# National Health Council

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April 8, 2019

Aaron Zajic
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue SW
Washington DC, 20201

Re: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protect for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

Dear Mr. Zajic:

The National Health Council (NHC) appreciates the opportunity to comment on the Department of Health and Human Services' (HHS) proposal to amend the safe harbor regulation concerning rebates and other discounts.

Founded in 1920, the National Health Council (NHC) is the only organization that brings together all segments of the health community to provide a united voice for the more than 160 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 125 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient advocacy organizations, which control its governance and policy-making process. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

The increasing cost of prescription drugs, role of rebates, and amount patients pay out-of-pocket for medicines create significant challenges for the patient community. The NHC prioritizes policies that address the rising costs of health care, including but not limited to, the costs of prescription medicines and affordability for patients. We support meaningful policies that promote competition to drive availability of lower-cost, high-quality products and services. We strongly oppose policies that achieve savings at the expense of patient safety, access, affordability, or quality of care.

As the NHC remains committed to ensuring adequate access to affordable, high-value medications for patients, we are supportive of the Administration's efforts aiming to reduce patient out-of-pocket costs. We

agree with HHS' premise that the rebating process is complex, opaque, poorly understood, and is likely one of many factors contributing to rising list prices and patient out-of-pocket expenses. Thus, **the NHC supports the Administration's proposal to eliminate the safe harbor protecting rebates between manufacturers and Part D plans and introduce a new safe harbor to protect discounts given to beneficiaries at the point of sale if patient safeguards, such as those outlined in this letter, are implemented alongside it to mitigate unintended consequences and ensure beneficiaries are the ultimate recipients of realized cost savings.**

The NHC notes the proposed change is dramatic and implementation within such a short timeframe comes with the potential for unintended consequences that must be considered. Further, the success of this proposal will be determined by how different stakeholders in the supply chain react, including whether manufacturers reduce list prices (which they are not required to do), the amount of the fixed-fee pharmacy benefit managers (PBMs) will charge, and how plans manage their formularies to address different incentives.

As the Centers for Medicare & Medicaid Services (CMS) considers the operational aspects of this rule, we offer the following recommendations to ensure the proposal has the intended effect of reducing out-of-pocket costs without creating new access challenges. CMS should:

- Call on Congress to change the Part D benefit structure by placing a cap on out-of-pocket costs for patients;
- Engage in a more comprehensive review of formulary adequacy;
- Clarify the definition of negotiated price and adjust Part D benefit design parameters accordingly;
- Take extra steps to ensure optimal transparency for patients using Plan Finder;
- Ensure pharmacies are fully reimbursed for Part D medications in an appropriate timeframe;
- Ensure that value-based contracts are not hampered by the rule and its implications; and
- Exclude Medicaid Managed Care Plans from its finalized changes to the anti-kickback statute.

Each is discussed in detail below.

**CMS should call on Congress to change the Part D benefit structure by placing a cap on out-of-pocket costs for patients.**

In 2018, the Medicare Part D program provided coverage for prescription drugs for 43 million of the 60 million people with Medicare. Despite the legislative tweaks the program has undergone since it was created, the Part D program still lacks a real cap on out-of-pocket costs for all enrollees who do not qualify for the low-income subsidy. Medicare beneficiaries who reach the catastrophic threshold still face five percent coinsurance for the remainder of their benefit year. For some patients, this amount of cost sharing could reach thousands, or upwards of $10,000, in a single year.

The changes introduced in this proposed regulation do not completely solve the affordability crisis for patients enrolled in Medicare Part D. While the proposed changes offer one possible path to reducing prices, and thus cost sharing, the lack of a hard cap on out-of-pocket expenses

will continue to pose a fundamental crisis for the most vulnerable portion of the Medicare population. The Medicare program must offer better coverage for the nation's most vulnerable patients. Thus, the NHC asks CMS to continue advancing the administration's goal of reducing patient out-of-pocket costs by calling on Congress to introduce out-of-pocket maximum to Part D.

