



AMERICAN BENEFITS COUNCIL

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Submitted electronically via email

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**RE: Comments in Response to Request for Information Regarding Reporting on
Pharmacy Benefits and Prescription Drug Costs**

Dear Mr. Khawar, Ms. Levy, Ms. Rivers, Ms. Weiser and Mr. Wu:

I write on behalf of the American Benefits Council (“the Council”) regarding the Request for Information (RFI) Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs issued by the U.S. departments of Health and Human Services (HHS), Labor (DOL), and Treasury (“the Departments”), related to the requirements under Section 204 of the Consolidated Appropriations Act, 2021 (“prescription drug

reporting requirement”). We respond to many of the questions posed in the RFI, reiterate our support for increased transparency throughout the pharmaceutical supply chain, and identify specific areas where additional guidance and additional time for implementation is needed.

The Council is a national nonprofit organization dedicated to protecting employer-sponsored benefit plans. The Council represents more major employers – over 220 of the world’s largest corporations – than any other association that exclusively advocates on the full range of employee benefit issues. Members also include organizations supporting employers of all sizes. Collectively, Council members directly sponsor or support health and retirement plans covering virtually all Americans participating in employer-sponsored programs.

Pharmaceutical drug therapies have played a significant role in treating and curing injury, illness and disease. They allow millions of Americans to overcome debilitating conditions, return to work and live longer, healthier, more productive lives. Moreover, money spent wisely on drugs can reduce hospital, physician and other medical expenditures. Although the benefits of pharmaceutical drug therapies are substantial, these benefits often come with significant financial costs to both participants and payers in the health care system, including employer-sponsored plans. Total retail prescription drug spending in the United States reached \$333 billion in 2017, after accounting for rebates, with employer-sponsored health plans paying for 42% – \$140 billion – of the total prescription drug spend.¹

In an effort to manage drug costs, employers have sought to implement innovations and strategies while still ensuring that employees and their families have access to needed drugs and services. Nonetheless, prescription drug costs continue to represent a considerable portion of overall plan costs. Retail prescription drug spending accounted for 21% of total spending in employer-sponsored health plans in 2018, before accounting for drug manufacturers rebates (adjusting for an estimate of rebates lowers the share of spending in employer plans for drugs to 18%).²

As the largest purchaser of prescription drugs in the United States, employers are deeply concerned about prescription drug costs and, relatedly, about the absence of appropriate price – and cost – transparency. The current rebate structure used in the marketplace is complex and opaque for many employers, making it hard for employers as well as plan participants and beneficiaries, to understand the true prices and value of drugs.

¹ <https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/>.

² https://www.healthsystemtracker.org/chart-collection/who-is-most-likely-to-have-high-prescription-drug-costs/#item-high_rx_retail-drug-spending-as-a-share-of-national-health-spending-and-as-a-share-of-total-spending-by-people-with-employer-coverage-2018.

Accordingly, the Council has supported various efforts to lower prescription drug costs.³ We have undertaken these efforts on our own and along with other employer groups, including as part of the Employers' Prescription for Affordable Drugs (the "Employers Rx Coalition").

One of our main goals is to increase transparency throughout the pharmaceutical distribution system to ensure that public and private payers and patients spend resources more wisely. This includes drug manufacturer unit costs and increased transparency from pharmacy benefit managers (PBMs), including regarding rebates. Increased availability of cost information, if properly designed and carefully implemented, could help employer plan sponsors and their employees make better informed purchasing decisions that result in higher-value pharmacy expenditures.

As to the matter at hand, we appreciate that Section 204 of the CAA, the prescription drug reporting requirement, is intended to bolster these efforts by increasing transparency by requiring plans and issuers to annually provide new, detailed information to the Departments about prescription drug spending. We are hopeful that the resulting report produced by the Departments will provide meaningful information that employers and other stakeholders will be able to use to address prescription drug costs. In addition, because much of the information required to be reported will be provided by PBMs to plans, this provision should result in increased transparency between PBMs and plans, which has been an important goal of employers for years.

As such, we are supportive of the prescription drug reporting requirement, and our members are working hard toward implementation. At the same time, as discussed in detail below, for employers and plans to be able to implement the prescription drug reporting requirement, additional guidance is needed on a number of topics, as is additional time for implementation, to ensure that plans can implement these requirements correctly and accurately.

We also applaud the administration's efforts to address prescription drug costs, including through implementation of the prescription drug reporting requirement and more generally, as set forth in the recent Executive Order on Promoting Competition in the American Economy⁴ (the "executive order"), which directs HHS to issue a comprehensive plan to address prescription drug costs. We also support the administration's efforts to increase price and quality transparency throughout health care, as explained in our recent letter to the Departments on transparency, and we were glad to see the administration reiterate its support for transparency in the executive

³ <https://www.americanbenefitscouncil.org/pub/?id=AFDB6C11-1866-DAAC-99FB-FDB0C0329A76>.

