NFIB

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Via www.regulations.gov

December 14, 2021

Hon. Janet L. Yellen
Secretary of the Treasury
RIN 1545-BQ10/1545-BQ27/REG-117575-21
Department of the Treasury
1500 Pennsylvania Avenue
Washington, DC 20220

Hon. Martin J. Walsh
Secretary of Labor
RIN 1210-AC07, EBSA
Department of Labor
200 Constitution Ave. NW, N-5653
Washington, DC 20210

Hon. Xavier Becerra
Secretary of Health and Human Services
CMS-9905-IFC
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Hon. Kiran Ahuja
Director
RIN 3206-AO27
Office of Personnel Management
1900 E Street NW
Washington, DC 20415

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

RE: OPM/Treasury/Labor/HHS Notice of Interim Final Rules, File Code CMS-9905-IFC, and Treasury Notice of Proposed Rulemaking, REG-117575-21, Both Titled "Prescription Drug and Health Care Spending," 86 *Fed. Reg.* 66662 and 86 *Fed. Reg.* 66495 (November 23, 2021)

This letter presents comments of the National Federation of Independent Business (NFIB) in response to the OPM/Treasury/Labor/HHS notice titled "Prescription Drug and Health Care Spending," and the Treasury notice with the same title, both published in the *Federal Register* of November 23, 2021. The two notices contain interim final rules and proposed rules to implement the extensive reporting requirements enacted by section 204 in Division BB of the Consolidated Appropriations Act, 2021 (Public Law 116-260, December 27, 2020) on prescription drug and health care spending.

NFIB continues to request that, in implementing those requirements, your agencies minimize regulatory burdens on small businesses as requested in the NFIB letter of July 21, 2021 (attached and incorporated in these comments by reference), so as to leave those businesses with greater freedom to grow their businesses and create jobs.

Sincerely,

David S. Addington
Executive Vice President and General Counsel

Attachment as stated

ATTACHMENT

(NFIB letter of July 21, 2021)

NFIB

555 12th St. NW, Ste. 1001
Washington, D.C. 20004

Via www.regulations.gov
and U.S. First Class Mail

July 21, 2021

The Honorable Janet L. Yellen
Secretary of the Treasury
RIN 1545-BQ10
Department of the Treasury
1500 Pennsylvania Avenue
Washington, DC 20220

The Honorable Martin J. Walsh
Secretary of Labor
RIN 1210-AC07, EBSA/OHPSCA
Department of Labor
200 Constitution Ave. NW, N-5653
Washington, DC 20210

The Honorable Xavier Becerra
Secretary of Health and Human Services
CMS-9905-NC
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Kiran Ahuja
Director
RIN 3206-AO27
Office of Personnel Management
1900 E Street NW
Washington, DC 20415

The Honorable Shalanda D. Young
Acting Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Dear Secretaries Yellen, Walsh, and Becerra, Director Ahuja, and Acting Director Young:

RE: OPM/Treasury/Labor/HHS Notice Titled "Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs," File Code CMS-9905-NC, 86 *Fed. Reg.* 32813 (June 23, 2021)

This letter presents comments of the National Federation of Independent Business (NFIB) in response to the "Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs" published in the *Federal Register* of June 23, 2021. As the Biden White House stated in a fact sheet on February 22, 2021, "[s]mall businesses account for 44 percent of U.S. GDP, create two-thirds of net new jobs, and employ nearly half of America's workers." As your agencies implement the extensive reporting requirements in section 204 in Division BB of the Consolidated Appropriations Act, 2021, please minimize regulatory burdens on small businesses as requested below (see material in boldface type below), so as to leave them with greater freedom to grow their businesses and create jobs.

NFIB is an incorporated nonprofit association representing small and independent business members across America. NFIB protects and advances the ability of Americans to own, operate, and grow their businesses and ensures that governments of the United States and the fifty states hear the voice of small business as they formulate public policies. Small and independent business owners often seek health insurance coverage for themselves and their families and seek to assist or encourage their employees to obtain coverage for themselves and their families.

1. Newly-Enacted Requirements to Report on Pharmacy Benefits and Drug Costs

Section 204 in Division BB of the Consolidated Appropriations Act, 2021 (Public Law 116-260, December 27, 2020) enacted new, substantially similar sections in the Public Health Service Act (PHSA) (sec. 2799A-10), the Employee Retirement Income Security Act (ERISA) (sec. 725), and the Internal Revenue Code (IRC) (sec. 9825) for reporting on pharmacy benefits and drug costs. The new sections require "a group health plan or health insurance issuer offering group or individual health insurance coverage (except for a church plan)" (sec. 2799A-10), "a group health plan (or health insurance coverage offered in connection with such a plan)" (sec. 725), and "a group health plan" (sec. 9825) to report annually to the Secretaries of Health and Human Services, Labor, and the Treasury ten data elements on pharmacy benefits and drug costs.

Under the new legislation, the ten reportable data elements are: (1) the beginning and end dates of the relevant plan year; (2) the number of enrollees, participants, or beneficiaries; (3) each State in which the plan or coverage is offered; (4) the 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each such drug; (5) the 50 most costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug; (6) the 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year; (7) total spending on health care services, broken down by the type of costs, including hospital costs, health care provider and clinical service costs, for primary care and specialty care separately, costs for prescription drugs, and other medical costs, including wellness services, and spending on prescription drugs, both by the health plan or coverage and by the enrollees, participants, and beneficiaries; (8) the average monthly premium paid by employers on behalf of enrollees, participants, and beneficiaries and by enrollees, participants, and beneficiaries; (9) any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, with respect to prescription drugs prescribed to enrollees, participants, or beneficiaries, including the amounts so paid for each therapeutic class of drugs, and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year; and (10) any reduction in premiums and out-of-pocket costs associated with the rebates, fees, or other remuneration.

The provisions of law enacted by section 204 in Division BB of the Consolidated Appropriations Act, 2021, impose a heavy and costly burden of collecting and reporting a broad range of data. In implementing those provisions, your agencies should take special account of the needs of small businesses.

2. Congressional Policy for Agencies to Take Special Account of the Needs of Small Businesses

Congress has established by law a clear policy that federal agencies should consider the special needs of small businesses when the agencies issue regulations. In section 2(a)(4) of the Regulatory Flexibility Act (RFA) (Public Law 96-354, 5 U.S.C. 601 note), Congress declared that "the failure to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace, discouraged innovation and restricted improvements in productivity. . . ." Congress also noted in section 2(a)(6) of the RFA that "the practice of treating all regulated businesses, organizations, and governmental jurisdictions as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems, and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation. . . ." Accordingly, your agencies should take special account of the needs of America's small and independent businesses as they administer the reporting requirements enacted by section 204 in Division BB of the Consolidated Appropriations Act, 2021.

Small businesses cannot afford the lawyers, accountants, and recordkeeping clerks that larger companies use to decipher regulations and implement business systems necessary to comply with detailed reporting requirements of the kind imposed by section 204 in Division BB of the Consolidated Appropriations Act, 2021. Small businesses mostly engage in low-technology, do-it-yourself compliance, in which a business owner trying to keep the business afloat attempts to keep up with recordkeeping and reporting as much as the owner can. Thus, your agencies, in administering section 204, should focus on ways to mitigate the impact of the data collection and reporting requirements of that section on small businesses.

In light of the special needs of small businesses in relation to section 725 of ERISA, section 2799A-10 of the PHSA, and section 9825 of the IRC, NFIB requests actions by the Secretaries of Labor, Health and Human Services, and the Treasury, as set forth below.

3. Minimization of Burden on Small Businesses of Collection and Reporting of Data Required by Section 204 in Division BB of the Consolidated Appropriations Act, 2021

NFIB asks the Secretary of Labor to exempt small businesses (defined as having one hundred or fewer employees) in relation to their welfare benefit plans from section 725 of ERISA, as enacted by section 204 in Division BB of the Consolidated Appropriations Act, 2021, using the exemption authority granted by section 104(a)(3) of ERISA (29 U.S.C. 1024(a)(3)). NFIB also asks the Secretary of Health and Human Services and the Secretary of the Treasury to seek to identify similar statutory exemption authority and exercise it to exempt small businesses (defined

as having 100 or fewer employees) in relation to their welfare benefit plans from sections 2799A-10 of the PHSA and section 9825 of the IRC, respectively. If the Secretary of Health and Human Services or the Secretary of the Treasury, or both, cannot identify statutory authority to make such exemptions for small businesses, then NFIB asks that they seek legislation the President judges necessary and expedient to provide such authority and, until its enactment and exercise, adopt the following regulatory provision to minimize the burden that the statutory data collection and reporting requirements impose on small businesses:

Sec. __.__ Minimization of Collection and Reporting Burden on Small Businesses

(a) *Definition*. For purposes of this section, the term "small business" means any entity that (1) has a duty, for itself, or on behalf of or in relation to a group health plan, a health insurance issuer, an insurance coverage, enrollees, participants, or beneficiaries, to collect and report information under any or all of sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code; and (2) has one hundred or fewer employees.

(b) *Duty of Third-Party Administrator or Health Insurance Issuer.* Any administrator under contract to or otherwise engaged by a small business to administer for that business or its employees a group health plan or health insurance coverage offered in connection with such a plan, or a health insurance issuer for such business or its employees in connection with such a plan, shall perform, on behalf of the small business, the recordkeeping and reporting functions with respect to such plan or coverage required by sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code.

(c) *Good Faith Estimates*. In complying with paragraphs (a)(4), (5), (6), (7), (8), (9), and (10) of sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code, a small business, or an entity or person reporting on its behalf, may report based on estimates made in good faith.

(d) *Willfulness State of Mind*. (1) If any enforcement action occurs for an alleged violation by a small business, or any owner, director, officer, member, manager, or employee thereof, of any or all of sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code, the state of mind required for such violation is willfulness.

(2) In any proceeding to enforce (including by imposition of any administrative, civil, criminal or other penalty) against a small business, or any owner, director, officer, member, manager, or employee thereof, sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code, the burdens of pleading, production

of evidence, and persuasion (including with respect to willfulness) shall rest with the department or agency concerned and the burden of persuasion shall require proof by clear and convincing evidence.

(f) *Assistance with Compliance.* (1) The department or agency concerned shall provide, upon request, assistance to a small business with respect to complying with the collection and reporting requirements of sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code.

(2) The department or agency concerned shall take steps (including furnishing a fillable Portable Document Format (PDF) form on the department or agency website) to permit a small business to file in either electronic or paper format any report under sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code.

(3) Subject to the availability of appropriations, the department or agency concerned shall, upon request and in accordance with a simplified claim procedure, reimburse a small business for its cost of collecting and reporting information in accordance with sections 2799A-10 of the Public Health Service Act, 725 of Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code.

* * * * *

The federal government must recognize that a mandate to report information to the government is not cost-free. When government mandates that businesses report information periodically to the government, the businesses must keep records of the information and report it, both of which cost the business time and money. Small businesses, in particular, face financial and practical difficulties in complying with the ever-growing number of government reporting requirements.

To help America's small businesses survive, grow, and create jobs, the Departments of the Treasury, Labor, and Health and Human Services, and the Offices of Management and Budget and Personnel Management, should, in their regulatory processes, seek to minimize the financial and other burdens imposed by regulations on America's small businesses. With the regulations your agencies issue to implement section 204 in Division BB of the Consolidated Appropriations Act, 2021, please minimize as requested the burden to small businesses of collecting and reporting data on pharmacy benefits and prescription drug costs.

Sincerely,

David S. Addington

David S. Addington
Executive Vice President and General Counsel

DirectPath®
To Reduce Health Care Costs

January 11, 2022

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-9905-IFC
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-9905-IFC, Prescription Drug and Healthcare Spending

To Whom It May Concern:

We appreciate the opportunity to submit comments on the Interim Final Rule related to Prescription Drug and Healthcare Spending Transparency under the Consolidated Appropriations Act, 2021, as published in the Federal Register on November 23, 2021.

For sixteen years, DirectPath, a CNO Financial Group company, has been an industry leader in employer-sponsored benefits plan management, advocacy, compliance, and communications, with a particular focus on helping employees—and their employers—make informed decisions to save money on healthcare costs. Based on this experience, we have met with the members of the Department of Labor, Treasury, and CMS in the past to offer recommendations and input on compliance communications materials and electronic distribution requirements (these have reflected our clients' concerns and feedback, as well), and we are pleased again to offer our insights.

Background

Section 9825(a)(7) of the Code, section 725(a)(7) of ERISA, and section 2799A-10(a)(7) of the PHS Act require plans and issuers to report the total annual spending on healthcare services, broken down by the types of cost, including: (1) hospital costs; (2) healthcare provider and clinical service costs, for primary care and specialty care separately; (3) costs for prescription drugs; and (4) other medical costs, including wellness services. For prescription drug spending, plans and issuers must report separately the costs incurred by the plan or coverage and the costs incurred by participants, beneficiaries, and enrollees, as applicable.

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Understanding that most plan sponsors and employers will not have access to this information, the Agencies have stated that the plan's third-party administrator (TPA) may provide such data. Further, TPAs may aggregate such data for all plans for which they serve as administrator.

And while aggregated data may be useful to track larger trends over time, it will do little to help manage costs in the here and now.

More focus is needed to encourage plan sponsors to track and share this data with plan participants in a way that clearly demonstrates how thoughtful decisions about when and where to receive care can help them manage their out-of-pocket spending without compromising the quality of their health and health care. As such, we recommend that the final regulations be amended to require TPAs to share plan-specific data with plan sponsors (or designated representatives such as a broker or consultant) and require plan sponsors, in turn, to report relevant information in a meaningful way with their plan members—much as they will be doing under the upcoming Transparency in Coverage rules.

Cost Transparency

As noted above, we are concerned that the aggregated data reported to the Agencies will do little, if anything, in the short- or long-term to reduce healthcare cost trends unless and until disaggregated data is shared first with the applicable plans, and then with plan participants.

As the health insurance industry is currently structured, even self-insured plans are typically unaware of the specific discounts carriers have negotiated on their behalf with local providers—or how those discounts differ from similarly situated carriers and/or plan sponsors in their area. This makes it difficult, if not impossible, for them to exert pressure on either providers or the carriers themselves to reduce costs.

As a result, many employers have pushed some or all responsibility for managing costs onto plan participants through high deductible health plans. Theoretically, when individuals are forced to pay for more of the cost for goods and services upfront, they will shop for the best price.

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Unfortunately, it is well established that most individuals are not aware that they can, and should, shop for health care. Nor were they ever shown precisely how to do so. So rather than shopping for care, too many consumers avoid or postpone care due to fear of high costs. As a recent issue of Managed Healthcare Executive[1] notes, citing a study by the Commonwealth Fund, "Turning Americans into value-seeking, price-watching shoppers for healthcare remains an unfinished, patchy project at best. Success…will require integrating price data, quality information, and financial incentives so people can look for and select lower-cost, higher-quality providers and care."

As you are well aware, the same product or service cost can vary dramatically within the same network and zip code and even from provider to provider within that network zip code. Until consumers understand this fact—which won't happen until they can see the costs of such care before receiving it—we will not begin to see behavior change that will drive cost reduction. But merely making this information available will not have the desired impact. Consumers must be educated on:

- The fact that costs for health care services depend on what the provider chooses to charge, the discount negotiated by the applicable insurance company, the cost-sharing provisions of the plan's coverage (if applicable), and the individual's cost-sharing status under that plan.
- How to easily obtain cost information from multiple providers and compare costs in a meaningful way.
- WHY they should do such a comparison, rather than merely taking their doctor's recommendation.
- How their decisions will affect their out-of-pocket costs, and how to weigh the information they obtain to make the right decision for them.

Understanding the Drivers of Healthcare Costs

It is critical for employers, plan sponsors and administrators, and the public to understand the drivers of increasing health care costs to make better decisions about the plans they offer, choose and use. But there is much work to be done to dispel myths and misunderstandings about what, exactly, is driving rising healthcare costs, so we know where to focus our attention.

1 https://www.managedhealthcareexecutive.com/view/how-to-make-americans-better-shoppers-of-healthcare

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For example, a 2019 consumer opinion study[2] found that the public believes that prescription drugs and hospital fees are far away from the most significant contributors to rising health care costs (62 percent and 48 percent, respectively), with physician fees, social determinants (inadequate access to healthy food and safe housing and/or exposure to violence) and chronic conditions effectively tied for a distant third (18 percent, 18 percent, and 17 percent).

Yet, while CMS' research[3] on actual 2020 health care spending shows the same top three areas of concern, there is clearly a disconnect between public perception of cost drivers and reality:

- Hospital care (31%)
- Physician services (20%)
- Prescription drugs (8%)
- Other personal healthcare costs (5%)

In both cases, the top three drivers—hospital care, prescription drugs, and physician services--are costs that can and should be "shopped" for. But it may be that consumers are focusing on the wrong "bucket" of expenses—prescription drugs—when they ought to be focused on their inpatient care. After all, the relative impact on the average consumer of a hospital stay versus annual prescription drug costs is substantial, as is the risk for costly billing errors (according to Becker's Hospital Review, 80% of medical bills include errors)[4].

Will Data Drive Results?

While the Agencies' efforts to track the drivers of health care costs with the idea of managing such costs in the future is laudable, we feel that reporting two years after receiving data that is already months, if not years, out of date will not be particularly helpful. Data will be quickly outdated as workforce demographics shift, new and different health trends develop (e.g., a new pandemic), and new drugs and treatments enter the market (with accompanying high costs). And most employers/plan sponsors adjust their plan designs annually, based on claims experience and utilization over the past 12 months.

[2] https://www.statista.com/statistics/751013/patients-opinion-healthcare-cost-drivers-in-us/
[3] https://www.cms.gov/files/document/highlights.pdf
[4] https://etactics.com/blog/medical-billing-error-statistics

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Until and unless plan sponsors can see real-time plan utilization and short-term trends, they will be unable to exert market pressure on the carriers and providers offering services to their participants. And until plan sponsors are held accountable for the ability of their participants to act as true health care consumers, we will not see the behavior change needed to truly drive cost reductions. Data is just one small part of the solution—acting on that data on a timely basis is what will truly drive change.

Thank you for considering our feedback and recommendations on the interim final regulation. If you have any questions or would like additional information, please feel free to contact me at 781.996.5594 or kbuckey@directpathhealth.com.

Sincerely,

Kim A. Buckey
Vice President, Client Services
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NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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January 20, 2022

Re: CMS-9905-IFC ("Prescription Drug and Health Care Spending")

Filed electronically via regulations.gov

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of provider-administered medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in safe, more efficient, and cost-effective alternatives to hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost setting.

NICA thanks the Departments of Health and Human Services, Labor, and Treasury ("the Departments") and the Office of Personnel Management (OPM) for the opportunity to provide feedback on implementation of section 204 of the *Consolidated Appropriations Act, 2021* ("CAA section 204"). Over the summer, NICA took advantage of the Departments' and OPM's Request for Information (RFI) on this topic; we remain thankful for the Departments' and OPM's willingness to consider public input on this complex subject. To that end, we hope that the following feedback on the above-referenced interim final rules with request for comments (IFC) is helpful as you implement CAA section 204. As with our RFI response, we have limited our feedback to only those issues NICA is well-positioned to answer.

DEFINITIONS

Rebates, fees, and other remuneration

In its RFI response, NICA urged the Departments and OPM to include all fees and payments in the definition of "rebates, fees, and any other remuneration," because the statute's expansive language ("***any*** other") indicates that Congress intended for this transparency provision to have the broadest possible reach. Additionally, full disclosure without exemptions is the only way to avoid definitional gaming by the regulated entities. **We thank the Departments and OPM for taking this expansive approach in the IFC's definition of "rebates, fees, and any other remuneration."** More specifically, the definition will include all remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing PBM services to the plan or issuer, regardless of the source of the remuneration. Furthermore, the IFC provides a detailed but non-exhaustive list of examples of remuneration that would qualify: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. **We strongly support such a broad definition of rebates, fees, and other remuneration and believe this will provide the Departments**

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and OPM with wide-ranging transparency into pharmaceutical pricing, which is precisely what CAA section 204 was intended to accomplish.

In its RFI response, NICA also urged the inclusion of *bona fide* service fees in the definition of "rebates, fees, and any other remuneration." The IFC takes this approach and includes such fees in its definition, but will require reporting of these fees at the aggregate level (rather than at the level of therapeutic class or drug). While we understand that contractual realities may render it impossible to "prorate" service fees or "assign" them to particular drugs or therapeutic classes, **we urge the Departments and OPM to consider creating more granular reporting of *bona fide* service fees in future rulemaking**. One possible way to accomplish this is to require more detailed disclosure of service fees that are tied to a particular therapeutic class or a specific drug, if a contract entered into by a regulated entity creates such a linkage. That would require no additional tracking by the regulated entity beyond what it already tracks for purpose of meeting its contractual obligations; it would also enable the Departments and OPM to determine whether *bona fide* service fees are disproportionately high for certain therapeutic classes or drugs.

Finally, the IFC took the view that cost-sharing assistance should not be included in the definition of "remuneration" because these amounts are not credited to the plan. However, these amounts will be included in the definition of "total annual spending" so that the Departments and OPM can gain visibility into the extent to which these amounts impact total annual spending by health plans or by beneficiaries. **As CAA section 204 is further implemented, we urge the Departments and OPM to consider ways to increase transparency into this opaque area. Specifically, payers increasingly use so-called "copay maximizers" or "accumulators" that prohibit cost-sharing assistance from accruing towards meeting annual deductibles, which can create serious financial burdens on patients with chronic illnesses. Increasing transparency into this practice and its effect on adherence would be helpful to explore in future rulemaking**.

Therapeutic class

The IFC defines "therapeutic class" as a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, to be grouped in the manner specified by the Departments in guidance. Importantly, **the Departments will require all plans and issuers to use the same classification system. NICA strongly supports this uniformity in approach**. As we noted in our RFI response, the fact that there is no commonly agreed upon definition of "therapeutic class" is harmful to patients because it enables insurers and PBMs to define the term in the most contractually advantageous way, regardless of clinical implications. The Departments and OPM note that further guidance may be promulgated on this topic, so **we urge the Departments and OPM to work with the Food and Drug Administration and other stakeholders such as patient and provider groups, to solicit comprehensive stakeholder input in any further definition of therapeutic class.**

Reporting Entity

The IFC broadly defines a reporting entity as one that submits some or all of the information required under the IFC, to include entities who submit the information on behalf of plans and issuers. The IFC notes that the data collection system will allow multiple reporting entities to submit different subsets of the required information, which we strongly support. As we previously stated, allowing insurers to provide limited data based on the fact that the PBMs (many of which are now owned by insurers) are different legal entities will further distort the already disproportionate balance of power over information in this over-consolidated market. **We support the Departments' and OPM's plan to design a data collection system that reflects this fact**.

REQUIRED DATA

Medical Benefit versus Pharmacy Benefit

Although many other commenters urged the Departments to exclude prescription drugs covered under the medical (versus pharmacy) benefit from the section 204 data submissions, the statute does not include such an exemption. Thus, the IFC requires reporting of the total annual spending on prescription drugs administered in a hospital, clinic, provider's office, or other provider setting and covered under the hospital or medical benefit separately from the total annual spending on drugs covered under the pharmacy benefit. However, at this time, plans and issuers will be required to report only the total annual spending for drugs covered under the hospital or medical benefit. The Departments note they may modify this approach in the future.

In our RFI response, NICA urged the Departments and OPM to require reporting of medical benefit drug data and to ensure that these data can be tracked by site of care, because a significant body of research now indicates that site of care is a key driver of differentials in medical benefit drug spending. For example, the Employee Benefit Research Institute (EBRI) studied cost differences in healthcare services by site of treatment, including for the delivery of non-oncology specialty medications and found that, "if site-of-treatment price differentials for specialty medications were eliminated, employers and workers would save as much as 36 percent, depending on the medication."[1] For some of the drugs studied, the hospital outpatient department charges were *more than double* those of office-based administration. UnitedHealth recently studied this issue and arrived at the same conclusion, finding that administering specialty medications outside of the hospital outpatient department could save $4 billion per year.

In light of these data, the proportion of medical benefit drug spend on hospital outpatient-based administration versus office-based administration (e.g., doctor's offices and freestanding infusion centers) is a critical data point for employers and policymakers seeking to reduce medical benefit drug spending

[1] EBRI Issue Brief No. 525: "Location, Location, Location: Cost Differences in Health Care Services by Site of Treatment — A Closer Look at Lab, Imaging, and Specialty Medications" by Paul Fronstin, Ph.D., Employee Benefit Research Institute, and M. Christopher Roebuck, Ph.D., RxEconomics, LLC (Feb. 18, 2021).

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without reducing patient access. **Therefore, we support the IFC's requirement for separate reporting of medical benefit drug data, but we also urge the Departments and OPM to require in future rulemaking that medical benefit drug spending data be reported by site of delivery**.

Pass-Through of Rebates, Fees, and Other Remuneration

The IFC requires reporting of total rebates, fees, and other remuneration passed through to the plan or issuer, passed through to beneficiaries, and retained by the PBM. Additionally, the IFC requires reporting of the difference between total amounts that the plan pays the PBM and total amounts that the PBM pays pharmacies. **We strongly support this requirement, particularly in combination with the Departments' and OPM's broad definition of "rebates, fees, and other remuneration," but urge the Departments and OPM to require these data at the therapeutic class level rather than the aggregate level. Additionally, we urge the Departments to, with respect to the amounts passed through to beneficiaries and enrollees, require reporting of the amounts passed through in the form of reduced premiums versus the amounts passed through in the form of reduced cost-sharing (i.e., coinsurances, copays, deductibles)**. This can help the Departments, OPM, employers, policymakers, and researchers gain insight into the extent to which rebates and discounts on high-priced drugs for sick beneficiaries are used to hold down premiums for all beneficiaries. In other words, these data would help quantify the extent to which the sick are subsidizing the healthy, which is one of the key underlying distortions in our current market.

I hope this feedback is helpful as you move forward with implementation of CAA section 204. If you have any questions or if I can provide any additional information, please do not hesitate to contact me.

Sincerely,

Brian Nyquist, MPH
Chief Executive Officer
National Infusion Center Association

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9905-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Filed electronically via regulations.gov

January 21, 2022

To Whom It May Concern:

The Alliance for Transparent and Affordable Prescriptions Action Network (ATAP-AN) is a coalition of patient and provider groups who are committed to reforming the role pharmacy benefit managers (PBMs) play in drug pricing and patient access. ATAP-AN thanks the Office of Personnel Management (OPM) and the Departments of Treasury, Labor, and Health and Human Services ("Departments") for their deliberative approach to implementation of section 204 of the Consolidated Appropriations Act, 2021 ("section 204"), which creates new disclosure requirements for group health plans and issuers offering group or individual coverage. We provided comments on OPM's and the Departments' request for information (RFI) last year on section 204 and we were thankful to see much of our feedback reflected in the interim final rules with request for comments (IFC) entitled "Prescription Drug and Health Care Spending" (CMS-9905-IFC). We hope that our comments on the IFC contained herein will be helpful as the Departments and OPM continue implementation of section 204.

Section 204 used broad language to describe the types of remuneration subject to disclosure. In the past, when Congress intended to exempt certain categories of remuneration from disclosure by payers or PBMs, it expressly said so. For example, in 2010, the Affordable Care Act created the "PBM Transparency for Qualified Health Plans" disclosure requirements in section 6005 and explicitly excluded certain types of remuneration (such as *bona fide* service fees) from disclosure. In CAA section 204, Congress created no such exemption. Instead, the final legislation uses the broad phrase "and ***any other*** remuneration." (Emphasis added.)

The IFC reflects this broad statutory language in its definition of "rebates, fees, and other remuneration," by including all remuneration received by or on behalf of a plan or issuer, its

administrator or service provider. This will include remuneration received by and on behalf of entities providing PBM services to the plan or issuer, regardless of the source of the remuneration. **ATAP-AN strongly supports this approach, because the statutory language makes clear that full disclosure was the goal of Congress**. Additionally, a broad definition without exemptions provides the only way to ensure that insurers and PBMs will not stretch the definitions of any exempted category of remuneration so as to render disclosure meaningless.

While *bona fide* service fees will be subject to disclosure, the IFC proposes to require disclosure of such fees only at the aggregate/total level. Upon receipt of the first data set, **we urge the Departments and OPM to consider requiring additional granularity in service fee disclosure**, particularly if the *bona fide* service fee totals are large relative to other disclosures. More detailed disclosures of service fees can help uncover whether certain therapeutic classes or specific drugs are tied to larger service fees, which may indicate that the "service fees" are in fact price concessions.

As we noted in our RFI response, with regard to copay assistance, coupons, and copay accumulators, it would be useful to understand how much of the value of copay assistance and coupons is captured directly by the patient in the form of reduced out-of-pocket costs. We suggested that one way to accomplish this would be to have insurers disclose the total annual dollar amount of copay assistance and coupons used by patients per therapeutic class and the total annual dollar amount captured by copay accumulators per therapeutic class. **While we were thankful that the IFC requires that cost-sharing assistance amounts be included in "total annual spending," we reiterate the need to disclose cost-sharing assistance by therapeutic class**. **Additionally, in the case of accumulator programs that prohibit the application of the value of copay assistance to a patient's deductible, insurers should disclose where that value is applied, if anywhere.**

The IFC provides a high-level definition of "therapeutic class" as a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, but plan to provide further detail in guidance. As we have previously noted, the lack of consistency in the definitions of key contractual terms (such as "therapeutic class") is a critical challenge in creating more transparency and consistency across the PBM industry. Even within Medicare Part D, insurers use their own existing classification systems, such as the U.S. Pharmacopeia and the American Hospital Formulary Service, or they simply create their own, subject to approval by the Centers for Medicare and Medicaid Services. This lack of standardization even in the largest federal drug benefit allows insurers to vary their classification systems year to year or among the different insurance products they offer, which leaves even the most proactive and informed healthcare consumers unable to find accurate and consistent information about whether the drugs they require are covered in any given plan year. Therefore, in our RFI response, **we urged the adoption of a single, publicly accessible classification system for purposes of the section 204 disclosure requirements. Although the IFC does not identify an existing classification system, we strongly support the Departments' and OPM's clear**

statement that every reporting entity will use the same definition and classification for "therapeutic class." This is a modest first step towards creating consistency and transparency in prescription drug benefits.