**CMS should engage in a more comprehensive review of formulary adequacy.**

If the proposed changes to rebates are finalized, the Part D program will face an entirely new set of incentives compared to the current landscape, and they will do so on a relatively short timeline. Particularly because of the timeline, the NHC is concerned that the current approach CMS takes to ensuring formulary adequacy has, like the rest of the program, been developed and honed within the current incentive structure. The entirely new approach that will result from new contracting incentives between manufacturers, plans, and PBMs, if finalized, would likely result in new pressures leading to new approaches to Part D plan formulary management. Thus, the current mechanism CMS uses to review Part D plan formularies may need similar adjustment.

The NHC is asking CMS to go beyond its standard methods to determine if year-to-year proposed benefit and formulary changes have the potential to discriminate against patients with high-cost needs and chronic conditions. Reviews should include assessments of the breadth of coverage of drugs and use of utilization management techniques within each therapeutic area as well as comparisons for these measures across the set of proposed plans and to the prior year's plans. Further, CMS should assess the out-of-pocket costs in these proposed plans across a variety of health conditions to determine whether the beneficiaries who are likely to pay more or pay less under this new set of incentives disproportionately harms patients in a discriminatory manner. It is imperative that CMS compares its plan-level analyses of 2020 formularies to 2019 formularies to ensure any significant negative changes are understood by the Agency and can be addressed. Without reassurance that the Agency will commit to review and address potentially discriminatory benefit and formulary design practices, implementation of this rule may have unintended consequences that can harm patient access and reduce affordability in a discriminatory manner.

**CMS should clarify the definition of negotiated price and adjust Part D benefit design parameters accordingly.**

Negotiated prices in Part D establish costs and spending within the Part D program. The overall cost of the program is based on expected quantity of drugs used multiplied by the negotiated prices of those drugs. The government, plans, beneficiaries, and manufacturers each share in paying a portion of the overall cost calculation, with retrospective adjustment for rebates occurring after the plan year. The proposed rule would cause some portion of rebates to be shifted directly into discounted prices, resulting in reduced negotiated prices and no retrospective adjustment for rebates.

To ensure consistency across stakeholders, the NHC is asking CMS to clarify the definition of negotiated price to clearly reflect the discounts protected by the OIG's new safe harbor. A uniform interpretation would ensure patients fully realize the benefits the rule aims to provide. First, this clarification should help patients realize lower out-of-pocket costs in the deductible as well as for any prescription where coinsurance is required. Second, it would mean that the

overall cost of the program that determines the share of expenses paid by each stakeholder—government, plans, beneficiaries, and manufacturers—is calculated on the true net cost of the plan. By making this clarification, the NHC believes that CMS should adjust the Part D benefit design to accommodate the reduced negotiated prices.

In other words, CMS should recalculate the portion of the overall program cost that beneficiaries are responsible for paying using the reduced negotiated prices. This adjustment would lower the deductible, the initial coverage limit, and the catastrophic threshold to reflect the reduced cost of the standard benefit package. It would also likely result in Part D plans lowering copayment amounts on specific formulary tiers, since those are also calculated based on the portion of the negotiated price for drugs placed on those tiers.

The reduction of list prices and out-of-pocket costs that this proposed rule is intended to create will be most acutely realized in therapeutic classes with higher levels of competition and current rebating. It is unclear whether this same direct impact will occur in classes with high-cost drugs with little competition. However, if the definition of negotiated price is reduced as a result of this proposal, it will likely benefit a greater number of people with chronic condition via lower deductibles and cost-sharing obligations.

**CMS should take extra steps to ensure optimal transparency for patients using Plan Finder.**

Plan details for 2020 are scheduled to go live on the Medicare Plan Finder October 1, 2019. Medicare patients use this website each year as an information and enrollment tool to select their Part D coverage for the upcoming plan year.

The Part D marketing period begins each year on October 1, and plan information, including formulary coverage, cost sharing, and negotiated prices, are live on the tool at that time. The October 1 "go-live" date for Plan Finder is only four months after the end of the comment period for this proposed rule. The NHC is concerned that the proposed timeline outlined by the Administration makes it difficult to ensure access to accurate information on Plan Finder on October 1.

It is critical that patients are able to compare Part D plans to determine which one best fits their needs—particularly for patients with chronic conditions and high health care utilization. This will be even more important in a plan year with so many potential shifts in costs. Without accurate pricing information, patients will be unable to anticipate future out-of-pocket costs and make well-informed decisions to find affordable and quality prescription drug coverage. Thus, the NHC is also asking CMS to modify its current set of tools (including Medicare.gov) as well as model notices to help patients understand how Part D is changing for beneficiaries in 2020.