⁴ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>.

order.⁵ We look forward to continuing to work with the administration and Congress on these important issues.

Below we provide specific feedback in response to many of the questions in the RFI, as well as comments on other, related issues. In terms of process, we appreciate that the Departments are seeking feedback through the RFI, but we also ask that the Departments propose rules, through the rulemaking process, to implement the prescription drug reporting requirement and afford stakeholders a chance to comment, due to the importance and complexity of these issues.

GENERAL IMPLEMENTATION CONCERNS

Reporting Deadlines

Section 204 of the CAA requires that the first reporting under the prescription drug reporting requirement be provided to the Departments not later than one year after the date of enactment (*i.e.*, December 27, 2021), and not later than June 1 of each year thereafter. The RFI asks what issues the Departments should be aware of that would impact the ability of plans and issuers to meet the statutory deadlines.

Although, as noted above, we are supportive of this new requirement and our members are willing to work as quickly as possible to implement these provisions, we understand that it will be very challenging, and in some cases impossible, for plans and issuers to meet a December 27, 2021, reporting deadline for a number of reasons.

To begin with, self-insured plans (which are the type of plans sponsored by the vast majority of our members) will need to rely on their PBMs for much of the required information in order to meet the reporting requirement. Many of the specific required data elements relating to prescription drugs are currently held by the PBM (*i.e.*, the 50 brand prescription drugs most frequently dispensed and the total number of paid claims for each such drug; the 50 most costly prescription drugs and the annual amount spent for each such drug; the 50 prescription drugs with the greatest increase in plan expenditures and the change in amounts; and the rebates, fees, or other compensation paid by drug manufacturers including amounts paid for the 25 drugs with the highest rebates and other compensation).

Employers rarely get drug-by-drug information regarding rebates -- the rebate information generally is provided by PBMs in the aggregate. In addition, PBM contracts are complex, and are already in place for 2021. Such contracts are between the employer and the PBM, or the TPA and the PBM. In either case, the contract generally governs what information may be disclosed to employer plans/TPAs. Given that the plan or

⁵ See <https://www.americanbenefitscouncil.org/pub/1B02F5E9-1866-DAAC-99FB-317E572D37E8>.

issuer is liable for the reporting (and not the PBM directly) and the plan or issuer may need additional information from the PBM, these contracts may need to be re-negotiated based on these new reporting requirements. These negotiations cannot be completed until the final guidance and final technical reporting specifications have been provided. In addition, based on member feedback we understand that the re-negotiation process can be lengthy and resource intensive.

In addition, systems will need to be developed to aggregate the prescription drug information provided by the PBM with information provided by the plan's TPA and other service providers such as a wellness program vendor, including information on other health care costs (*i.e.*, total spending on health care services, broken down by category) and information from the employer/plan sponsor (*i.e.*, any reduction of premiums and out-of-pocket costs associated with rebates, fees, or other compensation and average monthly premiums paid by employers and employees). It will take time to develop this system due to the coordination involved and the extent of the data to be gathered, both on prescription drug costs and other health care costs, and to integrate that data as required.

Moreover, we have heard concerns from our members about resource bandwidth to successfully implement these reporting requirements near year-end 2021 due to COVID-19 return to the workplace efforts and the extensive work required near year-end, for some employers, due to annual open enrollment activities.

Additionally, this is a new reporting requirement, and we do not have guidance yet on how this information will need to be reported. And as is evidenced throughout this letter, there are a number of issues and definitions where clarification is needed and where more information is needed, including on how the reporting system will operate and how reports will be submitted. As a practical matter, plans and TPAs will not be able to build new systems needed to comply with the reporting requirement, and contracts and agreements cannot be negotiated or finalized, until there is final guidance and forms and/or instructions.

On this note, the RFI asks how much time plans and issuers will need to implement these provisions after the Departments finalize rulemaking and publish the reporting format and instructions. We raised this question to our members and in general it seems that plans and issuers will need 12 months from final guidance and final reporting format and instructions in order to complete the first required reporting.

In light of the foregoing, we strongly recommend that the Departments provide that the first reporting under the prescription drug reporting requirement be due 12 months from the date on which final guidance *and* final technical reporting specifications (including the final paperwork reduction act package) are released. Based on our understanding of the work involved, this deadline is ambitious, but we support efforts to stand this system up as soon as possible, due to the value of increased transparency

regarding prescription drug costs and employers' desire to obtain increased information from their PBMs. It is essential that plans and issuers have sufficient time for implementation, because the value of the report that will result will be directly correlated to the quality, accuracy and consistency of the data reported, which will be substantially stronger if the timeframe for the reporting process is realistic and not rushed and all stakeholders are operating with clear, consistent, final guidance.

