy price concessions reported as DIR, rather than passed at the POS, are producing undesirable outcomes that, although contribute to lower Part D premiums, also deprives beneficiaries from experiencing lower drug costs for the drugs that they actually use. Moreover, when the POS price of a drug that a Part D sponsor reports on a prescription drug event (PDE) record as the negotiated price does not include such discounts, the negotiated price of each individual prescription is rendered less transparent and less representative of the actual cost of the drug for the sponsor, according to CMS, which in turn undermines competition and beneficiary's ability to accurately evaluate Part D plans. Pharmacy price concessions reported as DIR also enables cost-shifting, both to beneficiaries who utilize high-cost drugs, and to the government who reinsures high-cost beneficiaries.

CMS describes what it believes to be perverse incentives associated with pharmacy price concessions as follows:

> "Pharmacy price concessions reduce plan costs, and having the concessions not be applied at the point-of-sale reduces plan costs and plan premiums at the expense of the beneficiary having lower cost sharing at the point-of-sale, thus shifting some of the net costs to the beneficiary via higher cost sharing. We believe that Part D sponsors are incentivized to have lower premiums versus lower cost sharing because anecdotal evidence suggests beneficiaries focus more on premiums instead of cost sharing when choosing plans.

Proposal

"Negotiated Price" Definition – CMS is proposing to amend the definition of "negotiated prices" at 42 C.F.R. § 423.100 to require that the prices available to Part D enrollees at the POS are inclusive of all pharmacy price concessions. CMS describes this revision as involving the deletion of the existing plural term "negotiated prices" and replacing it with "negotiated price" in the singular to reflect that a negotiated price can be set for each Part D drug. Moreover, CMS is proposing to define a "negotiated price" as the lowest possible reimbursement a network pharmacy may receive, in total, for a particular drug.

CMS proposes the regulatory definition of "negotiated price" to read as follows in regulations at 42 C.F.R. 423.100:

> "*Negotiated price means the price for a covered Part D drug that—*
>
> > *(1) the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;*

(2) Meets all of the following:

(i) Includes all price concessions as defined in this section) from network pharmacies or other network providers;

(ii) includes any dispensing fees; and

(iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; and

(3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale."

Definition of "Price Concession" – CMS is also proposing to define a "price concession." A "price concession" has never been specifically defined in regulations, but CMS believes it may be necessary to define the term in order to implement the new proposed treatment of pharmacy price concessions. CMS is proposing the following regulatory definition:

"Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind."

Lowest Possible Reimbursement - To effectively capture all pharmacy price concessions at the point-of-sale consistently across sponsors, CMS proposes to require that the negotiated price reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug. Under this approach, the price reported at the point-of-sale would need to include all price concessions that could potentially flow from network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts that could flow to (explained further below) network pharmacies and thus increase prices over the lowest possible reimbursement level, such as incentive fees.

For example, if a performance-based payment arrangement exists between a sponsor and a network pharmacy, the POS price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that drug under the arrangement if the pharmacy's performance score were the lowest possible.

Contingent Incentive Payments Excluded – All contingent incentive payments (i.e. payments to the pharmacy, instead of price concessions from the pharmacy) would be excluded from the negotiated price. CMS states that based on its experience, such incentive payments are rare. In any event, including such payments would mean that the negotiated price is higher a "high performing pharmacy", thereby

potentially creating a perverse incentive for beneficiaries to choose "lower performing" pharmacies for the advantage of a lower price.

No Effect on other DIR - Part D sponsors would retain ability to pass-through other non-pharmacy price concessions and other DIR (e.g., legal settlement amounts and risk-sharing adjustments) to enrollees at the POS.

Additional Considerations – CMS states that it would likely use the rebate POS on the PDE record to collect the POS pharmacy price concessions. The agency would also likely use fields on the Summary and Detailed DIR Reports to collect finally pharmacy price concession at the plan and NDC levels.

Negotiated Price in Coverage Gap – CMS does not propose to require all pharmacy price concessions to pass through at the POS for applicable drugs in the coverage gap. CMS wants to allow plans flexibility on how to treat pharmacy price concessions for applicable drugs in the coverage gap.

Legal Justification

CMS supports its proposed requirement that pharmacy price concessions be passed at the point of sale by arguing that the agency's proposal is a reasonable interpretation of the statutory definition of "negotiated price" that does not run afoul of the separate non-interference provision.