**CMS should ensure pharmacies are fully reimbursed for Part D medications in an appropriate timeframe.**

The changes proposed in this regulation rely on a relatively undefined process for chargebacks, in which manufacturers pay pharmacies for the difference between the prices the pharmacies paid for medications and the reimbursements received from plans and patient cost sharing. The proposed rule does not establish an approach, such as designating an entity to "own" the process

for ensuring payment of chargebacks. Absent these details, we are concerned about the unintended consequence of a negative impact on patients' ability to receive their needed medicines.

The implementation timeline of the proposed rule leaves little room for error in terms of creating, establishing, testing, and implementing entirely new payment system processes. The NHC is concerned about the risk to patients if chargeback payments to pharmacies are not timely or accurate. Specifically, the NHC is concerned that pharmacies may be receiving substantially smaller reimbursements (from Part D plans plus cost sharing) than they paid to obtain the medications. In these cases, if payments are not accurate or timely, pharmacies could have considerable debt as they await repayment. Those most likely to struggle with this scenario are smaller pharmacies who are less able to cover these costs. In such a scenario, some pharmacies might choose not to purchase some medications or fill prescriptions for Part D plan enrollees. This could severely impact access for Medicare beneficiaries and might specifically harm access for beneficiaries in rural areas who have limited pharmacy choice.

Further, the extent to which PBMs would take on the role of a chargeback administrator remains unclear. As CMS does not have direct contractual relationships with PBMs, the Agency may not be equipped to respond to pressing issues on chargebacks and may not be able to adequately oversee the expectations established by this rule.

The NHC is asking CMS to ensure that the chargeback system is running effectively prior to the proposed start date and to mandate a chargeback timeline that allows pharmacies to remain whole. The NHC would like CMS to consider a process that could proactively prepay a chargeback entity, subject to reconciliation, which could improve the process and reduce the risk burden placed on pharmacies and beneficiaries.

**CMS should ensure that value-based contracts are not hampered by the rule and its implications.**

The NHC shares the Administration's view that value-based contracts are an important method of paying for quality in the Part D program. The proposed rule suggests that the changes do not alter the current protections afforded to value-based arrangements in Part D. However, the proposed rule does not enumerate the specifics of the current protections for value-based arrangements. The NHC is concerned that additional clarity is needed to protect the future of value-based arrangements in the Part D program.

CMS must offer clarification since there is inherent contradiction within the text of the proposed changes. The rule clearly states that any discount offered by a manufacturer to a Part D plan must be determined prior to the point of sale. However, patient outcome metrics are regularly used to determine manufacturer's price concessions in value-based arrangements. However, the patient outcomes, by definition, occur after the point of sale. Without additional clarity from the agency, the NHC is concerned that value-based arrangements that require post-point-of-sale information will be prohibited.

**CMS should exclude Medicaid managed care plans from its finalized changes to the anti-kickback statute.**

The proposed rule offers that changes to safe harbors should apply to Medicaid managed care plans in addition to Part D plans. However, these two markets are dramatically distinct. Rebates within the Part D market have led to higher out-of-pocket and federal government costs as well as misaligned incentives in the program. Medicaid beneficiaries, however, have very low or no cost-sharing obligations for prescription drugs.

Should this proposed rule be finalized to apply to Medicaid managed care plans, the NHC is concerned that these plans would respond by further restricting their benefit design and placing additional utilization management restrictions onto beneficiaries. Considering there is no evidence that the misaligned incentives related to rebates in the Part D program exist within Medicaid, and that Medicaid managed care plans would likely restrict access for patients, the NHC strongly urges this provision be removed as it would result in much harm and zero gain.

***Conclusion***

The NHC thanks you for the opportunity to comment on this proposal. We share the Administration's goal of reducing patients' out-of-pocket costs and agree that reconsidering the role of rebates is one method of achieving our shared goal. However, we urge HHS to consider addressing the additional patient protections outlined above to prevent unintentionally reducing patient access.

Please do not hesitate to contact Eric Gascho, our Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

Marc Boutin, JD
Chief Executive Officer
National Health Council