Please see later in this letter for issues to consider regarding the ability of plans and issuers to meet the ongoing filing due date (*i.e.*, June 1).

Data Sources

In the RFI, the Departments ask which data elements, if any, are not readily accessible to plans and issuers and how plans will gain access to this information. As discussed above, many of the data elements will need to be provided by PBMs, some of which may not currently be provided, such as drug-specific rebate information.

We note that our plan sponsor members have expressed concerns about their ability to obtain the required information from their PBMs. **Timely provision of information by PBMs to plan sponsors will be an essential element in the ability of the Departments and plans and issuers to implement these provisions and for valuable information to be provided under these new requirements.**

Our hope and assumption is that employers will work with their PBMs to obtain the needed information, including as part of contract re-negotiations. We understand that the reporting requirements apply to group health plans and health insurance issuers, but we also ask that the Departments encourage PBMs to timely provide the necessary information to plans. The Departments also should consider requiring the reporting to identify the plan's PBM. In addition, we encourage the Departments to consider providing guidance clarifying the extent to which the gag clause prohibition under Section 201 of the CAA can bolster plan efforts to obtain information from PBMs and other service providers in order to complete the prescription drug reporting. More generally, we note that we are continuing to consider additional specific recommendations to support plan sponsors' ability to obtain the information needed to complete the prescription drug reporting and will follow up with the Departments on this issue as our thinking develops.

We also note that the Council has supported efforts by Congress to increase transparency throughout the pharmaceutical supply chain, including with respect to PBMs. As a general matter, employers find the current rebate structure complex and opaque, hiding the true prices of drugs and the true value of how the rebate is calculated. While some PBMs disclose the nature and extent of specific drug rebates, this practice varies by PBM. Moreover, when PBM compensation is tied to a percentage of the list price of the drug, this can create a market incentive that encourages higher list

prices and larger rebates, specifically where the PBM compensation is factored into the cost of the drug by the drug manufacturer (and gets reflected in the list price set by the drug manufacturer).

Accordingly, the Council has supported provisions that require greater transparency with respect to PBMs and the pass-through of rebates or discounts to plan sponsors, including provisions that would require that group health plan sponsors receive reports on the costs, fees and rebate information associated with the PBM contracts and to require PBMs to pass on 100% of any rebates or discounts to the plan. In tandem with our regulatory advocacy, the Council will continue to urge Congress to pass measures along these lines.

Special Considerations for Self-Insured Plans

The RFI asks if there are different or special considerations for various types of health plans, including self-insured health plans, in terms of their ability to meet the statutory requirements. As noted earlier, one key issue to keep in mind for self-insured plans is that many of the key data elements will need to be provided by their PBMs, and in some cases their TPAs. In addition, we expect that self-insured plans will rely heavily on their TPAs to complete and submit this reporting (that will have been provided by the PBM and the plan sponsor, aggregated with the data of the TPA).

In addition, unlike some other types of coverage, plan sponsors of self-insured plans oftentimes also obtain stop-loss coverage, to cover high-cost claimants who incur claims above a certain level. We understand that in many instances, if the stop-loss coverage is invoked with respect to a high-cost claimant (*e.g.*, because the coverage's attachment points have been met) and the employer (or other contract holder) is paid by the stop-loss carrier, and the stop-loss claims included drugs for which a rebate was received by the plan, the stop-loss carrier will require the plan (or plan sponsor) to repay the rebated amount to the stop loss carrier. Our assumption is that these rebates will still need to be reported with respect to the prescription drug reporting requirement, if applicable, but we note that in these circumstances, the rebate amounts ultimately will not belong to the plan given they are required under the policy's terms to be paid to the stop-loss carrier.

Reporting System

The RFI asks what data reporting tools and systems the Departments should consider when deciding on the format of the data collection and how the Departments could implement the reporting requirements to facilitate compatibility with the systems most commonly used by plans and issuers.

One option for the Departments to consider is for group health plans that are required to report annual information to the DOL using the Form 5500 Annual

Returns/Reports of Employee Benefit Plan (“Form 5500”) to use that system, including by providing the required information as a new or updated schedule to the Form 5500. We understand that not all health plans are required to file the Form 5500 (and so plans exempt from the Form 5500 requirement would need another method to meet the prescription drug reporting requirement) and that the filing deadlines for the Form 5500 do not sync up with the filing deadlines for the prescription drug reporting requirement. But we raise this as something to consider, as many health plans have already established methods for filing Form 5500s and oftentimes it is more efficient to use a system that already exists, rather than building a new system. If the Departments are to update or revise the Form 5500 reporting requirements, we request a meaningful amount of time to comment on any such proposals.

