March 7, 2022

Chiquita Brooks La-Sure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Proposed Rule "Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (CMS-4192-P)

Dear Administrator Brooks-LaSure:

On behalf of the West Health Policy Center (West Health), I am sharing comments on the Centers for Medicare & Medicaid Services' (CMS') proposed rule, "Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (CMS-4192-P) ("proposed rule"). The West Health Policy Center is a non-partisan, non-profit organization dedicated to reducing the cost of healthcare in order to promote successful aging. Specifically, our comments address CMS' proposal to include the pharmacy portion of Direct and Indirect Remuneration ("DIR") in the definition of negotiated price for purposes of calculating beneficiary cost-sharing in the Medicare Part D program. West Health shares CMS' goal of reducing beneficiary cost-sharing and better spreading the net cost of drugs across premiums, the true goal of insurance.

However, we are concerned that the proposed rule would unduly increase total Medicare drug spending by decreasing drug manufacturer contributions under the Coverage Gap Discount Program, which closed the "donut hole" for beneficiaries and has been an important factor in reducing Medicare drug spending. Moreover, by only targeting pharmacy DIR and not manufacturer rebate DIR, which CMS notes is the vast share of DIR, CMS' proposal will have only a minimal effect on beneficiary cost-sharing while significantly increasing Medicare drug spending.

We strongly encourage CMS to revise its proposal to establish two separate definitions of negotiated price. The first definition, the actuarial negotiated price, is used for the actuarial calculation of beneficiary cost-sharing and would include all DIR; the second definition, the benefit negotiated price, is used to calculate beneficiary progression through the phases of the Part D benefit and would exclude DIR. As CMS notes in the rule, it has authority for the first definition under section 1860D–2(d)(1)(B) of the Social Security Act. In practice, CMS has already established a separate definition for progression through the benefit phases through the creation of the True Out-Of-Pocket (TrOOP) metric, and we believe CMS should follow this same precedent to exclude DIR from the definition used for benefit phase progression. Under our proposed approach, beneficiaries would see significant reductions in cost-sharing without a concomitant reduction in manufacturer contributions in the coverage gap, mitigating the increase in Medicare drug spending. This approach is similar to CMS' proposed approach of establishing a separate definition of negotiated price for the coverage gap phase, but our proposal mitigates the reduction in manufacturer contributions that occurs from a slower progression to the coverage gap phase and establishes consistent definitions across benefit phases.

We share CMS' concern that Part D plans' current use of pharmacy DIR distorts premiums by shifting costs to beneficiaries at the pharmacy counter, and we agree that a greater portion of these costs should be allocated to premiums. However, we are concerned that the proposed approach overly increases both beneficiary premiums and Medicare spending by reducing manufacturer coverage gap contributions, mitigating the reduction in beneficiary cost-sharing. We strongly encourage CMS to adopt our separate definitions of negotiated price to limit premium increases that flow from the reduction in beneficiary cost-sharing. Additionally, while we agree with CMS' assertion that there is strategic underestimation of DIR from plans as part of the incentives under the risk-sharing program (87 Fed. Reg. 1913), we believe this is better addressed through reforms to the estimation framework for DIR in future plan years rather than including pharmacy DIR in the definition of negotiated price.

Inclusion of DIR in Definition of Negotiated Price

We agree with CMS' determination that it has authority to ensure beneficiaries have access to all DIR through the definition of negotiated prices under 42 U.S.C. §1395w-102(d) (87 Fed. Reg. 1911), and we encourage CMS to use this authority to ensure that all DIR, and specifically including manufacturer rebates, are extended to beneficiaries through lower cost-sharing. In the proposed rule, CMS notes that it declines to fully use this authority because of the moratorium on the implementation of the final rule titled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees" (the "rebate rule"). We support the moratorium on the implementation of the rebate rule because of its increase in Medicare spending and windfall to pharmaceutical manufacturers, but we are concerned that CMS' current proposal addressing pharmacy DIR has the same flaws as the rebate rule – namely, that the proposed inclusion of pharmacy DIR in a unified definition of negotiated price would substantially reduce manufacturer coverage gap payments, resulting in greater Medicare spending. CMS' own spending impact estimates in the proposed rule make this clear: while the proposed rule would reduce beneficiary costs by up to $29.1B over ten years, Medicare spending would increase by $50.7B. This discrepancy is explained by a $17.9B windfall to drug manufacturers, who would substantially reduce their coverage gap payments (87 Fed. Reg. 1948). Given that drug manufacturers receive over a third of the benefit of this proposed policy, we do not support CMS' proposed approach to including pharmacy DIR in a unified definition of negotiated price, as it suffers from the same flaws as the rebate rule.

Instead, we strongly encourage CMS to establish a definition of actuarial negotiated price for purposes of calculating beneficiary cost sharing and a separate definition of benefit negotiated price for purposes of calculating benefit progression, similar to TrOOP. The first definition, actuarial negotiated price, would include all DIR (both pharmacy and manufacturer), while the second, benefit negotiated price, would exclude DIR. This would extend the benefit of both pharmacy and manufacturer DIR to beneficiaries in the form of lower cost-sharing without decreasing manufacturer's existing coverage gap discount obligations. Further, by more rapidly moving beneficiaries through the Part D benefit phases, beneficiaries would face lower cost-sharing by more quickly progressing to the catastrophic phase where these beneficiaries' cost-sharing would be only five percent of the drug's cost, net of both pharmacy and manufacturer DIR.