ATAP-AN also supports the IFC's broad view of "reporting entities" and the Departments' and OPM's plan to create a system for data collection that will allow for multiple reporting entities to submit different subsets of the required disclosures. As we previously noted, it is likely that some of the insurers subject to section 204 will not be able to comply with the new disclosure requirements without their PBMs, but this should not serve as a barrier or excuse to avoid full compliance. **We urge the Departments and OPM to ensure that any and all insurer and PBM subsidiaries, whether organized in the U.S. or abroad, disclose the data to which the Departments and OPM are entitled pursuant to section 204**. Funneling price concessions to offshore entities should not serve as a foil to avoid disclosure.

Section 204 requires disclosure of prescription drug rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers. The statute requires these amounts to be reported for each therapeutic class and for each of the twenty-five drugs that yielded the highest amount of remuneration during the plan year. The IFC will require reporting of total remuneration with respect to amounts passed through to the plan or issuer, amounts passed through to beneficiaries, and amounts retained by the PBM. We strongly support this approach, as it will begin to create some transparency into how this remuneration is applied by the plans. Additionally, the IFC requires plans and issuers to report the impact of remuneration from drug manufacturers on premiums and out-of-pocket costs. **With regard to the amounts passed through to beneficiaries, we urge the Departments to create a data collection system that will require reporting entities to quantify the proportion of drug company remuneration passed through to beneficiaries used to lower cost-sharing (i.e., coinsurances and copays) on medications versus that used to lower premiums across the plan**.

Finally, we support the IFC's requirement for disclosure of the difference between total amounts that the plan pays the PBM and total amounts that the PBM pays pharmacies. So-called "spread pricing" has been a topic of much media coverage in recent years and both federal and state policymakers have attempted to address this issue. Disclosure of the "spread," even at the aggregate level, will indicate whether additional reforms are needed.

Thank you for your consideration of these comments. Please do not hesitate to contact me, should you require additional information.

Sincerely,

Dr. Michael Schweitz
President
Alliance for Transparent and Affordable Prescriptions Action Network

HIV+HEP
POLICY INSTITUTE

January 21, 2022

Christina Whitefield
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9905-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Comments on Drug Pricing Transparency Interim Final Rule [CMS-9905-IFC]

Dear Ms. Whitefield:

The **HIV+Hepatitis Policy Institute,** a national, non-profit organization whose mission is to promote quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, is pleased to submit comments on the Interim Final Rule regarding **Transparency in Prescription Drug and Health Care Spending.**

The patients we represent rely on prescription drugs to treat their health conditions and prevent others. We are pleased that the Biden administration is moving forward with the requirement that insurance plans must report on various data points associated with prescription drug spending. We believe with this greater understanding and transparency of prescription drug costs, you can better implement policies and measures that increase competition, improve prescription drug affordability and access for the American people.

Patients today face significant prescription drug affordability challenges that have only grown worse due to the cost of medications along with insurance benefit design, including high deductibles and high patient cost-sharing often in the form of co-insurance. This negatively impacts patient adherence and leads to worse health outcomes and increased costs across the healthcare system.

As you implement the prescription drug cost reporting requirements for health plans, we offer the following comments:

1. **Require Plans to be Transparent on the Treatment of Copay Assistance.** Many health plans are instituting policies that do not count drug manufacturer copay assistance towards a patient's annual deductible or out-of-pocket maximum. In doing so, issuers are collecting the value of the assistance, which often exceeds the out-of-pocket maximum, and then, after it runs out, collecting additional payments by the patient until the out-of-pocket maximum is reached again. In another scheme, plans designate certain medicines as "non-essential" and then raise the cost-sharing to ensure that they collect all of the patient assistance offered by the manufacturer. Under this scheme, the plans often collect payments far exceeding the out-of-pocket maximum. While we continue to urge you to prohibit both of these practices, in the

meantime, these double and excess payments to the insurer must be made public and considered a violation of the Affordable Care Act (ACA) out-of-pocket limit.

We are pleased that when issuers and PBMs collect copay assistance that reduces their spending, you will require those amounts to be collected separately. We look forward to those reports and analysis.

2. **Cost-sharing Assistance from Manufacturers Not Included in Definition of Rebates:** We agree with the departments that drug manufacturer cost-sharing assistance to beneficiaries should not be included in the definition of prescription drug rebates because, as you correctly state, "these amounts are not credited to the plan or coverage or its administrators or service providers."

3. **Accounting of Rebates and Pharmacy Benefit Managers.** We are very pleased that you are moving forward with the data collection on the amount of rebates, fees, and other remuneration paid by drug manufacturers to the plan and how these rebates reduce premiums and out-of-pocket costs for patients. While there has been some delay in its implementation, we strongly urge you to move forward with this requirement without any further delays.

   The high level of rebates influences the list price of drugs. Since more and more health plans carry high deductibles and utilize co-insurance to determine patient cost-sharing, patients are unfairly being overly burdened with higher out-of-pocket costs. Additionally, while the portion of rebates plans receive may be benefiting all enrollees by reducing premiums, those who rely on prescription drugs and are responsible for generating those rebates for the plans are not directly benefiting. We hope the collection of rebate information will create greater drug price transparency and help establish a system in which patients who rely on prescription drugs can directly benefit from the rebates that they generate. Enrollees benefit from negotiated discounts for all other medical services. It is time that patients benefit from prescription drug discounts.

   We realize that the amount of rebates, fees, and other remuneration is often cloaked in secrecy by pharmacy benefit managers (PBMs), insurers, and drug manufacturers and affected parties are concerned with disclosure of competitive practices; however, we believe you have devised a way to overcome these obstacles by requiring the reporting at more of an issuer and drug class level. PBMs, which are frequently not regulated at the state level, have successfully and artfully tried to escape any attempt to report on how the billions in rebates and other fees they collect are distributed to plans, patients, or to their profits. To further add to the complexity, the three largest PBMs, which now account for over 75 percent of all drug claims, are either owned by or own an insurance company. We are pleased that you have resisted their attempts to limit transparency and move forward with these statutory required data reporting without further delay.

We thank you for the opportunity to share these comments and look forward to working with you and each of the other agencies implementing the prescription drug data reporting system.

If you have any questions or comments, please contact me at cschmid@hivhep.org.

Sincerely,

Carl E. Schmid II
Executive Director

CSRO
Coalition of State Rheumatology Organizations

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January 21, 2022

Filed electronically via regulations.gov

RE: *Prescription Drug and Health Care Spending* (CMS-9905-IFC)

To Whom It May Concern:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist. CSRO thanks the Departments of Health and Human Services, Labor, and Treasury and the Office of Personnel Management ("the Departments and OPM") for the opportunity to provide feedback on implementation of section 204 of the *Consolidated Appropriations Act, 2021* ("section 204"), following the Request for Information (RFI) last year.

Our drug supply chain is opaque and complex, two characteristics that work to the benefit of those resistant to reform. As practicing rheumatologists, we experience firsthand the consequences that high out-of-pocket costs have on medication adherence and, thus, our patients' quality of life. The drugs available to treat rheumatoid arthritis and other autoimmune diseases are often heavily rebated, yet still prohibitively expensive for patients. This tells us that the current system is broken. The Interim Final Rules with request for comments (IFC) take a wide-reaching and thorough approach to the implementation of the transparency provisions created by Congress, which we support. We offer the following feedback as additional areas for improvement.

Definitions

One of the key challenges facing the Departments and OPM is to define statutory terms in a way that prevents gaming by the entities subject to the new disclosure requirements. The IFC takes a broad approach to achieve this goal. For example, the IFC defines "rebates, fees, and any other remuneration" to include **all** remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing pharmacy benefit manager (PBM) services to the plan or issuer, regardless of the source of the remuneration. The IFC provides a detailed (though not an exhaustive) list of examples that would meet this definition. *CSRO thanks the Departments and OPM for this broad definition of "rebates, fees, and any other remuneration," because it will hopefully minimize the ability for regulated entities to reclassify certain revenue streams to avoid disclosure*.

With regard to *bona fide* service fees, as we noted in our response to the RFI, the statute included no limitation on or exemptions to what must be disclosed. The Congress is aware that *bona fide* service fees are a routine feature of contracts between insurers, PBMs, and drug companies, but chose not to exclude these or any other fees from section 204's disclosure requirement, despite having done so in previous similar legislative provisions (e.g., Affordable Care Act section 6005). Since no such exclusion appears in the language of section 204, we urged the Departments and OPM not to create a regulatory exemption where Congress did not want one. *Thus, we strongly support the IFC's inclusion of bona fide service fees in the definition of remuneration. However, we urge the Departments and OPM to consider requiring granular reporting of bona fide fees in future rulemaking, rather than only aggregate level reporting as the IFC will initially require.* If a contract ties service fees to a particular therapeutic class or even a specific drug, that should be disclosed to ensure that the transparency goals of section 204 are met. Furthermore, if a regulated entity is already tracking bona fide service fees in this way per its contracts, then a disclosure requirement would create no new or additional administrative burden.

With regard to therapeutic class, the IFC defines this as a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions. The Departments and OPM will provide further detail in guidance. As we noted in our RFI response, *the most important aspect of the definition of "therapeutic class" is to ensure that all reporting entities use the same classification system.* To provide just one example, etanercept is classified in three different ways by three different PBMs in Part D formularies. Allowing each reporting entity to define therapeutic class for itself would have left the Departments and OPM with inconsistent data sets. *Thus, we are thankful that the IFC takes this position and will require uniformity in therapeutic classification among reporting entities*.

Reporting Entities

In the RFI, the Departments and OPM asked whether insurers should be allowed to rely on PBMs to provide the required data. Several stakeholders, including CSRO, noted that the PBMs would be a necessary entity in the disclosure required by section 204. *We support the IFC's broad view of reporting entities, as well as the Departments' and OPM's plan to build a data collection system that will allow for submission of data subsets by multiple reporting entities*. Reporting entities must work with all of their contractual partners to obtain the required data, including data from PBMs and any of their subsidiary entities, whether organized under United States law or the laws of any foreign jurisdiction. As we noted in our RFI response, one of the newest challenges is that some of the large PBMs have organized group purchasing organizations in Switzerland, which may enable them to partially avoid the reach of U.S. legislation or regulation. We urge the Departments and OPM to keep in mind this scenario as they continue to implement section 204.

Quantifying the Amounts of Remuneration Pass-Through

The IFC requires reporting of total rebates, fees, and other remuneration and the total amount passed through to the plan or issuer, the total passed through to beneficiaries, and the total retained by the PBM. We support this attempt to quantify the flow of remuneration, but urge the Departments to consider the problem of the offshore "rebate aggregators" or group purchasing organizations mentioned above as it receives the first data sets. We believe that the IFC's broad definition of remuneration would include any

remuneration sent to offshore entities, but we urge the Departments and OPM to ensure that this is the case. Additionally, with regard to the amount of remuneration passed through to beneficiaries, *we ask that the Departments and OPM consider requiring two subsets of data here: the amount of remuneration passed through to beneficiaries in the form of reduced premiums and the amount of remuneration passed through to beneficiaries in the form of reduced cost-sharing on medications*. Certain medications are highly rebated, so one key point of interest is to determine whether the rebates and other remuneration on those medications find their way to the patients who actually need these medications, rather than being diverted to other causes, such as profits.

Medical Benefit Drugs

As we noted previously, with regard to medications administered by a healthcare professional, we strongly support collecting drug spending information based on setting. Data indicates that medical benefit drug administration can be twice as expensive in a hospital outpatient department, as compared to a physician's office. This is likely because outpatient departments charge facility fees and have a higher cost basis on which to request reimbursement. Drug spending differentiated by site of care would be useful information as healthcare purchasers such as employers consider site neutrality policies for medical benefit drug administration. *While we support the IFC's requirement for disclosure of total annual spending on medical benefit drugs, we reiterate our request to require disclosure of spending on medical benefit drugs based on the setting: home, physician's office, or hospital outpatient department*.

In closing, thank you again for the opportunity to provide our feedback. We are always available as a resource to you, so please don't hesitate to contact us if you have follow-up questions or if we can provide any additional information.

Sincerely,

Madelaine A. Feldman, MD
President
Coalition of State Rheumatology Organizations

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January 21, 2022

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

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

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

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

Submitted via the Federal Rulemaking Web Portal: http://www.regulations.gov.

Re: Interim Final Rules with Request for Comments Regarding Prescription Drug and Health Care Spending

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

I write on behalf of AHIP to offer comments in response to the interim final rules with request for comments (IFC) from the Office of Personnel Management (OPM), as well as the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (collectively, the Departments) on Prescription Drug and Health Care Spending, published November 23, 2021 in the Federal Register.[1]

AHIP supports the Administration's and Congress' goal to understand how high-cost prescription drugs are increasing health coverage premiums and to identify which drugs are the primary drivers of increased costs for patients and plans. Prescription drugs play an important role in our health care system by treating disease and helping patients heal. In recent years, drug manufacturers have routinely pushed through dramatic price increases for their life-saving products and have set high prices for new drugs. These initial high prices and subsequent increases place severe burdens on patients that drive up costs for employers and consumers through higher premiums and out-of-pocket costs.

We appreciate your strong steps based on our feedback on the Request for Information to minimize the administrative burden for plans and issuers of this data reporting.[2] Allowing

[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

[2] 86 FR 32813, AHIP comments are available at: https://www.regulations.gov/comment/EBSA-2021-0005-0015

reporting entities to aggregate data at the state and market level will reduce plans' reporting burdens and will improve the Administration's ability to identify the drugs that are increasing patients' monthly premiums. Aligning definitions and data fields in this reporting with definititons and data fields in other required reports (such as reporting for determining plans' medical loss ratios) will both reduce confusion and expedite the data collection and submission. Additionally, establishing that reporting will done by calendar year and clarifying delegation and responsibility for reporting are helpful and appreciated.

While the IFC makes tremendous progress in minimizing reporting burdens, more can be achieved. **AHIP urges the Departments to include a safe harbor for good faith compliance, particularly for the first two rounds of data submission (for the 2020, 2021, and 2022 reference years), as the requirements were unknown to plans and employers when those contracts were signed.** According to our members, some of them no longer have business relationships with employers for whom they previously provided administrative services, or the employers may no longer be in business.

Regarding the applicability to Federal Employee Health Benefit Plans (FEHB), AHIP remains concerned about OPM's extension of the reporting requirements to FEHB carriers. Given the complexity of implementing the requirements, **AHIP recommends that OPM pause extension of the requirements to FEHB plans until the Departments have fully implemented the statute, finalized technical specifications, and addressed outstanding stakeholder concerns.** Further, OPM should consider issuing a Carrier Letter in lieu of the current joint regulatory approach.

Finally, further clarification is needed to improve plans' ability to report accurate information to the Departments. **AHIP encourages the Department to hold a series of technical assistance calls with reporting entities, particularly once the rules and technical specifications are finalized, to answer questions and provide support.** While the reporting system will be familiar to many reporting entities, others will be registering for and using it for the first time. Significant education and technical assistance will be necessary for reporting entities to submit properrly formatted and accurate reports in a timely manner.

We have attached detailed comments in the attachment. We welcome the opportunity to discuss these issues as the Departments and OPM continue their work.

Sincerely,

Jeanette Thornton
Senior Vice President, Product, Employer, and Commercial Policy

Attachment
AHIP Detailed Comments

I. Comments on the Interim Final Rules with Request for Comments

Enforcement Delay & Safe Harbor

AHIP appreciates the Department's one-year enforcement delay to December 27, 2022. However, our members continue to have concerns that the lack of detail in the file layouts and inability to access the data needed to comply with the reporting requirements will make it difficult to satisfy their reporting obligations. AHIP urges the Departments to finalize the reporting instructions and technical specifications as soon as possible. In our previous comments, we recommended that reporting entities have at least one year after the technical specifications are finalized. Further delays reduce our members' ability to report completed and valid data.

As AHIP noted previously, some of the required data elements may not be available to or obtainable by plans or issuers. This is particularly true of information that will be included in the reports for the 2020, 2021, and 2022 reference years. Our members have shared with us that they no longer have business relationships with certain employers or vendors with whom they contracted for the 2020 reference year. In fact, some of those employers and vendors have gone out of business in the intervening period, making data collection impossible. Another consideration is that, in order to complete the D5 data file for the Top 50 Drugs by Spending Increase, plans require drug data for each of the required fields from the 2019 reference year, the administration of which may have been handled by a different pharmacy benefit manager (PBM). As the business contracts and agreements that governed these relationships were in effect before passage of the No Surprises Act (NSA), they likely do not include provisions related to sharing or reporting the data as required. Therefore, AHIP urges the Departments to include a safe harbor for good faith compliance when the data cannot be obtained, particularly for the 2020, 2021, and 2022 reference years. AHIP further requests the Departments provide clear instructions to reporting entities on how to proceed if certain data is not obtainable.

Applicability to FEHB Plans

Our comments and recommendations on the proposed reporting requirements described in detail in other sections of our response also apply to our members' FEHB line of business.

Although Congress did not apply the NSA's Section 204 reporting requirements to FEHB plan carriers, OPM has applied these requirements to carriers participating in the FEHB program through its general statutory authority. We continue to recommend that issues and concerns raised in our letter by our members, by AFHO, and by other stakeholders be fully addressed, and that the reporting requirements and specifications be finalized prior to consideration of extending the reporting requirements to FEHB carriers.

Given that the NSA did not compel OPM to extend the reporting requirements to FEHB carriers, we also recommend that OPM issue a Carrier Letter in lieu of the joint regulatory approach. Issuing a Carrier Letter similar to Carrier Letter No. 2020-17 would provide OPM with more discretionary authority and flexibility to make additional changes to the requirements to address operational and other issues raised by FEHB plan carriers.

Reporting Premiums

AHIP urges the Departments to reconsider the requirement that plans and issuers report data they do not have – specifically, the division of the monthly premium amount paid by the employer and employee. Our members have examined and re-examined their data, and the information for the premiums paid by employers and employees is not available. AHIP requests the Departments rescind this requirement or consider reasonable alternatives, such as allowing plans to report only the information that is available for reference years 2020, 2021, 2022 or to estimate the division of premiums and explain the methodology behind the reasoning in the Narrative Response file.

As the Departments note, plans collect total premium dollars directly from employers with fully insured coverage or may calculate the premium equivalent for self-funded plans. However, plans do not have a way to separate the amount contributed by employees nor the information to derive it. While some plans may have access to an employer's contribution schedules, these are often complex and do not include the information necessary to apply the employer's contribution rules. For example, an employer may have different contribution requirements for certain cohorts of employees, but plans have no way to know which employees fall into the various cohorts. When it is obtained, such information is typically available only on paper and not in a form or format that is maintained electronically or reportable. This type of intake and storage capability will have to be built in order to create a reportable repository of the information.

Additionally, our members expressed concern about obtaining and reporting this information for the 2020, 2021, and 2022 reference years in instances where an employer group no longer uses the services of the plan or issuer, as a contractual relationship no longer exists between the entities. For those reference years, AHIP recommends the Departments allow reporting entities to report only the total premium amount.

Data Submission Date

The June 1 deadline for submitting the required data is too soon after the end of the reference year. Pharmacy claims are often not completed this quickly, and the quality of the data will be lower. We appreciate the Departments' efforts to evaluate the reliability of the estimates and trends by collecting restated amounts for prescription drug rebates, fees, and other remuneration for the preceding reference year. However, this will duplicate reporting burden for plans to provide this information. Further, the reporting instructions note that plans should report data paid or received through March 31 of the calendar year immediately following the reference year. This would mean that reporting entities would have only 61 days to validate and produce

their annual reports, which is a insufficient period of time. AHIP encourages the Departments to use its enforcement discretion to allow reporting entities to submit information up to nine months following the end of the reference year to ensure the completeness and maximize the validity of pharmacy claims data.

Data Aggregation
AHIP appreciates the Departments' allowing reporting entities to aggregate data by state and market with limited, targeted requirements for plan-specific data. This structure will greatly reduce administrative burden for plans, address privacy concerns for those enrolled in small plans, and allow the Departments to detect significant trends with respect to prescription drugs that are increasing consumers' premiums across all market segments.

However, the Departments could further reduce administrative burden by allowing reporting entities to submit all of their data aggregated at the state and market level. The IFC states that reporting entities' data may not be aggregated at a less granular level than the entity reporting the total spend (*e.g.*, if a PBM has 50 books of business or plans in a state and one third-party administrator (TPA) reports on 20, and another TPA reports on 30, the PBM must report at the 20/30 level).

Reporting at these higher levels will reduce the burden on reporting entities reporting on behalf of multiple entities while still allowing the Departments to detect significant trends with respect to prescription drugs that are increasing consumers' premiums and out-of-pocket costs.

The aggregated reporting should include identifying information at the plan or coverage level, such as name and Federal Employer Identification Number (FEIN) and other relevant identification numbers, for plans, issuers, plan sponsors, and any other reporting entities to verify receipt of data from all plans and issuers subject to the section 204 data submission requirements.

Bona Fide Service Fees
The IFC defines bona fide service fees as those fees paid by a drug manufacturer to a PBM that represent fair market value for a bona fide, itemized service performed on behalf of the manufacturer, and that are not passed on in whole or in part to a client or customer of the PBM. Bona fide service fees should be removed from the definition of rebates, fees, and other remuneration as these fees are fair market value payments for services performed and for which a fee is not passed on to clients or customers. Further, the explicit exclusion of these fees in the definition would align this reporting with the definitions of rebates and remuneration used elsewhere (*e.g.*, medical loss ratio reporting at 45 CFR 158.103, qualified health plan PBM reporting at 45 CFR 184.50) and could reduce confusion for reporting entities as they comply with reporting requirements across several statutes.

Prescription Drug Coupons
The IFC requires plans to report the extent to which drug manufacturer cost-sharing assistance reduces spending by the plan or its enrollees, to the extent that the information is available to the plan or its service providers. AHIP appreciates the Departments' recognition that plans and issuers often lack visibility manufacturers' cost-sharing assistance programs, particularly coupons used at retail pharmacies. The information will only be available in limited cases, and its inclusion in those plans' reports would not be useful to the Departments' review of all plans. As such, AHIP urges the Department to remove the requirement that reporting entities include data related to the use of manufacturers' cost-sharing assistance.

Written Agreements
The IFC allows plans and issuers to have third parties (such as TPAs and PBMs) submit information on their behalf, provided the plan or issuer enters into a written agreement with the third party. As the Departments note, they "expect that it will be rare for group health plans to report the required information on their own," thus the creation of these agreements will be necessary in almost every case. AHIP encourages the Departments to consider the administrative costs of this requirement and clarify the Departments' expectations for written agreements with former business entities.

II. AHIP Comments on the Information Collection Request

We offer the following comments on the information collection request:

AHIP's members continue to have concerns regarding their ability to satisfy the reporting requirements and meet the extended reporting deadline. AHIP urges the Departments to finalize the reporting instructions and technical specifications as soon as possible. In our previous comments, we recommended that reporting entities have at least one year after the technical specifications are complete, finalized, and posted. Further delays reduce our members' ability to report completed and valid data. According to our members, finalizing as late as March 31 would make compliance difficult.

The reporting instructions refer to a website where the data dictionary and file layouts are available, and while the file layouts were recently posted, the data dictionary is not available. AHIP encourages the Departments to finalize all reporting instructions and post a detailed data dictionary as soon as possible.

AHIP strongly opposes the inclusion of spread pricing in the reporting instructions, as the statute includes no mention of this information in the enumerated and extensive list of reporting elements plans and issuers must report. The statute requires reporting on rebates, fees, and other remuneration from manufacturers to the extent those transfers impact premiums. The statute in no way suggests that plans and issuers should report nor the Departments collect and analyze

spread amounts. AHIP urges the Departments to remove all references to spread amounts in the reporting instructions.

Additionally, our members have asked us to submit to the Departments the following list of questions, including requests for clarification, and technical notes related to the reporting instructions and related files.

- With respect to the file templates, the following information is needed but not included:
    - Field lengths
    - Guidance on whether values are alpha, numeric, or alphanumeric
    - Guidance as to whether issuers may leave fields blank if they are not applicable or if the information is unavailable and if the fields may not be blank, guidance as to the appropriate value for each value types
        - For example, Individual Grandfathered Plans and Student Health Plans do not have a HIOS ID. Is there another value that should be included in its place?
        - If a reporting entity (for example, a TPA) is not reporting pharmacy data, should the entity complete the pharmacy information in the P1 and P2 files? This may be difficult if the TPA and PBM have no contractual relationship with one another.

- In the event a plan or issuer only has a partial year of data, should the partial year information be submitted and if so, what information should accompany the files to ensure that information is appropriately processed?

- In the Plan List files, the combination of "Plan Beginning Date" and "Plan End Date" and "Member as of 12/31" and their descriptions is unclear for plans that do not follow the calendar year.
    - For example, an employer with a July renewal date offered a dual option Plan X and Plan Y to employees in the contract period 7/1/2019-6/30/2020, and then upon renewal switched all employees to Plan Z for the contract period 7/1/2020-6/30/2021. How many rows would appear for this employer in the 2020 reference year report, and how would these three fields be filled out? Would Plans X and Y report zero enrollees, as the plans were no longer effective on 12/31/2020, although data from those plans would be included in the report?

- As drafted, the reporting element "Amounts Not Applied to Deductible or Out-of-Pocket Maximum" cannot accurately convey meaningful information and will be easy to misinterpret. The description of this field is very broad: "Report billed amounts that were (1) not applied to a member's deductible or out-of-pocket maximum, (2) not paid by the plan, issuer, or carrier, and (3) not included in Total Spending". These amounts would include

"Disallowed amounts for non-covered services or for prescription drugs not on a plan or coverage's formulary".

A literal reading of the definition implies that the difference between billed claim amounts and allowed amounts for all claims would be captured here, mixing in-network claims where balance billing cannot happen and out-of-network claims where members may be balance billed. If the intent is to capture where balance billing may take place, it should be noted that plans and issuers may not know whether out-of-network providers send balance bills to members and to what extent these providers charge the full balance of billed charges, as some providers may write off a portion of the balance bill and not charge the member the full balance. AHIP recommends the Departments clarify that this data element exclude amounts above the allowable charge for in-network services and also recommends the Departments consider how the implementation of the No Surprises Act's balance-billing prohibitions might affect reporting on this data element in the future.

The inclusion of "disallowed amounts for non-covered services" would benefit from clarification and additional boundaries, such as whether the service is covered by the plan. For example, a denied vision claim for a medical plan that does not cover vision services should not be categorized with a denied claim for a medical service that may be more routinely covered by a carrier but is denied for different reason (such as exceeding a plan's quantitative limit for physical therapy services). AHIP recommends the Departments exclude non-covered (including non-formulary) items and services from the reporting.

However, even with clearer definitions, AHIP remains concerned that combining all of the listed categories into a single total will result in the larger data element ("Amounts Not Applied to Deductible or Out-of-Pocket Maximum") being poorly understood and frequently misinterpreted.

- As with other data fields that may be inaccessible to reporting entities, the Form 5500 Plan Number may be difficult to find and report, particularly in instances where a contractual relationship no longer exists between a plan and a reporting entity. AHIP encourages the Departments to allow a null reporting value for this field in the reports for the 2020, 2021, 2022 reference years.

- In our response to the Departments' request for information, AHIP recommended that the definition of "wellness services" include only services offered by the plan that generate a claim. In the reporting instructions, the Departments define "wellness services" as "expenses for activities primarily designed to implement, promote, and increase health and wellness and not billed as a claim" and offer a series of examples. Reporting this spending accurately without further detailed specifications will be exceptionally challenging. As such, AHIP

requests the Departments limit the definition of “wellness services” to include only services that are offered by the plan.

- With respect to reporting primary care spending, the reporting instructions require reporting entities to “Include the portion of laboratory and radiology services provided in a primary care setting that are billed independently by the laboratories.” Our members report that they may not be able to discern which laboratory claims are performed in primary care settings, so additional specification and instructions are needed.

Comment on CMS Interim Rule for Prescription Drug and Health Care Spending (CMS-9905-IFC)

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The Department of Health and Human Services, Labor, and Treasury have proposed an interim rule to require health plans and health insurance issuers to submit information to the Departments on health plan enrollment and premiums, total healthcare spending (broken down by type of cost), and a number of specific details related to prescription drug spending. The Departments will review this information and then publish biennial public reports on drug pricing and out-of-pocket (OOP) costs. Given that information on OOP costs and healthcare spending in the private insurance market are currently inaccessible to the general public, this proposal is a significant improvement above the status quo. However, by exclusively limiting data access to 3 Departments within the executive branch of the federal government, along with the focus on "top" drugs (i.e., the 50 most frequently dispensed brand prescription drugs; the 50 costliest prescription drugs by total annual spending; the 50 prescription drugs with the greatest increase in plan or coverage expenditures from the previous year; and prescription drug rebates,

fees, and other remuneration paid by drug manufacturers to the plan or issuer in each therapeutic class of drugs, as well as for each of the 25 drugs that yielded the highest amount of rebates), this rule does not go nearly far enough. In order to improve transparency, promote competition, and enable more informed and individualized patient choices on prescription drug plan coverage, all requested data on the pricing, OOP costs, and spending submitted by issuers should be made publicly available for either all prescription drugs, or at least for a larger number than the top 25 or 50, such as the top 1000; there are currently more than 20,000 prescription drug products approved for marketing by the U.S. Food and Drug Administration.[1]

High OOP costs directly contribute to the state of inadequate health insurance coverage for millions of Americans. Despite the vast majority now having health insurance, the proportion who are underinsured (defined based on OOP healthcare costs as a proportion of income) has increased from 16% to 23%.[2] In the past year, 51% of adults in the U.S. have reported delaying or foregoing at least one type of medical care due to costs.[3] For patients with acute and chronic health conditions, the situation is often much worse. Nearly half of adults with cardiovascular disease under age 65 have financial hardship from medical bills, with one in 3 reporting high financial distress, difficulty paying for food, skipping medications, or delaying care due to costs, regardless of whether they had health insurance.[4, 5] Low income families of those with cardiovascular disease are especially vulnerable, with a nine to fourteen-fold increased risk of catastrophic OOP healthcare expenses.[6, 7] The cost-sharing burden on patients for inpatient hospitalizations has also steadily increased in recent years, particularly for enrollees in individual market plans.[8] Even under Medicare, average OOP costs are well over $5000 per year, amounting to more than 20% of total annual income for nearly half of Medicare beneficiaries.[9, 10]

High OOP costs for prescription medications are harmful to patients. They contribute to higher rates of nonadherence and abandonment of prescribed medications, which can lead to poor health outcomes and be potentially life-threatening for many patients including those with cancer and cardiovascular diseases.[11-17] A case example is seen in the price of insulin, a life-saving medical therapy for millions of children and adults with diabetes. The cost of insulin has increased by up to five-fold in recent years, leading to dramatically increased OOP costs, psychological stress, social insecurity, and hospitalizations for patients with diabetes, which prompted an investigation by the U.S. Senate Finance Committee.[18-23]

Despite the negative impact of OOP costs on most patients, they remain hidden from view. For example, healthcare providers including physicians, advanced practitioners, and pharmacists rarely ever know what the OOP costs of newly prescribed medications will be for a patient until a prescription is actually ordered and filled at the pharmacy. This often blindsides patients who otherwise can't afford the OOP costs of beneficial medications that have no good generic alternatives. They may either reluctantly pay and later discontinue or skip doses of medications they need, or may decide to not fill the medication at all (frequently unknown to their prescribing provider). In short, the complete lack of transparency on OOP costs leads to universal and never-ending frustration experienced by patients, pharmacists and prescribers.