In addition, we understand that the Departments, at least at one point, were considering using the same system that health insurance issuers use for reporting insurance data to the Department of Health and Human Services (“Health Insurance Oversight System” or “HIOS”), such as for medical loss ratio reporting, at least for the first few cycles of reporting. We note that self-insured plans have no experience with HIOS and do not have HIOS IDs. As such, we would advise against use of that system for self-insured plans. We do recommend that the system to be used be on-line and that it provide confirmation of receipt and acknowledgement that the reporting is complete.

DEFINITIONS

Rebates, Fees and Any Other Remuneration

Under the prescription drug reporting requirement, plans and issuers must report the amount of rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its administrators or service providers, with respect to prescription drugs prescribed to participants or beneficiaries in the plan, including the amounts paid for each therapeutic class of drugs and the amounts paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration during the year. The RFI asks what considerations the Departments should take into account in defining “rebates, fees and any other remuneration.”

We emphasize that it will be vital for the Departments to provide a clear definition of the term “rebates, fees and any other remuneration” to ensure that the information intended to be obtained via the reporting is so captured. As noted earlier, PBM contracts are highly complex and there are not industry standards for many terms, so the same term can have different meanings in different contracts. It is also important that the definition provided be sufficiently broad and focus on the substance of the payments rather than what any particular payment is labeled or how it is characterized in any particular contract, to avoid undermining the intent of this provision by allowing parties to re-label and/or re-characterize as something else amounts otherwise considered encompassed by the term.

Relatedly, we note that clarity is needed regarding which rebates need to be included in the reporting for any given year. The reason there is confusion on this issue is that the rebates that are associated with a claim in a given plan year are oftentimes not reconciled or provided to the PBM or plan sponsor until a few months following the plan year (typically, within one quarter). Sometimes the delay can be longer, including 9 months to a year *after* the end of the respective plan year. We also understand that there is a validation process after the rebates are determined, which can also take several months. In many cases, drug manufacturers and PBMs will agree to some base level of rebates, with additional rebates being provided if certain performance or utilization metrics are met by the PBM. These metrics are often based upon a twelve-month period (or longer) that is divorced from a given plan year or even the calendar year. Accordingly, the cadence of rebates is variable and dynamic and there seems to be an almost constant, ongoing reconciliation process that can happen over months or even years.

All that said, we think that it is important that the prescription drug reporting include information on rebates and other remuneration and that that information be as current and complete as possible. Ideally, the rebates that will be reported for a given plan year will be those associated with participant *claims* made during the plan year (rather than those rebates paid within the year). However, this will mean that, as explained above, relevant data needed to report for a year will not be known until several months after the plan year and even when the information is known to the PBM, TPA and plan sponsor, it will then need to be analyzed and aggregated consistent with the reporting requirement and the reporting itself will need to be completed. Our sense is that it will be difficult for plans and issuers to complete the required reporting by June 1, and we ask the Departments to consider whether additional time could be provided, to ensure reporting regarding rebates that is as complete as possible. One benefit of providing sufficient time to capture the rebates for a year is that it will avoid the need for any post-reporting true-ups or corrections to reflect rebates that continue to be reconciled after the reporting deadline, which would be very burdensome and time consuming.

In addition, as a point of clarity, we note that it would be helpful for the Departments to confirm that the reporting on rebate amounts is limited to reporting of the amounts paid for each therapeutic class of drugs and the amounts paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration during the year. The statutory language has caused some confusion and so we would appreciate confirmation that the reporting is limited to these two categories (*i.e.*, reporting by therapeutic class, reporting of top 25).

Prescription Drugs and Pharmacy

The RFI asks what considerations the Departments should take into account in defining prescription drugs and pharmacy. Below we provide some general thoughts and we will follow-up to the extent we develop more specific recommendations.

As a general matter we note that prescription drugs are provided in various way to participants under group health plans. This includes generic, brand and specialty drugs provided through pharmacies (“retail drugs”), specialty drugs provided through mail-order only (“nonretail specialty drugs”) and prescription drugs provided directly by providers and facilities as part of their service profile, such as certain inpatient and outpatient facilities, infusion centers, home health providers, and at physicians’ offices (“nonretail medical benefit drugs”). While the benefits for the retail and nonretail specialty drugs are generally part of the prescription drug benefit under a plan, which is usually administered by a PBM, the nonretail medical benefit drugs will run through the medical benefit, usually administered by the TPA.

In order to provide the most complete and useful information, our understanding is that the prescription drug reporting requirements apply to all of these various categories of prescription drugs. In fact, spending on nonretail drugs is a significant factor in health care spending, with nonretail drug spending expected to grow faster than retail spending for at least the next few years.⁶ However, based on questions we have received from our members on this point, it would be helpful for the Departments to provide guidance confirming the scope of prescription drugs captured for purposes of reporting, for the sake of clarity.

