July 21, 2021

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
US Department of Labor
Attention: CMS-9905-NC
200 Constitution Avenue NW, Room N-5653
Washington, DC 20210

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

Dear Sir or Madam:

We are an independent third-party administrator of multiple health and welfare plans who will be subject to the reporting requirements under Section 204 Title II of the Consolidated Appropriations Act, 2021. We thank the agencies for the opportunity to submit comments in response to the forthcoming data reporting requirements. Since we anticipate that some of the reporting requirements will be contracted to us by the plans we administer, we are submitting comments on the administrative ability to comply with the regulations. Our comments are solely from our perspective as a third-party administrator, and are not on behalf of any of the plans we administer, nor their Trustees or vendors. For that reason, we are opting to submit our comments anonymously, since our comments may or may not represent the opinion of our plans.

I. In the Request for Information, the agencies ask whether there are operational, formatting, or technical considerations that may impact plans' abilities to meet the statutory deadline for reporting. Operational and technical considerations are of concern from the perspective of a third-party administrator, assuming the reporting requirements are contracted to us. Even if the data exists regarding the top 50 most frequently dispensed drugs, total number of claims for each drug, 50 most costly drugs, total annual spending broken down by type of service, etc., it would take significant time to first determine whether our data system contains the information required by the reporting obligations, and then develop programming to pull the specific information from our available data files and input this into a spreadsheet or other workable format. This will involve a significant amount of programming trial and error to determine whether our current data system can produce the requested info. We anticipate programming will need to be developed internally to be able to produce the information necessary to meet the reporting obligations.

Similarly, the requirement of "total spending broken down by the type of health care service" will depend on whether our data system has the appropriate parameters to distinguish these costs by "types of health care service." (We note that, on this specific data element, it is our opinion that it would be preferable to disaggregate by particular service/CPT code). If our current data system does not have the ability to pull the necessary information in order to fulfill the data request, we face an operational time constraint

to develop and implement a system that can handle these significant data requests before the regulations take effect. Likewise, if this reporting requirement is contracted to us as an administrative manager through an administrative services contract, we also must consider that contractual obligations may now encompass our ability to comply with the data request and will hinge upon our available programming and/or technical resources. We also express our concern that much of the data requested is information held by a Pharmacy Benefits Manager, not readily accessible by us. This means our ability to comply with the reporting requirements relies largely on our ability to obtain information from another entity.

Given that the agencies have yet to finalize rulemaking and issue guidance on which we might rely, and the first deadline is set for December 27, 2021, this leaves a tight time frame in which to implement administrative, technological and operational processes in order to produce the large amount of information required. We believe we can and will have the ability to comply with the data reporting requirements, however, we believe there is significant administrative and operational trial-and-error before we are able to meet these requests. We suggest, and respectfully request, that the agencies forego the initial deadline of December 27, 2021, and set the first mandatory deadline at June 1, 2022, to allow plans and administrators time to develop a system for pulling the necessary data and compiling it into a reportable format.

II. Under Section C(4) of the RFI, the agencies ask "…would allowing separate reporting forms, modules, or data collection systems for PBMs and issuers and plan administrators to report such information be administratively and operationally feasible? How would separate reporting forms change the costs or burdens associated with compliance?" This question leads us to ask whether the agencies intend for some of the reporting requirements to fall on the PBMs directly, or whether the plans carry the burden of reporting all data. If the agencies intend for certain data to be reported directly by the PBMs, we believe it would be beneficial to allow for separate reporting forms to PBMs, issuers and administrators separately, as applicable. As we noted above, there is data held by the PBMs that is not readily accessible by the plans or administrators. It would be significantly less burdensome if we were required to report only on the data elements which are readily available to the plan. However, we request that the agencies specify and differentiate which data elements are required by the plans versus the PBMs.

III. Under Section C(3), the agencies ask whether it is administratively feasible to submit data in aggregate on behalf of multiple plans and coverage options, rather than reporting information separately for each group health plan. From the perspective of a third-party administrator that handles multiple plans, it may be impossible to report in aggregate on behalf of all plans we administer, since each plan's particular data reporting may be significantly different (for example, different plan years, multiple coverage options, different service providers from whom each plan would obtain necessary information, different administrative services contracts with each plan).

Regarding the agencies' question on whether data should be collected on a calendar year basis or by plan year, we suggest that it be based on plan year. The agencies ask "what is the last plan year end date that should be included in data submitted by June 1 of each year?" We respond with an alternative approach

to data reporting based on plan year. Rather than a set deadline of June 1 of each calendar year, we suggest a deadline of 6 months following the end of the applicable plan year. If the agencies are set on a June 1 deadline for reporting, then we respond that the last plan year end date that should be included in the June 1 deadline should be December 31 of the preceding year.

IV. The regulation includes reporting of rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its administrators or service providers. Under Section B, the agencies ask "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…be included in this definition?" From our perspective, it does not make sense to lump together administrative fees paid to an administrative manager together with drug rebates, as these don't seem to go hand in hand. Administrative fees are not tied to, nor dependent on, drug costs or drug rebates, nor are drug costs and rebates affected by administrative fees. These are independent of each other. Additionally, the fee structure in an administrative services contract between the plan and administrator is not so specific as to break down which portion is attributable to the services involving drug manufacturers. If the agencies wish for administrative fees to be reported, we suggest these be reported separately from drug rebates and remuneration.

V. Finally, the agencies ask what actions they can take to minimize the compliance costs of the reporting requirements. While sufficient time for accurate compliance remains our chief concern, we do expect that the costs associated with the new reporting requirements will be significant. We suggest that the agencies consider some form of relief to entities that face excessive financial burden in complying with the regulations. We also suggest that the data collection requirements include a report of the associated costs, so that the true financial impact of compliance can be analyzed over the first few years.

We thank the agencies for their consideration of our comments, and we look forward to the agencies' forthcoming clarification and guidance.

Sincerely,

A Concerned Third-Party Administrator