Due to challenges such as these as well as the very tangible impact OOP costs have on individual lives, a majority of Americans report attempting to look for cost data prior to receiving care and 69% say insurance issuers should be required to report cost data.[24] Making OOP cost data publicly available would be particularly beneficial to patients who require treatment for life-threatening diseases such as cancer. Greater knowledge on costs would enable patients and families to make better, more individualized choices on their health insurance and

healthcare providers, allow them to more appropriately budget for expected costs, apply for financial assistance when needed, and engage in shared decision-making with their physicians.[25]

As an illustrative example, several authors of this comment recently published a study estimating the OOP costs an older adult enrolled in a Medicare prescription drug plan would incur for the treatment of 8 common chronic conditions in 2009 and in 2019.[26] This study showed that the median inflation-adjusted OOP costs for guideline-recommended medications decreased between 2009 and 2019, with the exception of costs for conditions for which brand-name medications without generic alternatives became guideline-recommended. To concurrently manage all 8 commonly comorbid conditions (atrial fibrillation, chronic obstructive pulmonary disease [COPD], heart failure with reduced ejection fraction, hypercholesterolemia, hypertension, osteoarthritis, osteoporosis, and type 2 diabetes), the median annual cost was $3630 in 2019, a 41% increase from 2009.[26]

Though many healthcare policies are needed to address these and other related issues, a straight-forward first step would be to make all data received from issuers publicly available as part of implementation of the newly proposed CMS rule on healthcare cost reporting. This could be done through a government sponsored website, as is already being done with extensive data from Medicare and Medicaid.[27, 28] For costs related to drugs, including OOP costs, the current rule already proposes that the Departments use a database to group prescription drugs by name, active ingredient, and therapeutic class, which could also be made available to the public for information sharing and decision-making. Improving transparency on healthcare costs by making data publicly available also has recent precedent. On January 1, 2021, the Department of Health and Human Services implemented a transparency rule through CMS requiring that all U.S. hospitals make payer-specific negotiated costs for all items and services publicly available.[29]

However, greater transparency shouldn't be expected only from hospitals. Revising the interim rule CMS-9905-IFC to also require that healthcare insurance issuers make data including OOP costs publicly available is the next logical step.

We fully agree that review of all data by the Departments and publishing biannual public reports as outlined in the current rule would be of immense value to the public. However, greater transparency is needed for this rule to positively impact patient welfare, promote competition, and help bend the curve on healthcare costs. In particular, given the broad scope of this effort and the relatively small number of medications included in reporting, it would be virtually impossible for a single report to comprehensively examine costs relevant to specific medical conditions, which are of primary interest to individual patients and providers. For this reason, and in order to improve transparency, promote competition, and enable more informed and individualized patient choices on prescription drug plan coverage, all requested data on the pricing, OOP costs, and spending submitted by issuers should be made publicly available for all prescription drugs, or at least for a larger number than the top 25 or 50, such as the top 1000. In addition, the interim rule limits data reporting to the state/market level, rather than separately for each plan. However, patients do not enroll in insurance at the state or market level – they enroll in individual plans. Therefore we would also recommend that data on individual plans be included in reporting.

In summary, we believe interim rule CMS-9905-IFC will help improve healthcare cost transparency, but could be further enhanced. If made publicly available, the reported data based on this rule will more broadly inform insurance issuers, healthcare providers, administrators, researchers, employers and, most importantly, patients.

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RE: Docket Nos. TD 9958/CMS-9905-IFC
Prescription Drug and Health Care Spending

JDRF is pleased to submit comments in response to the Departments of Health and Human Services, Labor, and the Treasury (the Departments) and the Office of Personnel Management (OPM) interim final rules regarding implementation considerations on collecting and reporting information on pharmacy benefits and prescription drug costs.

Insulin list prices and the subsequent out-of-pocket cost to patients who require insulin to manage their disease and survive, are increasing at a rapid pace. For example, according to a report published by the Mayo Clinic, "one vial of Humalog (insulin lispro), which used to cost $21 in 1999, costs $332 in 2019, reflecting a price increase of more than 1000%".[1] These ongoing increases in insulin prices are occurring at the same time that average annual deductibles for

[1] Rajkumar, S. V. (2020). The High Cost of Insulin in the United States: An Urgent Call to Action. *Mayo Clinic Proceedings*, *95*(1), 22–28. https://doi.org/10.1016/j.mayocp.2019.11.013

employer-sponsored insurance plans have nearly tripled since 2008.[2] These cost-shifting efforts result in more Americans forgoing or rationing necessary care. For example, recent studies suggest that 1 in 4 patients have rationed their insulin due to the high cost.[3] This cost-shifting impacts those living with chronic conditions especially hard, as any rationing of care can lead to dangerous clinical events that further imperil health and can even result in death. Efforts by the Departments to implement transparent, public reporting of drug price and benefit information is a vital step in better understanding and controlling rising drugs costs.

ABOUT JDRF

JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications and we collaborate with a wide spectrum of partners in the community to achieve this mission. Founded in 1970 by parents of children with T1D, JDRF has invested over $2.5 billion in research since its inception and employs doctorate-level scientists to manage our research portfolio.

ABOUT TYPE 1 DIABETES

Type 1 diabetes (T1D) is an autoimmune disease that strikes children and adults suddenly and can be fatal. According to the CDC, 1.6 million Americans are living with T1D, including 187,000 people under the age of 20. Until a cure is found and in order to stay alive, people with T1D require lifelong and continuous insulin therapy coupled with continuous blood glucose monitoring. Too much insulin can result in seizures, coma, or death from hypoglycemia, or low glucose levels. Too little insulin over time leads to devastating kidney, heart, nerve, and eye damage from hyperglycemia, or high glucose levels.

Due to the nature of T1D, patients and their caregivers use insulin daily and in many cases around the clock, relying on it to help maintain glucose control that avoids both short- and long-term complications. The unmet needs in T1D are still significant specifically as it relates to access to affordable, lifesaving insulin. Recent studies have shown that one in four patients at an urban diabetes center reported rationing their insulin resulting in poor glycemic control.[4] This study simply highlights the health risks associated with unaffordable costs of insulin for some living with T1D.

COMMENTS ON REQUESTED INFORMATION

The Departments should require information be collected and reported at a level of detail sufficient to promote better decision making by health plans and policymakers.

JDRF is generally supportive of the provisions of the interim final rule particularly those provisions aimed at promoting detailed public data. We support CMS's effort to balance the

[2] Kaiser Family Foundation. (2020, October). *Employer Health Benefits 2020 Annual Survey*. https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf
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need to accommodate the reporting burden of payers with the desire to meet statutory requirements and public need.

We are supportive of the policies outlined regarding the allowance of health plans to utilize TPAs and PBMs to report required data. However, we believe the value in the data collected is if it can be stratified by plan and market segment as this will provide the greatest insight to support better benefit decision making. We believe this value is eroded if TPAs and PBMs can generally aggregate data across multiple health plans clients to report blended rates.

It is important to be sensitive to the potential reporting dynamics and challenges associated with drug spending attributed to a medical benefit and hospital-based drug costs. However, the impact of drug costs on patients is the same whether the drug costs occurred inside a hospital or as outpatient care. It also does not matter to the patient if the costs occur because the drug is covered under a medical vs drug insurance benefit. The most important factor to patients is that the cost occurred as a result of care and in the case of T1D, the cost must be endured in order to access lifesaving medication. Where and how a drug is dispensed may impact cost-sharing, thus this information is vital to understand the impact on out-of-pocket costs. As such, the dynamics of drug spending under both the hospital and medical benefits are vital to collect and report to the Departments. We encourage the Departments to find pathways to ensure that there is transparent reporting on all prescription drugs covered under the hospital or medical benefit as this is the only way to truly garner a complete picture of prescription drug costs and trends.

As described in the interim-final rule, we agree with the Departments' approach to prioritize reporting of those data elements that impact consumer and payer decision-making. Specifically, we believe that those elements that have the greatest impact on patient care include out-of-pocket costs, application of utilization tools such as prior authorization, and formulary tier placement. As an organization that believes savings generated from rebates should be shared directly with those patients prescribed a rebated drug, we encourage the public reporting of rebates by drug class and by benefit plan.

We also encourage the Departments to consider releasing data, including complete data sets, to the public more frequently than the planned biennial public reports. While provisions of the PHS Act require section 204 reports to be published on a biennial basis, there is nothing precluding the Departments from publishing deidentified, aggregated data that is reported by health plans on an annual basis. The annual publishing of data would be a public good that would be valuable information for researchers, patient advocacy organizations, and policymakers that would be supported by the more thorough biennial public report.

The Departments should consider requiring data collection and reporting on specific chronic conditions that drive health spending.

Given the impact of prescription drugs on certain consumer and patient populations, we believe it important, and of great potential value, that prescription data reporting requirements consider key chronic conditions and diseases. We encourage the Departments and OPM to consider how

it may categorize reporting by key diseases and chronic conditions to ensure information is relevant to specific patient populations.

As described in Section D we continue to encourage the Departments to consider the criteria for the 50 drugs that must be reported by plans take into consideration specific chronic conditions and diseases that represent significant costs to the plan, require prescription drugs for the survival of the patient, and align with broader public health goals. We would recommend that the Departments specifically require the reporting of drugs relevant to the treatment of certain conditions such as diabetes and this information be categorized specifically by disease.

Diabetes is a disease that 34 million Americans are currently living with; nearly 1 in 8 adults.[5] In 2017, estimates project that one of every 4 health care dollars spent was spent on diabetes related care.[6] A 2020 survey of employers found that diabetes was one of their top drivers of cost.[7] There are likely several ways to determine which drugs must be reported that would include the treatments for diabetes based on its prevalence in the population such as claims volume or price increase. However, there is value in understanding the similarities and difference between health plans by disease category as it can provide helpful insight for not only plans and regulators but also researchers, public health officials, and employers crafting benefit strategies.

In closing, given the daily importance of prescription medication for the 1.6 million Americans living with T1D, we encourage you to continue to give weight to data reporting requirements that are not only operationally considerate of health plans but ones that promotes greater transparency for patients. We are encouraged that the Departments are accepting public feedback on implementation considerations associated with collecting and reporting key prescription drug information and we hope this dynamic continues as implementation is refined in future years.

Thank you for the opportunity to comment on this request for information. If you have any questions, please contact Aaron Turner-Phifer at aturner-phifer@jdrf.org.

[5] U.S. Department of Health and Human Services Centers for Disease Control and Prevention. (2020). *National Diabetes Statistics Report 2020*. Centers for Disease Control and Prevention. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf
[6] Economic Costs of Diabetes in the U.S. in 2017. (2018). *Diabetes Care*, *41*(5), 917–928. https://doi.org/10.2337/dci18-0007
[7] *Managing Health Care Costs*. (2021, March 29). SHRM. https://www.shrm.org/resourcesandtools/tools-and-samples/toolkits/pages/managinghealthcarecosts.aspx

Association of Federal Health Organizations
1101 Vermont Ave NW, Suite 1002, Washington DC 20005
— Established 1983 —

January 24, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services,
P.O Box 8016
Baltimore, MD 21244–8016

SUBMITTED VIA REGULATIONS.GOV

Attention: CMS–9905–IFC

Dear Agency Representatives:

Thank you for the opportunity to comment on the third No Surprises Act interim final rule reporting requirements implementing Section 204 of Division BB of the Consolidated Appropriations Act of 2021 ("CAA") which was published at 86 Fed. Reg. 66,662 (November 23, 2021) (hereafter "IFC 3").[1] The Association of Federal Health Organizations ("AFHO") is a trade association of Federal Employees Health Benefits plan carriers whose combined enrollment encompasses approximately 80% of the FEHB Program's total enrollment. These comments, therefore, focus on the RFI's discussion of the FEHB Program.

The June 23, 2021, Request for Information ("RFI") stated that

> Title I of Division BB also amended 5 U.S.C. 8902(p) to include specified provisions of the CAA into FEHB carrier contracts. Although section 204 is not enumerated as a specified provision in section 8902(p), FEHB carrier compliance with the Departments' collection pursuant to this section helps accomplish the CAA's intended purpose of achieving national health data transparency and lower costs. Therefore, references to ''plans'' for purposes of this request for information include FEHB health benefits plans.

Id. at 32,814.

We asked OPM to point out its statutory authority for imposing this obligation and in the preamble to IFC 3, OPM relied on Section 8910 of the FEHB Act. Id. at 66,680. That provision reads in pertinent part as follows:

> (a) The Office of Personnel Management shall make a continuing study of the operation and administration of this chapter, including surveys and reports on health benefits plans available to employees and on the experience of the plans.
>
> (b) Each contract entered into under section 8902 of this title shall contain provisions requiring carriers to--
>
> (1) furnish such reasonable reports as the Office determines to be necessary to enable it to carry out its functions under this chapter; and
>
> (2) permit the Office and representatives of the Government Accountability Office to examine records of the carriers as may be necessary to carry out the purposes of this chapter.

Since 2019, OPM has utilized Section 8910 to obtain aggregated pharmacy data from carriers in a format much more detailed than the format outlined in Section 204. OPM Carrier Letters No. 2020-17

[1] AFHO members reserve the right to submit their own organization's comments on IFC 3.

(Attachment A hereto). Accompanying OPM's Carrier Letter were a set of instructions and a reporting template. That is OPM's standard approach to making a reporting request to carriers.

OPM purports in 5 C.F.R. Section 890.114(a) as amended by IFC to apply the Section 204 regulations to FEHB carriers. 86 Fed. Reg. at 66,680. Because Congress chose not to apply Section 204 to FEHB carriers, OPM has no authority to apply Section 204 implementing regulations to FEHB carriers.[2] Indeed, these inappropriate references in Section 890.114(a) are unenforceable.[3]

Instead, to achieve its objective, OPM simply should issue a carrier letter on Section 204 reporting, similar to Carrier Letter No. 2020-17. Accomplishing that task would be quite feasible because CMS already has issued draft Section 204 instructions and it plans to issue Section 204 reporting templates.

Finally we suggest that consistent with Section 8910, the carrier would send a copy of its completed Section 204 report to OPM at the same time it submits the report to CMS. That would relieve CMS of the unnecessary burden of transmitting the FEHB Carrier Section 204 reports to OPM pursuant to Section 8910(c). See 86 Fed. Reg. at 66,680.[4]

Thank you for considering our comments.

Sincerely,

Rocky Midgett

Rocky Midgett
Chairman

cc: AFHO Board of Directors
Laurie Bodenheimer, Associate Director, OPM
David Ermer

---

[2] "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43, 104 S. Ct. 2778 (1984). Agency decisions "which rest on an erroneous legal foundation" "must, of course, [be] set aside." *Oregon v. Ashcroft*, 368 F.3d 1118, 1129 (9th Cir. 2004) (quoting *NLRB v. Brown*, 380 U.S. 278, 291-92, 85 S. Ct. 980 (1965)); National Federation of Independent Business v. Occupational Safety and Health Administration, -- U.S. -- 2022 U.S. LEXIS 496, slip op. at 5 (January 13, 2022):

> Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.

[3] OPM's general contracting authority is considered under principles of statutory interpretation to be limited by a specific statute such as Section 8902(p). "As always, '[w]here there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment.'" *Crawford Fitting Co. v. J. T. Gibbons, Inc.*, 482 U.S. 437 (1987).

[4] We suggested the same approach in our comments on the proposed air ambulance reporting rule, Attachment hereto.

ATTACHMENT A

FEHB Program Carrier Letter

All FEHB Carriers

U.S. Office of Personnel Management
Healthcare and Insurance

Letter No. 2020-17 **Date: November 19, 2020**

Fee-for-Service [14] Experience-rated HMO [14] Community-rated [15]

SUBJECT: Aggregate Healthcare Cost and Utilization Data Reporting Requirements

This Carrier Letter provides guidance to all Federal Employees Health Benefits (FEHB) Carriers on their obligation to supply aggregate healthcare cost and utilization data to the U.S. Office of Personnel Management (OPM).

Background

5 U.S.C § 8910 mandates that OPM make a continuing study of the operation and administration of the FEHB Program and requires carriers to furnish reasonable reports that OPM determines to be necessary to enable it to carry out its functions. This is further outlined in Section 1.7 of the Fee-For-Service, Experience Rated, and Community Rated contracts.

In 2019, FEHB Carriers reported 2018 aggregate pharmacy cost (including rebates) and utilization data to OPM. This data by FEHB enrollment code, product, distribution channel etc., gave OPM important insight into the operation and administration of the FEHB pharmacy benefit and is essential for effective FEHB Program oversight and evidence-based decision making. OPM will continue to collect pharmacy cost and utilization data on an ongoing basis. One of OPM's strategic goals is to provide affordable and high-quality health plans to FEHB enrollees and their families. This letter details changes in the 2019 and 2020 FEHB pharmacy data collection and submission process.

Aggregate Pharmacy Cost and Utilization Data Files

FEHB Carriers will be required to provide 2 pipe-delimited text data files for each year:

- Pharmacy Cost and Utilization File
- Rebates file

A template that outlines the standard file format for submission of cost (including rebates) and utilization data for pharmacy claims is included along with this paper as Attachment 2. Detailed instructions are included in Attachment 1. Please note that, while we have provided instructions in PDF and Excel to make the expected files easier to visualize, we are

maintaining the requirement that carriers submit only pipe-delimited UTF8 text files (ASCII is a subset of the UTF8 character encoding set).

Attachment 1 includes the same information requested in 2019 except that, going forward, OPM is also requiring that the pharmacy cost and utilization data is broken out by age bands as shown below.

Values	Age Bands
1	0-5 years
2	6-10 years
3	11-17 years
4	18-22 years
5	23-34 years
6	35-44 years
7	45-54 years
8	55-64 years
9	65-74 years
10	75-84 years
11	85+ years

The age bands in the cost and utilization reports are based on attained age at the date the prescription was filled.

Also new this year is the addition of the Medi-Span GPI8 column which more clearly identifies the drug name in the rebates file.

Proposed Submission Time Frame

The aggregate cost and utilization data will be hosted in the OPM Health Insurance Data Warehouse (HIDW).

OPM will work closely with Carriers on the file transfer requirements.

Each Carrier will submit FEHB pharmacy cost (including rebates) and utilization data to the HIDW using a Secure File Transfer Protocol (SFTP) account and encryption. HIDW SFTP transfer steps are included as Attachment 3. FEHB Carriers using the same server for submission of enrollment files to HIDW can skip Step 1 and 4 of the SFTP transfer steps.

No later than April 30, 2021, Carriers will have successfully submitted two years of historical cost (including rebates) and utilization data (2019 and 2020). Carriers that have participated in the FEHB Program for fewer than two years should send cost and utilization data dating

back to the beginning of their participation. Thereafter, Carriers will submit an aggregate cost and utilization file to OPM on an annual basis by April 30th.

Conclusion

OPM is committed to providing affordable and high-quality health plans to FEHB enrollees and their families. If you have any questions, please contact OPMPharmacy@opm.gov with a copy to your Health Insurance Specialist.

Sincerely,

Laurie E. Bodenheimer
Acting Director
Healthcare and Insurance

Attachment 1 – Pharmacy Cost and Utilization Instructions (see attached PDF)

Attachment 2 – Pharmacy Cost and Utilization Template (see attached Excel file)

Attachment 3 – HIDW SFTP Transfer Steps

All SFTP technical questions or issues should be directed to the HIDW Technical Team at HIDWSupport@opm.gov.

1. **Initiate Account Set-up** – To request an SFTP account, contact the HIDW SFTP Administrators at HIDWSupport@opm.gov with a Point of Contact (POC) to coordinate set-up.

2. **File Specifications** – All transmitted files must be in ASCII or UTF8 pipe-delimited text format with variable names in the first row and data beginning in row 2. The variable names should be identical to those indicated by OPM in the attached template in row 8 of the RxCostUtilization and RxRebates sheets. They are case-sensitive and should appear in the same order.

3. **Select Encryption Software** - The HIDW SFTP process requires that all transmitted data be encrypted. The Carrier must use the same software as the HIDW. File encryption software performs data compression and data encryption. Coordinate with HIDW SFTP Administrators to determine which software will be used.

4. **File Testing** - Coordinate with HIDW SFTP Administrators to transmit test files. Once testing has been completed, a date and time for the initial data transfer and recurring transmissions will be scheduled. OPM prefers that the Carrier send an email to HIDWSupport@opm.gov each time a test file has been transmitted.

5. **File Naming Conventions** – We request the following naming conventions be followed for the transmitted files:

   FEHB_CarrierID_FileType_ExtractStartDate_ExtractEndDate_TransferDate.File Extention.pgp

   Please note the change in the file naming convention from the one used during submission of 2018 data. The four-character Carrier ID provided by OPM replaces the two-digit alphanumeric plan code in the file name. This allows data for multiple plan codes that belong to the same FEHB Carrier to be included in the same file, reducing the number of files that carriers will have to produce and transfer. The SFTP transmission mechanism can accommodate larger files.

Carrier ID: A four-character Carrier ID provided by OPM, the same as the one used to submit enrollment information to HIDW and the CLER system.

File Type: RXCU for prescription drug cost and utilization, RXRB for prescription drug rebates.

All Dates: YYYYMMDD format

- Example file names for the 2019 and 2020 prescription drug cost and utilization files, assuming they will be transmitted on 30 Apr 2021:

  FEHB_ATOZ_RXCU_20190101_20191231_20210430.txt.pgp

  FEHB_ATOZ_RXCU_20200101_20201231_20210430.txt.pgp

- Example file names for the 2019 and 2020 prescription drug rebate files, assuming they will be transmitted on 30 Apr 2021:

  FEHB_ATOZ_RXRB_20190101_20191231_20210430.txt.pgp

  FEHB_ATOZ_RXRB_20200101_20201231_20210430.txt.pgp

We will not accept any files that do not follow the appropriate naming convention.

6. **Confirmation Email** – Carriers must email HIDWSupport@opm.gov after each file/group of files has been transmitted so that OPM can confirm receipt of file(s). In the e-mail, please include the following:
   I. Record count for Column C (Product/Service ID) for each Pharmacy Cost and Utilization file
   II. Record count for Column D (product Description) for each Rebate file
   III. Sum total for Column R (Plan Paid Amount) for each Pharmacy Cost and Utilization file
   IV. Sum total for Column E (Plan Paid Amount) for each Rebate file

United States
Office of Personnel Management
The Federal Government's Human Resources Agency

FEHB Rx Costs, Utilization and Rebates File Instructions 2020

To be submitted in 2020 based on plan year 2019 pharmacy benefit experience with a three-month runout.

Please read and follow these instructions carefully before providing the requested information. Files will be processed automatically, and incorrect/incomplete files will be rejected.
After producing the pipe-delimited text files as explained below, please transfer them via SFTP as indicated in Attachment 2.

If you have questions or concerns, please email OPMPharmacy@OPM.gov.

Instructions

New

- Patient Age Bands have been added in column M of the RxCostUtilization sheet. They are based on the attained age at the date the prescription was filled. Please see the FullECLDefinition sheet for details.
- The MediSpan GPI8 which more clearly identifies the drug name has been added in column C of the RxRebates sheet.
- The file naming convention has changed to allow plan codes belonging to the same carrier to be included in the same file and thus reduce the number of files prepared and transmitted by carriers.
- All files should be encrypted and transferred to OPM via SFTP as indicated in Attachment 2.

RxCostUtilization File

The information provided should be based on all records with a date of adjudication (National Council for Prescription Drug Programs (NCPDP) data field 578) in the reporting year paid by 31 March of the following year (three-month runout period).

The first row of the pipe delimited text file should contain the variable names exactly as provided by OPM in row 10 of the <RxCostUtilization> sheet, in the same order, separated by the pipe operator |. Variable names are case sensitive.

Carriers can append multiple plan codes in the same file. The three-digit FEHB enrollment codes as they appear in the brochure(s) must be filled for all records.

The information provided should be the number of scripts, sum totals of quantities dispensed, days supplied, and amounts in each column between N-W for each unique combination of values in columns A-M.

Each file must contain all fields for each three-digit FEHB enrollment code that appears in your plan brochure(s) and each drug/product/service ID by pharmacy type, specialty claim indicator, age band etc.

Please provide the breakdown of utilization/costs (columns N-W in blue) for each unique combination of values in columns A-M (in orange).

There should be multiple records (rows) for each product/service ID, as many as the unique combinations of values of columns in orange (columns A-M) for which there is utilization or non-zero amounts in any of the N-W columns.

The three-character FEHB enrollment codes are the codes that appear in FEHB plan brochure(s) and capture the plan, option, and Self / Self + 1 / Family enrollment.

Carriers are responsible for providing the FEHB Enrollment Codes to other entities that help produce these files (PBMs).

Please submit NDCs in HIPAA 11-digit format without dashes for all drugs/products that have an NDC. Submit other appropriate IDs only for non-drug products or services that do not have NDCs.

The instructions and variable names refer to drug, product, or service ID and qualifier somewhat interchangeably to accommodate non-drug items, but most products should be drugs and most IDs should be National Drug Codes (NDCs).

The NCPDP list of valid values for the drug/product/service id qualifier is included in the <FullECLDefinition> sheet. The value for NDC for example is 03. Please provide a detailed mapping if other codes are used.

Please provide the pharmacy information described in the <RxCostUtilization> sheet as pipe-delimited text files. The pipe delimiter is |.

Encrypt the files and follow the file naming convention as outlined below and in Attachment 3.

FEHB_CarrierID_FileType_ExtractStartDate_ExtractEndDate_TransferDate.FileExtention.pgp

A four-character Carrier ID will be provided by OPM, the same as the one used to submit enrollment information to HIDW and the CLER system

The file type for prescription drug cost and utilization files is RXCU.

All dates should be in YYYYMMDD format.

Example file names for the 2019 and 2020 prescription drug cost and utilization files, assuming they will be transmitted on 30 Apr 2021:

FEHB_ATOZ_RXCU_20190101_20191231_20210430.txt.pgp
FEHB_ATOZ_RXCU_20200101_20201231_20210430.txt.pgp

Rebates File

The information provided should be based on all rebates and other credits and fees (such as price protection and manufacturer administrative fees) for the plan year utilization/costs (the rebates and other credits associated with drug costs/utilization included in the RxCostUtilization file).

The first row of the pipe delimited text file should contain the variable names exactly as provided by OPM in row 9 of the <RxRebates> sheet, in the same order, separated by the pipe operator |. Variable names are case sensitive.

Please provide an accompanying rebates file for each cost and utilization file. Carriers can append multiple plan codes in the same rebates file. The three-digit FEHB enrollment codes as they appear in the brochure(s) must be filled for all records.

Please allocate the total rebates and other credits such as price protection and manufacturer administrative fees for the drug/product to the respective three-character FEHB enrollment code and distribution channel.

Please use your standard allocation methodology or allocate proportionally to FEHB Plan and Enrolment Code and Pharmacy Type.

If rebates or other credits are based on a market basket of drugs/products and are not specific for the drug/product, please calculate the separate rebate and other credit for each drug/product by multiplying the total rebates and credits on the market basket by the percentage represented by each drug/product in the market basket (and distribute by FEHB enrollment code and Pharmacy Type).

If the last quarter information is not available, please estimate the total rebates and other credits for the year from the experience over the first three quarters.

Please provide the pharmacy information described in the <RxRebates> sheet as pipe-delimited text files. The pipe delimiter is |.

Encrypt the files and follow the file naming convention as outlined below and in Attachment 3.

FEHB_CarrierID_FileType_ExtractStartDate_ExtractEndDate_TransferDate.FileExtention.pgp

A four-character Carrier ID will be provided by OPM, the same as the one used to submit enrollment information to HIDW and the CLER system.

The file type for prescription drug cost and utilization files is RXRB.

All dates should be in YYYYMMDD format.

Example file names for the 2019 and 2020 prescription drug rebate files, assuming they will be transmitted on 30 Apr 2021:

FEHB_ATOZ_RXRB_20190101_20191231_20210430.txt.pgp
FEHB_ATOZ_RXRB_20200101_20201231_20210430.txt.pgp

Formatting Instructions for Both Types of Files

The pipe character | should not appear inside any of the variables. It should be used only to delimit fields. If there are n variables in the file, there should be n-1 pipe operators in each record, one after each field except the last one.

Each row in the text file should represent a separate record.

Zero values for numeric fields (e.g. zero copay) should be represented as 0, not null or missing values.

Do not pad amounts with zeroes and do not pad character variables with spaces or any other characters.

Dollar amounts should include the dot but no commas or dollar sign.

Null values should be represented by || (do not include space(s), dot(s), quotations, NA or any other character(s) between the pipe characters delimiting the end of the previous variable and the end of the null variable).