We note that for nonretail medical benefit drugs, the provider may be the entity that receives the rebate in which case the plan sponsor or issuer will not be in a position to know or report on those amounts. However, we also understand that in some cases the TPA or plan can receive a rebate for those drugs which we understand would be captured by the reporting requirement. That is, to the extent rebates are received related to prescription drugs (described in the three categories noted above) by the plan sponsor or a third party service provider that directly contracts with the plan (*e.g.*, TPA or PBM), we assume those rebates are to be captured by the reporting, whereas rebates received by other entities, such as the health care provider, are outside the scope of this reporting requirement. Again, confirmation would be helpful.

Therapeutic Class

Under the prescription drug reporting requirement, plans and issuers must report the amount of rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its administrators or service providers including the amounts paid for each therapeutic class of drugs. The RFI asks what the Departments should take into account

⁶ <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2776040>.

in defining the term therapeutic class and asks how plans and issuers currently determine this classification.

We note that self-funded plans rely on their PBM's definition and designation of therapeutic class and its meaning can depend on the software used for processing. To ensure that the information that the Departments receive is consistent, we ask that the Departments provide a specific definition.

ENTITIES THAT MUST REPORT

Challenges for Specific Health Plans

The prescription drug reporting requirement applies to group health plans but based on its placement in the Code, ERISA and the Public Health Service Act, the requirement does not apply to excepted benefits or retiree-only coverage. It appears that it does apply to both grandfathered and non-grandfathered plans. The RFI asks if there are special considerations for certain group health plans, such as health reimbursement arrangements (HRAs), that make it challenging to satisfy the reporting requirements and what the impact of an exemption would be on the public analysis.

We recommend that the Departments provide that account-based group health plans, such as HRAs, need not provide their own reporting under this requirement. This is because generally if an individual has an HRA, they also have other major-medical coverage, either a group health plan or individual health insurance coverage, and that plan or policy will be required to provide the reporting. The reporting from the account-based plan would not provide valuable information regarding prescription drug spending as, by definition, the amount of reimbursements under the plan is limited, at a relatively low dollar limit. For these reasons, it seems unnecessary to require reporting by these plans. (And we note that account-based group health plans that are excepted benefits, such as most health flexible spending arrangements (FSAs), are already exempt from the requirement by virtue of the statutory structure).

Use of TPAs by Self-Insured Plans

The RFI asks if the Departments expect that self-insured plans will contract with TPAs or other service providers to submit the required data on their behalf. The answer is yes but it will be a complex process because no single service provider currently holds all the required data. This is because, as noted earlier, some of the data required to be reported will need to come from the PBM, some from the TPA or other service providers, and some from the plan sponsor itself. We expect that plan sponsors of self-insured plans will look to their TPAs to aggregate and submit this data and so it will be essential that TPAs have access to the necessary data, including from PBMs. Note that sensitive pricing information exchange between PBMs and TPAs is further complicated

because TPAs might own or contract with a PBM that competes with the plan sponsor-contracted PBM. As referenced earlier, guidance must allow time for contractual arrangements to be made to comply with the reporting requirements.

Aggregated Data

The RFI asks if there are ways for TPAs to submit data on behalf of multiple plans and what benefit there would be to giving TPAs the ability to submit aggregated data, as opposed to reporting for each plan separately.

While we are not entirely sure what kind of system the Departments are contemplating here, our initial reaction is that the information the Departments receive, and that the public ultimately sees in the report, will be most valuable if it is reported on a plan-by-plan basis, so that trends will be clear. We also note that many of the data elements in the prescription drug reporting requirement are plan specific (*e.g.*, top 50 drugs dispensed, top 50 drugs by expense, total health care spend, average premiums). It is unclear how those elements would retain their meaning if aggregated across all plans administered by a particular TPA. While the Council is certainly supportive of reducing any unnecessary reporting burdens on plans and issuers, we would not want to save on some reporting burdens only to end up with data that is overly-aggregated such that its utility is marginalized.

Role of PBMs

The RFI asks what role PBMs will play in compliance with the prescription drug reporting requirements, whether PBMs could obtain all the information that needs to be reported, and whether, if PBMs were allowed to do so, plans/issuers would rely on PBMs to help satisfy the requirements.

As noted throughout this letter, PBMs have the prescription drug data that is submitted through the prescription drug plan. However, the information that is being requested related to the health care services, including drugs that are submitted through the medical plan, would be outside of their knowledge, as would the extent to which rebates, fees and other remuneration paid by the drug manufacturers impact premiums and out-of-pocket costs.

