ERIC | THE ERISA INDUSTRY COMMITTEE
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Mercer

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Submitted Electronically via: www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9905-IFC
Mail Stop C4-2-05
7500 Security Boulevard
Baltimore, Maryland
21244-1850

RE: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs

To Whom It May Concern:

The ERISA Industry Committee ("ERIC") and Mercer thank the Departments of Treasury, Labor, and Health and Human Services (the Departments) for issuing the interim final rules (IFR) that will provide more transparency to our health care system. We greatly appreciate your willingness to delay the requirement to report the most frequently dispensed prescription drugs covered, their costs, premiums, and drug rebates as required under Section 204 of Title II of Division BB of the *No Surprises Act* transparency requirements in the *Consolidated Appropriations Act of 2021* (CAA) until December 27, 2022. We are also pleased that the Departments allow employers to assign third-party administrators (TPAs) and pharmacy benefit managers (PBMs) to satisfy the reporting obligations under this interim final rule. However, we are pleased to submit the following additional comments in response to the Request for Information ("RFI") regarding new employer requirements related to reporting on pharmacy benefits and prescription drug costs.

ERIC is the only national association advocating exclusively for large employer plan sponsors that provide health, retirement, paid leave, and other benefits to their nationwide workforces. With member companies that are leaders in every economic sector, ERIC advocates on the federal, state, and local levels for policies that promote flexibility and uniformity in administering their employee benefit plans against a patchwork of conflicting and burdensome rules.

You engage with an ERIC member company every day when you drive a car or fill it with gas, use a cell phone or a computer, watch TV, dine out or at home, enjoy a beverage, fly on an airplane, visit a bank or hotel, benefit from our national defense, receive or send a package, go shopping, or use cosmetics.

Mercer is a global consulting leader and a business of Marsh McLennan. For 150 years, we have been side-by-side with our clients finding opportunity and navigating uncertainty in the areas of risk, strategy and people. As we confront this new world together, we will be there for our clients in the moments that matter. In the United States, Mercer provides health care and group benefits consulting, brokering, and actuarial services to approximately 5,000 companies of all sizes with varying employee demographics.

ERIC and Mercer are proud to work together again in responding to the RFI on behalf of employers that provide comprehensive benefits to their employees. Our responses to specific questions are based on our members' and clients' current experiences, benefits knowledge and expertise, and market factors.

Additional Plan Types That Should be Considered Exempt

Some employer-sponsored medical benefits (such as expatriate plans, standalone telehealth plans, and other unique benefit designs) provide insignificant coverage of prescription drugs. Requiring these plans to report prescription drug information would be statistically inconsequential and would not benefit the Departments.

We believe reporting by expatriate plans would negatively affect reporting since the cost data would primarily be from outside the United States. It would frustrate the overall aim of the reporting and prove to be impractical.

Reporting by standalone telehealth plans would also be impracticable and statistically insignificant at this time. Currently, telehealth cannot be offered as a standalone benefit to anyone not enrolled in the full medical plan due to the Affordable Care Act (ACA) rules. However, the Department of Labor has allowed employers to expand telehealth offerings with two key restrictions[1]:

- Standalone telehealth may only be offered to individuals ineligible for the full medical/surgical benefit; and

- Standalone telehealth may be offered to these individuals only until the end of the public health emergency.

When guidance was issued in June 2020, employers acted. In fact, as a result, millions more Americans have telehealth benefits today. A broad array of ERIC member companies rolled these programs out to part-time workers, seasonal workers, interns, and more – with especially significant gains in the retail industry. Patients have used telehealth visits for primary care, chronic disease management, mental and behavioral health, and more. Standalone telehealth is an example of agile policymaking that resulted in tangible benefits for many people, and one ERIC hopes to build on in Congress. Currently, telehealth plan vendors and other point solution vendors may cover prescription drugs when the standalone telehealth benefit or unique benefit design is integrated with the medical plan, so having these types of plans report could cause unnecessary duplication. Also, because standalone telehealth plans are tied to the public health emergency, reporting on a non-permanent benefit would be futile and show little data.

Complying with the transparency requirements in the CAA would be unrealistic and burdensome for these specific plans, and we urge the Departments to exempt these plan types from the interim final rules.

[1] Department of Labor. FAQ Part 43. June 23, 2020

Definition of Rebates, Fees, and Any Other Remuneration

The Departments requested comments on the impact and definition of "prescription drug rebates, fees, and other remuneration" on plan costs. The information requested in the IFR will assist tremendously in quantifying the impact of rebates. In the last two years entities referred to as rebate aggregators or "Group Purchasing Organizations" (GPOs) have become key components of the rebate system. Three large PBMs have their own GPO, and many other PBMs either contract with one of these GPOs or other independent GPOs. Today, roughly 80 percent of rebates are accessed through a GPO or aggregator.

GPOs levy fees to participating PBMs to access the negotiated rebates in many cases. In the case of a smaller PBM, this fee may be passed through to their clients. Therefore, we suggest that GPO fees from PBMs to clients be included in the requested rebate reporting. Their inclusion will result in a complete picture.

We would also like to address cost-sharing assistance, copay assistance cards or coupon cards, as they have become a significant factor in the rebate conversation. The IFR discussed this remuneration in the context of impact to participants, beneficiaries, and enrollees. Currently, there are many programs offered to employers called copay maximizer and accumulator programs that allow the value of these programs to be captured by plan sponsors. Approximately half of self-insured plan sponsors have a maximizer or accumulator program in place and reporting on these programs is still evolving. In most cases, their adoption has a material impact on plan cost.

The Departments' approach excludes this type of cost-sharing assistance from the definition of "prescription drug rebates, fees and other remuneration." We encourage the Departments to provide guidance that is more explicit indicating that any employer who received reporting on the impact of a copay maximizer or accumulator program include the cost-sharing assistance in their total spending on health care services.

Definition of Prescription Drug

There are still growing differences in how PBMs define prescription drugs. We suggest that reporting captures the full scope of plan sponsor payments under the plan. So, the definition should be for a "prescription claim" rather than a "drug" as some items paid under the plan are not drugs but are covered items such as diabetic test strips. A suggested definition of "prescription claim" we propose is:

> "Prescription Claim" means any electronic or paper request for payment or reimbursement arising from retail participating pharmacies, mail-order pharmacies, and specialty pharmacies, providing Covered Products to a Plan Participant processed under this Agreement in accordance with the Client's Plan. For purposes of this "claim" definition, "covered products" shall also include products that are approved to be covered through the bidder's review processes (e.g., PA or medical exception process) or through the appeals process (including external review).

A suggested definition of "covered product" we propose is:

> **"Covered Product" means prescription drugs, over-the-counter medications and other services or supplies that are covered under the terms and conditions outlined in the description of the client's plan.**

Definition of Health Care Services

Many self-funded plans have wellness services that one or more third parties administer. Currently, the Department of Health and Human Services (HHS) reporting instructions for plan sponsors impose an obligation for them to "use a reasonable method to allocate expenses across state and market segments and describe the method used… and why you believe it is reasonable." These requirements will be challenging for plan sponsors to provide for what often is a small portion of overall spending on health care services.

The definition of "wellness services" for reporting total annual spending on health care services needs to be better defined. This will allow for a single standard. Plan sponsors should also be permitted to report overall cost, allowing the reporting entity to allocate proportionally across states and market segments without the need for a narrative on the method used.

Impact of Mergers, Splits, and Similar Transactions

The Departments sought comments on the need for further rulemaking when an insurer or PBM has a merger, split, or similar transaction. We encourage the Departments to address these situations when they occur for plan sponsors, who are ultimately held responsible for Section 204 compliance. Specifically, the Departments should consider addressing a plan sponsor's obligations where a plan sponsor has a similar business transfer during a reference year. **Employers need guidance on their obligations when they acquire a separate employer during a reference year as to the target employer's reporting obligations.**

Hospital and Provider Reporting

The Departments indicate that due to operational and other challenges no reporting would be required for drug utilization provided under a plan's hospital or medical benefit other than total spending on health care services. Currently, reporting for outpatient hospital and physician-administered drugs under the medical benefit is extremely complex. Therefore, the omission of these drugs from the initial reporting request is prudent.

However, we do encourage the Departments to work with key stakeholders to make this reporting more consistent in the future. Many of the high-cost therapies under Gene Therapy and Chimeric Antigen Receptor T-cell (CAR-T) drugs will be the main drivers of the future pharmacy trend. These drugs are typically administered under the plan's hospital or medical benefit, so their future inclusion is sensible for comprehensive reporting.

Data Submission Requirements

While the CAA imposes data submission requirements on plans and issuers, the IFR encourages aggregate data reporting by reporting entities such as issuers, TPAs, and PBMs. The Departments believe that it will be "rare" for self-funded plan sponsors to report their own claims data and that aggregate data reporting will be "significantly less burdensome." However, this causes plan sponsors to rely on these third parties to comply with a rule where they have limited means (other than contractual) to ensure compliance.

It is also important to note that the IFR allows aggregated reporting to minimize administrative burden. For self-funded plans with carved-out PBMs, the PBM's report will need to include total annual health

care spending data from an often unrelated medical TPA. Self-funded plan sponsors may have limited means to ensure that sufficient PBM-medical TPA cooperation occurs so that reporting is accurate, timely, and complete.

All plan sponsors have little or no way of verifying compliance or accessing reported data, yet they are ultimately held responsible for the accuracy and completion of the reporting. Self-funded plan sponsors lack the means to aggregate and report their information if a TPA or PBM does not report for them. Reporting may be a particular challenge for plan sponsors if/when they change a TPA in the year after the reference year. For example, a report for the 2023 reference year would be due on June 1, 2024, but compliance may be an issue if the plan sponsor changes a TPA/PBM on January 1, 2024. Lastly, the IFR provides no good faith compliance relief for plan sponsors who reasonably rely on issuers, TPAs, and PBMs.

We urge the Departments to consider the following recommendations to best address compliance challenges facing plan sponsors with ERISA plans:

- **Revise the IFR to confirm that CAA Section 204 "Reporting on pharmacy benefits and drug costs" data is subject to Section 202 "Disclosure of direct and indirect compensation for brokers and consultants to employer-sponsored health plans and enrollees in plans on the individual market."**

- **Impose reasonable cooperation requirements for PBMs, TPAs, and insurers regarding the reporting obligation.**

- **Provide good faith compliance relief for plan sponsors relying on PBMs, TPAs, and insurers to submit their data.**

- **Update the RxDC module in the Health Insurance Oversight System to send a confirmation notice to plan sponsors when a report is successfully submitted.**

Conclusion

Thank you in advance for considering these comments. Please do not hesitate to contact us with any questions or if ERIC and Mercer can serve as a resource on these very important issues. For additional information, please contact James Gelfand at ERIC, or David Dross at Mercer.

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