THE COUNCIL
The Council of Insurance Agents & Brokers

July 23, 2021

VIA ELECTRONIC MAIL – www.regulations.gov

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Attn: CMS-9905-NC
200 Constitution Avenue NW
Washington, DC 20210

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

To Whom It May Concern:

The Council of Insurance Agents and Brokers ("The Council") appreciates this opportunity to comment on your request for information regarding reporting on pharmacy benefits and prescription drug costs to implement Section 204 of the Consolidated Appropriations Act of 2021.[1] The Council strongly supports and appreciates your continued focus on transparency and reducing unnecessary costs and burdens in the healthcare system, and we agree that addressing drug costs is an essential part of that effort.

By way of background, The Council represents the largest and most successful employee benefits and property/casualty agencies and brokerage firms. Council member firms annually place more than $300 billion in commercial insurance business in the United States and abroad. In fact, they place 90 percent of all U.S. insurance products and services and they administer billions of dollars in employee benefits. Council members conduct business in some 30,000 locations and employ upward of 350,000 people worldwide, specializing in a wide range of insurance products and risk management services for business, industry, government, and the public.

Our comments focus on questions raised in the RFI that we believe are most relevant to and impactful for the employer-sponsored market. We note the following overall themes that emerged from Council members' feedback on the RFI:

[1] Request for Information, *Reporting on Pharmacy Benefits and Prescription Drug Costs*, 86 Fed. Reg. 32813 (June 23, 2021) (hereinafter "RFI").

- Given that health plans typically outsource to either insurance carriers, third-party administrators ("TPAs"), or pharmacy benefits managers ("PBMs"), employer plans and plan sponsors do not currently have access to the required reporting information;

- PBMs, TPAs, and insurance carriers must play a critical role in providing the required reporting information to plans, plan sponsors, and the Department;

- The definition of "rebates, fees, and any other remuneration" should broadly include all manufacturer derived revenue and specify data elements to ensure consistent reporting across the industry;

- Because account-based health plans do not have access to meaningful pharmacy benefit and prescription drug cost data, the Department should consider exempting such plans from the required reporting; and,

- To ensure compliance and avoid redundant reporting, the Department should consider clarifying the roles and responsibilities of the health plan, PBM, and TPA in providing required information for the reports.

Below we provide more specific responses to some of the questions posed in the RFI.

- ***Do plans or issuers currently have access to all of the required information to report? How much time will plans need to gather the required reporting information?***

Group health plans and employer plan sponsors do not currently have access to the required reporting information, even in the self-insurance context. Council members report that, in the employer-provided healthcare space, administration of the medical plan, and the pharmacy benefits in particular, are typically outsourced to either an insurance carrier for fully insured plans or to a TPA or PBM for self-insured plans. Those entities maintain the information that is going to be required for reporting and compliance (e.g., top drugs, rebates, and fees) and that information generally is not shared with the health plans. As such, reporting will require active engagement and direct information from the insurance carriers, TPAs, and PBMs to or on behalf of group health plan clients.

Ultimately and as a practical matter, insurance carriers, TPAs, and/or PBMs should be required to provide the specified reporting information in a format that mirrors the requirements in the regulations for ease of submission, and on a timeline that allows the group health plans to timely report the data.

We do urge the Department to require that any such information be submitted on a de-identified basis and that publicly available data sets exclude any information about the specific health plan to which that data relates because of the sensitive and confidential nature of that information. This de-identification should extend to all of the pharmaceutical data.

- ***What should the Departments consider in defining "rebates, fees, and any other remuneration?" Should service fees – like administrative fees, data sharing fees, formulary placement fees, credits, and market share incentives – be included in that definition?***

Generally, we believe that the definition of "rebates, fees, and any other remuneration" should broadly include all manufacturer-derived revenues to best enable plans to evaluate the overall remuneration package and to limit the ability of industry participants to avoid disclosure by reclassifying revenues into categories that need not be disclosed. Thus, such definition should include administrative fees, data sharing fees, formulary placement fees, credits, and market share incentives.