The pipe-delimited text files should be ASCII or UTF8 (UTF8 is a character encoding capable of encoding a large number of characters in multiple languages. ASCII is a subset of Unicode UTF8, developed for the English Language that includes only 128 characters, primarily letters, numbers, and punctuation signs).

Pharmacy Cost and Utilization File Variables

Variable labels are in row 6. Variable descriptions/instructions are in row 7. Variable types are in row 8. Corresponding NCPDP data element codes are in row 9.
Variable names are in row 10 and should be included in the first row of the pipe delimited text file exactly as spelled here, separated by the pipe operator |.
Values for the productIDQualifier, formularyStatus, and ageBand are in the FullECLDefinition tab. For example 03 stands for NDC, 01 for UPC etc.
The numerical variables in columns N-W (in blue) are sum totals for each drug/product for which there is utilization or nonzero amounts broken down by the distinct combinations of values of the columns A-M (in orange).

FEHB Enrollment Code	Pharmacy Type	Product / Service ID	Product / Service ID Qualifier	Product / Service Name	Product Description	Specialty Claim Indicator	Prior Authorization Indicator	Step Therapy Indicator	Formulary Status	In Network Indicator	Compund Code Indicator	Age Band	Number of Scripts	Unique Users	Days Supplied	Quantity Dispensed	Plan Paid Amount	Patient Pay Amount (Liability)	Other Payer(s) Paid Amount(s)	Total Amount Paid by All Sources	Taxes	Gross Amount Due
The three digit FEHB enrollment code as it appears in the FEHB plan brochure. There should be separate records for each three digit enrollment code, that is, for Self/Self+1/Family enrollment for each plan option for which utilization or amounts are not all zero.	R for Retail, M for Mail, S for Specialty	Use NDC in 11 digit HIPAA format (without dashes) for drugs. If this is a product without an NDC (e.g. syringes, diapers etc.) then use another appropriate code (e.g. Universal Product Code (UPC)). Please see FullECLDefinition sheet for valied values and provide a detailed mapping if other values are used).	Code qualifying the type of Drug ID. For most drugs / products it should be the NDC, but it could also be UPC, procedure code etc. as other products / services are sometimes dispensed / provided through the pharmacy benefit.	Product or Service Description or Product Label Name.	Name of the drug/product for which rebates and other credits and fees were available. Corresponds to and should match the field with the same name in the Rebates file (please see the RxRebates sheet).	1 Specialty Claim, 2 Not a specialty claim.	Y if Prior Authorization, N if not	Y for Step Therapy, N if not	Indicates the formulary status of the drug. Please see the list of NCPDP external code values in the FullECLDefinition sheet.	Y for In-Network, N for Out of Network Pharmacy	0 for Not specified, 1 for Not a Compound, 2 for Compound	Patient Age Band as of the date the prescription was filled. Please use the list of values in column B of the FullECLDefinition sheet.	Number of prescriptions adjudicated for the drug / product. Do not double count partial fills.	Number of unique members using the drug / product.	Total days supplied for the drug (NDC)	Total quantity dispensed for the drug (NDC)	Total amount paid by plan	Total amount paid by patient (total member liability)	Total amount paid by other payers	Should equal the sum of plan paid, patient paid and other payer(s) paid amounts.	Total sales taxes paid by all parties (flat and percentage taxes paid by the plan, member, and other payer(s)).	Total Amount Claimed from all Sources
Character (3)	Character(1)	Character (11)	Character (2)	Character (80)	Character(30)	Character (1)	Character(1)	Character(1)	Character (1)	Character(1)	Numeric	Numeric(1)	Numeric	Numeric	Numeric	Numeric	Numeric	Numeric	Numeric	Numeric	Numeric	Numeric
		407-D7	436-E1	397	801-20	A37	461-EU		257	266	406-D6				405-D5	442-E7	281	505-F5	225	834		430-DU
fehbEnrCode	pharmacyType	productID	productIDQualifier	productName	productDescription	specialty	priorAuthYN	stepTherYN	formularyStatus	networkYN	compundCode	ageBand	scripts	users	daysSupplied	quantityDispensed	planPaid	memberPaid	otherPayerPaid	amountPaidAllSou	taxes	grossAmount

Rebates File Variables

Variable labels are in row 5. Variable descriptions/instructions are in row 6. Variable types are in row 7. Corresponding NCPDP data element codes are in row 8.
Variable names are in row 9 and should be included in the first row of the rebates pipe delimited text file exactly as spelled here, separated by the pipe operator |.
Please allocate rebates and other credits by product, distribution channel, and FEHB Enrollment code.

FEHB Enrollment Code	**Pharmacy Type**	**GPI-8**	**Product Description**	**Rebates and Other Credits**
The three digit FEHB enrollment code as it appears in the FEHB plan brochure. There should be separate records for each three digit enrollment code, that is, for Self/Self+1/Family enrollment for each plan option for which utilization or amounts are not all zero.	R for Retail, M for Mail, S for Specialty	Generic Product Identifier (GPI)-8 from Medi-Span which identifies the drug name	Name of the drug/product for which rebates and other credits and fees were available. Corresponds to and should match the field with the same name in the Rx Utilization and Cost file (please see the RxUtilizationCosts sheet).	Total rebates and other credits and fees such as price protection and manufacturer administrative fees for the drug/product allocated for the respective three character FEHB enrollment code and distribution channel (Pharmacy Type). Please use your standard allocation methodology, or allocate proportionally to FEHB Enrolment Code and Pharmacy Type. If rebates and other credits and fees are based on a market basket of drugs/products and are not specific for the drug/product, please calculate the separate rebate for this drug/product by multiplying the total rebate on the market basket by the percentage represented by this drug/product in the market basket (and distribute by FEHB enrollment code and Pharmacy Type). If the last quarter information is not available, please estimate the total rebates and other credits for the year from the experience over the first three quarters.
Character (3)	Character(1)	Character (8)	Character(30)	Numeric
			601-20	
fehbEnrCode	pharmacyType	gpi8	productDescription	rebates

Extract from the NCPDP External Code List (ECL)
Ø stands for the digit 0, so it isn't confused with the letter O.
Most products should be drugs, for which the pproductID should be an NDC and the values for the productIdQualifier should be 03

436-E1 – Product/Service ID Qualifier

NAME OF VALUE	VALUES	PRODUCT/SERVICE ID QUALIFIER (436-E1)	COMMENTS
Not Specified	Blank	X	Used only in Telecommunication Standard Versions 9.Ø through C.4 and Post Adjudication Standard Version 1.Ø. Value was deleted for use in higher versions of these standards.
Not Specified	ØØ	X	Only to be used when needed to conform in fixed file layout specifications.
Universal Product Code (UPC)	Ø1	X	Formatted 11 digits (N)
Health Related Item (HRI)	Ø2	X	Formatted 11 digits (N)
National Drug Code (NDC)	Ø3	X	NCPDP Formatted 11 digits (N)
Health Industry Business Communications Council (HIBCC)	Ø4	X	Variable A/N
Department of Defense (DOD)	~~Ø5~~	X	This value was deleted in the publication of the July 2ØØ7 ECL and should not be used by any of the standards from that date forward.
Drug Use Review/ Professional Pharmacy Service (DUR/PPS)	Ø6	X	
Common Procedure Terminology (CPT4)	Ø7	X	5 character (A/N)
Common Procedure Terminology (CPT5)	Ø8	X	5 character (A/N)
Health Care Financing Administration Common Procedural Coding System (HCPCS)	Ø9	X	5 character (A/N)
Pharmacy Practice Activity Classification (PPAC)	1Ø	X	
National Pharmaceutical Product Interface Code (NAPPI)	11	X	South African Code
Global Trade Identification Number (GTIN)	12	X	14 digits (N) – UCC Standard (UPN)
Drug Identification Number (DIN)	~~13~~	X	This value was deleted in the publication of the July 2ØØ7 ECL and should not be used by any of the standards from that date forward.
First DataBank Formulation ID (GCN)	15	X	
First DataBank Medication Name ID (FDB Med Name ID)	28	X	
First DataBank Routed Medication ID (FDB Routed Med ID)	29	X	
First DataBank Routed Dosage Form ID (FDB Routed Dosage Form Med ID)	3Ø	X	
First DataBank Medication ID (FDB MedID)	31	X	
First DataBank Clinical Formulation ID Sequence Number (GCN_SEQ_NO)	32	X	
First DataBank Ingredient List ID (HICL_SEQ_NO)	33	X	
Universal Product Number (UPN)	34	X	
Representative National Drug Code (NDC)	36	X	
Gold Standard Marketed Product Identifier (MPid)	42	X	
Gold Standard Product Identifier (ProdID)	43	X	
Gold Standard Specific Product Identifier (SPID)	44	X	
Device Identifier (DI)	45	X	
Other	99	X	

257 Formulary Status

CODE	DESCRIPTION
Blank	Not Specified
I	Drug on Formulary; Non-Preferred - The medication submitted on the claim is included in the list of products in that patient's plan formulary but there is a preferable product in the therapeutic category.
J	Drug not on Formulary; Non-Preferred - The medication submitted on the claim is NOT included in the list of products in that patient's plan formulary, and there is a more preferable product in the therapeutic category.
K	Drug not on Formulary; Preferred - The medication submitted on the claim is NOT included in the list of products in that patient's plan formulary, but the product is still considered the preferable choice.
N	Drug not on Formulary; Neutral - The medication submitted on the claim is NOT included in the list of products in that patient's plan formulary, and the plan has no specific preference as to the drug's status.
P	Drug on Formulary - The medication submitted on the claim is included in the list of products in that patient's plan formulary.
Q	Drug not on Formulary - The medication submitted on the claim is NOT included in the list of products in that patient's plan formulary.
T	Drug on Formulary; Preferred- Therapeutic interchange occurred on this claim – The medication submitted on the claim is included in the list of products in that patient's plan formulary and the plan has allowed the substitution of an equivalent product.

Y	Drug on Formulary; Neutral - The medication submitted on the claim is included in the list of payable products in that patient's plan formulary, and the plan has no specific preference as to the drug's status.

Age Bands

Patient Age Bands below are attained age at the date the prescription was filled.

Values	Age Bands
1	0-5 years
2	6-10 years
3	11-17 years
4	18-22 years
5	23-34 years
6	35-44 years
7	45-54 years
8	55-64 years
9	65-74 years
10	75-84 years
11	85+ years

ATTACHMENT B

Association of Federal Health Organizations
1101 Vermont Ave NW, Suite 1002, Washington DC 20005
— Established 1983 —

October 18, 2021

Center for Medicare & Medicaid Services
Department of Health and Human Resources
Attention: CMS-9907-P
P.O. Box 8016
Baltimore, MD 21244-8016

SUBMITTED VIA REGULATIONS.GOV

Comments on Requirements related to Air Ambulance Services

Dear Agency Representatives:

Thank you for the opportunity to comment on the Requirements Related to Air Ambulance Services proposed rule, as requested at 86 Fed. Reg. 51,730 (July 13, 2021) (hereafter the "Proposed Rule"). The Association of Federal Health Organizations ("AFHO") is a trade association of Federal Employees Health Benefits ("FEHB") plan carriers whose combined enrollment encompasses approximately 80% of the FEHB Program's total enrollment. The following comments therefore focus on the IFC's discussion of the FEHB Program.

In its preamble to the Proposed Rule, the U.S. Office of Personnel Management solicits "comment on its proposal to require air ambulance services claims data to be reported by FEHB carriers to HHS and for HHS to share this data with OPM." 86 Fed. Reg. at 51,755. The preamble concedes, as it must, that the air ambulance reporting provision of No Surprises Act ("NSA") is inapplicable to the FEHB. Indeed no NSA provision is directly applicable to the FEHB Program. Rather, Congress specified that OPM should contractually require carriers to comply with the requirements of PHSA Sections 2799A-1 (the general NSA provision), 2799A-2 (the NSA provision applicable to air ambulance providers) and 2799A-7 (the provision extending certain patient protections to grandfathered plans) and the equivalent provisions of ERISA and the Internal Revenue Code. Section 102(d)(1) of the Consolidated Appropriations Act, Division BB. OPM relies on its authority under the Section 8910 of the FEHB Act, 5 U.S.C. § 8910, to require carriers to comply with the Proposed Rule.

Under these circumstances, the approach most consistent with both the NSA and the FEHB Act would be for OPM to make a Section 8910 reporting request to carriers that aligns with the Proposed Rule's data elements for health plans and issuers. Carriers would submit those air ambulance claim reports to OPM's aggregated claims data warehouse, and OPM would submit the FEHB's air ambulance records to HHS as if it were a health plan.

Under AFHO's approach, FEHB carriers would be excluded from the Proposed Rule consistent with the NSA. OPM would achieve its goals as stated in the Proposed Rule's preamble by receiving air ambulance claims reports for the FEHB and arranging to share those reports for HHS to fill the FEHB gap in its air ambulance reporting records. *See* 86 Fed. Reg. at 51,755.

We appreciate your consideration of these comments.

Sincerely,

Rocky Midgett

Rocky Midgett
Chairman

cc: AFHO Board of Directors
Laurie Bodenheimer, Associate Director, OPM
David Ermer

January 24, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–9905–IFC,
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Prescription Drug and Health Care Spending
Interim Final Rule

Submitted Electronically: www.regulations.gov

Dear Sir/Madam:

UnitedHealthcare (UHC) is submitting comments in response to the Interim Final Rule (IFR) from the Departments of Health and Human Services, Labor, and the Treasury (the "Departments") and the Office of Personnel Management (OPM). The IFR implements provisions of the Consolidated Appropriations Act (CAA, Pub. L. 116–260) requiring health insurers and group health plans to submit annual reports to the Departments on prescription drug benefits and health care spending. OPM has extended this requirement to carriers participating in the Federal Employees Health Benefits (FEHB) program. The IFR was published by the Departments in the *Federal Register* on November 23, 2021 (86 FR 66662).[1]

UHC is dedicated to helping people live healthier lives and making the health system work better for everyone by simplifying the health care experience, meeting consumer health and wellness needs, and sustaining trusted relationships with care providers. In the United States, UHC offers the full spectrum of health benefit programs for individuals, employers, and Medicare and Medicaid beneficiaries, and contracts directly with more than 1.3 million physicians and care professionals, and 6,500 hospitals and other care facilities nationwide. The company also provides health benefits and delivers care to people through owned and operated health care facilities in South America.

As an initial matter, we appreciate the Departments' decision to address many of the concerns raised in prior comments by UHC and other stakeholders regarding the reporting provisions – in particular, the extension of the reporting deadline to December 27, 2022, allowing submission of information on an aggregated basis, and permitting multiple service providers to submit data on behalf of a group health plan. Our comments and recommendations in this letter are intended to further streamline the reporting process and reduce operational and administrative challenges for reporting entities. We are also offering suggestions for changes to the Prescription Drug Data Collection (RxDC) Reporting Instructions (the "Reporting Instructions) to further these goals.

[1] As used in this letter, our reference to "the Departments" is directed at the Departments of Health and Human Services, Labor, and the Treasury and the Office of Personnel Management.

Reporting Premium Amounts

Health insurers and group health plans are required to report the average monthly premium amount paid by participants, beneficiaries or enrollees and by employers or other plan sponsors for each plan or coverage. We want to address the requirement to report premium amounts separately for participants, beneficiaries, and enrollees and for employees and plan sponsors. In addition, we recommend clarifying the definition of premium amount used in the Reporting Instructions.

Reporting Group Health Plan Premiums

In the preamble to the IFR the Departments recognize the concerns raised by many stakeholders, including UHC, that health insurers do not maintain information on the amount of premiums paid by participants and beneficiaries compared to amounts paid by the employer or other plan sponsor, however, "the Departments are of the view that the information on the trends in the employer versus employee contributions to premium amounts is integral to analyzing the extent to which the impact of prescription drug costs on premiums affects employers versus employees." (86 FR 66674).

Insurers and plans are required to separately report "(t)he impact of prescription drug rebates, fees, and other remuneration on premium and cost sharing amounts." (45 CFR §149.740(b)(9)). According to the Reporting Instructions, insurers and plans must submit the following narrative as part of the annual report:

> Describe the impact of rebates, fees, and other remuneration on premium and out-of-pocket costs in your narrative response. Provide as much detail as possible. Describe how and why the impact may vary based on the market segment or for particular types of plans, such as high deductible health plans. Describe the impact of prescription drug rebates on the tier assignment of prescription drugs in the formulary, or the removal of generic equivalents from a formulary. If possible, provide a quantitative estimate of the impact.

(Reporting Instructions, Section 8). Based on the requirement to disclose premium impacts, we believe separate reporting of the premium amounts paid by participants, beneficiaries or enrollees and by employers or other plan sponsors is not necessary.

We also note, as we have in prior comments, that collection of this information by health insurers from group health plan sponsors raises significant challenges. UHC provides health insurance coverage to over 200 thousand small and large employer groups. These groups may provide multiple coverage options, increasing the scope of premium amounts that must be collected from plan sponsors and submitted to the Departments. **UHC recommends the Departments require health insurers and group health plans to report the total premium amounts collected from group health plans for the reference year and not separately report premium amounts for the participant or beneficiary and plan sponsor.**

Regardless of how the Departments decide to structure reporting of premium amounts, we strongly urge that health insurers not be required to separately report premiums paid by participants and beneficiaries and by plan sponsors for the 2020 and 2021 reference years (i.e., the first annual report that will be submitted no later than December 27, 2022). Health insurers will simply not be able to collect this information from all of their employer and union clients on a retroactive basis.

UHC will need to reach out to over 200 thousand group health plans requesting the premium amounts for participants and beneficiaries and for the plan sponsor for 2020 and 2021. We have no guarantee sponsors will respond to such

requests and no ability to force reporting if the information is not provided – especially for employers or other plan sponsors that are no longer purchasing insurance coverage from UHC. While we believe the Departments do not need and should not collect this level of detailed information, the Departments should at a minimum recognize the significant challenges health insurers will face in reporting separate premium amounts for the first report that will be submitted this year. **UHC recommends the Departments eliminate the requirement for health insurers to separately report premium amounts paid by participants and, beneficiaries and by the employer or other plan sponsor for reference years 2020 and 2021.**

Earned Premium

The premium amount for insured coverage is defined by a reference to the rules for reporting Medical Loss Ratio (MLR) information (45 CFR §158.130). According to the Reporting Instructions, health insurers report earned premium as follows:

> Earned premium means all money paid by a member, policyholder, subscriber, and/or plan sponsor as a condition of the member receiving coverage. Earned premium includes any fees or other contributions associated with the health plan.

(Reporting Instructions, Section 4). In order to ensure uniformity across other regulatory filings, we suggest adding the following language, similar to those in the MLR instructions for business as of December 31 of the MLR reporting year:

> . . . . as reported to the regulatory authority in the issuer's State of domicile or as filed on the NAIC SHCE filing for the MLR reporting year.

(*see:* MLR Instructions, Part 2, Section 1, Line 1.1, Column 12/31 as an example). **UHC asks that the definition of earned premium be revised to include language that reconciles the Reporting Instructions and RxDC filing back to existing filings such as the Supplemental Health Care Exhibit and/or MLR Filing.**

Group Health Plan Information

The IFR and Reporting Instructions require health insurers to report several data elements that we believe are not needed by the Departments, specifically the beginning and end dates of the plan year and the applicable Form 5500 number for the group health plan. Health insurers may not have such information and we do not believe it is needed for purposes of the reporting requirements.

Reporting Plan Years

The IFR requires health insurers and group health plans to report the beginning and end of the plan year. However, for purposes of consistency and ease of reporting, all other information is reported on a calendar year basis. As a result, there is no relationship between the plan year data and the other information reported to the Departments and capturing the plan year is not necessary.

In addition, the Departments have access to plan year information through the annual Internal Revenue Service Form 5500 reporting submitted to the Department of Labor. If the Departments believe plan year information is necessary for purposes of the reporting provision, they should coordinate the information available from the Form 5500 report submitted to the Department of Labor with the plan sponsors identified on the prescription drug report from health insurers.

UHC recommends that the Departments eliminate the requirement to report plan year beginning and end dates.

Form 5500 Identifier

The Reporting Instructions require health insurers to report the Form 5500 identifier for covered group health plans. Health insurers do not file Form 5500 reports on behalf of plan sponsors and therefor do not collect this information. As a result, it will be challenging for insurers to collect and maintain a list of the Form 5500 number. In addition, as discussed above with respect to the beginning and end date of the plan year, the Departments already have access to this information from the Department of Labor which can be coordinated with the plan sponsor name reported by the insurer.

We also believe collecting Form 5500 number information for prior years raises the same challenges as collecting premium data. Give the number of insured group health plans, it will be extremely difficult to obtain numbers for all covered plans. We ask that if the Departments determine this information is necessary for reporting purposes, that health insurers not be required to submit Form 5500 numbers in connection with the report that must be submitted by December 27, 2022.

UHC recommends the Departments not require health insurers to report the Form 5500 identifier for covered group health plans. If such information is included on the report, we ask the Departments to not require the Form 5500 identifier for Reference Years 2020 and 2021.

Reporting Primary and Specialty Care

The IFR requires health insurers and group health plans to report aggregated health care costs including "(h)ealth care provider and clinical service costs, for primary care and specialty care separately . . . ." (45 CFR §149.740(b) (4)(ii)). According to the Reporting Instructions the costs must include radiology and laboratory services performed in the primary or specialty care setting (Reporting Instructions Section 5.2).

Health care claims do not indicate spending category (i.e., primary or specialty care). A claim may include a taxonomy code for the health care provider, but even in these situations there may be an inaccurate categorization of the type of care. For example, is care provided by an Obstetrics and Gynecology Physician (Taxonomy Code 207V00000X) considered specialty care or primary care – especially under plan designs where the individual is permitted to designate an OGBYN as their primary care provider?

We believe the Departments should provide a recommended, standard methodology for reporting entities on how to categorize claims into the requested categories. This approach is similar to that used for allocating prescription drug rebates, fee, and other remuneration (Reporting Instructions, Section 7.2). The adoption of uniform reporting methodologies will inform stakeholders on how to determine different types of health care cost spending and ensure accurate categorization of medical spending across all submitters. As an alternative, the Departments should clarify that health insurers and group health plans can use any reasonable method to allocate health care costs among the categories. This is the same guidance provided in the Reporting Instructions for reporting prescription drug rebates, fees, or other renumeration:

> Describe the methods you used to allocate prescription drug rebates, fees, and other remuneration. If you used an allocation method other than one of the methods described as reasonable in the table

above, your description must include enough detail for CMS to evaluate whether the method is reasonable.

(Reporting Instructions, Section 8).

UHC recommends the Departments adopt a standard methodology for health insurers and group health plans to categorize claims into the requested categories for primary and specialty care. As an alternative, the Departments should provide guidance that reporting entities can use any reasonable method to allocate costs.

Extension of Annual Reporting Deadline

The IFR requires the annual report to be submitted no later than June 1 each year. We believe this deadline does not permit sufficient run-out of claims and other payments. In the preamble to the IFR, the Departments recognize that a later annual submission deadline could lead to the submission of more accurate data but point to the June 1 statutory deadline. There are two approaches the Departments should consider to allow health insurers and group health plans sufficient time to ensure data submitted for a reference year is complete and reflects the run-out period for claims and other payments.

The Departments could structure the reporting process such that reporting entities are required to begin the report submission process by June 1 of the reporting year – and must complete all submissions no later than August 1. This gap gives insurers and plans flexibility to continue processing claims and other payments for the reference year. Alternatively, the data reported on June 1 could reflect the reference year that is two years prior to the reporting year (e.g., the June 1, 2023 report would be for the 2021 reference year). Both of these methods will lead to more accurate reporting of prescription drug spending and health care costs.

UHC recommends the Departments consider modifications to the reporting requirements to allow sufficient run-out of claims and other payments resulting in more accurate submission of data. One approach would allow reporting entities to begin the submission process no later than June 1 of the reporting year and to complete the submission no later than August 1 of the reporting year. As an alternative, the data would submitted for a reporting year would be for the reference year two years prior to the reporting year.

Reporting Rebates, Fees, and Other Renumeration

We continue to have concerns regarding the submission of data on rebates, fees, and other renumeration that does not impact premiums and as a result, reporting is not authorized by the CAA. In particular, we ask that the Departments not require reporting of rebates, fees, and other renumeration paid to a service provider that is not shared with the plan sponsor or passed on to the member at the pharmacy point-of-sale.

The Reporting Instructions require submission of data on manufacturer rebates paid to a pharmacy benefit manager (PBM) but not shared with another entity. In addition, the amount of rebates paid to a PBM and rebates passed to a member at the point-of-sale must be reported (Reporting Instructions, Section 7). We believe that payments to a PBM that are not shared with the group health plan or passed on to a member is not required by the CAA and should not be reported.

The CAA requires submission of data that will be used by the Departments to report "(a)ny impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, with respect to prescription drugs prescribed to enrollees in the plan or coverage . . . ." (Public Health

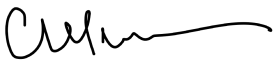
Service Act 2799A-10(a)(9) *emphasis added*). Payments by a manufacturer to a service provider that are not passed on to the plan or that are shared with the member at the point-of-sale would not impact premiums

.

UHC asks the Departments to eliminate reporting of the amount of rebates, fees, and other renumeration paid to a PBM or other service provider that is not shared with the plan sponsor.

Thank you for your thoughtful consideration of our comments. Should you have any questions, please do not hesitate to contact me.

Sincerely,



Christine McCartney Harris

KAISER PERMANENTE®

January 24, 2022

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9905-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically to www.regulations.gov

Re: ***Prescription Drug and Health Care Spending – Interim Final Rules with Request for Comments*** **[CMS-9905-IFC]**

To Whom It May Concern:

Kaiser Permanente appreciates the opportunity to respond to the Interim Final Rules with Request for Comments governing "Prescription Drug and Health Care Spending" (the "IFC") issued jointly by the Office of Personnel Management and the Departments of the Treasury, Labor, and Health and Human Services (collectively, "the Departments").[1]

Kaiser Permanente is the largest private integrated healthcare delivery system in the U.S., delivering health care to 12.5 million members in eight states and the District of Columbia.[2] Kaiser Permanente's mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

Within our footprint, we maintain a primarily internalized pharmacy system, including over 550 outpatient, hospital, infusion, specialty and mail order pharmacy sites staffed by over 14,000 pharmacy personnel. Kaiser Permanente spends approximately $10 billion annually on pharmaceuticals. Our Permanente Medical Group (PMG) physicians and other authorized practitioners prescribe, and our pharmacies dispense, over 90 million prescriptions annually.

Kaiser Permanente believes that health care, including prescription drugs, should be affordable for all, and we recognize the importance of price transparency in allowing consumers to understand the costs of their care and make informed decisions regarding their health plan benefits. We commend the Departments' work to expeditiously issue this IFC implementing the pharmacy benefit and prescription drug cost reporting requirements under section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021 ("CAA"). Similarly, we appreciate the Departments recognizing "the significant operational challenges that regulated entities may face in meeting the initial deadlines for the section 204 data submissions" and exercising their discretion to defer enforcement until December 27, 2022 pursuant to the *FAQs about Affordable*

[1] 86 Fed. Reg. 66662 (November 23, 2021).
[2] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., one of the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 700 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members.

Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49.[3]

The IFC provides helpful guidance as we prepare the Section 204 data submissions, including several clarifications that align with recommendations offered in our response to the *Request for Information (RFI)* on this topic issued in June 2021.[4] Notwithstanding these helpful efforts, we still have significant concerns with the overlapping pharmacy reporting requirements that remain outstanding pursuant to the PBM Transparency rule[5] and the Transparency in Coverage final rule[6]. We continue to recommend withdrawing those requirements and only moving forward with the Section 204 reporting requirements contained in the IFC. We also would like to highlight a few additional considerations related to the IFC where further clarity and direction will be most impactful to producing meaningful reporting submissions.

Overlapping and Competing Pharmacy Reporting Requirements

Although not directly addressed in the IFC, the Departments previously sought input, through the June 2021 RFI, on whether there were "opportunities to remove other reporting requirements applicable to plans and issuers . . . to reduce administrative burdens or costs associated with complying with the new requirements."[7] We continue to recommend the Departments withdraw the pharmacy reporting requirements as established in the PBM Transparency rule and Transparency in Coverage final rule.

The requirements contained in the IFC assist in "identifying any excessive pricing of prescription drugs driven by industry concentration and monopolistic behaviors, promoting the use of lower-cost generic drugs, and addressing the impact of pharmaceutical manufacturer rebates, fees, and other remuneration on prescription drug prices and on plan, issuer, and consumer costs."[8] The data supplied in meeting this objective largely meets the purposes of the other reporting requirements. Indeed, the Departments acknowledged that "some of the data envisioned for reporting under the [CAA] may, to an extent, be similar to some of the data sought by collection under the [PBM Transparency rule]."[9] Furthermore, the Transparency in Coverage final rule echoes similar goals of addressing market competition and pricing power through transparency reporting.[10] Preserving the requirements in the IFC and withdrawing the other rules' similar, overlapping requirements would reduce administrative burden while meeting the stated transparency goals.

Moving forward with the requirements under the PBM Transparency rule and Transparency in Coverage final rule would also not result in meaningful or actionable information for most consumers. Instead, this would lead to a large amount of non-personalized pricing information that could confuse and overwhelm consumers, especially for the Transparency in Coverage final rule requirements. Instead, there is an opportunity to move forward with a single, cohesive framework

[3] FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (Aug. 20, 2021), Q12, available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.
[4] 86 Fed. Reg. 32813 (June 23, 2021).
[5] 86 Fed. Reg. 24140 (May 5, 2021).
[6] 85 Fed. Reg. 72158 (November 12, 2020).
[7] 86 Fed. Reg. at 32816.
[8] 86 Fed. Reg. at 66663.
[9] 86 Fed. Reg. 24241 (May 5, 2021).
[10] 85 Fed. Reg. 72160 (November 12, 2020).

for reporting prescription drug and health care spending under the provisions of the IFC.