Total Impacts

In conjunction with the actuarial firm Milliman, we have modeled the effects of a variation of this approach, which includes manufacturer DIR in the definition of actuarial negotiated price for cost-sharing purposes but excludes all DIR from the benefit negotiated price definition used for benefit phase progression.[1] (In this modeling exercise, pharmacy DIR were excluded from the definition of actuarial negotiated price, thereby underestimating the reduction in beneficiary cost-sharing relative to our current proposal.) While this model also included changes to the Medicare Part D benefit design under the proposed Prescription Drug Pricing Reduction Act of 2019, the directionality of the results are illustrative of the benefits of excluding DIR from the definition of actuarial negotiated price used to calculate progression through the Part D benefit phases while including DIR in the definition of benefit negotiated price used for benefit progression and calculation of manufacturer coverage gap payments. This analysis demonstrates that including all manufacturer DIR in a unified definition of negotiated price, akin to the rebate rule and CMS' proposed rule, would increase Medicare spending by $63B, reduce beneficiary costs by $19B, and generate a pharmaceutical manufacturer windfall of $44B. However, by including manufacturer DIR only in the calculation of beneficiary cost-sharing (actuarial negotiated price) and not in the calculation of benefit phase progression and coverage gap payments (benefit negotiated price), Medicare spending would only increase by $25B, with an equal $25B in beneficiary cost reductions; manufacturer coverage gap payments would remain the same. We believe this estimate is illustrative of the change in Medicare spending and manufacturer windfall that would occur if CMS' revised its proposed unified inclusion of pharmacy DIR in negotiated prices to apply more selectively – rather than a $50.7B increase in Medicare spending with a $17.9B manufacturer windfall, manufacturers would maintain their existing projected coverage gap contributions and the increase in Medicare spending would be commensurate with total beneficiary cost savings.

Premium Impacts

Our modeling also demonstrates that a dual definition of negotiated price will mitigate premium increases due to reductions in cost-sharing. Our model estimates that a dual definition of negotiated prices would increase beneficiary premiums by $11B over the period, while a unified definition would increase premiums by $18B. This is consistent with CMS' own modeling in the proposed rule – adopting a unified definition of negotiated price across all benefit phases would increase premiums by $15.2B, while adopting a separate definition in the coverage gap would increase premiums by $11.8B. Adopting two definitions of negotiated price – one for actuarial cost-sharing purposes and another for benefit progression – will mitigate the premium effects of the reduction in beneficiary cost-sharing by maintaining manufacturers' existing contribution obligations during the coverage gap.

Therefore, we encourage CMS to revise its proposed rule and establish separate definitions of negotiated price for the calculation of beneficiary cost-sharing (actuarial negotiated price) and for progression through the Part D benefit phases and calculation of manufacturer coverage gap payments (benefit negotiated price). Under this dual definition system, we encourage CMS to include both

[1] Extending PBM Rebates to Medicare Beneficiaries without Increasing Medicare Spending, July 22, 2021. https://www.cidsa.org/publications/extending-pbm-rebates-to-medicare-beneficiaries-without-increasing-medicare-spending

pharmacy DIR and manufacturer DIR in the definition of actuarial negotiated price for the calculation of beneficiary cost-sharing while excluding all DIR from the definition of benefit negotiated price for benefit progression and manufacturer coverage gap payments. This approach would best embody the idea of insurance – spreading the net costs equitably across all beneficiaries through premiums while reducing the cost burden on those who require treatment. Our modeling indicates that this would create an equal tradeoff between increases in Medicare spending and reductions in beneficiary cost-sharing. This differs from the proposed rule, which increases Medicare spending above the reduction in beneficiary cost-sharing, with the difference retained by manufacturers as a windfall from reduced coverage cap discount payments.

Risk Sharing and DIR Estimation Reforms

While CMS has not proposed specific changes to the either the risk-sharing construct or DIR estimation framework of the Medicare Part D program, CMS' discussion of these issues in the preamble indicates areas for additional rulemaking in the final rule or future proposed rules. Specifically, we encourage CMS to establish more rigorous DIR bid estimation parameters that more fully account for any DIR underestimation that resulted in additional plan profits under the risk-sharing construct, as CMS discusses in the preamble (87 Fed. Reg. 1913). While CMS notes that the underestimation of DIR has resulted in over-bids of relatively small amounts, between 0.6 percent and 3 percent of gross drug costs, this practice can increase both Medicare and beneficiary spending through premium overpayments that fall within the five percent threshold of the risk-sharing construct. We encourage CMS to both narrow the risk-sharing construct threshold for shared savings between plans and Medicare to reduce Medicare spending as well as to require that plans more accurately trend their DIR estimation based on prior experience rather than consistently underestimating DIR from year-to-year. The first would still encourage plans to find additional savings but to share those savings with Medicare, while the latter would put continued downward pressure on plan bids, extending these savings to beneficiaries as well.

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West Health shares CMS' goal of reducing beneficiary cost-sharing by ensuring that drug cost reductions due to DIR are shared with plan beneficiaries. However, we are concerned that the current proposed rule only minimally reduces beneficiary cost-sharing relative to Medicare spending increases and generates a $17.9B windfall for pharmaceutical manufacturers. Instead, we strongly encourage Medicare to establish two separate definitions of negotiated price: one for the calculation of beneficiary cost-sharing and the second for the calculation of progression through the benefit phases and calculation of coverage gap payments, with the former inclusive of both pharmacy and manufacturer DIR and the latter exclusive of all DIR. Under this framework, our modeling projects that any increase in Medicare spending would be accompanied by a similar decrease in beneficiary cost-sharing without any additional windfall to pharmaceutical manufacturers. We further encourage CMS to revise the risk-sharing construct and the DIR bid estimation to discourage Part D plans from routinely underestimating DIR, thereby increasing their profits through higher Medicare and beneficiary premiums. Should you have any questions regarding our comments, please contact me at sdickson@westhealth.org.

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