We also believe that it is critical the terms be specifically defined to best enable a sound comparative evaluation across providers. We suggest that the Department consider broadly defining "rebates" as

> all compensation or remuneration received directly or indirectly from a pharmaceutical manufacturer, attributable to the purchase and/or utilization of covered products by an eligible participant, including all such compensation or remuneration received by the vendor's rebate aggregator or group purchasing organization arrangement.

We also suggest that "compensation" be as broadly defined as possible and to ***include but not be limited to***

> discounts; credits; rebates (regardless of how categorized); formulary management fees; implementation allowances; market share incentives/credits; promotional and submission allowances; educational grants received from manufacturers concerning the provision of utilization data to manufacturers for rebating, marketing, and related purposes; market share incentives; commissions; data fees; manufacturer administrative fees; and, price inflation protection payments.

- ***Are there special considerations for certain types/sizes of group health plans – like individual coverage health reimbursement arrangements and other account-based plans?***

The required reporting information will be particularly challenging for account-based plans—including individual coverage health reimbursement arrangements ("ICHRAs"), health reimbursement arrangements ("HRAs), health savings accounts ("HSAs"), and health flexible spending accounts ("FSAs")—because they currently do not track the information as they are not otherwise required to do so. Thus, given the function of account-based plans for prescriptions (e.g., reimbursing copays and prescriptions reported through a group's medical plan), the Departments should consider an exemption for account-based plans. We believe that such an exemption would have minimal impact (if any) on reported information since most prescription drug expenses flow through the medical plans directly.

- ***What role, if any, will PBMs play in providing the reporting information to plans, insurers, or the Departments?***

As noted above, PBMs have the required reporting information and necessary internal processes to report and employer-sponsored plans do not. Therefore, as a practical matter, the PBMs will have to play the lead role in aggregating this information for submission.

- ***Are there types of payments that flow from plans, insurers, or PBMs directly to manufacturers? Are there types of rebates and price concessions that are passed directly to the participant, beneficiary, or enrollee? If so, how should they be included or acknowledged in the reporting?***

In the fully insured context, the plans pay the insurers who are then responsible for all coverage costs (excluding deductibles and co-pays). In the self-insured context, PBMs make the payments on behalf of the plans. We are unaware of the extent to which either the insurers or the PBMs are making payments directly to the manufacturers.

There are some rebates and price concessions that are passed on directly to plan beneficiaries including point-of-sale rebates, embedded rebates (e.g., where the PBM keeps the rebate and reduces the ingredient cost by having a higher average wholesale price discount representing the rebate's amount), copay manufacturer assistance cards, and accumulator programs. Copay assistance or coupon cards are direct-to-patient "rebates" from drug manufacturers. Accumulator programs generally are designed to provide drug manufacturer copay assistance so that it may count towards a participant's deductible or out-of-pocket maximum (even if it is not paid by the participant).

Employer health plans generally have little to no access to this information but they would greatly benefit from the reporting of this information so that they are better positioned to adequately assess the impact of such programs. The Department thus should not require plans and plan sponsors to provide such information but should impose such reporting obligations on the PBMs and manufacturers who are providing these purchase finance incentives directly to plan participants.

- ***To reduce administrative burdens or costs associated with these new requirements, are there opportunities to remove duplicative reporting requirements (e.g., removing the separate PBM transparency rules that require qualified health plans or their PBMs to report prescription drug information to HHS)?***

We recommend that the Department clarify reporting responsibilities (i.e., defining the responsibilities of the plan sponsor, PBM, and TPA) to ensure compliance and to avoid overlap of responsibilities. Furthermore, and for the reasons discussed at length above, the Department should require PBMs to report the prescription drug-related cost and associated rebate/discount information for fully insured and self-funded employer groups to avoid an undue burden on employers.

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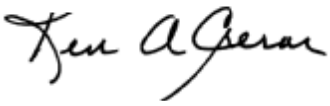
Again, we appreciate this opportunity to provide comments. Please do not hesitate to contact us if we can provide further information or answer any questions.

Respectfully submitted,



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