It is our sense that what is most essential is that PBMs timely provide the required information to plan sponsors or their agents, as requested by the plan sponsor so that the reporting requirements can be met. As plan sponsors are liable for compliance with these requirements, it should be up to plan sponsors to determine who compiles the data and completes and submits the reporting.

The RFI also asks, if PBMs cannot get access to all the required information to report, whether the Departments should set up separate forms, modules and data collection systems presumably so that different data elements would be reported by different

entities. This approach strikes us as overly complex and seems to raise an array of situations in which incomplete reporting may result, in which case the plan will be liable for failure to comply. In addition, this could undermine one of the benefits of the new reporting requirement – which is to increase transparency and information sharing between PBMs and plans. A more reasonable approach is for the reporting to be submitted to the Departments by one entity and for plan sponsors to determine which entity will provide the submission, on behalf of the plan.

INFORMATION REQUIRED TO BE REPORTED

Increase in Plan Expenditures

The RFI asks what considerations are important for plans and issuers in determining the 50 prescription drugs with the greatest increase in plan expenditures and whether this should be measured based on the absolute increase in dollars, percentage increase in price, the increase relative to another measure (*e.g.*, total plan spending or plan prescription drug spending), or something else.

While we think it is important that the Departments avoid guidance on the reporting requirements that renders them overly complex, we see the value in the Departments looking at the absolute increase in dollars, in addition to a percentage increase in a price, as a way to focus on the drugs that will have the greatest impact on plan costs. We also note that guidance will be needed on how plans and issuers are to determine plan expenditures.

Health Care Spending

The prescription drug reporting requirement requires plans and issuers to report total spending on health care services separately for hospital costs, health care provider and clinical services costs (for primary care and specialty care separately), prescription drug costs, and “other medical costs, including wellness services.” The RFI asks which elements should be included in each category. As a general comment, we note that it is important that the Departments provide a clear definition for each category.

We note that one aspect of this requirement that has caused confusion is the meaning of “wellness services.” As noted above, the statute requires reporting of “other *medical costs, including* wellness services.” Given the use of the word “including” and the reference to “medical costs,” there is some question as to whether the reporting requirement only encompasses wellness-related expenses that are a “medical cost” – such as a health care service (*e.g.*, a biometric test or diagnostic) or whether it encompasses all wellness services even if not a medical cost (*e.g.*, wellness education). There is a significant lack of clarity regarding what is encompassed under the definition of a wellness service that is not a medical cost. Accordingly, we recommend that the

Departments state in future rulemaking (or guidance) that only a wellness service that constitutes a medical cost is required to be reported.

Collection of Information by Market

The RFI asks whether the Departments should collect information separately by market, state, or employer size and if so, which requirements should apply to which categories.

While we are not suggesting that different types of plans have different types of reporting requirements, we do note the public report will be most useful if the information is analyzed and discussed, at least in part, by plan/employer size and market, so that the trend information is clear, and as specific as possible.

Impact of Rebates

The RFI asks what considerations are important for plans and issuers in measuring the impact of rebates on premiums and out-of-pocket costs. We want to reiterate timing issues here, to provide context for the Departments. As noted earlier, the full extent of rebates typically is not known until several months after the end of the plan year, and it is our understanding that they are not accounted for, either in premiums or out-of-pocket costs or otherwise, until the plan year after the next plan year. For instance, consider a calendar year plan. Rebates for 2020 would be received mid-2021; any plan design and contribution decisions for 2020 were set in mid-2019 and for 2021 were set in mid-2020. Accordingly, the rebates received for 2020 in 2021 would not be a factor in setting premiums or out-of-pocket costs until the 2022 plan year. So this means that the reporting about rebate amounts for a given plan year will relate to that plan year (*i.e.*, 2021 reporting will address amount of rebates for 2021 claims) but the reporting about the impact of rebates on premiums or out-of-pocket costs will relate to rebates associated with an earlier plan year (*i.e.*, amount of premium or out-of-pocket cost reductions in 2021 is based on the amount of rebates associated with 2019).

We also note that members have asked what “premiums” means in this context (*i.e.*, the total cost to the plan or the portion the participant pays for the coverage). We also note that we understand that not all employers have a direct formula as to how rebates impact member premiums and out-of-pocket costs, if at all, so the responses to this reporting element may vary and may in some cases be difficult to determine.

More generally, although the statute is focused on whether rebates affect premiums and out-of-pocket costs, we note that plan sponsors may use rebates for a range of purposes, including of course premiums and out-of-pocket costs but also benefit enhancements, offsets of plan administration costs, and other proper plan expenses such as participant education. To give a full picture of how rebate amounts are used by

plan sponsors, the Departments should consider capturing this information as well.

