AMERICAN BENEFITS COUNCIL

January 24, 2022

Submitted via regulations.gov

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RE: Comments on Regulations Regarding Prescription Drug and Health Care Spending

I write on behalf of the American Benefits Council ("the Council") to provide comments in response to the interim final regulations regarding Prescription Drug and Health Care Spending (IFR, or the "regulations") issued by the U.S. departments of Health and Human Services (HHS), Labor and Treasury (collectively, "the departments"), implementing requirements under Section 204 of the Consolidated Appropriations Act, 2021 ("prescription drug reporting requirement").

The Council is 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.

As an introductory matter, we note that employers appreciate that 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. 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.

Accordingly, the Council has supported various efforts to lower prescription drug costs.[2] 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 has been to support initiatives that increase transparency throughout the pharmaceutical distribution system to ensure that public and private payers and patients spend resources more wisely. This includes increased transparency

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[1] *See* How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid? | KFF. 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.americanbenefitscouncil.org/pub/?id=AFDB6C11-1866-DAAC-99FB-FDB0C0329A76.

regarding drug manufacturer unit costs and with respect to pharmacy benefit managers (PBMs), including regarding rebates that are paid by manufacturers to PBMs and other entities. Increased availability of cost information 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 detailed information to the departments about prescription drug and health care spending. And we are hopeful that the resulting public report produced by the departments will provide meaningful information that employers and other stakeholders will be able to use to address prescription drug costs. We also appreciate that the IFR responds in several respects to our requests for additional clarity and for additional time for plans to come into compliance with these requirements.[3]

At the same time, based on our understanding of the statute, our hope and expectation had been that the prescription drug reporting requirement would also increase transparency between PBMs and plans, by virtue of the fact that plans would be required to report plan specific information, much of which is held by PBMs. Increased access for plans to their own plan data, including regarding rebates, has been an important goal of employers for years. However, based on the reporting system contemplated in the current IFR, this new reporting requirement will not meaningfully support increased transparency for plans, with respect to their own data. In our comments we provide suggestions for how the departments can address this issue, while also addressing a handful of technical issues.

TRANSPARENCY FOR PLAN SPONSORS

The prescription drug reporting requirement is intended to increase transparency and support efforts to address drug costs by requiring plans and issuers to annually provide detailed information to the departments about prescription drug spending. A principal purpose of the prescription drug reporting is to provide information to the departments so they can issue a public report on prescription drug reimbursements under group health plans, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under plans.

As enacted, the prescription reporting requirements under the CAA apply separately to each plan and issuer, providing that "a group health plan and a health insurance issuer offering group or individual health insurance coverage (except for a church plan) shall submit" to the departments a list of information "with respect to the

[3] https://www.americanbenefitscouncil.org/pub/?id=E48D7036-1866-DAAC-99FB-2F7E872C7FA5.

health plan or coverage in the previous plan year." While group health plans (and their sponsors and fiduciaries) would, of course, prefer to avoid unnecessary compliance burdens, the Council and its members were supportive of this reporting requirement because, in addition to resulting in a hopefully useful public report, it would also indirectly provide plans with access to their own crucial information. The additional transparency would result from the fact that if plans were required to provide the departments with plan-specific information that is held by their PBMs, their PBMs would effectively be required to share that information with the plans (either to share what had been filed with the departments on the plan's behalf or to allow the plan or another service provider to file the information).

Notwithstanding that the legal liability for the reporting remains with the plan or issuer, the IFR facilitates reporting by certain third party "reporting entities" directly to the departments on behalf of each respective plan or issuer. The departments make clear that they expect that plans will look to PBMs and third party administrators (TPAs) to perform some or all of the reporting on behalf of plans and issuers. The departments also note that different elements of the reporting may come from different entities (*e.g.*, information on premiums could come from the plan sponsor, information on health care costs could come from the TPA, and information on prescription drug spending and rebates could come from the PBM). As a result, the departments provide in the IFR that entities other than the plan or issuer may, on behalf of such plan or issuer, perform the required reporting and that the reporting system will allow multiple, different entities to submit the required information for a particular plan or issuer.

Additionally, the IFR allows for "aggregate" reporting by such reporting entities, meaning that a TPA or PBM will report the relevant information (*e.g.*, top 50 most frequently dispensed drugs) across all of the plans it administers (in a given market segment, as defined by the IFR, and a given state). The rationale for allowing aggregate reporting is that collecting aggregate data is necessary for the departments to be able to draw conclusions about market trends for purposes of developing a meaningful and accurate public report, aggregate reporting will reduce the administrative burden of reporting for plans, issuers and the departments, aggregate reporting will better protect personally identifiable information and protected health information, and prescription drug rebates, fees, and other remuneration generally are not negotiated separately for each plan (rather, they tend to be driven by sales volume and other considerations at the PBM level), so the departments note it makes sense to collect this information in the aggregate.

