

July 23, 2021

Submitted via regulations.gov

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

The Honorable Martin J. Walsh
Secretary of the Department of Labor
S-2521
200 Constitution Ave NW
Washington, DC 20210

The Honorable Janet Yellen
Secretary of the Department of the Treasury
U.S. Department of Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

The Honorable Kiran Ahuja
U.S. Office of Personnel Management
1900 E Street, NW
Washington, DC 20415-1000

Re: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs. CMS-9905-NC

Dear Secretaries Becerra, Walsh, and Yellen, and Director Ahuja:

On behalf of the National Association of Chain Drug Stores (NACDS), we are writing in response to the Departments of Health and Human Services, Labor, and the Treasury's (the "Departments") and the Office of Personnel Management's ("OPM") request for information ("RFI") on reporting requirements for health plans and issuers under section 204 of Title II of Division BB of the Consolidated Appropriations Act of 2021.

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while

offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

Our specific recommendations are as follows:

- The Departments and OPM should define “rebates, fees, and any other remuneration” to encompass all remuneration that plans collect from pharmacies.
- The Departments and OPM should apply separate definitions to the term “pharmacy” as it relates to retail and mail-order books of business, similar to the Centers for Medicare and Medicaid Services (“CMS”) proposed rule for fiscal year 2019.
- The Departments and OPM should ensure that reports made public protect the competitive landscape and provide the public with the most useful information to make healthcare decisions.

I. The Departments and OPM should define “rebates, fees, and any other remuneration” to encompass all remuneration that plans collect from pharmacies.

The RFI asks: “1. What considerations should the Departments and OPM take into account in defining “rebates, fees, and any other remuneration”? Should bona fide service fees—for example, administrative fees, data sharing fees, formulary placement fees, credits, and market share incentives—be included in this definition? Are there additional fees that the Departments and OPM should include in this definition? How should manufacturer copay assistance programs and coupon cards be accounted for? How should copay accumulator programs be accounted for?”

Health plans and issuers not only receive “rebates, fees, and any other remuneration” from manufacturers, but also from retail pharmacies. The reporting of both is not a novel concept for insurance companies. In fact, plans and their PBMs must report rebates, fees, and any other remuneration – collectively known as direct and indirect remuneration or DIR – to the Centers for Medicare and Medicaid Services (“CMS”) in the Medicare Part D program. It should be noted that DIR is a term of art created in the Part D program as a way for CMS to account for “price concessions” from manufacturers and pharmacies that would impact the gross prescription drug costs of Medicare Part D plans. While the usage and application of DIR in the Part D program is not completely analogous, it serves as a helpful example. The Departments and OPM should consider how the Medicare program defines DIR/price concessions, including a pharmacy’s negotiated price and any remuneration not captured in that negotiated price, to establish a comprehensive definition for rebates, fees, and any other remuneration that health plans and issuers collect from pharmacies.¹ Such

¹ NACDS has consistently raised its concerns with how DIR is utilized and applied in the Part D program. Such concerns still stand. We are highlighting the collection and reporting of DIR in Part D as a starting point to

comprehensive information offers further transparency to the true cost health plans and issuers pay for prescription drugs.

Specifically, NACDS urges the Departments and OPM to utilize a broad definition to account for the various types of rebates, fees, and any other remuneration currently utilized by health plans and issuers, and to account for future types that may be used in the future. The definition should include any form of discount, direct or indirect subsidy, or rebate received by the plan or its intermediary contracting organization from any source, that serves to decrease the costs incurred by the plan or issuer. NACDS offers the following language for consideration:

Rebates, fees, and any other remuneration means any form of discount, direct or indirect subsidy, or rebate, fee paid by a pharmacy or deducted from payments to a pharmacy, or any other remuneration received directly or indirectly by the health plan or issuer or its intermediary contracting organization from any source, that serves to decrease the costs incurred by the health plan or issuer. Examples include but are not limited to: discounts, chargebacks, rebates, cash discounts, transaction fees, network participation fees and other administrative fees collected from pharmacies, free or reduced cost goods contingent on a purchase, coupons, free or reduced-price services, and goods or services in kind.²