Participant Price Concessions

The RFI asks if there are types of rebates and price concessions that are passed to participants and if so, how they should be treated for purposes of reporting and whether they should be included or acknowledged in the data collection.

It is our understanding that there are certain pricing methodologies that use applied rebates or point-of-sale rebates in which the PBM estimates the amount of rebate that a plan may receive from a drug and applies that to the cost of the drug at the point of sale. If the participant has a co-pay, then the co-pay does not change but if the participant pays a deductible and/or co-insurance, the participant could receive the benefit from the estimated rebate being applied at the point-of-sale. (Due to the focus of the RFI, we are not addressing possible health savings account issues at this time). After the plan year, the actual rebates are reconciled against the estimate. Our understanding is that if the actual rebate is more, depending on the contractual arrangement, some PBMs will give that back to the plan.

As to whether these types of arrangements should be reflected in the reporting in some way, we think that would be useful in order for the Departments to understand, and the public report to provide, the full picture of how plan sponsors use and apply rebates as well as the impact of rebates on formulary design and drug costs.

Snapshot Dates

The prescription drug reporting requirement includes a number of elements where clarity as to when the item is measured will be needed – namely, the number of participants and beneficiaries and the states in which the plan is offered. These elements may vary over the course of the plan year. In order for plans and issuers to have clarity, and for the reporting provided to be consistent, we ask for the Departments to provide a snapshot date (*e.g.*, the first day of the plan year) on which these elements are to be measured/determined.

Average Premiums

The prescription drug reporting requirement includes a requirement that plans and issuers report the average monthly premium paid by employers on behalf of participants and beneficiaries, as applicable and paid by participants and beneficiaries.

Guidance on exactly how this amount is to be determined would be helpful, based on questions we have received from members including how this amount is determined if the plan has different tiers of coverage based on family size. We also note that we

have heard that in some cases, there may be complexities with this determination due to collective bargaining agreements and related participation agreements.

COORDINATION WITH OTHER REPORTING REQUIREMENTS

The RFI asks whether there are opportunities to remove other reporting requirements or to leverage or combine the new reporting with existing reporting to reduce administrative burdens and the costs associated with compliance.

As noted earlier, while we understand that the Form 5500 does not substantively cover the information required by the prescription drug reporting requirement, the Departments should consider whether that form could be updated to capture this information, to leverage a system that already exists, for plans that are required to file Form 5500s.

On substance, we have not identified reporting requirements that are substantially duplicative with the reporting the Departments will receive under the prescription drug reporting requirement. We considered the fact that under the Transparency in Coverage final regulations⁷, plans are required to report both negotiated rates and historical net prices (*i.e.*, prices that will reflect the impact of rebates received), for in-network prescription drugs. While these files may allow the Departments to analyze the data to attempt to approximate rebate-related information, the information does not fully line up with the information provided under the prescription drug reporting requirement and will not be organized in the way contemplated by the prescription drug reporting requirement (*i.e.*, therapeutic classes and 25 drugs with highest rebates). In addition, the Departments would be required to gather, from many locations, each plan's machine-readable file.

For these reasons, we do not see a basis for eliminating any of the elements of the prescription drug reporting requirement by virtue of other reporting requirements. We do however encourage the Departments to review and analyze information made available publicly under other transparency requirements, including the Transparency in Coverage regulations and the hospital transparency rules, in completing the public report on prescription drug costs to determine whether information provided in those files provides useful supplemental information or valuable context.

⁷ <https://www.govinfo.gov/content/pkg/FR-2020-11-12/pdf/2020-24591.pdf>.

PUBLIC REPORT AND PRIVACY PROTECTIONS

Use of Public Report

The RFI asks in what way the Departments can facilitate use of the reports by a variety of interested parties. As a general matter, we suggest the report provide information that is, at least in part, organized by market type and plan size, to show the extent to which the substance of the reporting varies by market and by plan size. We also ask that, at least for the first report and ideally for all reports, stakeholders be given a chance to comment on the format and contents of the report, to increase the value and usefulness of future reports.

Year to Which Reporting Relates

Section 204 of the CAA requires that plans and issuers report specific information by June 1 of each year (and by December 27, 2021) “with respect to the health plan or coverage in the previous plan year.” The RFI asks how “previous plan year” should be determined (*e.g.*, what is the last plan or policy year end date that should be included in the data submitted by June 1 of each year?).

We appreciate that the Departments raised this question because non-calendar plan years that end close to June (*e.g.*, April, May) will have very little time to comply. The statute appears to contemplate and assume calendar year plans for reporting purposes, in which case such plans will have several months from year-end to collect the requisite data, analyze the data, and prepare and finalize the reporting. (Also see our prior comments regarding rebate-reconciliation issues related to the June 1 timeframe even for calendar year plans.) Due to the extent of data to be reported and the coordination required on the various elements, it is essential that all plans have a meaningful amount of time after the plan year before the reporting due date, to support accurate and complete data for the Departments.

To provide sufficient time for compliance by non-calendar year plans and to avoid unfair/impractical application of the rules, we ask that the Department provide that for non-calendar year plans, the “previous plan year” be interpreted to be the plan year that ended in the previous calendar year. For example, for a plan year that runs from May of one year to April of the next, the June 2022 reporting (if the Departments decide to stick with a June due date) would relate to the May 2020-April 2021 plan year. We understand that this rule will provide varying amounts of time for different plans depending on their plan years, but we suggest this rule because it avoids undue complexity and ensures all plans have sufficient time to comply.

If the Departments are open to varying reporting deadlines on a plan-by-plan basis, a rule could also be provided in which plans have several months from the end of the plan year to provide the annual report, which would then mean the deadline would

vary by plan. And if the Departments pursue an approach in which the Form 5500 is leveraged, in that case, group health plans subject to the Form 5500 reporting requirements would have seven months to complete the reporting.

In addition, as noted above, we are requesting that the Departments not require reporting on December 27, 2021, due to the substantial challenges with that timeframe. However, we note that if the Departments proceed with that deadline, clarity will need to be provided on the meaning of the “previous plan year” in that case. Similar issues will arise for non-calendar plan years as described above regarding the June deadline – that is, a plan with a plan year ending November 30 would only have 27 days to prepare the reporting, which is not sufficient. We ask that if the Departments proceed with a requirement that reporting be provided December 27, 2021, that information to be reported relate to the plan year that ended in 2020 or some similar rule which ensures that non-calendar plan years have sufficient time to prepare the reporting.

Relatedly, the RFI asks if the report will have greater value or data utility if the data is collected on a calendar year basis or plan year basis or a combination of the two. We understand why the Departments are considering this issue, because in an ideal world the data reported would relate to the same time period for the sake of consistency and trend measurement. However, we considered this issue and are of the view that, due to the nature of the requirements and the ways in which they align with the plan year, reporting by plan year makes the most sense and avoids additional complexity that would come from reporting that crosses plan years.

Comparative Analysis

The RFI asks whether the report should provide comparative analysis of prescription drug costs for plans and issuers, relative to costs under Medicare or in other countries.

We think that providing comparative analysis with Medicare rates would be helpful. This will be helpful not only for general benchmarking but also to demonstrate whether payers in certain markets (*i.e.*, commercial markets) pay more, and perhaps subsidize, costs in other markets (*i.e.*, public coverage) and the extent to which changes in cost in some markets impact costs in others.

As to a comparison to information from other countries, that could be helpful for context but seems less salient than a comparison to Medicare. While informative, comparisons to other countries can provide an incomplete comparator as the price of drugs in other countries does not account for more limited availability and foreign government policies that restrict access to drugs.

REGULATORY IMPACT ANALYSIS

Costs of Compliance

The RFI asks what the Departments can do to minimize compliance costs. We do note as a general matter that our members expect that compliance with the prescription drug reporting requirement will impose substantial costs on plan sponsors. As noted earlier in this letter, clear guidance, including clear, consistent defined terms will be helpful in minimizing compliance costs, as well as in ensuring that the Departments receive useful information to provide a valuable public report. Also, a standard, clear format for reporting will be necessary as well.

In addition, while we support efforts to implement this provision as quickly as possible, we also note the difficulties that come with new, detailed, extensive requirements of this nature, and the significant consequences of failing to fully, timely meet the requirements. In acknowledgment of these factors, we urge the Departments to provide a good faith compliance standard for the first several years, consistent with similar relief provided by the Departments in the face of other similar new requirements.

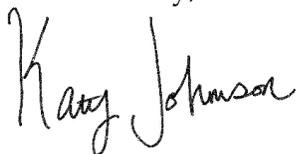
Also, as is often the case (including with the Transparency in Coverage rule and Summary of Benefits and Coverage rule), we request that the Departments provide that if coverage is insured, the plan and the issuer can enter into an agreement for the issuer to be contractually responsible for the reporting, and the plan will not have liability for issues relating to the reporting. Absent such a rule, there is unnecessary cost and burden on the system and an increased potential for conflicting reporting by multiple entities.

* * * *

The Council looks forward to continuing to work with the administration to address prescription drug costs and to increase price and quality transparency throughout the health care system in order to provide workers and their families with higher-value, lower-cost health care.

Thank you for considering these comments. If you have any questions or would like to discuss these comments further, please contact us at (202) 289-6700.

Sincerely,



Katy Johnson
Senior Counsel, Health Policy