The Council understands the development of implementing rules that seek to minimize the economic and administrative burdens on plans and issuers in complying with the new prescription drug reporting requirements, and like the departments, we expect PBMs and TPAs to be essential in helping plans meet their reporting obligations. As such, we understand how direct reporting by reporting entities and aggregate

reporting can reduce burdens for plans and issuers and we are not suggesting that the departments remove those elements from the IFR. However, we are concerned that the current approach set forth in the IFR will leave plan sponsors and fiduciaries without access to important and valuable information about their plans that the statute contemplates they have access to and so we provide several recommendations to ensure access for plans to this essential information.

First, while under the IFR plans are not required to participate in aggregate reporting, and so could instead wish to undertake plan-level reporting (to indirectly allow themselves to plan-level information) with the assistance of their TPA or PBM, we are concerned that this may not be a practical option. This is because plans may lack the commercial bargaining position to require "reporting entities" to assist with plan-level reporting or to otherwise provide plan-level reporting detail (even for a stated fee) and that reporting entities (PBMs and TPAs) will seek to only provide for aggregate level reporting with respect to the new requirement. This would have the unfortunate result of denying plans access to plan-level information that could otherwise facilitate the development of alternative plan designs – for example with respect to provider network designs, drug formularies, or plan benefits more generally.

As a result, our expectation is that, as currently written, the IFR will not bring about additional information for plan sponsors with respect to their plan's own information on prescription drugs. This is disappointing given the Administration's and Congress' focus on increased transparency in order to lower health care costs and improve value, including regarding prescription drug benefits, which should not be trumped by commercial practices based on the current IFR. We do believe this can be rectified, without undermining the administrative rules contained in the IFR. Specifically, we urge the departments to amend the IFR to require "reporting entities" that provide aggregate reporting to the departments to provide plan-level detail to plans or issuers, upon request by the plan or issuer. This could be provided by the reporting entity to the plan or issuer after the aggregate reporting is submitted to the departments but we ask that reporting entities be given a specific, reasonable timeframe in which the information about plan-level detail must be provided. Such a rule would recognize, and be based on, the fact that the statute contemplates plan-by-plan reporting. We also ask that the departments confirm that if a plan does provide plan-level reporting to the departments (with the assistance of its PBM or TPA), such a plan must also be given access to the information provided to the departments on its behalf.

In addition, as mentioned above, although plans and issuers may enter into agreements with other third parties (and likely multiple third parties) to assist with the reporting, the plan or issuer, as applicable, remains *liable* for compliance with the legal reporting requirement. Accordingly, it is imperative that plans and issuers be able to verify that the information has been reported by a "reporting entity" in furtherance of the plan's or issuer's satisfaction of its reporting obligation. The reporting instructions provide that a reporting entity (*i.e.*, usually not the plan sponsor) will be able to view

only the file that it uploads and cannot view files uploaded by another reporting entity even if related to the same plan or coverage. The instructions provide that "[c]urrently, no mechanism exists for CMS to notify plans, issuers or carriers that data has been submitted on their behalf. To confirm submission, plans, issuers and carriers should contact their reporting entities directly." Given that plans and issuers remain liable under the departments' current interpretation, it is imperative that plans and issuers be permitted to confirm, within the departments' system, that their reporting obligation has been satisfied and we ask that the departments update the reporting system to provide such verification.[4]

OTHER EFFORTS TO INCREASE TRANSPARENCY

The transparency in coverage regulations, finalized by the departments in 2020, contain several requirements, including that plans and insurers publicly post on the internet information regarding in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services and negotiated rates and historical net prices for covered prescription drugs in three separate machine-readable files.[5]

In August 2021, the departments announced that, among other things, they would defer enforcement of the prescription drug machine-readable file requirement indefinitely, pending notice-and-comment rulemaking regarding whether the prescription drug machine-readable file requirement remains appropriate in light of the prescription drug reporting requirement under the CAA (the "August FAQs").[6] As a justification, the departments noted that "stakeholders have expressed concern about potentially duplicative and overlapping reporting requirements for prescription drugs" noting "some of the same" prescription drug information must be reported under both.