Section 1860D-2(d)(1)(B) of the Social Security Act requires that negotiated prices "shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . . ."

CMS acknowledges that it is changing its interpretation regarding to what extent negotiated prices "shall take into account" pharmacy price concessions. Historically, CMS states that it interpreted the statute to mean that some, but not all pharmacy price concessions must be applied to the negotiated price that determines the beneficiary's cost sharing. CMS asserts that its proposal to require all pharmacy price concessions be applied to the negotiated price is consistent with the "plain language of section 1860D-2(d)(1)(B) to "take into account" at least some price concessions (recall that the proposal does not address the treatment of non-pharmacy price concessions).

Moreover, CMS argues that its proposal does not run afoul of the non-interference clause because CMS is not dictating what Part D plans may arrange in their contracts with network pharmacies regarding payment adjustments after the POS. Part D plans, for example, may continue to negotiate post-POS price adjustments with network pharmacies as they see fit. Instead, CMS will be requiring that Part D plans pass these post-POS price adjustments to the beneficiary at the POS by using the lowest possible reimbursement amount under these arrangements. In this way, CMS argues, Part D plans retain flexibility to negotiate with pharmacies the terms of their contracts without CMS interference on which terms they can negotiate.

Impact Analysis

CMS acknowledges that premiums would rise, but that it would likely have a more significant impact on government costs, which would increase overall due to the significant growth in Medicare's direct

funding of plan premiums and low-income premium payments. Government liability would be partially offset by fewer beneficiaries proceeding through the Part D benefit and into catastrophic coverage.

CMS estimates that non-low-income beneficiaries would see lower prices at the pharmacy POS and on Plan Finder for most drugs beginning immediately in CY 2023, and that on average these cost-sharing decreases would exceed the premium increases. That is, CMS expects more than half of the non-low-income, non-employer group beneficiaries to see lower total costs, inclusive of cost-sharing decreases and premium increases. For low-income beneficiaries, whose out-of-pocket costs are funded through Medicare's low-income cost-sharing payments, cost-sharing savings resulting from lower point- of-sale prices would accrue to the government.)

Below are CMS' Tables 15 and 16 outlining the fiscal impact of its proposal, which shows cost-sharing reductions for enrollees, but general increases in premiums and government costs.

TABLE 15*: IMPACT (BILLIONS) OF CONCESSIONS EXCLUDES APPLICATION TO APPLICABLE DRUGS IN THE COVERAGE GAP

Label	Item/Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
(A)	Gross Drug Cost (GDCC)	-$14.4	-$15.8	-$17.2	-$19.0	-$20.9	-$22.9	-$25.0	-$27.3	-$29.8	-$32.4
(B)	Drug Cost Covered by Plan (Supplemental and non-Part D) CCP	-$10.5	-$11.6	-$12.7	-$13.6	-$14.6	-$15.6	-$16.7	-$17.9	-$19.1	-$20.3
(C)	OOP including Gap Discount	-$3.9	-$4.2	-$4.6	-$5.4	-$6.3	-$7.2	-$8.3	-$9.4	-$10.7	-$12.1
(D)	General Premium Payment	$4.8	$5.2	$5.6	$6.3	$7.0	$7.8	$8.6	$9.5	$10.4	$11.4
(E)	Reinsurance	-$1.4	-$1.6	-$1.7	-$1.7	-$1.7	-$1.7	-$1.6	-$1.6	-$1.5	-$1.4
(F)	LIS Cost-Sharing	-$1.2	-$1.3	-$1.4	-$1.7	-$2.1	-$2.4	-$2.8	-$3.3	-$3.8	-$4.3
(G)	LIS Premium	$0.2	$0.2	$0.2	$0.3	$0.3	$0.4	$0.4	$0.5	$0.5	$0.6
(H)	Total Government	**$2.3**	**$2.5**	**$2.7**	**$3.1**	**$3.6**	**$4.0**	**$4.5**	**$5.1**	**$5.7**	**$6.3**
(I)	Enrollee Cost Sharing	-$1.7	-$1.9	-$2.0	-$2.4	-$2.8	-$3.3	-$3.8	-$4.4	-$5.0	-$5.7
(J)	Enrollee Premiums	$0.6	$0.7	$0.7	$0.9	$1.0	$1.2	$1.4	$1.6	$1.8	$2.0
(K)	Total Enrollee Costs	-$1.1	-$1.2	-$1.3	-$1.5	-$1.8	-$2.1	-$2.5	-$2.8	-$3.2	-$3.6
(L)	Total Benefits	2.9	3.2	3.5	4.0	4.6	5.2	5.9	6.7	7.5	8.4
(M)	Gap Discount	-$0.9	-$1.0	-$1.1	-$1.2	-$1.4	-$1.5	-$1.6	-$1.8	-$1.9	-$2.1

*Negative numbers indicate savings. Positive numbers indicate costs. Row totals are found in Table 16.

TABLE 16*: TOTAL IMPACTS FOR 2023 THROUGH 2032 WITHOUT APPLICATION TO APPLICABLE DRUGS IN COVERAGE GAP

	Total (in billions)	Per Member-Per-Year 2023–2032[1]	Percent Change
Beneficiary Costs (K)	($21.30)	($36.66)	-2%
Cost Sharing (I)	($33.10)	($57.03)	-6%
Premium (J)	$11.80	$20.37	5%
Government Costs	$40.00	$69.17	3%
Direct Payment (D)	$76.70	$132.47	83%
Reinsurance (E)	($15.80)	($27.27)	-2%
LI Cost-Sharing (F)	($24.40)	($42.15)	-5%
LI Premium (G)	$3.50	$6.13	7%

Revisions to Marketing and Communications Requirements

In 2021, CMS codified much of the communications and marketing guidance previously contained in the Medicare Communications and Marketing Guidelines (MCMG). For this Proposed Rule, CMS proposes to codify additional guidance from the MCMG, in addition to proposing several new requirements aimed

at “safeguarding Medicare beneficiaries”. These include reinstating the requirement that plans include a multi-language insert with specified required materials, and various requirements to address concerns associated with third-party marketing activities.

Codification of Additional Requirements from MCMG

CMS proposes to codify the following requirements from the MCMG as part of this rulemaking:

- The disclaimer for Part D sponsors with limited access to preferred cost sharing pharmacies, which provides important safeguards for Medicare beneficiaries enrolled in Part D plans that only provide access to preferred cost sharing through a limited number of pharmacies.
- The requirement that plans post instructions about how to appoint a representative on their website and include a link to a downloadable version of the CMS Appointment of Representative Form.

Reinstate of Multi-Language Insert (MLI)

CMS is proposing to reinstate the requirement for plans to include the MLI with all required materials, such as the Summary of Benefits, Annual Notice of Change/Evidence of Coverage, and the enrollment form. The MLI must state “We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who peaks [language] can help you. This is a free service.” In the 15 most common non-English languages in the U.S., in addition to any language that meets the five percent threshold for a plan’s service area.

CMS notes that to the extent the Office of Civil Rights (OCR) proposes and adopts more robust requirements, and plans adopt those requirements, CMS will consider plans compliant with the MLI requirements proposed in this rulemaking.

Third-Party Marketing Organizations

CMS expresses concern about the increasing role third-party marketing organizations (TPMOs) are playing in Medicare beneficiary enrollment. CMS states that there has been a significant increase in third paryt marketing (television adds, direct mailers, etc.) in the past few years, while also a significant increase in marketing related complains from beneficiaries directly attributed to these marketing activities. CMS states that CTM data reveals that beneficiaries are often confused by TPMOs, including confusion regarding who they are speaking to, what plans the TPMOs represent, and beneficiaries may be unaware that they are enrolling into a new plan during these phone conversations.

To provide additional protections to Medicare beneficiaries, CMS proposes several things:

- **Defining “TPMO**” – TPMOs will be defined as organizations that are compenstated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment. In addition, TPMOs may be first tier, downstream or related entities (FDRs), and they may also be other businesses which are customers of an MA or Part D plan or customers of an MA or Part D plan’s FDRs.
- **TPMO Standardized Disclaimer** – TPMOs will be required to have a standardized disclaimer that states “We do not offer every plan available in your area. Any information we provide is limited to those plans we do offer in your area. Please contact Medicare.gov or 1-800-Medicare to get information on all of your options.” MA and MA-PD plans must ensure that TPMOs they engage

with comply with this requirement. Moreover, statements such as "we will help pick the best plan for you" are misleading since TPMO's help will be limited to the plans they offer, and not necessary the best plan for the beneficiary. The TPMO must be prominently displaed on the TPMO's website and marketing materials, and be communicated verbally, electronically, or in writing depending on how the TPMO is interacting with the beneficiary. To the extent a phone conversation is involved, the disclaimer must be provided within the first minute.

- **Plan Oversight of TPMOs** – CMS is proposing to adopt new regulations expressly requiring plans to ensure compliance with the requirements applicable to TPMOs regardless of whether the TPMO's services to the plan are provided directly or indirectly (e.g., where the plan or its FDR purchases leads or otherwise receives leads indirectly from a TPMO). Plans (and their FDRs), would also be required to include in their contracts, written arrangements, or agreements with TPMOs, a requirement that TPMOs disclose to the plan any subcontracted relationships used for marketing, lead generation, and enrollment; require sales calls with beneficiaries to be recorded in their entirety; and have TPMOs report to plans any staff disciplinary actions associated with Medicare beneficiary interaction on a monthly basis.
- **Notifications of TPMO Lead Generation Activities** – TPMOs must inform beneficiaries that their information will be provided to a licensed agent for future contact, or that the beneficiary is being transferred to a licensed agent who can enroll him or her into a new plan. This is intended to address the problem that CMS has observed where beneficiaries are contact by agents and brokers who acquired their contact information from a business reply card or response to an advertisement that the beneficiary filled out and submitted.

<u>Regulatory Changes to Medicare Medical Loss Ratio Reporting Requirements</u>

CMS is proposing to reinstate detailed MLR reporting requirements for both the Part C and D programs. Previously, MA and MA-PD plans were required to submit an MLR report to CMS that included the data needed by the MA organization or Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract such as the amount of incurred claims, expenditures on quality improvement activities, non-claims cost, taxes, licensing and regulatory fees, total revenue, and any remittance owed to CMS. In 2019, CMS finalized the removal of much of these requirements in an effort to reduce administrative burdens on plan sponsors. Thus, MA organizations and Part D sponsors are currently only required to report each contract's MLR and the remittance amount, if any.

However, CMS states that in light of subsequent experience overseeing the administration of the MLR program, CMS is reconsidering the relaxed MLR reporting requirements. CMS states that there has been an increase in both the amount of remittances that MA organizations and Part D sponsors have reported owing, and in the number of contracts that failed to meet the MLR requirement in the years since 2019. In turn, this creates a significant potential for costly errors in the MLR calculation that should be a concern not only for the government, but also for the MA organizations and Part D sponsors. Thus, CMS is now proposing to reinstate the detailed MLR reporting requirements that were in effect prior to 2019. CMS is also proposing to collect additional data on certain categories of expenditures, and to make conforming changes to its data collection tools.

CMS's proposed MLR reporting modifications include:

- A requirement that MA organizations must submit to CMS a report that includes the data needed to calculate and verify the MLR and remittance amount, if any, for each contract, including the amount of incurred claims for Medicare-covered benefits, supplemental benefits, and prescription drugs; expenditures on quality improving activities; non-claims costs; taxes; licensing and regulatory fees; total revenue; and any remittance owed to CMS.
    - Similar amendments would be made to the regulations governing Part D MLR reporting requirements.
- MA organizations and Part D sponsors would use the MLR Reporting Tool to submit the required information, which is the same tool used to report MLR data for CY 2014 through 2017. If the new detailed MLR reporting requirements are finalized, CMS is proposing to make additional changes to the MLR Reporting Took to facilitate implementation, including:
    - Update the MLR Reporting Tool's formulas to incorporate changes to the MLR calculation that have been finalized since CY 2017.
    - Separate out certain items that are currently consolidated in or otherwise accounted for in existing lines of the MLR Reporting Tool (e.g., low-income cost-sharing subsidy amounts).
    - Separate out the current line for claims incurred during the contract year covered by the MLR report into separate lines for benefits covered by Medicare Parts A and B, certain additional supplemental benefits (except those that extend or reduce cost sharing for items covered under Parts A and B), and Part D prescription drug benefits.
- CMS will allow MA organizations and Part D sponsors to resubmit MLR reports where the resubmission is to correct the prior MLR report or data submission.