Recommendations to Further Clarify the Reporting Requirements

While the IFC makes important progress in clarifying the reporting obligations, we want to highlight some additional issues and recommendations that would assist plans and issuers with reporting accurate information.

Premium Reporting

We continue to urge the Departments to withdraw the requirement to report data regarding the division of the monthly premium amount paid by employers and employees. Plans and issuers lack access to the information necessary to report this data, with issuers generally only having access to the entire premium amount billed to the employer group.

Moving forward with the current requirement would also create additional challenges for issuers trying to obtain and report this information for the 2020 and 2021 reference years in instances where an employer group no longer uses the services of the issuer. Under these circumstances a contractual relationship no longer exists between the entities and procuring the information will be extremely difficult. Issuers will need guidance with respect to reporting this information. At a minimum, we would recommend that if an issuer is unable to obtain the premium amounts paid by the employer/plan sponsor and the employee for a particular group, the calculation for the aggregated total annual premium amount and the total number of life-years should exclude groups for which such data are not available.

Applicability to FEHB Medicare Plans

We recognize that FEHB carriers are also required to comply with these interim final rules.[11] In particular, the IFC notes that the requirements are applicable to FEHB plans "in the same manner as plans and issuers must provide such data under [the relevant statutes]."[12] It is our understanding that reporting would be required only for FEHB commercial plans and not for FEHB Medicare plans, consistent with the overall approach for this reporting. We would appreciate the Departments' confirmation of this understanding.

Accounting for Reinsurance in Total Prescription Drug Spending

The Prescription Drug Data Collection (RxDC) Reporting Instructions, issued in conjunction with the IFC for the information collection instrument, directs submitters to subtract any net payments from any federal or state reinsurance or cost-sharing reduction arrangement or program for reporting related to "Total Spending."[13] As it relates to reporting total spending for prescription drugs, applicable state reinsurance programs provide payment at an aggregate level and issuers are unable to attribute those values specifically to prescription drug spending. We recommend clarifying the "Total Spending" definition in the instructions to account for this nuance.

Support for Provisions of the IFC

We appreciate the Departments responsiveness to our feedback on the RFI and for taking

[11] *See* 86 Fed. Reg. at 66665.
[12] *Id*. at 66663.
[13] Information Collection Requests (CMS-10788/OMB control number 0938-NEW), 86 Fed. Reg. 66662 (Nov. 23, 2021).

important steps to reduce the administrative burden for plans and issuers of this data reporting. We support the following helpful clarifications made in the IFC:

- Allowing reporting entities to aggregate data at the state and market level, which will reduce reporting burdens and improve the Departments' ability to identify costly prescription drugs impeding health care affordability efforts.

- Aligning definitions and data fields in this reporting with definitions and data fields in other required reports, which will both reduce confusion and expedite the data collection and submission process. This includes calendar-year reporting, and measuring the increase in plan expenditures based on the absolute amount of the increase.

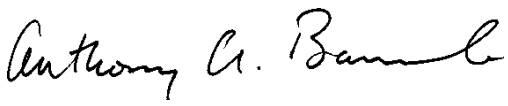
- Permitting the use of premium equivalent amounts for self-funded group health plans, which will ensure more consistent reporting between fully-insured and self-funded plans.

- Designing an information collection instrument in a manner that will enable plans and issuers to provide a qualitative description regarding the impact of prescription drug rebates on premiums and cost sharing. This is especially important for Kaiser Permanente, as our integrated system and drug purchasing that favors upfront price concessions prevent us from precisely accounting for how the price concessions we receive from drug manufacturers are reflected in member premiums.

* * *

We look forward to working with the Departments on the continued implementation of these reporting requirements. We share the goal of creating a reporting framework that illuminates how prescription drug costs burden patients and employers, while simultaneously minimizing the operational challenges for plans and issuers. Thank you for considering our comments. Please feel free to contact Anthony Barrueta (510-271-6835; email: anthony.barrueta@kp.org) or Simon Vismantas (425-677-1267; email: simon.p.vismantas@kp.org) with any questions or concerns.

Sincerely,



Anthony A. Barrueta
Senior Vice President
Government Relations

ACAP
Association for Community Affiliated Plans

1155 15th Street, N.W., Suite 600 | Washington, DC 20005
Tel. 202.204.7508 | www.communityplans.net
Christopher D. Palmieri, Chair | Margaret A. Murray, Chief

January 24, 2022

Centers for Medicare & Medicaid Services, Department of Health & Human Services
Employee Benefits Security Administration, Department of Labor
Internal Revenue Service, Department of the Treasury
Office of Personnel Management

Submitted electronically via: www.register.gov
RE: CMS-2021-0178

To Whom It May Concern:

On behalf of the Association for Community Affiliated Plans, I am pleased to offer the following comments in response to the interim final rule entitle Prescription Drug and Health Care Spending, pertaining to implementation of the No Surprises Act.

By way of background, ACAP is an association of 74 not-for-profit and community-based Safety Net Health Plans (SNHPs). Our member plans provide coverage to more than 20 million individuals enrolled in Medicaid, the Children's Health Insurance Program (CHIP) and Medicare Special Needs Plans for dually-eligible individuals, including nearly 800,000 Marketplace enrollees. Nationally, Safety Net Health Plans serve almost half of all Medicaid managed care enrollees. Eighteen of ACAP's Safety Net Health Plan members and Partner Plans offer qualified health plans (QHPs) in the Marketplaces. With this mission in mind, we are pleased to provide the following input on the interim final rules.

Treatments of Short-Term Products

As we have in the past, we again applaud the departments for confirming that short-term, limited-duration insurance (STLDI) is not individual health insurance. ACAP agrees with this position and has long been concerned by marketing of these products and their proliferation. Just last year, a Government Accountability Office (GAO) undercover investigation on STLDI marketing practices found that sales agents used deceptive marketing practices, including claims that products were Affordable Care Act (ACA) compliant plans, in more than 25 percent of the test cases.[1]

ACAP is pleased that the recently issued Office of Management and Budget (OMB) Unified Agenda calls for rulemaking on this topic by August 2022 to "ensure this type of coverage does not undermine the Affordable Care Act, including its protections for people with pre-existing conditions, the Health Insurance Exchanges, or the individual, small group, or large group markets for health insurance in the United States."[2] We encourage the Administration to meet or exceed this projected issuance date so that previous guardrails and limitations on the maximum allowable length of such products can be

[1] See: https://www.gao.gov/products/gao-20-634r
[2] See: https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0938-AU67

restored to the three-month maximum. Consistent with our previous comment letters, we are concerned about the confusion that will exist regarding No Surprises Act protections and people enrolled in these products. This includes ensuring people in STLDI products are treated as non-insured or cash-pay customers and thus eligible to receive good faith estimates and able to participate in the Select Dispute Resolution (SDR) process if they receive a balance bill in excess of the estimate.

While we appreciate the recognition that STLDI products are not individual health insurance, we do see value in requiring the issuers of such products to report the data required under the interim final rule. Collecting information as to what these products are spending on medical care and pharmaceuticals would provide needed transparency. Collected data could help consumers, policymakers and other stakeholders compare the benefits and overall spending of ACA-compliant insurance products and non-compliant products. We encourage the departments to give further consideration to this point, particularly as you are working toward issuing updated rules and regulations on these products over the coming months, to ultimately leverage any authorities that may enable collection and reporting of data on such products.

Annual Reporting of Reference Year Data

We support the proposal to collect data on a calendar-year basis. We also support and appreciate the departments' decision to exercise enforcement discretion through December 27, 2022. Given the time needed to write and issue rules to implement the law, we believe this action was essential for the reasons outlined in the rule. We also recognize that the reporting deadline for each reference year following December 27, 2022 will be June 1st. We ask that the departments consider setting this annual deadline for reference year reports as July 1st rather than June 1st. A July 1st deadline would provide additional time for completion of rebate reconciliation and other reporting that occurs at the end of April, enabling reporting of more complete information and reducing burdens on plans and issuers.

Reporting on Pharmaceutical Data

With regard to reporting on brand prescription drug spending, ACAP urges the departments to issue greater clarity in future guidance as to how plans and issuers should be reporting this data. Specifically, we urge the departments to require plans to report using a single standard such as the Medi-Span Generic Product Identifier (GPI) classification system. We are concerned that absent further clarity and standardization, plans may use different approaches for reporting data which will skew the data and hinder the ability to make comparisons across products. We also request that the departments consider issuing more explicit information as to drugs that should not be reported or that are excluded from reporting to guard against a plan unwittingly including a data point that should not be included.

Similarly, we urge the departments to move with alacrity to provide additional details to further inform issuer and plan reporting on rebates, fees and other remuneration. We note that the preamble notes that the departments "intend to specify a level of detail that will assist plans, issuers and other reporting entities in correctly determining the total amount of prescription drug rebates, fees, and other remuneration, and that will be generally consistent with the categories of rebates, fees, and other remuneration specified in the data collection requirements under the Exchange establishment rule and the PBM Transparency rule." We appreciate this commitment and encourage that such guidance be issued as soon as possible to inform data reported for the 2020 and 2021 reference year reports. If this

guidance is not made available soon, we are concerned that issuers may report incomplete or discordant data.

Reporting Tools & Templates

Building upon the previous points, ACAP encourages the departments to put forward additional templates or models to inform reporting on prescription drug and health care spending. I note that the departments have previously issued extensive guidance and templates on other elements of the No Surprises Act, such as a standard good faith estimate, dispute resolution form and notification to consumers of their right to receive a good faith estimate. It would be most helpful to issuers and plans for the departments to issue similar resources to aid in our reporting.

Data Reporting

ACAP appreciates that the departments have taken steps to limit the reporting burden placed on plans and issuers. This includes by aligning reporting periods and standards with other sector requirement as well as allowing some data to be reported in the aggregate. As the departments know, a number of states have laws and regulations pertaining to reporting of pharmacy benefit managers (PBM) and related data. ACAP recognizes the unevenness of state-by-state reporting requirements and that the NSA seeks to secure reporting of such data at the federal level. We urge the departments to take additional actions to reduce issuer and plan reporting burdens, particularly by aligning such requirements with state requirements to the greatest extent possible. Taking this action would enable plans to report desired data to states and the federal government while limiting cost and other burdens.

Reporting on Rebates, Fees and Other Remuneration

ACAP recognizes that the issue of rebates and other remuneration remains one of high interest and appreciates the need for capturing this data. With regard to collection of data on rebates passed through to participants, beneficiaries and enrollees, we urge the departments to clarify that this will enable plans to report on rebates given to plan participants at the point-of-sale. We see this level of detail as being an important differentiator given the variety of approaches to applying rebates and would like to see additional clarity as to how such data can be reported and displayed. ACAP urges that this capability be reflected within the intended “collection instrument” “to provide both quantitative and qualitative information regarding the impact of prescription drug rebates on premiums and cost sharing” and that the departments issue said instrument as quickly as possible.

Future Data Elements

ACAP appreciates that the departments will look closely at the initial data reports and may propose modifications going forward. ACAP appreciates this point and encourages the departments to maintain a process for regularly considering modifications – including reporting of additional data points or sunsetting some requirements – and subsequently proposing such changes. We think an ongoing feedback loop and process will be needed to optimize the desired impact of the law and this component of it, and we stand ready to actively participate in any such process.

Conclusion

Thank you for issuing the interim final comment on this important component of the No Surprises Act. ACAP appreciates the significant amount of work done during a very short period of time to implement this law. I hope you have found these comments helpful as you consider further refinements and modifications to this data collection and reporting program. If you have follow-up questions or if there are ways ACAP or our members can be helpful, please feel free to reach out at your convenience.

Sincerely,

/s/

Meg Murray, CEO
Association for Community Affiliated Plans

THE COUNCIL
The Council of Insurance Agents & Brokers

January 24, 2022

VIA ELECTRONIC MAIL – www.regulations.gov

Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Ave. NW
Washington, DC 20210

Internal Revenue Service
Department of the Treasury
1111 Constitution Ave. NW
Washington, DC 20224

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Request for Comments Regarding the Prescription Drug and Health Care Spending Interim Final Rule — CMS-9905-IFC:

To Whom It May Concern:

The Council of Insurance Agents and Brokers ("The Council") appreciates this opportunity to comment on your Prescription Drug and Health Care Spending Interim Final Rule implementing Section 204 of the Consolidated Appropriations Act of 2021 ("CAA").[1] The Council strongly supports and appreciates your continued focus on transparency and reducing unnecessary costs and burdens in the healthcare system, and we agree that addressing drug costs is an essential part of that effort. The Council subscribes to and supports the comments submitted by the American Benefits Council which represents many of the employer self-insured health plans that are clients of Council member firms. The Council is submitting the immediate comments to request that the Department of Labor ("DoL") issue guidance making clear that Pharmacy Benefit Managers ("PBMs") and Third-Party Administrators ("TPAs") are "covered service providers" that act as "consultants" to self-insured group health plans under CAA Section 202 and therefore are subject

[1] Prescription Drug and Health Care Spending Interim Final Rule, 86 Fed. Reg. 66662 (November 23, 2021) (hereinafter the "Rule").

to the CAA Section 202 plan fiduciary compensation disclosure obligations. That clarification will ensure both that self-insured plans are able to comply with their Section 204 reporting obligations and that plan fiduciaries are able to evaluate the "reasonableness" of the PBM and TPA compensation arrangements as they are required to do to satisfy their Employee Retirement Income Security Act ("ERISA") obligations.[2]

The Council represents the largest and most successful employee benefits and property/casualty agencies and brokerage firms. Council member firms annually place more than $300 billion in commercial insurance business in the United States and abroad. In fact, they place more than 90 percent of all U.S. commercial insurance products and services and they administer billions of dollars in employee benefits. Council members conduct business in some 30,000 locations and employ upward of 350,000 people worldwide, specializing in a wide range of insurance products and risk management services for business, industry, government, and the public.

Our comments build upon earlier feedback submitted by the Council in July 2021 in response to the Request for Information ("RFI") issued jointly by DoL, the Department of the Treasury, and the Department of Health and Human Services (collectively, "the Departments") in anticipation of this rulemaking.[3] Many of our suggestions in that submission were largely adopted in this Rule and we are grateful for your consideration of the issues impacting the employer-sponsored market. The comments below focus on our key outstanding concern with the Rule: the obligations on TPAs and PBMs to provide the required reporting information to employer plans and plan sponsors.

As detailed in our July 2021 comments, in the employer-provided healthcare space, administration of the medical plan, and pharmacy benefits in particular, are typically outsourced to either an insurance carrier for fully insured plans or to a TPA or PBM for self-insured plans. Those entities maintain the information and internal processes required for reporting and compliance (e.g., top drugs, rebates, and fees) and that information generally is not shared with the health plans. It is well-understood that employer plans and plan sponsors currently have little to no access to the required reporting information under Section 204; indeed, the Departments recognize that TPAs and PBMs "will make the Section 204 data submissions on behalf of most self-funded group plans in the vast majority of cases."[4] The Rule does not, however, create any specific obligations on TPAs, PBMs, or other third parties to report this information to the plans because Section 204 imposes those reporting obligations directly on issuers and plans. While both insured and self-insured plans are allowed to enter into written agreements with other third parties – including TPAs and PBMs – to report the requisite information, self-insured plans remain directly responsible for any reporting violations. This leaves self-insured plans with no recourse in the event the third parties on which they heavily rely fail to produce this information.

Notably, Congress passed a separate reporting requirement in *Section 202* of the CAA that amends Section 408(b)(2) of the Employee Retirement Income Security Act of 1974 by adding a new

[2] Employee Retirement Income Security Act, Pub. L. No. 93-406, § 408(b)(2)(A) (1974) (codified at 29 U.S.C. § 1108(b)(2)(A)) (establishes that "reasonable compensation" must be paid for "services necessary for the establishment or operation of the plan") (hereinafter "ERISA").

[3] Request for Information, Reporting on Pharmacy Benefits and Prescription Drug Costs, 86 Fed. Reg. 32813 (June 23, 2021).

[4] Rule at 66669.

subsection (B) which requires a plan fiduciary to receive compensation disclosures from "covered service providers" before the fiduciary may contract with such providers to provide services to group health plans. Under 202, "covered service providers" include service providers providing "consulting" services with respect to group health plan "pharmacy benefit management" and "third party administration."

The requisite Section 202 disclosures must include the information maintained by TPAs and PBMs that plans will be responsible for reporting under the Section 204 Rule, such as rebates, fees, and other remuneration PBMs receive from manufacturers.[5] In explicitly including TPA and PBM services in its definition of consulting, the statute clearly intends for those entities to fall under Section 202's reporting requirement. We have learned through our discussions with DoL, however, that at least some TPAs and PBMs have pushed back on this reading, and have asked DoL to "clarify" that they are not "consultants" under the statute and are therefore not subject to the Section 202 transparency obligations.

Any such interpretation would, however, be at odds with the plain terms and structure of Section 202 and with the reporting obligations imposed directly on self-insured plans under Section 204. First, Section 202 defines "consulting" as any services "related to the development *or implementation of*" a laundry list of services, specifically including both "pharmacy benefit management services" and "third party administration" services.[6] Second, the requisite disclosures that must be made by the "covered service providers" include –

> If applicable, a statement that the covered service provider . . . will provide, or reasonably expects to provide, services pursuant to the contract or arrangement directly to the covered plan as a fiduciary (within the meaning of section 3(21)).[7]

PBMs and TPAs both exercise discretionary control over plan assets because they control the expenditure of plan assets to pay plan-related pharmacy and health claims as they deem appropriate in accordance with the governing plan documents. As DoL itself has noted:

> PBMs are third-party administrators that manage the prescription drug benefit for a contracted entity. This administration typically involves processing claims, maintaining drug formularies, contracting with pharmacies for reimbursement for drugs dispensed, and negotiating prices with drug manufacturers.[8]

Moreover, it is unclear what entities other than PBMs and TPAs perform fiduciary services on behalf of the plans they administer that would trigger the special "fiduciary" disclosure dictated by the statute.

Third, Section 202 requires covered service providers to comply with plan fiduciary requests for additional information needed to comply with the plan's own reporting obligations –

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[5] The disclosures are required in part to enable the plan fiduciary to evaluate the reasonableness of the overall "covered service provider" compensation or cost. *See, e.g.,* ERISA § 408(b)(2)(B)(ii)(II) (as added by CAA § 202)

[6] ERISA § 408(b)(2)(B)(ii)(I)(bb)(BB) (as added by CAA § 202) (*emphasis added*).

[7] ERISA § 408(b)(2)(B)(iii)(II) (as added by CAA § 202).

[8] 86 Fed. Reg. 24140, 24314-5 (May 5, 2021).

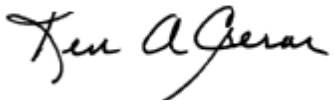
> Upon the written request of the responsible plan fiduciary or covered plan administrator, a covered service provider shall furnish any other information relating to the compensation received in connection with the contract or arrangement that is required for the covered plan to comply with the reporting and disclosure requirements under this Act.[9]

With respect to the relationship between 202 and 204, as the Departments have recognized, Section 204 imposes reporting obligations directly on self-insured plans. The Section 202 service provider PBM and TPA reporting obligations enable plan fiduciaries to satisfy their own Section 204 reporting obligations and Section 202 must therefore be read to require such PBM and TPA disclosures.

For these reasons, we therefore urge the Department of Labor to issue guidance stating that PBMs and TPAs are subject to Section 202's compensation disclosure obligations to ensure that plans obtain the specific information they are required to report under Section 204.

Again, we appreciate this opportunity to provide comments. Please do not hesitate to contact us if we can provide further information or answer any questions.

Respectfully submitted,



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[9] ERISA § 408(b)(2)(B)(vi)(I) (as added by CAA § 202)

SUBMITTED ELECTRONICALLY

January 24, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9905-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-9905-IFC; Prescription Drug and Health Care Spending Interim Final Rules

Dear Administrator Brooks-LaSure:

Gilead Sciences, Inc. (Gilead) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS), Office of Personnel Management, Internal Revenue Service (IRS), and Employee Benefits Security Administration's (collectively, the Departments') Interim Final Rules with request for comments entitled "Prescription Drug and Health Care Spending" (Interim Final Rules).[1] Gilead is a US-based, global biopharmaceutical company that is committed to discovering, developing, and delivering innovative therapeutics for people with life-threatening diseases in areas of unmet medical need. Our marketed products include medicines for the prevention and treatment of HIV/AIDS and treatment of liver diseases including hepatitis B and C, cancer, and COVID-19, as well as certain cardiovascular and respiratory diseases.

Gilead supports the Departments' efforts to help patients better understand their out-of-pocket costs and afford their medicines. As currently drafted, the Interim Final Rules require health plans to report limited information regarding accumulator adjustment programs publicly and at an aggregated level.[2] As described further below, we urge the Departments to go further and require that health insurance issuers and group health plans disclose to the public—in real time—information about accumulator adjustment programs that plans or their Pharmacy Benefit Managers (PBMs) have imposed. This disclosure would give beneficiaries more visibility into

[1] 86 Fed. Reg. 66,662 (Nov. 23, 2021).

[2] 86 Fed. Reg. at 66,670.

plan benefit designs, so they can choose the best plan for them. This can help individuals with chronic diseases avoid inadvertently enrolling in a plan that effectively discriminates against them through increased cost-sharing for the medicines they need.

Real time disclosure of copay accumulators could also support continued provision of cost-sharing assistance by manufacturers. A forthcoming price reporting change that was promulgated by CMS in a December 2020 rulemaking (the "2020 Final Rule") will threaten the viability of all manufacturer cost-sharing assistance. This change, which becomes effective January 1, 2023, requires manufacturers to include cost-sharing assistance when calculating Best Price unless they can "ensure" that an accumulator adjustment program has not applied.[3] Because there currently is no mechanism to reliably "ensure" that accumulator adjustment programs do not apply to their patient assistance, we will be forced to either account for such assistance in Best Price, risking substantially higher Medicaid rebate liabilities (which may not be economically feasible), or reduce or stop offering patient assistance altogether, resulting in harm to patients. Increased transparency of when accumulator adjustment programs apply could help manufacturers comply with the 2020 Final Rule while continuing to offer cost-sharing assistance. However, the best way to ensure that manufacturers are able to continue offering cost-sharing assistance as they do today would be to rescind these price reporting changes in the 2020 Final Rule.

Our comments below further explain the need for greater transparency of accumulators and by elaborating on the following points:

- Plan benefit designs increase out-of-pocket costs, which threaten patients' ability to receive prescribed medicines.
- Manufacturer cost-sharing assistance provides critical support for patients facing rising out-of-pocket costs.
- Accumulator adjustment programs are an important part of the plan's benefit package because they undermine affordability – therefore they should be transparent to patients.
- Forthcoming changes to government price reporting rules threaten manufacturers' ability to provide cost-sharing assistance and should be rescinded.
- To support patient affordability, the Departments should require uniform public disclosure of accumulator adjustment programs.

In addition, we support the comments of our trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA). These comments are intended to further build on suggestions included in PhRMA's comments.

I. Plan Benefit Designs Increase Out-of-Pocket Costs, Threatening Patients' Ability to Receive Prescribed Medicines

[3] 85 Fed. Reg. 87,000, 87,048-57 (Dec. 31, 2020). Note that manufacturers would also be required to account for cost-sharing assistance in Average Manufacturer Price (AMP).

Due to the prevalence of high deductibles, coinsurance, and increasing out-of-pocket costs, patients are experiencing unprecedented challenges in accessing critically important therapies that their physicians have prescribed for their care. In fact, on average, patients pay for a greater share of medications out of pocket than for other items and services.[4] Over the past decade, plans have increasingly subjected medicines to deductibles and high cost-sharing on plan specialty tiers. This has led to significant increases in patients' out-of-pocket drug spending.[5]

Studies have shown that patients with higher cost-sharing are more likely to delay or abandon their prescribed course of treatment because they are unable to afford it. For example, in a *Health Affairs* literature review of studies on the effects of higher cost-sharing for certain specialty medications, the reviewers noted that "when monthly out-of-pocket costs for prescription drugs exceed $150–$200, rates of new therapy abandonment approximately double, the odds of being adherent are reduced by 39 percent, and the risk of discontinuation increases by 27–58 percent."[6] Other studies have shown that patients who have high-deductible plans and multiple chronic conditions are much more likely to delay therapy and to have higher amounts of medical debt.[7] Moreover, other research indicates that high out-of-pocket costs diminish and adversely affect quality of life and survival.[8]

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[4] *See CMS,* National Health Expenditure Data (last modified Dec. 15, 2021), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.

[5] *See, e.g.,* IQVIA, *Patient Affordability Part One: The Implications of Changing Benefit Designs and High Cost-Sharing* (May 18, 2018), https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-one; Kaiser Family Foundation, *Tracking the Rise in Premium Contributions and Cost-Sharing for Families with Large Employer Coverage* (Aug. 15, 2019), https://www.kff.org/health-costs/issue-brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/; Rae M, Levitt L, Claxton G, et al.; *Kaiser Family Foundation. Patient cost-sharing in marketplace plans* (2016), https://www.kff.org/health-costs/issue-brief/patient-cost-sharing-in-marketplace-plans-2016/.

[6] Catherine Starner et. al, *Specialty Drug Coupons Lower Out-Of-Pocket Costs And May Improve Adherence At The Risk Of Increasing Premiums*, 33 Health Affairs 1761-1769 (Dec. 2014) (examining biologic anti-inflammatory drugs and drugs for multiple sclerosis).

[7] Anuradha Jetty et. al, "High-Deductible Plans May Reduce Ambulatory Care Use," Robert Graham Center (Nov. 1, 2016), https://www.graham-center.org/rgc/publications-reports/publications/one-pagers/high-deductible-ambulatory-2016.html; Michael Laff, "Study: High Deductibles Cause Patients to Delay Care," American Academy of Family Physicians (Nov. 22, 2016), https://www.aafp.org/news/practice-professional-issues/20161122highdeductible.html.

[8] Catherine Starner et. al, Specialty Drug Coupons Lower Out-Of-Pocket Costs And May Improve Adherence At The Risk Of Increasing Premiums, 33 Health Affairs 1761-1769 (Dec. 2014) (examining biologic anti-inflammatory drugs and drugs for multiple sclerosis).

II. Manufacturer Cost-Sharing Assistance Provides Critical Support for Patients Facing Rising Out-of-Pocket Costs

By removing or reducing prohibitive out-of-pocket costs, patient assistance programs provide critical support to help patients adhere to their prescribed regimen. This is particularly important where adherence to prescribed medications is critical for the treatment or prevention of infectious diseases. Recent analysis by IQVIA found that patients with copay accumulator adjustment programs discontinue their medicines much more often than those without them. As a specific example, patients with HIV discontinue their medicines 2.6 times as often if subject to an accumulator adjustment program. IQVIA also found that cost-sharing assistance reduces patient abandonment 90% across HIV, hepatitis B and hepatitis C and that patients using cost-sharing assistance are 5 to 19% more adherent than those not using assistance. [9]

Improved adherence can lead to better outcomes. In the case of HIV medicines, for example, reduced patient adherence correlates with poor clinical outcomes and higher healthcare costs (e.g., hospitalizations and physician office visits) that arise from preventable disease complication.[10] Widespread partial adherence to treatment regimens, where a patient takes some of their HIV medications but not all, also poses a significant public health threat, to the extent that it can lead directly to the development of resistant forms of the virus.[11] Drug resistance can lead to treatment failure and eliminates any further treatment from the class of drugs that the resistance impacts, thus requiring patients to switch to alternative treatment regimens that may be more limited and costlier. In addition, the drug-resistant form of the virus can then be spread to and infect other patients, which further undermines efforts to end the HIV epidemic.[12] Furthermore, studies now show that individuals living with HIV who take their medicine daily as prescribed and suppress their viral load to undetectable levels have effectively zero risk of transmitting HIV to their sexual partners.[13] In other words, adherence to HIV treatment also serves to prevent the spread of HIV.

To help patients afford their medicines and comply with prescribed treatment, Gilead has established cost-sharing assistance programs in the form of co-pay coupons provided to patients. These programs are only provided to patients not covered by federal healthcare programs. Gilead's Advancing Access® program, for example, helps patients understand their coverage and identify financial support options to access their Gilead HIV treatment, HIV prevention, and Hepatitis B (HBV) treatment. Among other things, this patient support program includes a co-

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[9] Based on an analysis of Commercial patients, including HIX, that utilized copay cards from Jan. 2018-Aug. 2021. Conducted by IQVIA, US Market Access Strategy Consulting and Analytics, Dec. 2021. All rights reserved. Copyright 2021 (data on file with Gilead).

[10] M. Christopher Roebuck, et al., *Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending*, 30 Health Affairs 1 (2011).

[11] Von Wyl V, Klimkait T, Yerly S, Nicca D, Furrer H, et al., *Adherence as a Predictor of the Development of Class-Specific Resistance Mutations: the Swiss HIV Cohort Study*, 8 PLoS ONE e77691 (2013).

[12] Guyer B, et al. AMCP 2010. San Diego. #17.

[13] NIH. The science is clear: with HIV, undetectable equals untransmittable. Jan. 10, 2019. https://www.nih.gov/news-events/news-releases/science-clear-hiv-undetectable-equals-untransmittable

pay coupon that provides co-pay support for eligible HIV treatment, HIV prevention and HBV treatment patients with commercial insurance who need help paying for their out-of-pocket medicine costs. Eligible patients could pay as little as $0 per month for the medications prescribed by their doctor. The administration of the Advancing Access® program has been guided by the core principle of facilitating rapid access to and initiation of treatment and prevention medicines with minimal logistical and administrative burdens, recognizing the significant social and systemic hurdles that often impede access to medication for people living with or at risk for HIV and those living with HBV. Rapid and equitable access remains an important tool in the US plans to end the HIV epidemic.