However, under our assessment, there is minimal overlap between the two requirements. The entity to whom the reporting is due varies significantly, with the prescription drug reporting being provided to the departments (and then shared with the public in the form of a de-identified, aggregated report), whereas the prescription drug machine-readable files are required to be provided fully to the public. The content of the reporting also varies significantly, with the prescription drug reporting capturing only certain information like top-50 drug lists and the machine-readable file requirement capturing information on all covered prescription drugs. In addition,

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[4] We understand that providing plans and issuers access to the actual aggregate reporting files may present challenges, as they will contain information from other plan sponsors. We ask that the departments provide a method for verification of reporting that takes this issue into account.

[5] See https://www.govinfo.gov/content/pkg/FR-2020-11-12/pdf/2020-24591.pdf.

[6] https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

under the IFR, the prescription drug reporting will be aggregated across TPA or PBM (by market segment and by state), while the prescription drug machine-readable file is to be provided on a plan-by-plan basis.

This is to say, due to the substantial differences in content and audience, duplication or overlap is not a sufficient basis to undermine the valuable price transparency provided by the prescription drug machine-readable file. A biannual report from the departments with aggregated, de-identified prescription drug and rebate information is not a substitute for plan-by-plan, public pricing information on all covered prescription drugs, updated monthly. As such, we ask that the departments begin the notice-and-comment rulemaking on the prescription drug reporting machine-readable file referred to in the August FAQs, so that we can move swiftly in the direction of increasing price transparency, in order to lower health care costs and increase value.

We also note that, while we are hopeful that the prescription drug cost trend report that the departments will release based on the information they receive under the prescription drug reporting requirement will be helpful, there is still a need for increased transparency throughout the pharmaceutical distribution system. As such, the Council has, and will continue to, urge Congress to focus on increasing transparency regarding drug prices and drug costs as well as the entire ecosystem needed to deliver medicines to patients. The Council strongly supports legislation to require greater transparency with respect to PBMs as well as drug manufacturers, in addition to supporting regulatory efforts to achieve these same goals.

CONTENT ELEMENTS TO BE REPORTED

Definition of Wellness Services

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 IFR sets out the content elements that will be required and the reporting instructions contain an extensive amount of additional detail, including file layouts, which specify all of the elements and the order in which they are to be reported. The reporting must include the total annual spending on health care services by the plan or coverage and by participants broken down by: (1) hospital, (2) primary care, (3) specialty care, (4) other clinical health care services and equipment, (5) wellness services, and (6) prescription drugs. Each category is defined in detail in the reporting instructions.

In our comments to the RFI, we noted that the 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 have been questions 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). In our comments to the RFI, we recommended that the departments provide guidance that only a wellness service that constitutes a medical cost is required to be reported.

Although the recently issued reporting instructions provide additional detail on the meaning of "wellness services," additional clarity is needed. Based on the definition provided by the departments in the reporting instructions, it appears that wellness services do not need to be "medical costs" as required by the CAA, and can be wellness education or even a public health education campaign that is performed in conjunction with state or local health Departments. We understand the departments may have chosen this definition for consistency with permissible quality improvement expenses under the Affordable Care Act's medical loss ratio requirements; however, this is not consistent with how plan sponsors categorize wellness services that are medical costs; nor does it appear to be consistent with the express statutory language given the statute's reference to "wellness services" as a category of "medical costs." Accordingly, we request additional clarity on this definition of wellness services and recommend that future guidance more fully adhere to the relevant statutory language. We also note that although the instructions provide additional detail on the other various categories, due to the array of items and services at issue, questions may arise with regard to the categorization of other items and services. We will continue to monitor this issue as implementation continues and will follow up with the Departments if additional questions or issues arise.

Drugs as Part of the Medical Benefit

The IFR provides that plans must report total prescription drug spending under the pharmacy benefit and total prescription drug spending under non-pharmacy benefits.[7] In this respect, the departments interpret the CAA to capture the costs for prescription drugs covered under the plan's hospital or medical benefit, in addition to those covered under the pharmacy benefit, and also state that these items contribute substantially to prescription drug costs. We appreciate the departments including these amounts as part of the reporting and providing that they should be reported separately. This is consistent with our prior comments, which indicated that drugs covered under the medical benefit are captured by the CAA and are a substantial source of drug costs.

[7] Due to the complexities involved, the departments provide that prescription drugs covered under the plan's hospital or medical benefit are only to be reported as a separate line-item, in the total annual spending table and are not to be included in the other reporting elements (*e.g.*, top-50 lists).

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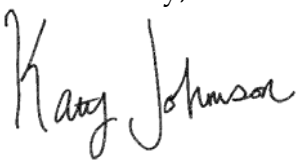
Thank you for the opportunity to submit these comments. We greatly appreciate your attention to these comments among the many other essential matters before you.

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

Sincerely,



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