This suggestion aligns with the goal of creating a broad definition that is meant to capture all types rebates, fees, and other remuneration. The proposed suggestion above includes pharmacy transaction fees, network participation fees, and any other fees that plans charge pharmacies. Pharmacies share the concern expressed by the data and policy experts that these fees, which are significant and growing in all market segments, are being collected from pharmacies and could be under accounted for if not defined comprehensively.

II. The Departments and OPM should apply separate definitions to the term “pharmacy” as it relates to retail and mail-order books of business, similar to the Centers for Medicare and Medicaid Services (“CMS”) proposed rule for fiscal year 2019.

The RFI asks: “2. What considerations should the Departments and OPM take into account in defining the term “pharmacy”? Are there different considerations for retail pharmacies versus mail order or specialty pharmacies? Are there different considerations for prescription drug dispensed in an inpatient, outpatient, office, home, or other setting?”

define the kinds of rebates, fees, and any other remuneration utilized by health plans and issues as sought under this RFI. See [Part D Plan Reporting Requirements \(cms.gov\)](https://www.cms.gov/medicare/plan-and-provider-participation/part-d-plan-reporting-requirements).

² NACDS offered a similar language to define the term “price concessions” in the Medicare Part D program, which was the subject of CMS’ proposed rule for fiscal year 2020. 83 Fed. Reg. 62152 (published Nov. 30, 2018).

In CMS' proposed Part D rule for fiscal year 2019, CMS made the important distinction between retail pharmacy and mail order pharmacy.³ NACDS urges the Departments and OPM to adopt such distinction as mail-order and retail pharmacies may be reimbursed at different rates due to a plan or issuer's benefit design and/or network participation.

CMS' proposed rule for fiscal year 2019 defined retail and mail-order pharmacies as (NACDS proposed revisions underlined):

***Retail pharmacy** means any licensed pharmacy that primarily dispenses prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.*

***Mail-order pharmacy** means a licensed pharmacy that primarily dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.*

While CMS did not adopt its proposed definition of mail-order pharmacy or NACDS' suggestions to either the retail or mail-order definitions, NACDS urges the Departments and OPM to adopt the spirit of these definitions to further transparency on what health plans and issuers pay for prescription drugs.

III. The Departments and OPM should ensure that all reports made public protect the competitive landscape and provide the public with the most useful information to make healthcare decisions.

The RFI states that no longer than 18 months after the plans and issuers report information under the Consolidated Appropriations Act of 2021, the Departments and OPM will publish reports on the internet on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases, among other items. The RFI indicates these reports will not include confidential or trade secret information.

We emphasize the need for information collected by the Departments and OPM to protect the competitive landscape of the industry and also provide meaningful and helpful information to the public to make informed healthcare decisions. Importantly, we highlight that pharmacies' negotiated-rate data should not be provided to patients because it is misleading and does not provide the patient with useful information about their actual cost-sharing liability. Patients' out-of-pocket costs are typically driven by their plan design, deductible, co-insurance, and co-payment requirements, not the rates negotiated between

³ 82 Fed. Reg. 56336 (proposed Nov. 28, 2017).

pharmacies and health plans or issuers. Disclosing of such information could create and exacerbate confusion as beneficiaries could mistakenly assume those published rates reflect their individual out-of-pocket costs. That could, in turn, discourage them from having their prescriptions filled. We look forward to working with the Departments and OPM to help combat this scenario and ensure that patients are provided with information to make informed healthcare decisions.

Conclusion

Thank you for the opportunity to provide information on the Departments' and OPM's request for information. If we can provide further assistance, please do not hesitate to contact Christie Boutte, cboutte@nacds.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer