November 1, 2022

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Martin Walsh
Secretary of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210

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

Director Kiran Ahuja
Office of Personnel Management
1900 E Street, NW
Washington, DC 20415

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

We, the undersigned groups representing health insurance providers, third-party administrators, employers and other group health plan sponsors, and related businesses are writing regarding the Prescription Drug and Health Care Spending reporting requirements (RxDC reporting requirements) enacted by the Consolidated Appropriations Act, 2021. Our collective members are fully committed to compliance with the RxDC reporting requirements and have been working tirelessly to prepare the first round of reporting due December 27, 2022. Throughout this process, we have been working together, including sharing feedback and questions from our members. We are writing to share several priority recommendations.

Good Faith Reporting Relief

Due to the complexity of the RxDC reporting, and the fact that it is brand new, many questions and issues have arisen, and our members have been closely monitoring the guidance from the Departments on a daily basis. The guidance includes the reporting instructions and their updates, an array of Frequently Asked Questions (FAQs), and the reporting user manual and its updates. Our members have also frequently reached out to the RxDC Policy Helpdesk to raise issues and ask questions not otherwise answered in guidance.

We appreciate the efforts of the CMS Help Desk staff to answer questions from and provide feedback to plan sponsors, issuers and other reporting entities, and we acknowledge that some of the guidance provided is in response to issues and questions raised by stakeholders including our members. However, the continuous updates and changes have also led to confusion and created additional operational complexities as our members work to build new data request/storage capabilities, construct the reports, and work to ensure the reported data is accurate and correctly submitted. As December 27, 2022 rapidly approaches (the final date for submission for the first reporting for Reference Years 2020 and 2021), many of our members have expressed deep concern over their ability to respond to and fully address continuous guidance updates and changes. We also note that as of today, no technical assistance workshops have been scheduled for reporting entities to ask questions and receive needed guidance.

We understand, based on our past experience, the challenges that come with setting up a new and complex reporting regime, including evolving guidance and new questions and issues arising on a daily basis. We also anticipate that notwithstanding the best efforts by plan sponsors, issuers and other reporting entities, and given the newness and complexity of the requirements, the continuous guidance changes, potential technical difficulties with the filing system, and the range of questions and issues that continue to arise, there may be errors or issues with the first round of reports despite good faith efforts by plan sponsors and issuers. For all these reasons, we urge the Departments to grant relief from any

penalties to plans and issuers that can show they made good faith compliance efforts for this first reporting and for the Departments to focus on compliance assistance. We note this approach was similarly applied for the first few years of the major reporting requirements in the Affordable Care Act.

Filing Acceptance Process

A substantial number of reporting entities will be using the CMS Enterprise Portal and Health Insurance Oversight System (HIOS) application for the first time, including some employer plan sponsors. Due to the complexity of the reporting and the fact that this reporting is brand new, reporting entities, particularly those new to using HIOS have shared their concerns about the system rejecting files submitted, potentially rendering the plan or issuer noncompliant with the statute. According to the recently updated HIOS User Manual, any file containing errors identified by the system will not be allowed to be uploaded. The inability to submit a full report if even one error is identified in the reporting has caused concern, especially for this first round of reporting in December. Rather than rejecting files that have incorrect data or other problems, we request that, for this first reporting, the Departments restrict HIOS from rejecting files and direct staff to work with reporting entities to correct any issues that may be present in their submissions. We also ask the Departments to make available staff for real-time questions and issues that arise during the submission process for several weeks leading up to the reporting deadline.

In addition, it is our understanding that the Departments intend to close the reporting system to new or updated submissions after December 27. While our members are making plans to submit the reporting in advance of the reporting deadline, we are concerned that this closure will unduly limit submissions to the Departments for those plans and issuers with filing issues that cannot be resolved timely. There are also concerns about possible issues with the filing system itself and its ability to accept a large volume of reports being submitted simultaneously. We urge the Departments to leave the reporting system open and provide a 30-day submission grace period for late or revised submissions following the December 27, 2022 deadline, when extenuating circumstances exist.

Reporting by Multiple Reporting Entities

We appreciate the recently posted and helpful FAQs that address data submission by multiple entities, as many group health plans, based on their design, are in a position where multiple reporting entities will need to submit data on their behalf, including the same data file type. While the FAQs provide guidance on how to complete this reporting, it assumes that as a default for a given plan or issuer, the various reporting entities will share data amongst each other in order to produce a complete file and that only in "extenuating circumstances" will the different reporting entities submit independent RxDC reports.

Based on our experience, the assumption that reporting entities will share data amongst themselves is incorrect, and the framing related to extenuating circumstances has caused confusion. Some reporting entities remain extremely concerned about gathering and reporting data from other unaffiliated entities, especially when the data is financial or competitively sensitive. We recommend that as a default, each reporting entity be responsible for reporting the data they administer and maintain regardless of whether it is in a single file or represents only a partially completed file, rather than having this rule apply only in "extenuating circumstances." This approach would ensure the data for each plan are reported completely without duplication, while being reported by the entity that is the "source of truth" for the data.

For this December, based on the FAQs, there is confusion as to whether plan sponsors and issuers need to notify CMS if they plan to have multiple reporting entities send the same data file, which will be the case for many. While the FAQ can be read to indicate that is not necessary it would be helpful for the Departments to clarify that plan sponsors "may but are not required" to contact CMS prior their vendors filing multiple files as needed. Finally, it is unclear how these multiple entity rules align with the "Aggregation Restriction" in Section 5.3 of the reporting instructions; no FAQs on this issue have been published to date.

Future Reporting Instructions
Looking forward to the June 1, 2023 reporting, we appreciate that the Departments will be updating the reporting instructions to incorporate the substance of the FAQs, the feedback the CMS Help Desk has provided thus far to reporting entities, and any additional policy changes. We recognize that the time between December 27, 2022 and June 1, 2023 is brief; however, we urge the Departments to engage stakeholders before finalizing the next set of reporting instructions, so that our members' experiences submitting the first reports, or working with their service providers to submit the first reports, may inform the next iteration of the instructions. It would be very helpful if stakeholders could have an opportunity, even if brief, to submit comments and feedback on updated draft instructions for the June 2023 reporting.

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Notwithstanding the issues raised above, we reiterate that our members are working in earnest to build and test the data they will submit by the December 27 deadline or are working with their service providers to ensure they do so. We appreciate the Departments' efforts to engage stakeholders throughout the implementation process and offer this feedback to raise issues identified by a broad spectrum of reporting entities and the health plans and issuers subject to the reporting requirements.

We also request an opportunity to discuss these requests with you at your earliest convenience.

Sincerely,

AHIP
American Benefits Council
Blue Cross Blue Shield Association
Business Group on Health
The Council of Insurance Agents & Brokers
The ERISA Industry Committee
Pharmaceutical Care Management Association
U.S. Chamber of Commerce

CC:
Laurie Bodenheimer
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Lisa Gomez
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