Patient assistance like that provided through Advancing Access® is particularly critical for vulnerable communities that may face a multitude of obstacles when seeking life-saving and preventative medications in addition to rising out-of-pocket costs. Stigma, homophobia and transphobia, racism, and lack of access to appropriate healthcare services are barriers to comprehensive HIV prevention and care. This particularly impacts the estimated one in four Latino gay and bisexual cisgender men and one in two Black gay and bisexual cisgender men who will be diagnosed with HIV in their lifetime.[14]

Health plans argue that manufacturer cost-sharing assistance undermines their benefit designs and increases healthcare costs.[15] This argument ignores several important facts about patients' use of medicines. First, as noted above, increasing patient out-of-pocket costs are the primary reason manufacturers provide cost-sharing assistance. Rising deductibles make many medicines unaffordable for patients who are essentially uninsured for that medicine and face its full cost. Second, even as manufacturers pay significant rebates to health plans on medicines,[16] plans often do not reflect those price concessions in the prices paid by patients. Third, many patients do not have a lower cost alternative to choose. For example, just 0.4 percent of commercial medicine claims were filled with a coupon for a brand medicine that had a generic alternative.[17] They are prescribed medicines they need by physicians, and often go through a health plan's prior authorization or step therapy only to face high cost-sharing after the medicine is approved by the plan.[18] In these cases, the manufacturer assistance is playing a critical role in

[14] CDC, Press Release, Half of Black Gay Men and a Quarter of Latino Gay Men Projected to be Diagnosed Within Their Lifetime (Feb. 23, 2016), https://www.cdc.gov/nchhstp/newsroom/2016/croi-press-release-risk.html.

[15] Optum. Making sense of copay cards: how copay cards can disrupt your benefit strategy. Available at: https://www.optum.com/business/resources/library/managing-copay-cards.html.

[16] Brownlee A and Watson J. The Pharmaceutical Supply Chain, 2013-2020. BRG. January 7, 2022. Available at: https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/.

[17] IQVIA, An Evaluation of Co-Pay Card Utilization in Brands After Generic Competitor Launch (IQVIA, 2018) https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization.

[18] VIBD Center. Reward the Good Soldier: A Dynamic Approach to Consumer Cost-Sharing for Prescription Drugs. AMJC. September 26, 2016. Available at: https://www.ajmc.com/view/reward-the-good-soldier-a-dynamic-approach-to-consumer-cost-sharing-for-prescription-drugs.

supporting the patient's ability to afford a medicine that his or her health plan has agreed, through its utilization management processes, is appropriate for the patient.

III. Accumulator Adjustment Programs Are an Important Part of the Plan's Benefit Package Because They Undermine Affordability – Therefore They Should Be Transparent to Patients

Accumulator adjustment programs are a component of health plans and PBM benefit designs that prevent manufacturer support from being counted toward the patient's deductible and annual out-of-pocket maximum, effectively increasing patient's out-of-pocket liability for their medicines.[19] In many cases, this increases the total out-of-pocket costs paid by patients. A report by the AIDS Institute demonstrated how a plan's copay accumulator can increase patient costs from $700 to $7,900 per year, while increasing the amount collected by the plan from $7,900 to $15,100 per year.[20]

In the 2020 Final Rule regarding accumulator adjustment programs, CMS acknowledged that it was "aware of situations when a patient has been subject to significant out-of-pocket costs because the patient has not progressed through the deductible phase of the health plan [precisely] because the value of the manufacturer-sponsored assistance was not applied to the patient's deductible."[21] As a result of accumulator adjustment programs, "the patient may be forced to stop taking the drug, switch to an alternative offered by the plan, or pay the full bill for the non-formulary drug, none of which are patient-friendly, especially for those patients with rare and life threatening conditions."[22] CMS further highlighted that "PBM accumulator programs are increasing in number, and that the value of these programs to the patient is diminishing" and cautioned that "[i]t is not clear how these programs can continue to benefit patients without some modifications and reforms."[23]

CMS' concern that accumulator adjustment programs could reduce patient adherence are well founded. IQVIA found that patients enrolled in accumulator adjustment programs take their medicines for 39 fewer days on average.[24] As outlined above, for patients with HIV this non-adherence can lead to worse outcomes, higher healthcare costs and greater disease transmission.

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[19] These programs are from, our perspective, contrary to the Affordable Care Act, Section 1302, which requires all non-grandfathered group health plans and health insurance issuers to count cost sharing for essential health benefits, including cost-sharing assistance, toward the annual limitation on cost sharing.

[20] The AIDS Institute. Copay Accumulator Adjustment Programs: Putting Insurance Company Profits over Patients. Available at: https://aidsinstitute.net/documents/TAI-CoPay_Accumulator_Adjustment_Program_Report-w-Appendix.pdf.

[21] 85 Fed. Reg. at 87,050.

[22] 85 Fed. Reg. at 87,050.

[23] 85 Fed. Reg. at 87,050.

[24] Based on an analysis of Commercial patients, including HIX, that utilized copay cards from Jan. 2018-Aug. 2021. Conducted by IQVIA, US Market Access Strategy Consulting and Analytics, Dec. 2021. All rights reserved. Copyright 2021. (Data on File with Gilead.)

Patient groups have also raised concerns about the impact that accumulators can have on patients' ability to afford their medicines.[25] To ensure that patients have the information they need to understand benefit designs, both when selecting a health plan and when utilizing their insurance, plans must be required to clearly disclose when accumulators are and are not being applied in a way that is easily understandable by consumers.

IV. Forthcoming Changes to Government Price Reporting Rules Threaten Manufacturer's Ability to Provide Cost-Sharing Assistance Programs and Should be Rescinded

Effective January 1, 2023, CMS will make changes to the AMP and Best Price regulations that will threaten the viability of all manufacturer assistance programs, and patients will suffer. According to this change, if manufacturers are unable to "ensure" that accumulator adjustment programs do not apply to their patient assistance, we will be forced to either account for such assistance in Best Price, risking substantially higher Medicaid rebate liabilities (which may not be economically feasible), or either reduce or stop offering patient assistance altogether, resulting in harm to patients. In the preamble to the 2020 Final Rule, CMS made clear that this change was targeted at cost-sharing assistance subject to accumulator adjustment programs, because "[i]n the PBM accumulator scenario, the PBM does not apply the manufacturer's copayment assistance to the deductible of the patient thus delaying the patient satisfying his/her deductible, which benefits the health plan."[26]

As previously conveyed to CMS and for the reasons set forth in our July 20, 2020 comment letter regarding the 2020 Final Rule, Gilead continues to believe that this aspect of the 2020 Final Rule is inconsistent with the Medicaid rebate statute and should be rescinded. Patient cost-sharing assistance is not a discount provided by Gilead to any health plan, as the 2020 Final Rule seems to suggest. We provide cost-sharing assistance exclusively to *patients* to help them afford their prescribed Gilead medicines. Even if a PBM or health plan imposes an accumulator adjustment program that prevents manufacturer-sponsored cost-sharing assistance from applying to the patient's deductible or out-of-pocket maximum after the patient receives that cost-sharing assistance, Gilead's cost-sharing assistance is still provided to the patient, who applies the full value of the assistance toward his or her prescription drug costs at the pharmacy counter. How these payments are applied toward an enrollee's deductible or out-of-pocket maximum under his or her plan (such as through application of an accumulator adjustment program) is a decision made independently by the health plan over which Gilead has no influence or control. Therefore, such cost-sharing assistance cannot constitute a price "available from the manufacturer" to the health plan that is eligible for Best Price under the Medicaid rebate statute.[27]

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[25] The AIDS Institute. Copay Accumulator Adjustment Programs: Putting Insurance Company Profits over Patients. Available at: https://aidsinstitute.net/documents/TAI-CoPay_Accumulator_Adjustment_Program_Report-w-Appendix.pdf.

[26] 85 Fed. Reg. at 87,048.

[27] 42 U.S.C. § 1498r-8(c)(1)(C)(i).

Moreover, we are not aware of any reliable mechanisms for manufacturers to ensure that their coupons and other cost-sharing assistance programs are not subject to accumulator adjustment programs. Because accumulator adjustment programs are implemented without manufacturer consent or involvement, we are aware of no way for manufacturers to completely prevent (or even detect) accumulator adjustment programs from applying after the patient has redeemed his or her cost-sharing assistance to divert some of the savings from that assistance to health plans. In particular, it is not feasible for manufacturers to obtain information about use of accumulators for each of their products from each payer and plan in the country. Therefore, we do not believe it is currently possible for us—or any manufacturer—to address the concerns highlighted by CMS in the 2020 Final Rule by "ensuring" that all of our cost-sharing assistance only applies to patients enrolled in plans that do not adopt an accumulator adjustment program.

As a result, if the 2020 Final Rule goes into effect, we anticipate that the viability of all manufacturer assistance programs will be threatened by the potential inclusion of such assistance in Best Price. Manufacturers will be forced to reduce or stop offering patient assistance altogether, leaving patients exposed to the high cost-sharing imposed by their health plans. This is likely to reduce adherence and lead to worse health outcomes. Looking only at six conditions for which Gilead has either approved or pipeline medicines — HIV, Hepatitis B, C, and/or D, Rheumatoid Arthritis, or increased risk of HIV — we estimate that roughly 1 million patients could have their copay assistance affected, undermining some of the Administration's other efforts to improve affordability for patients.[28]

Accordingly, as we have commented in the past, Gilead urges CMS to withdraw the provisions of the 2020 Final Rule regarding accumulator adjustment programs, so that manufacturers are not forced to change their coupon assistance programs in ways that could undermine affordability and adherence for over a million patients.

V. To Support Patient Affordability, the Departments Should Require Uniform Public Disclosure of Accumulator Adjustment Programs

The Departments should, at a minimum, establish a mechanism for real-time, uniform public disclosure of accumulator adjustment programs. This will give patients greater transparency about how accumulators are being implemented in real time – including when they choose a health plan. If CMS declines to rescind the accumulator-related provisions in the 2020 Final Rule, such disclosure will also provide manufacturers with reliable information upon which to make good-faith price reporting determinations as they determine how to adapt their cost-sharing assistance programs to the 2020 Final Rule.

The Interim Final Rules generally exclude manufacturer cost-sharing assistance from the prescription drug rebates and other price concessions the health insurance issuers and group health plans must report; "[h]owever, to the extent these amounts impact total annual spending by health plans or issuers, or by participants, beneficiaries, and enrollees, these [I]nterim [F]inal

[28] Based on an analysis of Commercial patients, including HIX, that utilized copay cards from Jan. 2018-Aug. 2021. Conducted by IQVIA, US Market Access Strategy Consulting and Analytics, Dec. 2021. All rights reserved. Copyright 2021. (Data on file with Gilead).

[R]ules include drug manufacturer cost-sharing assistance in the definition of 'total annual spending.'"[29] Further, the Interim Final Rules provide that "[t]o the extent drug manufacturer cost-sharing assistance reduces spending by the health plan or coverage or by participants, beneficiaries, and enrollees, and to the extent information regarding the amount of these reductions is available to plans, issuers, their administrators, or their service providers such as PBMs (for example, when the drug manufacturer cost-sharing assistance is excluded from the annual limitation on cost-sharing) and thus can be reported to the Departments, the Departments intend to collect data on these reductions separately and incorporate such reductions into the analysis conducted for the … public report" published by the Departments pursuant to section 204 of division BB of the Consolidated Appropriations Act, 2021 (Section 204).[30]

As a threshold matter, we reiterate that the cost-sharing assistance Gilead provides to patients does not constitute remuneration to the patient's plan or its PBM, because such assistance does not alter the price Gilead charges to the plan or PBM for the medicine, nor does Gilead offer or intend such assistance to reduce the costs of the plans or PBMs. Any reduction in drug costs that the plan or PBM unilaterally achieves through accumulator adjustment programs occurs against the will of and without the consent of Gilead and at the expense of patients. We also support PhRMA's comments asking for clarification of the information collection requests released in conjunction with the Interim Final Rule.

In addition, we view the Interim Final Rule's required disclosures by plans to the Departments regarding accumulator adjustment programs as a step in the right direction, but ultimately an inadequate and incomplete measure. As presently contemplated, the required reporting is insufficient and untimely because manufacturers need information about accumulator adjustment programs at the time manufacturer assistance is provided (*i.e.*, when a patient purchases his or her prescriptions, and on a plan-by-plan and drug-by-drug basis). Likewise, patients need this information prior to enrollment so that they can account for this information when selecting a plan. Instead, the Interim Final Rule provides for public disclosure years after the applicable period—eliminating any utility for manufacturers and any benefits for patients who use copay assistance programs. Further, to ensure compliance with the forthcoming price reporting changes, manufacturers need information about every health insurance issuer and group health plan that imposes an accumulator adjustment on any drug, since only a limited number of drugs are covered by the Interim Final Rule. Additionally, much of the data submitted under the Interim Final Rule must be aggregated at the entity, state, and market segment level, and the Departments' Section 204 report must be "aggregated in such a way as no drug or plan specific information will be made public."[31]

[29] 86 Fed. Reg. at 66,669.

[30] 86 Fed. Reg. at 66,670.

[31] 86 Fed. Reg at 66,663; Section 204, CONSOLIDATED APPROPRIATIONS ACT, 2021, PL 116-260, December 27, 2020, 134 Stat 1182.

The Departments have stated that they will reexamine the health plan disclosure requirements in the Transparency in Coverage Final Rules[32] and issue additional rulemaking.[33] This rulemaking will provide an opportunity for the Departments to require real-time disclosure of information regarding the use and applicability of accumulator adjustment programs at the plan and drug levels. As the Departments have acknowledged, after finalizing the Transparency in Coverage Final Rules implementing the disclosure requirements in section 2715A of the Public Health Service Act (Section 2715A), Congress enacted Section 204, which imposed new and potentially duplicative and overlapping prescription drug reporting requirements.[34] Accordingly, the Departments have committed to revisit the prescription drug machine-readable file requirement implementing Section 2715A in the Transparency in Coverage Final Rules through future notice-and-comment rulemaking.[35]

As currently contemplated, the historical net price disclosures required under the Transparency in Coverage Final Rules provide little useful information to patients, but they could greatly disrupt the competitive market for prescription medicines by requiring disclosure of confidential and commercially sensitive net price information that is distinct from patient cost-sharing. By contrast, requiring the disclosure of real-time information regarding the use and applicability of accumulator adjustment programs at the plan and drug levels would provide important information about aspects of benefit plans that directly affect patient affordability. As such, the Departments have the authority to require the disclosure of such information under Section 2715A, which requires accurate and timely disclosure to the public of "claims payment policies and practices," among other information relevant to patient coverage and affordability.[36] Given the impact such programs have on patient access, adherence, and outcomes, it is important that patients and the public in general have insight into when such programs are being applied. Because accumulator adjustment programs often apply only to a subset of drugs, the required disclosures should be specific to particular plans and particular drugs. We urge the Departments to require prominent, plain language disclosure of accumulator adjustment programs to prospective enrollees and in the annual summary of benefits and coverage and on plan websites, including an explanation for what that means for patients as they progress through their benefit and/or reach their deductible or out-of-patient maximum. In addition, health plans should be required to maintain and update a machine-readable database in real time. Such a database could support development of tools for patients and manufacturers to understand when accumulators are being applied and would allow the information to be incorporated into websites that patients use to select their health plans such as healthcare.gov.

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[32] 85 Fed. Reg. 72,158 (Nov. 12, 2020).

[33] CMS, FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (Aug. 20, 2021), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf ("CMS FAQs").

[34] *Id.*

[35] *Id.*

[36] *See* 42 U.S.C. § 18031(e)(3).

Finally, because Section 2715A does not apply to grandfathered health plans, the Departments should give serious consideration to requiring that the implementation of an accumulator adjustment program results in the loss of grandfathered status given that these programs greatly alter the value proposition of those plans for patients.

* * *

We appreciate this opportunity to provide comments on this important proposed rulemaking. If you have any questions, please do not hesitate to contact Kristi Thompson at Kristi.Thompson3@gilead.com.

Sincerely,

Michael D. Boyd
Senior Vice President,
Government Affairs and Policy

the campaign for
SUSTAINABLE Rx PRICING

January 24, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, DC 20201

RE: CMS-9905-IFC

Dear Administrator Brooks-LaSure:
The Campaign for Sustainable Rx Pricing (CSRxP) is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

Prescription drug prices are needlessly high and continue to grow at unsustainable rates – even as far too many Americans continue to suffer from the severe health and economic consequences from the ongoing COVID-19 pandemic. Many big pharma companies implemented traditional start-of-year price hikes yet again in January 2022 despite the fact that approximately 18 million American adults could not afford to fill prescriptions for at least one prescribed medication in 2021.[1] [2] Excessively high prices threaten the financial security, health and wellbeing of U.S. consumers and their families on a daily basis, while simultaneously straining Federal and state health budgets and the taxpayers who fund them. Too often patients experience the unfortunate and unfair choice of either purchasing the medications they need to get well and stay healthy or paying their bills. Patients simply should never be presented with such a choice.

CSRxP therefore ardently believes it is more imperative than ever to rein in out-of-control drug prices – particularly given the significant and persistent economic hardship so many Americans are confronting as a result of COVID-19. We thus look forward to supporting the development and release of the first "section 204 public report" required by the Consolidated Appropriations Act (CAA) of 2020. This mandatory report will provide meaningful information to the public on

[1] Marsh, Tori. "Live Updates: January 2022 Drug Price Increases." GoodRx Health. January 6, 2022.
[2] Witters, Dan. "In U.S., an Estimated 18 Million Can't Pay for Needed Drugs." *Gallup*. September 21, 2021.

prescription drug pricing trends and the role of prescription drug costs in health care coverage costs.

However, while CSRxP welcomes the new pricing information that will become available in the "section 204 public report," we urge the Departments to implement drug pricing reporting requirements in a manner that imposes least burden on health plans and issuers, while more importantly, establishing accurate and enforceable reporting requirements on drug manufacturers. Indeed, despite efforts from the brand drug industry to suggest otherwise, manufacturers – and manufacturers alone – are the drivers of the high prescription drug prices that American consumers and taxpayers needlessly face today. Drug makers regularly justify their pricing decisions by citing industry-funded research claiming costs of approximately $2.6 billion to bring a new drug to market, even though the industry offers the public no way to independently verify this estimate.[3] Moreover, little to no information is available regarding other factors manufacturers consider when setting launch prices or raising prices for drugs already on the market. As a result, the government, employers, plans, and issuers lack the tools necessary to determine whether a drug is reasonably and affordably priced. Without improved transparency and insight into the pricing practices of the brand industry, policymakers simply cannot effectively address the root cause of the problem: brand manufacturers set high launch prices and typically increase those prices at rates that far exceed inflation and without measurable returns on taxpayers' ever-increasing investments.

Hence, CSRxP urges the imposition of pricing reporting requirements on manufacturers to improve prescription drug affordability. Enhanced pricing transparency critically will incentivize manufacturers to justify the prices they set and price them according to the benefit and value they actually deliver to patients and payers – rather than merely setting some exorbitantly high price without any opportunity for the public and policymakers to independently check on whether that price is reasonable, fair, or affordable.

With this background, CSRxP respectfully offers the following comments on the interim final rule with comment (IFC) entitled "Prescription Drug and Health Care Spending" (CMS-9905-IFC) published by the Office of Personnel Management (OPM), the Department of Health and Human Services (HHS), Department of Labor (DOL), and the Department of the Treasury ("the Departments"). In particular:

1. **Manufacturer cost-sharing assistance:** CSRxP supports obtaining manufacturer cost-sharing assistance data but recommends that the Departments require that manufacturers submit such data.

2. **Interchangeable biosimilar products:** CSRxP suggests that the Departments treat interchangeable biosimilar products as generics rather than as "brand prescription

[3] DiMasi JA, Grabowski, HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of Health Economics* 2016; 47:20-33.

drugs" to help foster and grow competition in the market for high-cost brand biological therapies.

3. **Drugs with Emergency Use Authorization (EUA):** CSRxP supports treating drugs with EUA from the Food and Drug Administration (FDA) as "brand prescription drugs" for purposes of reporting.

4. **Hospital and medical benefit drugs***:* CSRxP looks forward to working with the Departments to find a minimally burdensome reporting approach for future reporting years that allows for the collection of pricing and cost data on individual drugs covered under the hospital and medical benefits, given the oftentimes significant costs these therapies impose on consumers, issuers, plans, and taxpayers.

CSRxP's comments reflect our continued commitment to continue working with the Administration to develop and implement bipartisan, market-based approaches that improve prescription drug affordability while at the same time preserve access to innovative therapies that enable patients to get well and stay healthy. Without major actions from the Administration and the Congress, consumers and taxpayers will continue to face the unsustainable growth in drug costs that are already out-of-control.

1. Manufacturer Cost-Sharing Assistance

Third-party patient assistance programs can meaningfully help patients afford the often excessively high-priced medications they need to get well and stay healthy. In many cases however, drug makers are primarily funding these third-party assistance programs to increase sales. For example, the House Oversight and Investigations Committee recently found that Novartis used its patient assistance program for the cancer treatment *Gleevec* "to reduce patient price sensitivity…and…drive demand, particularly after loss of exclusivity." [4] Indeed, internal Novartis documents projected a potential rate of return on the Gleevec co-pay assistance program of $8.90 for every $1.00 invested at six months prior to loss of market exclusivity.[5] Thus, to better ensure that third-party assistance directly benefits patients and does not simply camouflage needlessly high drug prices, CSRxP welcomes and supports obtaining manufacturer cost-sharing assistance data but recommends that the Departments require that manufacturers submit such data; while plans and PBMs generally can track manufacturer cost-sharing assistance and coupons used in specialty and mail-order pharmacies, they cannot always do so for prescriptions filled at retail pharmacies, making any data submission from plans and PBMs on manufacturer cost-sharing assistance incomplete.

[4] U.S. House of Representatives House Committee on Oversight and Reform. "Staff Report: Drug Pricing Investigation Novartis – Gleevec." October 2020.
[5] *Ibid*.

2. Interchangeable Biosimilar Products

Robust interchangeable, biosimilar, and generic competition can place pressure on brand manufacturers to lower list prices and reduce overall prescription drug costs. One study funded by the Pharmaceutical Research and Manufacturers of America (PhRMA) found, for example, that prices of oral generic medicines decline by 66 percent in the first 12 months after generic entry and cost 80 percent less than the brands they replace within five years.[6] Similarly, meaningful competition from interchangeable biosimilar products has the potential to lower prescription drug costs for consumers and taxpayers. The HHS Assistant Secretary for Planning and Evaluation (ASPE) found, for example, that Medicare Part B expenditures on prescription drugs increased at a rapid average annual rate of 7.7 percent from 2005 to 2014. [7] During that period, specialty biologic medicines that in most cases faced little to no competition from interchangeable biosimilar and biosimilar products grew at a particularly fast rate, climbing from 39 percent to 62 percent of total spending, with a substantial share of the growth due to price increases rather than number of patients using the medications.[8]

Moreover, defining interchangeable biosimilars as "brand prescription drugs" for "section 204" reporting would establish a concerning precedent that interchangeable biosimilars in some way do not offer competition to brand biologics similar to that of biosimilars. Indeed, interchangeable biosimilars are intended to serve the same purpose as traditional generic drugs for purposes of state laws; just as a pharmacist can substitute an inexpensive generic for a costly brand drug without obtaining permission from a prescriber, a pharmacist can substitute a less costly interchangeable biosimilar for high-cost reference brand biologic without receiving permission from a prescriber. Characterizing interchangeable biosimilars as "brand prescription drugs" would set a problematic precedent that interchangeable biosimilars may not confer the same affordability and clinical benefits to consumers as traditional generic drugs and biosimilars even though they were intended to do so. Such an outcome indirectly could lead to policies that discourage development and utilization of lower cost biosimilars and interchangeable biosimilars that can improve affordability for patients – clearly an outcome not intended as the Departments work to improve prescription drug affordability for all consumers across the U.S.

Given that increased competition can lower costs, CSRxP supports policies that foster a more robust marketplace for interchangeable biosimilar products. Therefore, we respectfully suggest that the Departments revise the IFC to treat interchangeable biosimilar products as generics – rather than as "brand prescription drugs" – for purposes of meeting the "section 204" reporting requirements.

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[6] IMS Institute for Healthcare Informatics. "Price Declines after Branded Medicines Lose Exclusivity in the U.S." January 2016.
[7] HHS Assistant Secretary for Planning and Evaluation. "Medicare Part B Drugs: Pricing and Incentives." March 8, 2016.
[8] *Ibid*.

3. Drugs with Emergency Use Authorization from the FDA

The cost of COVID-19 countermeasures including antibody treatments and other therapies should not serve as a barrier to treatment for all patients, regardless of whether they are enrolled in federal health programs like Medicare and Medicaid, have commercial insurance, or no insurance at all. The Federal government must take steps to ensure that COVID-19 countermeasures are affordably and appropriately priced so that all patients can have access to the treatment needed to help recover from this serious virus. Just like the investments in vaccine research, the Federal government made significant upfront investments in antibody treatments and other COVID-19 therapies and therefore has a stake in guaranteeing they remain affordable and accessible for all Americans.[9] CSRxP thus supports the Departments' policy to treat drugs with FDA EUA authorization as "brand prescription drugs" for purposes of section 204 reporting so that the public and policymakers can better assess whether these therapies are reasonably and affordably priced.

4. Drugs Covered under the Medical and Hospital Benefits

CSRxP appreciates the Departments' recognition of the current challenges and compliance burden associated with operationalizing the reporting of information on individual drugs covered under the hospital and medical benefits for the "top 25" and "top 50" lists. We agree with the Departments, however, that obtaining pricing and cost data on individual drugs covered in the hospital and medical benefits is important given that so many of these therapies are high-cost and oftentimes have significant and frequent price increases. Thus, CSRxP looks forward to working with the Departments to develop reporting processes and procedures that minimize compliance burden in future years for health plans and issuers but ultimately allow for the collection of individual pricing and cost data on prescription drugs covered under the medical and hospital benefits.

Conclusion

In conclusion, CSRxP again thanks the Departments for the opportunity to comment on CMS-9905-IFC. We look forward to our continued work with the Administration on to establish market-based policies that promote competition, transparency, and value to make prescription drugs more affordable for all patients and their families while at the same time maintaining access to the treatments that can improve health outcomes and save lives, particularly as far too many Americans continue to suffer from the severe health and economic consequences arising from the COVID-19 pandemic.

[9] *Ibid*.

Sincerely,

Lauren Aronson
Executive Director
The Campaign for Sustainable Rx Pricing

ERIC | THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

Mercer

January 24, 2022

Submitted Electronically via: www.regulations.gov

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

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

To Whom It May Concern:

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

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

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

Mercer is a global consulting leader helping clients around the world redefine the world of work, reshape retirement and investment outcomes, and unlock real health and wellbeing for their people. In the United States, Mercer provides consulting, brokering, and actuarial services to nearly 5,000 health and benefit clients, including employers of all sizes, with varying employee demographics.

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

Additional Plan Types That Should be Considered Exempt

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

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

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

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

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

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

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

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

Definition of Rebates, Fees, and Any Other Remuneration

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

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

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

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

Definition of Prescription Drug

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

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

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

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

No matter the definitions the Departments decide, we urge you to consider the amount of reporting you would like to receive and what would be most helpful.

Definition of Health Care Services

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

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

Impact of Mergers, Splits, and Similar Transactions

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

Hospital and Provider Reporting

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

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

Data Submission Requirements

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

It is also important to note that the IFR allows aggregated reporting to minimize administrative burden. For self-funded plans with carved-out PBMs, the PBM's report will need to include total annual health care spending data from an often unrelated medical TPA. Self-funded plan sponsors may have limited means to ensure that sufficient PBM-medical TPA cooperation occurs so that reporting is accurate, timely, and complete.

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

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

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

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

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

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

Conclusion

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

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January 24, 2022

VIA ELECTRONIC FILING — *http://www.regulations.gov*

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Re: **Prescription Drug and Health Care Spending (CMS-9905-IFC)**

Dear Secretary Becerra, Assistant Secretary Batchelder, Acting Assistant Secretary Khawar, and Acting Associate Director DeHarde:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the Prescription Drug and Health Care Spending interim final rule with request for comments (the IFC).[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $91.1 billion in 2020 alone.

The Departments of the Treasury, Labor, and Health and Human Services (the Departments) and the Office of Personnel Management (OPM) have requested comments on the IFC implementing division BB, section 204 of the Consolidated Appropriations Act (CAA), 2021. As discussed in

[1] 86 Fed. Reg. 66662 (Nov. 23, 2021).

further detail below and in our prior comments,[2] PhRMA believes the section 204 reporting will be important in providing the Departments and OPM with significant information about health care costs across the pharmaceutical supply chain. Importantly, the section 204 reporting should be designed to demonstrate the magnitude of rebates, discounts, and other payments that biopharmaceutical manufacturers provide to pharmacy benefit managers (PBMs), their affiliated entities,[3] and health plans. Recent state government analyses provide evidence that properly accounting for drug manufacturer discounts can provide clarity on cost drivers, helping to inform policy solutions that will benefit patients. They have shown, for example, that when rebates were accounted for, pharmacy spending increased at a lower rate than other major health care service categories and that spending on prescription drugs net of rebates accounts for about 11% of total health plan premiums.[4] Unfortunately, some industry reports[5] do not properly account for manufacturer discounts, which can result in findings that do not adequately reflect the complexity of the pharmaceutical supply chain.

PBMs and health plans do not generally share manufacturer discounts directly with patients at the point-of-sale. Instead, plans and PBMs may profit from these substantial discounts while often requiring patients to pay high deductibles and coinsurance based on a medicine's full list price. Consequently, the sickest patients may pay more for medicines than their health plans do, a perverse form of "reverse insurance," as discussed in detail below. In our comments below, we encourage the Departments to use the annual public report required under section 204 to highlight these trends for health care consumers. To that end, we encourage the Departments to revise the regulatory text and the accompanying information collection requests (ICRs) under the Paperwork Reduction Act issued in conjunction with the IFC by the Centers for Medicare & Medicaid Services (CMS)[6] to ensure adequate data are available for accurate analysis and understanding of how much health plans and PBMs truly spend on prescription drugs. Failure to do so could undermine the intent of the Departments' reporting and misrepresent the amount of rebates, administrative fees, and other payments collected by PBMs and health plans.

In addition, the reporting should reflect how all sectors of the health care system, including hospitals, influence health care costs. The reporting should differentiate between the net ingredient costs of medicines administered by hospitals and the substantial markups commonly applied to these medicines. Administration costs and markups should be categorized as revenue received by hospitals, not as spending attributable to medicines. The reporting requirements should be modified to ensure that these hospital revenues are not misattributed to drug costs.

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[2] See, PhRMA. Comments on Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (CMS-9905-NC). July 23, 2021.

[3] The largest three PBMs have launched new contracting entities, including Ascent Health Services (Cigna/Express Scripts), Zinc (CVS Health/Aetna), and Emisar Pharma Services (UnitedHealthcare/OptumRx).

[4] *See*, Massachusetts Center for Health Information and Analysis. Annual report: performance of the Massachusetts health care system. March 2021. https://www.chiamass.gov/assets/2021-annual-report/2021-Annual-Report.pdf; California Department of Managed Health Care; Prescription drug cost transparency report for measurement year 2019. 2021. https://www.dmhc.ca.gov/Portals/0/Docs/DO/2019SB17PrescriptionDrugTransparencyReport.pdf.

[5] For example, see: AARP. Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2020. June 2021. https://www.aarp.org/content/dam/aarp/ppi/2021/06/trends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans.10.26419-2Fppi.00143.001.pdf

[6] Centers for Medicare and Medicaid Services (CMS). Prescription Drug Data Collection (RxDC) Reporting Instructions. November 23, 2021. https://www.cms.gov/httpswwwcmsgovregulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10788

Finally, among other comments below, PhRMA appreciates the Departments and OPM appropriately acknowledging that manufacturer cost-sharing assistance provided to patients to help pay deductibles, copayments, and coinsurance expenses is not a discount or price concession and should not be reported as remuneration to the plan or PBM, but we note that this has not been a consistent approach taken by the Departments. Additionally, the Departments and OPM should correct the reporting instructions that treat cost-sharing assistance as reducing total cost sharing under the plan. These instructions are inconsistent with the approach the IFC takes regarding cost-sharing assistance.

Please find our comments on specific sections of the IFC below.

Definitions (26 CFR 54.9825–3T, 29 CFR 2590.725–1, 45 CFR 149.710)

Prescription drug rebates, fees and other remuneration

Manufacturer cost-sharing assistance programs, also known as "coupons" or "copay cards," ("cost-sharing assistance") are types of assistance offered by manufacturers directly to patients to help them pay for the out-of-pocket costs charged by their health plans or PBMs for prescribed medicines. Cost-sharing assistance provides an important source of financial support for eligible patients and can improve patient adherence, leading to improved patient outcomes.[7] PhRMA supports the IFC's determination that cost-sharing assistance provided to enrollees does not constitute prescription drug rebates, fees, or other remuneration to the plan or coverage. Therefore, we ask that the Departments make a corresponding change to the regulatory definitions of "rebates, fees, and other remuneration" at 45 CFR 149.710, 26 CFR 54.9825-3T, and 29 CFR 2590.725-1 and remove the word "coupons."

As we noted in response to the request for information[8] in advance of this IFC, when patients' cost-sharing obligations rise, patients are more likely to abandon their medicines. In 2017, 69% of commercially insured patients did not fill their new prescriptions when they had to pay more than $250 out of pocket, while only about 11% of patients with out-of-pocket costs of less than $30 abandoned their prescriptions at the pharmacy.[9] Thus, high patient out-of-pocket costs imposed by plans and PBMs essentially erect a financial barrier around appropriate treatment for enrollees, even though the medicine has been prescribed by a health care provider and the health plan has agreed to cover the treatment. Additionally, commercial market health plans and PBMs' increasing reliance on plan designs with large deductibles and coinsurance has increased patients' out-of-pocket burden and created affordability challenges for many patients.[10]

[7] IQVIA analysis for PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/report/Commercially-Insured-Patients-with-Chronic-Conditions-Face-High-Cost-Sharing-for-Brand-Medicines.
[8] 86 Fed. Reg. 32813 (June 23, 2021).
[9] IQVIA. Patient affordability part two: implications for patient behavior & therapy consumption. May 2018. https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-two.
[10] IQVIA. Patient affordability part one: the implications of changing benefit designs and High Cost-Sharing. May 2018. https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-one; Peterson-Kaiser Family Foundation. Tracking the rise in premium contributions and cost-sharing for families with large employer coverage. August

Researchers have found that when patients cannot afford their cost sharing for medicines, non-adherence can lead to worse health outcomes, including higher rates of mortality.[11] For these reasons, HHS itself has recognized the importance of cost-sharing assistance, noting that it is crucial for "consumers whose drug costs would otherwise be extremely high due to a rare or costly condition."[12]

Total annual spending

PhRMA agrees with the IFC's general approach of instructing reporting entities, when calculating total annual spending, to account for the amount of cost-sharing assistance that is known to the plan or coverage, primarily when the plan or coverage applies an "accumulator adjustment program," which excludes the value of the cost-sharing assistance from the plan's annual limit on cost sharing and thereby reduces the plan's share of costs. However, PhRMA believes further clarifications are necessary, in light of the ICRs under the Paperwork Reduction Act that CMS released in conjunction with the IFC.

Accumulator adjustment programs implemented by health plans and PBMs prevent cost-sharing assistance provided to patients from being counted toward the patient's deductible or annual limitation on cost sharing (i.e., out-of-pocket spending limit). We reiterate that accumulator adjustment programs are contrary to the Affordable Care Act (ACA), which requires all non-grandfathered group health plans and health insurance issuers to count cost sharing for essential health benefits — including cost-sharing assistance — toward the annual limitation on cost sharing.[13]

When accumulator adjustment programs are implemented by health plans, they can substantially increase patients' out-of-pocket costs well above the intended protection of the annual limitation on cost sharing, increasing financial burden and health risk, especially for those with serious illnesses. Ignoring harms to patient adherence and well-being, health plans and PBMs continue to institute accumulator adjustment programs, under which patients are punished for using cost-sharing assistance and end up paying more out-of-pocket than their plans would otherwise require.[14] PhRMA urges the Departments to consider the negative impacts accumulator adjustment programs may have on certain racially/ethnically diverse populations, as numerous

2019. https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/ (showing a 205% increase in commercial market enrollee spending on deductibles from 2007 to 2017, vastly outpacing wage growth); Pharmacy Benefit Management Institute. Trends in specialty drug benefits report, 2017 edition. 2017 (noting that, in 2016, coinsurance overtook copays as the preferred form of cost sharing on commercial plans for specialty drugs).

[11] National Bureau of Economic Research. Higher Prescription Drug Cost-Sharing Raises Mortality among Medicare Beneficiaries. The Bulletin On Health: No. 2, June 2021. https://www.nber.org/bh20212/higher-prescription-drug-cost-sharing-raises-mortality-among-medicare-beneficiaries

[12] 84 Fed. Reg. 17454, 17544 (Apr. 25, 2019).

[13] ACA § 1302(c)(3), 42 U.S.C. § 18022(c)(3).

[14] Xcenda. Copay accumulators and the impact on patients. June 2021. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda-issue-brief_copay-accumulators-and-the-impact-on-patients.pdf?la=en&hash=B1FFDB57D51606569D9F8F6219F689FB9936DD24

studies have shown that lower utilization and/or adherence rates can perpetuate disparities in health outcomes and mortality rates as compared to white patients.[15,16,17]

Accumulator adjustment programs can potentially leave patients with thousands of dollars in unexpected costs at the pharmacy,[18] resulting in exactly the problems that cost-sharing assistance is designed to avoid: prescription abandonment, poor health outcomes, and potentially avoidable medical costs. One study conducted by the National Hemophilia Foundation found that 72% of survey respondents believed that many patients would no longer be able to afford their medications if cost-sharing assistance was not permitted to be applied to patients' annual out-of-pocket limits.[19] If patients cannot pay their full cost sharing at the pharmacy, they are typically turned away and leave the pharmacy without the medicines their doctors prescribed.

Regarding accumulator adjustment programs, HHS has acknowledged it is "aware of situations when a patient has been subject to significant out-of-pocket costs because the patient has not progressed through the deductible phase of the health plan [precisely] because the value of the manufacturer-sponsored assistance was not applied to the patient's deductible."[20] As a result of accumulator adjustment programs, "the patient may be forced to stop taking the drug, switch to an alternative offered by the plan, or pay the full bill for the non-formulary drug, none of which are patient-friendly, especially for those patients with rare and life threatening conditions."[21] As we have done several times before,[22] we continue to urge the Departments to implement the ACA as written and prohibit health plans from implementing accumulator adjustment programs.

To the extent that plans and PBMs continue to use accumulator adjustment programs, assistance provided by manufacturers to patients does not constitute remuneration to the plan or PBM because it does not alter the net price paid by the plan or PBM for the medicine, nor is it offered by or intended by the manufacturer to reduce the costs of the plans or PBMs. Any reduction in drug costs that the plan or PBM unilaterally achieves through accumulator adjustment programs

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[15] Mehta KM, Yin M, Resendez C, Yaffe K. Ethnic differences in acetylcholinesterase inhibitor use for Alzheimer disease. Neurology. 2005 Jul 12;65(1):159-62. doi: 10.1212/01.wnl.0000167545.38161.48. PMID: 16009909; PMCID: PMC2830864.

[16] Lauffenburger JC, Robinson JG, Oramasionwu C, Fang G. Racial/ethnic and gender gaps in the use of and adherence to evidence-based preventive therapies among elderly Medicare part D beneficiaries after acute myocardial infarction. Circulation. 2014; 129:754–763.

[17] Khunti K, Seidu S, Kunutsor S, Davies M. Association Between Adherence to Pharmacotherapy and Outcomes in Type 2 Diabetes: A Meta-analysis. Diabetes Care. 2017 Nov;40(11):1588-1596. doi: 10.2337/dc16-1925. Epub 2017 Aug 11. PMID: 28801474.

[18] PhRMA. Accumulator adjustment programs lead to surprise out-of-pocket costs and nonadherence, analysis finds. November 2020. https://catalyst.phrma.org/accumulator-adjustment-programs-lead-to-surprise-out-of-pocket-costs-and-nonadherence-analysis-finds

[19] National Hemophilia Foundation. Americans Believe Government Should Require Copay Assistance Be Applied to Out-of-pocket Costs. October 15, 2020. https://www.hemophilia.org/news/americans-believe-government-should-require-copay-assistance-be-applied-to-out-of-pocket-costs

[20] 85 Fed. Reg. at 87,050.

[21] *Ibid.*

[22] PhRMA. Comments on HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations (CMS-9914-P). December 30, 2020. https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-2022-NBPP-Comment-letter-20201230-FINAL.pdf; PhRMA. PhRMA. Comments on HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans (CMS-9916-P). https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2021-NBPP-Comment-Letter_FINAL.pdf

occurs against the will of and without the consent of the manufacturer and at the expense of patients. The plan or PBM should report the aggregate amount it actually spends accordingly. Additionally, the Departments should require prominent, plain language to disclose accumulator adjustment programs to prospective enrollees and in the annual summary of benefits and coverage, including an explanation for what that means for patients as they progress through their benefit and/or reach their deductible or out-of-pocket maximum.

We believe the IFC's definition of "total annual spending" is consistent with the approach we have described here. However, the PRA ICRs released in conjunction with the IFC appear to take a different approach, and we urge CMS to correct what appears to be an error in the PRA ICRs, so that they are consistent with the IFC. The IFC instructs plans to report cost-sharing assistance, when they are aware of it, and notes that plans may only be aware of cost-sharing assistance when they apply accumulator adjustment programs. Therefore, the reporting instructions in the PRA package appear to err when they say that "manufacturer cost-sharing assistance" should be subtracted from "total cost sharing."

Even if plans had data on cost-sharing assistance that was used to pay the enrollee's cost sharing and was not subject to an accumulator adjustment program, it would still be inaccurate for the plans to reduce "total cost sharing" by the amount of cost-sharing assistance used. Cost-sharing assistance does not change the cost-sharing parameters or other amounts due from the enrollee under a health plan, which are set in advance by the plan. Cost-sharing assistance is simply help to the enrollee in paying their share of the costs, much like a charity or family member might also help. None of these forms of assistance change the cost sharing that is due under the plan, and reducing the "total cost sharing" will result in inaccurate data on pharmacy and health care benefits being reported.

In addition to accumulator adjustment programs, some industry experts and commentators have noted that health plans and PBMs may be employing "copay maximizer programs," which subject certain patients to atypically high cost sharing, just because they rely on a particular medicine where the manufacturer has made cost-sharing assistance available.[23] PhRMA is concerned about the growing use of these programs and their potential impacts on patients. In a survey of commercial health plans conducted by MMIT in 2020, 23 percent of commercial enrollees were enrolled in plans where the plan sponsor had opted into a copay maximizer program, and this number is expected to grow.[24] The Departments should monitor use of these programs, their impact on patient access, and how they affect the pharmaceutical supply chain. Additionally, the Departments should consider updating the reporting instructions to ensure that, when a copay maximizer is in place, a plan reports its aggregate spending on drugs appropriately.

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[23] TrialCard. Co-Pay Accumulators & Maximizers: Your Questions Answered, PT. 3. July 27, 2020. https://corp.trialcard.com/co-pay-accumulators-maximizers-your-questions-answered-pt-3/; Drug Channels. Copay Maximizers Are Displacing Accumulators—But CMS Ignores How Payers Leverage Patient Support. May19, 2020. https://www.drugchannels.net/2020/05/copay-maximizers-are-displacing.html#:~:text=Under%20a%20copay%20maximizer%2C%20the%20full%20value%20of,it%20reduces%20or%20eliminates%20the%20patient%E2%80%99s%20out-of-pocket%20obligations.

[24] MMIT. Survey Shows That Copay Accumulators and Maximizers Continue to Be Popular. February 1, 2020. https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/survey-shows-that-copay-accumulators-and-maximizers-continue-to-be-popular/

Required Information (26 CFR 54.9825–6T, 29 CFR 2590.725–4, and 45 CFR 149.740)

Health care spending: 340B and provider-administered prescription drugs

PhRMA is concerned that the reporting of health care spending on provider-administered prescription drugs as currently mandated by the IFC does not require reporting on the substantial markups commonly applied to these medicines. Ignoring material hospital markups would paint an inaccurate picture of health care spending. A 2019 analysis found that the payments hospitals receive from commercial health plans for provider-administered medicines are, on average, nearly 2.5 times the amount paid by the hospital to acquire them.[25] Thus, hospitals often earn far more for administering a medicine than the company that discovered and manufactured the treatment. These markups can be even higher for medicines hospitals purchase at the discounted 340B price. One analysis of oncology treatments found that 340B hospitals price drugs at an average of 3.8 times their 340B acquisition costs.[26] For some drugs, the median markup is much higher—the median markup for one medicine was 11 times the acquisition cost.[27]

Without collecting data on both the acquisition cost of medicines and the markups applied to those medicines, reported spending on provider-administered drugs would inflate the spending attributable to the medicines themselves and make it more difficult for the Departments to issue policy-relevant reports. For example, based on the IFC, the data collected by the Departments would make it difficult to determine whether an increase in per-unit health plan spending on a specific physician-administered drug was due to an increase in how much hospitals were marking up the price of the medicine versus an increase in the price of the drug itself. This distinction is crucial for policy makers seeking to make "informed decisions in support of the goals of Executive Order 14036," which is one of the aims of the IFC according to the preamble.[28]

PhRMA encourages the Departments and OPM to revise the rules so that total drug spending is reported based on total *acquisition* costs. Reimbursement above acquisition costs should be reported as spending on provider services, not prescription drugs. Allowing hospitals to categorize the revenues they receive from administration costs and markups as spending attributable to prescription medicines would significantly obscure the role hospitals play in driving health care spending. At a minimum, if total acquisition costs cannot be determined based on collected data, any reports issued by the Departments should estimate markups using reasonable estimates of acquisition cost, such as Average Sales Price or a percentage of Average Sales Price.[29]

[25] The Moran Company. Hospital charges and reimbursement for drugs: 2019 update analysis of markup relative to acquisition cost. July 2019. http://www.themorancompany.com/wp-content/ uploads/2019/07/Hospital-Charges-Report-July-2019.pdf
[26] Community Oncology Alliance. Examining Hospital Price Transparency, Drug Profits & the 340B Program. Sept. 2021. https://communityoncology.org/wp-content/uploads/2021/09/Moto-COA-340BHospitalMarkupsReport.pdf
[27] Community Oncology Alliance. Examining Hospital Price Transparency, Drug Profits & the 340B Program. Sept. 2021. https://communityoncology.org/wp-content/uploads/2021/09/Moto-COA-340BHospitalMarkupsReport.pdf
[28] 86 Fed. Reg. 66663 (November 23, 2021).
[29] ASP does not include statutorily mandated discounts that, for some providers, result in acquisition costs that are significantly lower than ASP and therefore may underestimate hospital markups.

Additionally, when HHS analyzes data on medicines covered through plans' prescription drug benefit, we urge HHS to account for 340B discounts in its data analysis. The use of 340B for non-provider-administered drugs has grown dramatically due to contract pharmacy arrangements.[30] In 2018, 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B-purchased retail medicines.[31] Therefore, HHS reports analyzing prescription drug prices and spending should seek to account for 340B discounts. To improve the accuracy of data reported on the 340B program and on prescription drug spending in general, PhRMA supports methods to appropriately account for 340B prescriptions and policies that require all relevant parties to identify 340B claims to ensure that 340B claims information is reported and communicated as necessary for data collection.

Prescription drug rebates, fees, and other remuneration

PhRMA supports the IFC's implementation of the statutory requirement that plans report whether they use manufacturer rebates to reduce premiums or to benefit patients directly by reducing out-of-pocket costs. However, we urge the Departments to fully implement the requirements of the CAA by providing guidance on mandatory quantitative reporting of the impact that rebates, fees, and other remuneration have on premiums and out-of-pocket costs.[32] Additionally, we urge the Departments to clarify the regulatory text itself by adding the term "net" to those requirements to share information on "total annual spending" or "the greatest increase in expenditures" on prescription drugs.

PhRMA has long been concerned that health plans and PBMs have consistently failed to share rebates and discounts negotiated with manufacturers with patients at the point-of-sale. On average, the net costs of brand medicines are 44% lower than their list prices in part due to significant rebates, discounts, and other payments negotiated between manufacturers and PBMs,[33] which totaled $187 billion in 2020.[34] In 2020, more than half (50.5%) of all spending on brand medicines was received by entities other than the manufacturer that researched and developed the product, including PBMs, health plans, the government, providers, and others.[35]

Rebates, discounts, and other payments from manufacturers substantially reduce the net price paid by PBMs and plan sponsors. However, plans generally structure their benefits such that patients pay cost sharing based on a medicine's undiscounted list price, rather than the discounted price paid by the PBM and health plan. Coinsurance and deductibles account for

[30] S. Hasan and S. Peterson, "340B Drug Discount Program Growth Drivers," IQVIA, April 16, 2021, Available at: https://www.iqvia.com/locations/united-states/blogs/2021/04/340b-drug-discount-program-growth-drivers; GAO, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," June 2018.
[31] A. Vandervelde, K. Erb and L. Hurley, "For-Profit Pharmacy Participation in the 340B Program" BRG, Oct 7, 2020, Available at: https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/
[32] 42 U.S.C. § 300gg–120; 29 U.S.C. § 1185n; 26 U.S.C. § 9825.
[33] IQVIA. Use of medicines in the U.S.: spending and usage trends and outlook to 2025. May 2021. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us#:~:text=Total%20net%20spending%20on%20medicines,off%2Dinvoice%20discounts%20and%20rebates.
[34] Drug Channels Institute. The 2021 economic report on U.S. pharmacies and pharmacy benefit managers. March 2021. https://www.drugchannels.net/2021/03/new-2021-economic-report-on-us.html.
[35] Berkeley Research Group. "The Pharmaceutical Supply Chain, 2013–2020," January 2022. https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/

more than half of commercially insured patient spending on brand medicines across many therapeutic areas and are usually based on the undiscounted list prices, forcing many patients to pay cost sharing that does not reflect the cost net of rebates and discounts for their medicines.[36]

This practice can result in a plan or PBM realizing a net gain when a prescription is filled. For example, imagine a patient enrolled in a high-deductible health plan who takes a medication with a list price of $400. The patient's health plan has negotiated a 55% rebate on this medicine, which substantially reduces the cost to the plan. However, because the patient has not yet met her deductible, her plan does not provide any coverage for the prescription, and the patient's bill reflects the medication's full list price of $400. Despite paying nothing for this patient's medicine, the plan still collects the rebate, earning over $220.[37] In essence, plans and PBMs have historically "double dipped." Not only do they receive manufacturer rebates, but rather than allowing them to be carried forward to patients, they also generally calculate cost sharing and deductible obligations based on a list price that does not reflect the actual cost that has been incurred by the plan or PBM for the medicine.

Compounding these issues is the growth of benefit designs that impose high out-of-pocket cost sharing and deductible obligations on enrollees. Enrollment in high-deductible health plans and use of coinsurance for medicines has grown sharply in recent years, exposing many patients to high out-of-pocket costs based on medicines' undiscounted list prices.[38] Further, the out-of-pocket burden created by the increasing use of deductibles and coinsurance is particularly acute for new medicines that represent the most innovative therapies and often treat the sickest patients.[39]

High cost sharing is a cause for concern, as a substantial body of research clearly demonstrates that increases in out-of-pocket costs are associated with both lower medication adherence and increased abandonment rates, putting patients' ability to stay on needed therapies at risk.[40] For enrollees with a serious illness or multiple chronic conditions, out-of-pocket expenses for prescription medicines can easily add up to many thousands of dollars annually, resulting in patients with chronic or life-threatening illnesses such as HIV, diabetes, schizophrenia, multiple

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[36] IQVIA analysis for PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/report/Commercially-Insured-Patients-with-Chronic-Conditions-Face-High-Cost-Sharing-for-Brand-Medicines.

[37] *See*, PhRMA. Follow the dollar. November 2017. http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf (for illustrative examples of the flow of payment for prescription medicines across the supply chain).

[38] Peterson-Kaiser Family Foundation. Tracking the rise in premium contributions and cost-sharing for families with large employer coverage. August 2019. https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/.

[39] IQVIA. Medicine spending and affordability in the U.S. August 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us; IQVIA analysis for PhRMA. Commercially insured patients with chronic conditions face high cost sharing for brand medicines. January 2021. https://phrma.org/report/Commercially-Insured-Patients-with-Chronic-Conditions-Face-High-Cost-Sharing-for-Brand-Medicines.

[40] IMS Institute for Healthcare Informatics. Emergency and impact of pharmacy deductibles: implications for patients in commercial health plans. September 2015. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/emergence-and-impact-of-pharmacy-deductibles.pdf; Doshi JA, et al. High cost sharing and specialty drug initiation under Medicare Part D: a case study in patients with newly diagnosed chronic myeloid leukemia, 22 Am. J. Managed Care 4 Suppl. (2016):S78-S86; Brot-Goldberg ZC, et al. What does a deductible do? the impact of cost sharing on health care prices, quantities, and spending dynamics, NBER Working Paper 21632, October 2015; Eaddy MT, et al. *How patient cost sharing trends affect adherence and outcomes*, 37 Pharmacy & Therapeutics 1 (2012).

sclerosis, and cancer walking away from the pharmacy counter without filling vital prescriptions.[41] High rates of medication nonadherence raise fundamental concerns about patient health and safety, as well as increased costs for the broader health care system.

Plans often use funds directly intended to discount medicines for patients to otherwise defray overall plan spending,[42] creating fundamental misincentives with respect to plan design: in effect, the sick are subsidizing the healthy. As the actuarial firm Milliman has pointed out,[43] the practice results in a system of "reverse insurance" where payers require sicker patients using brand medicines with rebates to pay more out-of-pocket, while rebate savings are spread out among all plan enrollees, including those with no or low drug spending, in the form of lower premiums. Having sicker patients with high medicine costs subsidize premiums for healthier enrollees is the opposite of how health insurance is intended to work. In effect, the current system has created a tax on the sick.[44]

The questions of whether and how prescription drug rebates are impacting patients cannot be fully answered with a narrative description from health plans or PBMs. CMS should amend the PRA ICRs to mandate collection of quantitative information as contemplated by the CAA. One option is to require that plans separately report the amount of rebates, fees, and other remuneration that went to lower patient cost sharing for prescription medicines, so that the Departments can compare those amounts to the total rebate amounts reported. Quantitative reporting by health plans on the amount of rebates that are used to lower the cost of premiums, instead of reducing cost sharing for patients taking rebated brand medicines, as intended by the CAA, will help illuminate this problem and drive future policy solutions.

Perhaps in response to public scrutiny about the lack of transparency over how PBMs use manufacturer rebates, PBMs have moved to other sources of revenue generation. A recent report by the PBM Accountability Project finds that PBMs are shifting away from a compensation model based on retained rebates in favor of revenues collected from spread pricing and fees assessed on manufacturers, payers, and pharmacies.[45] According to the report, PBMs' gross profits from retained rebates decreased by 61% between 2017 and 2019.[46]

In the past few years, each of the three largest PBMs has created a new rebate contracting entity.[47] These new PBM constructs, which are responsible for negotiating, collecting, and disbursing manufacturer rebates, introduce an additional non-transparent layer to the prescription

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[41] IQVIA for PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/cost-and-value/commercially-insured-patients-with-chronic-conditions-face-high-cost-sharing-for-brand-medicines.

[42] Fein, A. "The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers," Drug Channels Institute. March 2021.

[43] Milliman. 2017 Milliman medical index. May 2017. https://www.milliman.com/en/insight/periodicals/mmi/2017-milliman-medical-index/.

[44] *Ibid.*

[45] PBM Accountability Project. Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers. December 2021. https://7f0edfbb-d1c0-491c-a980-f6efff91f8f6.filesusr.com/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true

[46] *Ibid.*

[47] These new contracting entities include Ascent Health Services (Cigna/Express Scripts), Zinc (CVS Health/Aetna), and Emisar Pharma Services (UnitedHealthcare/OptumRx).

drug supply chain and may complicate efforts by plan sponsors, employers, and regulators to audit the rebates negotiated by PBMs. We recommend the Departments adopt a functional definition of PBM that encompasses these entities, and suggest the Departments monitor these trends in the future to better understand the evolution of the biopharmaceutical supply chain and its impact on patient and health plan costs.

Finally, we are concerned that the Departments and OPM are content to allow PBMs to prepare self-reports of these data on behalf of plans. The reporting system under the IFC allows for reporting entities (e.g., PBMs and TPAs) to report information directly to the Departments on behalf of the plan and aggregate information across all the plans they administer (per market). Allowing PBMs to select the data that will go into the reports creates an environment where PBMs could use reporting flexibilities provided by the Departments and OPM to paint themselves in a more positive light than a more robust accounting of the data would suggest. Additionally, stakeholders representing employers have raised concerns that this reporting system may not allow plan sponsors to gain access to additional prescription drug information for their own plans from PBMs.

Public reporting of data

While the IFC did not explain how the Departments intend to publish the collected data, we note that, consistent with the CAA, the Departments and OPM have previously acknowledged the importance of maintaining confidentiality of information aggregated to create the public report. We note that pricing data specific to particular drugs and health plans reported to the Departments and OPM may contain "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential."[48] We also note that the Trade Secrets Act makes it illegal to disclose that information,[49] and the Departments and OPM would be prohibited from disclosing it, whether through a Freedom of Information Act request or otherwise. In particular, if the reported data for drugs listed on top 25 and top 50 lists could permit a user to calculate the net unit prices for an individual payer, the Departments would be prohibited from releasing this confidential commercial information. Therefore, neither the annual report nor any other public data releases should contain a payer's drug-specific data, including data that would allow the calculation of net unit prices.

That said, PhRMA believes it is important that the Departments' annual public report under section 204 appropriately put health care spending, including prescription drug spending, in context. The IFC's approach of aggregate reporting can achieve this by focusing on the relative expenditures on different categories of health care spending. As noted above, the Departments should revise the rules to ensure hospital markups on provider-administered drugs are accurately reflected as hospital spending, not drug spending. The Departments should clarify how the reporting requirements under section 204 will be impacted by the reporting requirements

[48] 5 U.S.C. § 552(b)(4).
[49] 18 U.S.C. § 1905. *See also Canadian Commercial Corp. v. Dep't of the Air Force*, 514 F.3d 37, 39 (D.C. Cir. 2008) ("unless another statute or a regulation authorizes disclosure of the information, the Trade Secrets Act requires each agency to withhold any information it may withhold under Exemption 4").

established under the Transparency in Coverage final rule and the enforcement of that rule. Further, reporting data on unit prices and price increases for individual drugs is less useful than analyzing aggregate spending and spending changes for drugs as compared to other health care categories, given the range of factors that drive health care spending. Lastly, as discussed briefly above, the Departments and OPM should appropriately caveat limitations of self-reported data from PBMs in any public reporting of that data.

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PhRMA appreciates the opportunity to comment on the interim final regulation. Please feel free to contact Ashley Czin (202-835-3400) if we can provide any further information or if you have any questions about the topics discussed in our comments. We are happy to discuss these comments if it is helpful and provide any further detail that you request.

Sincerely,

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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.

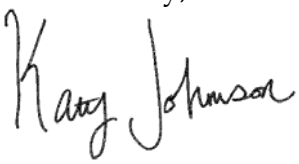
[7] Due to the complexities involved, the departments provide that prescription drugs covered under the plan's hospital or medical benefit are only to be reported as a separate line-item, in the total annual spending table and are not to be included in the other reporting elements (*e.g.*, top-50 lists).

* * * * *

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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January 24, 2022

Submitted electronically via federal eRulemaking Portal: http://www.regulations.gov

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Re: Tri-Department Interim Final Rule: Prescription Drug and Health Care Spending (CMS-9905-IFC)

Dear Acting Associate Director DeHarde, Deputy Commissioner O'Donnell, Acting Assistant Secretary Khawar, and Secretary Becerra:

On November 23, 2021, the U.S. Department of Health and Human Services (HHS), U.S. Department of Treasury, U.S. Department of Labor (together "the Departments") and the Office of Personnel Management (OPM) published an interim final rule with comment period (IFC) entitled "Prescription Drug and Health Care Spending."[1] This Interim Final Rule (IFR) followed an identically titled Request for Information (RFI) published five months earlier, on which the Pharmaceutical Care Management Association (PCMA) provided timely comments.[2] This IFC implements Division BB, Title II, Section 204 of the Consolidated Appropriations Act of 2021 (CAA), which requires group health plans and health insurance issuers to provide annually a narrowly delineated set of aggregated healthcare spending data to the Departments. Under this

[1] 86 Fed. Reg. 66662, November 23, 2021. The Departments have also opened an Information Collection Request under this title, on which PCMA is providing separate written comments.
[2] 86 Fed. Reg. 32813, June 23, 2021. PCMA's comments are available at https://www.regulations.gov/comment/EBSA-2021-0005-0035.

Section, the Departments will produce reports every two years describing prescription drug spending and pricing trends.[3]

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and through the Exchanges established by the Affordable Care Act. Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

As noted in our original comments on the RFI, PCMA is supportive of many efforts by this Administration to bring meaningful and actionable transparency to health care purchasers and consumers. **This interim final rule is a positive step in that direction. With minimal changes, this rule will provide the Departments with the insights they need to pinpoint that drug manufacturer pricing and anti-competitive behaviors directly lead to higher prescription drug spending. These data will also demonstrate the important role that plans and issuers and their pharmacy benefit managers (PBMs) play in reducing overall prescription drug costs.**

Two months following the publication of the RFI, the Departments and OPM have issued guidance delaying the reporting of these data under this provision by one year, until December 27, 2022.[4] The IFR acknowledges that much of the information an issuer needs is held instead by third-party administrators including PBMs.

In this letter, we first thank the Departments for incorporating much of PCMA's input on the RFI questions based on our initial public comments. We raise a number of concerns related to timing and data elements exceeding statutory authority. We have highlighted areas where we believe the Departments and OPM have veered from the clear statutory language set forth by Congress, impermissibly expanding the scope of the data Congress intended to be reported by health plans and health insurance issuers such as the extension of these requirements to Federal Employees Health Benefits (FEHB). As we explain further in these comments, Section 204 is very prescriptive in its definition of the data points to be reported. Based on what is exactingly required by the statute, we object to the expansion of data reporting to now also include: (1) rebates, fees, and other remuneration retained by PBMs; (2) manufacturer cost-sharing assistance; and (3) *bona fide* service fees. Each of these elements is well beyond the bounds of the data identified by Congress in Section 204 and, further, lacks any true meaning

[3] Public Law 116-260, December 27, 2020, added parallel provisions at section 9825 of the Internal Revenue Code (the Code), section 725 of the Employee Retirement Income Security Act (ERISA), and section 2799A-10 of the Public Health Service Act (PHS Act).
[4] U.S. Department of Labor. FAQS ABOUT AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART 49, August 20, 2021, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf.

within the context of the statute which is designed to track the role of prescription drug costs in contributing to premium increases or decreases.

1. **PCMA Thanks CMS for Heeding our Recommendations with Respect to Reporting Timelines and Data Aggregation.**

The IFR requires group health plans and health insurance issuers to report specified information to each of the Departments beginning December 27, 2022, and annually by June 1 of each year thereafter, in a specified form and manner. PCMA appreciates the Departments' exercise of enforcement discretion with respect to the reporting of CY 2020 and CY 2021 information to alleviate burdens related to timing and increase the completeness of reported data. We will revisit timeframes later in this document to discuss remaining industry concerns in this area. This reported data will capture both pharmacy and medical benefit drugs. However, we appreciate that medical benefit drugs will not be reflected in the "top-50" lists, as being outside the purview of typical pharmacy benefits. We appreciate the Departments' receptivity to receiving our feedback and believe many of the data elements included in the IFR are well-reasoned and flow directly from concepts first discussed in the RFI, accounting for stakeholder input.

2. **PCMA Recommends Additional Changes Related to Timing of Data Submission.**

   a. **The Departments should delay annual reporting from June 1 to August 1 (or later) to ensure full calendar year data is available.**

Under the IFR, data submissions will generally be due each June 1, beginning with data reporting for CY 2022 (due June 1, 2023). While this date is presumably designed to adequately capture any data collection lag associated with the reporting year, PCMA believes that an annual reporting deadline of August 1 will better accommodate for lag time between the closing of the plan year and the beginning of the reconciliation process and allow for plan year close-outs prior to reporting. Based on information received from our member companies, June 1, 2022 may not (for example) be enough time to close out a 2021 plan year that ends as of December 31, 2021. Assuming data reported on June 1 is "cut off" a month in advance, claims data will be immature. According to CMS, for the Medicare program, based on claims filed in 2010, only 85 to 95% of institutional and outpatient claims are finalized within four months. Only 78% of Part D prescription drug event data is considered "final" after four months.[5] Based on this data, a minimum of eight months is required, with a preference of 11 to 17 months for true data completeness.

The following example illustrates the importance of providing for a sufficient lag time in ensuring completeness of data, as discussed above. Rebates are currently reconciled upon the completion of a contract and are paid retrospectively. There may be a lag between the

[5] See https://www.ccwdata.org/documents/10280/19002256/medicare-claims-maturity.pdf. Table 3 for inpatient/outpatient and Table 7 for Part D.

closing of the plan year and the beginning of the reconciliation process, especially in the context of an outcomes-based agreement where patient data is also being collected. We believe an important potential use of these data is to identify the success PBMs have had in negotiating lower net costs for drugs. "Rushing" the reporting, thereby, would undermine a key finding and misrepresent the data through omission. Finally, plans and issuers will need to combine the data provided by their PBMs and other third-party vendors with their own data prior to any reporting. The June 1 reporting builds in no time for any of these necessary data cleaning steps.

3. The Departments Should Eliminate from the Final Regulations Any Data Reporting that is Beyond Its Statutory Authority.

In the IFR, the Departments propose to require plans to report not only drug pricing information delineated in the statute, but also a much broader scope of data far outside of the plain language of the statute. Included among these novel reporting elements are: (1) rebates, fees, and other remuneration retained by PBMs; (2) manufacturer cost-sharing assistance; and (3) *bona fide* service fees. The rule should also not apply to FEHB carriers, either. Such information is far outside of what is required or even intended to be required by Section 204 which, as plainly drafted by Congress, consists of a series of 10 distinct data elements and clearly related sub-elements.[6] As is well understood under the *expressio unius* canon of statutory construction, the Departments and OPM, while well-intentioned, clearly lack the statutory authority to regulate beyond the narrow bounds of the delineated statutory terms and programs.

a. PCMA is concerned that the Departments are exceeding their statutory authority by reading into the statute the inclusion of FEHB carriers under Section 204.

We would like to emphasize and note that under Title I, which deals with surprise billing, Congress amended 5 U.S.C. § 8902(p) to apply specified provisions of the CAA to FEHB carrier contracts. Congress conspicuously did not include among those requirements section 2799A-10 of the Public Health Service Act (PHSA), which is the provision that was added by Section 204 of the CAA and includes the various reporting provisions at issue here. Moreover, Section 204 of the CAA did not itself amend 5 U.S.C. § 8902(p) to directly extend its requirements to FEHBs, even while Congress expressly extended such requirements to the PHSA, Employee Retirement Income and Security Act (ERISA), and the

[6] *See O'Melveny & Myers v. FDIC*, 114 S. Ct. 2048, 2054 (1994) ("The expression of one thing implies the exclusion of others (expressio unius est exclusio alterius))". The *expresio unius* canon is strongest when the items expressed are members of an 'associated group or series,' justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence*." Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003) (quoting *United States v. Vonn*, 535 U.S. 55, 65 (2002)).

Internal Revenue Code (IRC). Therefore, we suggest that FEHB carriers be excluded from Section 204 reporting requirements.

b. Given the clear statutory guardrails imposed by Section 204, we urge the Departments to exclude from any final reporting requirements amounts retained by PBMs.

New section 149.740((b)(7)(ii) requires the reporting by plans and issuers of "prescription drug rebates, fees, and other remuneration" *including* "amounts retained by the entity providing pharmacy benefit management services to the plan or issuer." Yet, Section 204 (as codified in section 9825 of the Code, section 725 of ERISA, and section 2799A-10 of the PHS Act) by its plain language limits reporting of rebates, fees, and other remuneration to those amounts that have "any impact on premium" and "any reduction in premiums and out-of-pocket costs."[7] As a form of PBM compensation, amounts retained by PBMs and not passed through to the plan have a net-zero impact on premiums.[8] In order to comply with the statutory mandate, these data elements should be removed in the rule and from the file templates in the guidance before any submissions are made.

In the preamble, the Departments attempt to justify this improper expansion of the statute based on an incorrect reading of the statute. According to the rule: "[t]he Departments interpret section 9825(a)(9)–(10) of the Code, section 725(a)(9)–(10) of ERISA, and section 2799A–10(a)(9)–(10) of the PHS Act to require plans and issuers to report the total amount of rebates, fees, and any other remuneration, *and separately*, the extent to which rebates, fees, and any other remuneration impact premiums and out-of-pocket costs."[9] This is either a poor attempt at legal justification or a misreading of the statute, which very clearly conditions the reporting of rebates, fees, and remuneration in both sections (9) and (10) on a premium impact. Of course, this reading is also inconsistent with the statutory purpose of Section 204, which is focused specifically on "the role of prescription drug costs in contributing to premium increases or decreases under such plans or coverage."

In addition, even if the PBM were able to identify what portion of the rebates were "reasonably" related to various national drug codes, it does not provide any productive way to attribute those dollars to premiums or out-of-pocket (OOP) costs paid by members. Ultimately, a plan or plan sponsor will more often than not receive a lump sum of rebates

[7] *See*, e.g., PHS Act § 2799A–10(a)(9)–(10).
[8] PBMs are compensated by plans and issuers for their services under any number of models. They may retain rebates negotiated with manufacturers or pharmacies or pass those rebates back to the plans and be paid administrative fees by the plans instead. Other compensation models include risk mitigation contracting with pharmacies. In any case, PBM compensation is about the same under any model, with the same level of effect of premiums, so calling out one method of compensation for reporting will yield artificial results.
[9] 86 Fed. Reg. 66662, 66669 (November 23, 2021) (Emphasis added).

that they use to reduce various costs for plan members.[10] When making those determinations, the plan must establish premiums, maximum OOP thresholds, deductibles, and other cost sharing such as premiums and deductibles. Any metric that specifically assigned rebate dollars to any one element of coverage would be completely arbitrary and fail to provide any meaningful insight.

Given that a number of these data elements are well beyond the statutory authority included in Section 204 and have significant policy concerns and logistical hurdles, we have included an appendix (Data Elements Exceeding Statutory Authority) of these data elements by form at the end of these comments.

Additionally, due to the dual reporting mechanism included in the IFR, there is no effective way for PBMs and plan sponsors to communicate on how to report these data elements. PBMs would be able to report total rebate dollars, but plan sponsors would then be unable to use those figures to provide any further detail.

c. PCMA recommends that the Departments exclude manufacturer direct cost-sharing assistance from total annual spending.

PCMA appreciates the Departments' adoption of our recommendation to exclude from the definition of rebates and other price concessions, drug manufacturer cost-sharing assistance provided directly to enrollees on the basis that such amounts are not credited, or potentially even knowable, by the plan or coverage (or its service providers). However, we are disquieted that the Departments are moving forward with requiring the reporting of these amounts in terms of total spending.

As the Departments concede, health plans and issuers (and PBMs) do not have direct access to financial assistance provided by manufacturers directly to beneficiaries. Reporting on these will be incomplete since PBMs do not have access to this data. For example, many "eVoucher" and "switch" operations take visibility away from the PBM on these type of funds, essentially evading capture and reporting by PBMs. These claims are being paid without our detection, though we know this is occurring. Moreover, as National Council for Prescription Drug Programs noted in their report on copay assistance, contractual modifications and patient consent are needed to address privacy, data sharing and member rights prior to sharing such data.[11]

[10] Overall net drug prices in Medicare and Medicaid fell from 2009 to 2018 while brand-name drug prices rose sharply, according to a report released by the Congressional Budget Office Wednesday. **Link:** Prescription Drugs: Spending, Use, and Prices | Congressional Budget Office (cbo.gov)
[11] NCPDP Upstream Reporting of Copay Assistance Issues Brief

While the Departments acknowledge that such reporting will only be required "to the extent information regarding the amount of these reductions is available to the plan",[12] given the acknowledged incompleteness of this data, as well as its lack of relevancy to the statutory purpose of Section 204, PCMA urges the Departments to remove this data element from the required reporting fields. This requirement exceeds the congressional mandate of the agencies in both letter and spirit. It pulls in supply chain transactions explicitly excluded within the statute and has no rational basis in the law. By including transactions associated with other supply chain entities, the rules go far beyond the statutory authority by inferring the inclusion of entire other entities left unnamed in the statute. Additionally, they completely leave out these entities as filers, an implicit recognition that they were never meant to be included in the first place.

d. PCMA urges the exclusion of *bona fide* service fees (BFSF) since these amounts do not increase or decrease the costs of the drugs paid for by the plan.

The IFR requires plans to report the total amount of *bona fide* service fees but are not proposing to require that such amounts be reported separately for each therapeutic class or for each drug on the top-25 list. PCMA appreciates the Departments recognition that BFSF are not intended to directly affect the cost or utilization of specific prescription drugs. We further appreciate the limited reporting of this information. However, we continue to oppose the reporting of any BFSF amounts, as well as the inclusion of BFSFs in the definition of "prescription drug rebates, fees, and other remuneration."

PCMA opposes the reporting of BFSF on the basis that these are fair market value payments for services actually performed on behalf of drug manufacturers, unrelated to the processing of prescription drug claims, *and* for which a fee is not passed on, in whole or in part, to a client or customer of the entity. In line with Congress' goal of bringing transparency to health care items and services, it would be inconsistent to report on information that has no bearing on the price of health care items and services. Consistent with our comments above, section 9825(a)(9)–(10) of the Code, section 725(a)(9)–(10) of ERISA, and section 2799A–10(a)(9)–(10) of the PHS Act require that plans and issuers report rebates, fees, and other remuneration *only* to the extent that such amounts have any impact on premiums or result in the reduction in premiums and out-of-pocket costs.

Just like PBM-retained rebates, BFSFs are fair-market value payments for services actually performed. They have no bearing on premiums or out-of-pocket costs. Including such amounts is inconsistent with the statutory directive that these amounts be reported "with respect to prescription drugs prescribed to enrollees in the plan or coverage." BFSFs are regularly paid for services performed without respect to a particular drug and thus clearly fall

[12] 86 Fed. Reg. at 66670.

outside of this statutory directive. Further, treating BFSFs as rebates, fees, and other remuneration is inconsistent and should be excluded for consistency with the requirements under the Medical Loss Ratio (MLR) rule, the Exchange Establishment rule and the Qualifies Health Plan (QHP) PBM Transparency rule, as well as the definitions used by the Medicare and Medicaid programs.

While there is no single definition of BFSFs, largely as a result of a complex interplay among drug manufacturer federal price reporting requirements, the regulatory definition of *bona fide* service fees has been replicated across federal health care programs (see 42 C.F.R. § 423.501 (Part D definition), 42 C.F.R. § 414.702 (Part B definition), 42 C.F.R. § 447.502 (Medicaid definition)). In each of these cases, HHS defines these fees as fees paid by a manufacturer to an entity for meeting a set of specific conditions, distinct from rebates, fees, and other remuneration.

Because these fees are not passed on or retained by the client or customer of an entity (in this case, the issuer or health plan), existing federal programs generally treat such fees as unique and separate from other fees and remuneration. For example, in the Medicare Part D program, BFSFs that meet the safe harbor definition are not reported as direct and indirect remuneration and are not included in categories of administrative expenses for Part D plan sponsors.

The Departments risk disrupting existing arrangements that provide significant value to consumers should they require reporting of BFSFs. PBMs, by way of example, currently perform a wide array of service on behalf of entities including manufacturers, such as:

- Improving outcomes for patients taking chronic medications, controlled substances, or drugs with potentially serious adverse events;
- Administering REMS;
- Medication compliance and management programs;
- Medical education of pharmacists and prescribers;
- Medication monitoring; and
- Data management.

Treatment of such amounts as “remuneration” under Section 204 is inaccurate. Their inclusion in any reports would undercut the delicate balance between PBMs who perform these services and manufacturers who pay for them. Further, the fair market value (FMV) determination is made by the manufacturer – not the PBM – so a PBM would only know a fee is paid to them, not whether the manufacturer considers it to be FMV for the service.

Recommendation: **CMS should address and respond to the data reporting concerns raised and clarify their perspective regarding the relevance and rationale for including statutorily out-of-scope data reporting requirements.**

Conclusion

PCMA supports the IFR's intent to gather specific information regarding pharmacy benefits and prescription drug costs. However, we caution against collecting pricing and discount data that will adversely affect beneficiary experience. We thank the Departments for the opportunity to provide comments prior to full implementation, as we move toward a future of greater transparency. If you have any questions, please do not hesitate to reach out to me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube
Vice President, Regulatory Affairs

cc: Carol Weiser
Rachel Leiser Levy
Amber Rivers
Jeffrey Wu

APPENDIX
Data Elements Exceeding Statutory Authority

ICR File	Data Element	Rationale
D2	Disallowed amounts for non-covered services or for prescription drugs not on a plan or coverage's formulary	(a)(1)-(10) only refer to plan spending, and do not cover non-covered drugs or services
D2	Cost-sharing amounts not applied to the deductible or OOP maximum	(a)(1)-(10) do not include any elements related to deductibles or OOP maximums
D3	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D4	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D5	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D7	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D8	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers from a manufacturer to a member or pharmacy
D6	Bona Fide Service Fees as a Separate Element	(a)(9) only refers to transfers between manufacturers and a plan or PBM that are related to a member prescription. Bona fide service fees are not reasonably related
D7	Net Transfer of Remuneration from Manufacturers to Plans/Issuers/Carriers/PBMs by Therapeutic Class	(a)(9)(A) only requires a total transfer figure

D7	Net Transfer of Remuneration from Pharmacies, Wholesalers, and Other Entities to Issuers/Plans/Carriers/PBMs	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers between other entities
D7	Restated Prior Year Rebates, Fees and Other Remuneration	(a)(1)-(10) only refer to reporting for individual years
D8	Net Transfer of Remuneration from Manufacturers to Plans/Issuers/Carriers/PBMs by Drug	(a)(9)(B) only requires a total transfer figure
D8	Net Transfer of Remuneration from Pharmacies, Wholesalers, and Other Entities to Issuers/Plans/Carriers/PBMs	(a)(9) only refers to transfers between manufacturers and a plan or PBM, and does not include transfers between other entities

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Comments to Department of Health and Human Services Interim Final Rules (CMS–9905–IFC Implementing Provisions of ERISA and the PHS, As Enacted by the Prescription Drug and Health Care Spending Transparency Under the Consolidated Appropriations Act, 2021 (CAA). Federal Register Vol. 86, No. 223, Page 66662, November 23, 2021.

The interim final rule represents an essential step in illuminating the flow of profits and payments in pharmaceuticals under ERISA-covered plans. This information is critical to allow regulators and legislators at the state and federal levels, as well as the public, to identify any anticompetitive or inappropriate practices in the industry. Obscured behind secretive and convoluted agreements between drug manufacturers, pharmacy benefit managers (PBMs) and health plans, the price of a drug as it moves through the supply chain and the flow of profits and payments are often impossible to discern. The type of transparency represented in the interim final rules promotes fairer, price-lowering competition in prescription drug markets, and the rule is a welcome addition. As I explain below, certain improvements to the interim rule can amplify its impact, ensuring that regulators can hold insurance plans accountable to their patients.

I am the Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (C4i) at the University of California Hastings Law. In the course of authoring two books and dozens of articles on the pharmaceutical industry,[1] I have worked extensively with Medicare Part D insurance claims datasets—a rare source of currently available health plan information—to characterize anticompetitive and other inappropriate behaviors among drug-makers, PBMs, and health insurers.[2] I appreciate the opportunity to share that experience here. As explained in greater depth below, I recommend the following adjustments, pertaining to which categories of data are collected from health plans, the extent to which data are aggregated, and how certain terms are defined in the rule.

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[1] *See*, *e.g.*, ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES (2019); ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET (2017) [hereinafter FELDMAN, SECRET HANDSHAKES]; Robin Feldman, *The Devil in the Tiers*, 8 OXFORD J.L. BIOSCI. 1 (2021); Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303 (2020) Robin Feldman, *May Your Drug Price Be Evergreen*, 5 OXFORD. J.L. & BIOSCIE. 590 (2018).

[2] Feldman, *Devil in the Tiers* (using Medicare Part D claims to characterize how frequently drugs are placed on irrational formulary tiers).

Page 66663- The "top 50" lists

The most important comment I wish to make relates to the ability of the rules to meet the stated justifications when the rules require only aggregated data.

As stated in page 66663 of the Federal Register, the justification for the interim final rule explains that:

> "The data collection required by these interim final rules will provide valuable information about competition and market concentration in the pharmaceutical and health care industries. Policymakers can use the prescription drug and health care spending data to make informed decisions in support of the goals of Executive Order 14036, including identifying any excessive pricing of prescription drugs driven by industry concentration and monopolistic behaviors, promoting the use of lower-cost generic drugs, and addressing the impact of pharmaceutical manufacturer rebates, fees, and other remuneration on prescription drug prices and on plan, issuer, and consumer costs."

In that context and to obtain the full picture necessary to "addressing the impact of pharmaceutical manufacturer rebates, fees, and other remuneration on prescription drug prices and on plan, issuer, and consumer costs," one would want information at the level of each plan as related to the relevant drugs that includes the out-of-pocket cost to the patient; the cost to the plan at the point of sale; the net cost after accounting for all rebates, fees, and other remunerations; the terms of those rebates, fees, and other remunerations; the extent to which those rebates, fees, and other remunerations flow to the plan or stay with others; and the extent to which those rebates, fees, or other remunerations are used to reduce premiums. I recommend that revising the language of the rule to clearly encompass that range of information, such as the language at Federal Register page 66663:

> "Plans and issuers must also report the 50 most frequently dispensed brand prescription drugs, and the total number of paid claims for each such drug; the 50 most costly prescription drugs by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and the 50 prescription drugs with the greatest increase in plan or coverage expenditures from the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year (top 50 lists)."

And

> "Plans and issuers must report any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers including the amount paid with respect to each therapeutic class of drugs and

for each of the 25 drugs that yielded the highest amounts of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year (top 25 list)."

In addition, aggregated data do not provide the granularity necessary to analyze the information identified in the justification. The rule contemplates on Federal Register page 66669 that "plans and issuers expect that issuers and TPAs will report the information on behalf of most group health plans, including self-funded group health plans." And page 66679, "The Departments may also choose to allow data submitted by PBMs to be aggregated at a higher level than at the level of each issuer and TPA." Similarly, the rule discusses aggregation of data at Federal Register Page 66677 across groupings, rather than in a plan-specific manner.

The rule explains that aggregate data is preferable, among other reasons, because individual data may be too small to provide a broad picture, and that rebates, fees, and other remunerations tend to be driven by considerations at the PBM level, rather than in a plan-specific manner. However, much of the detail can be obscured by taking a view that is aggregated at such a high level. Granular data can be aggregated as needed; aggregated data, however, cannot be pulled apart. Moreover, to the extent that information is the same across a group of plans for a large issuer or TPA, or the same across a PBM level-group, the reporting entity could report individually, but indicate that the bases are the same.

In addition, one might also wonder whether it is fully accurate that PBMs are negotiating the same deals across all clients. That in itself, would be worth exploring as an example of a third-party creating a hub-and-spokes relationship among the insurance plans that should be competing with each other.

Providing information on a more granular level can be done in a way that preserves anonymity of patients and plans. This is an issue that researchers face all the time, and anonymity can be accomplished without giving up granularity.

Background—Section 204 Public Report

In addition to outlining which health plan information will be disseminated through the biannual Section 204 Public Report, the final rule should include language specifying that all information reported to the departments will also be made available to state governments and other relevant regulators (e.g., FTC). Although a Public Report can provide a helpful resource to promote a lay understanding of prescription drug price trends, releasing only a processed report does not leave state governments with enough information to design policies and properly regulate the pharmaceutical industry in their jurisdiction. To the extent that any anonymity concerns remain—all of which should be surmountable—governmental entities, at the very least, should have access to the full data regarding plans within their jurisdictions.

Page 66667-The Definition of Brand-Name Prescription Drugs

The rule at Federal Register page 66667 defines brand drug to include interchangeables. Specifically, the language provides that, "The term ''brand prescription drug'' includes drugs that the U.S. Food and Drug Administration (FDA) determines to be interchangeable biosimilar products under sections 351(i)(3) and 351(k)(4) of the PHS Act (42 U.S.C. 262)." Under the Biologics Price Competition and Innovation Act (BPCIA), both biosimilars and interchangeable drugs are considered follow-ons to the original biologic drug. Both biosimilars and interchangeables are expected to sell at prices below the original biologic, analogous to the way in which generic small-molecule drugs sell at prices far below the original brand version of the small-molecule. The PBCIA was designed to provide an accelerated and simplified pathway for approval of biosimilars and interchangeables when the intellectual property protection expires on the original biologic. Thus, interchangeables should not be classified with brands.

Page 66668- The Definition of a therapeutic class

The interim rule defines therapeutic class as follows:

> "a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, grouped in the manner specified by the Departments in guidance."

This definition is not wrong, but it is too broad. It is a necessary, but not a sufficient condition that two drugs considered to be part of the same therapeutic class have "similar mechanisms of action or treat the same types of conditions." Drugs that treat rheumatoid arthritis and Crohn's disease could both be placed in the therapeutic class of "anti-inflammatory agents."[3] However, it is common sense that a drug treating inflammation on account of Crohn's disease, and a drug treating inflammation on account of rheumatoid arthritis are not market competitors, which should be the touchstone for analyzing market behavior.

In order to make the definition of "therapeutic class" more useful for policymakers, the rule should strive to identify what one might call therapeutic competitors or indication competitors. The goal is to group drugs according to their market competitors, a grouping that health plans and PBMs should be able to determine. (Drug companies, of course, know who their competitors are, and one would assume that a careful health plan knows which drugs provide alternatives for patients.)Thus, this definition could be amended to say that "the term "therapeutic class" means a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions," *and historically have been in competition because they can be administered in the same types of medical situations.*

Page 66669 -Prescription Drug Rebates, Fees and Other Remuneration

[3] *See* USP THERAPEUTIC CATEGORIES MODEL GUIDELINES (March 2018) (https://www.fda.gov/regulatory-information/fdaaa-implementation-chart/usp-therapeutic-categories-model-guidelines) ("Anti-inflammatory Agents" are considered a "Therapeutic Category" in the chart on this webpage.).

The relevant language of the interim rule states:

> "The Departments interpret section 9825(a)...to require plans and issuers to report the total amount of rebates, fees, and any other remuneration, and separately, the extent to which rebates, fees, and any other remuneration impact premiums and out-of-pocket costs."

The interim rule is right to broadly define the types of rebates and other remunerations that plans must report and to require plans to calculate the rebates that reduce patients' premiums and out-of-pocket costs. However, regulators would be well-served by requiring health plans to report with increased granularity the *type* of rebates they receive. For example, some rebates are conditioned on volume discount, bundled discounts, or the tier placement of other drugs in the health plan's formulary.[4] Thus, an additional sentence in this section requiring health plans to categorize or specify the rebates they receive and any conditions of those rebates would help shed light on certain anticompetitive schemes.

The rule should also clarify that when non-plan entities such as PBMs or TPAs are the reporting entity for a group of plans, moreover, those entities should be required to report the total rebates, fees, and any other remuneration amount received in addition to the rebates, fees, and any other remuneration amount paid out to health plans by the PBM. Such a requirement would illustrate to regulators the amount of drug company rebates that are diverted by PBMs before reaching health plans, an important and often hidden payment flow in the pharmaceutical supply chain.

Reporting Entity

The interim rule anticipates "that issuers and TPAs will report the information on behalf of most group health plans, including self-funded group health plans." Tasking issuers and TPAs alone, rather than PBMs, with reporting may pose compliance issues. For example, plans could respond that their PBM contracts do not provide this level of information. In those circumstances, it could be difficult for agencies to induce compliance. Instead, the rule could require that to the extent the plan does not maintain its own information, the rule directs that the appropriate third-party who handles their claims must respond.

Once again, I applaud this undertaking of vital, competition information, and I appreciate the opportunity to share comments as the rules are finalized.

Warmest regards,
Robin Feldman

[4] Feldman, *Perverse Incentives*, at 329-334 (describing volume rebates, bundled rebates and other anticompetitive rebate schemes)

CHURCH ALLIANCE

BENEFITS FOR FAITH LEADERS SERVING COMMUNITIES

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January 24, 2022

Electronically to https://www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–9905–IFC
P.O. Box 8016
Baltimore, MD 21244–8016

Re: Prescription Drug and Health Care Spending (CMS–9905–IFC)

To Whom It May Concern:

The Church Alliance submits this letter in response to the Prescription Drug and Health Care Spending Interim Final Rule ("IFR") published by the Department of Health and Human Services, Department of Labor, Department of the Treasury, and the Office of Personnel Management (the "Departments") at 86 Fed. Reg. 66662 on November 23, 2021. The Church Alliance appreciates the opportunity to comment regarding the reporting requirement under Section 204 of Title II of Division BB of the Consolidated Appropriations Act ("CAA"), 2021, related to pharmacy benefits and prescription drug costs (the "Reporting Requirement").

As discussed below, the Church Alliance's view is that Congress intended to exempt all church plans from the Reporting Requirement. The unique characteristics of church plans strongly support an exemption from the Reporting Requirement. In the alternative, temporary non-enforcement and/or a limited scope exemption for church plan reporting is warranted until such time as practical guidance is issued that would improve the accuracy of the data reported for church plans and reduce the burdens that the Reporting Requirement imposes.

I. Introduction

The Church Alliance is composed of 37 church benefits organizations, covering mainline and evangelical Protestant denominations, three Jewish entities, and Catholic schools and institutions. Church Alliance organizations provide employee benefit plans, including retirement and/or health coverage, to approximately one million participants (clergy, lay workers, and their families), serving approximately 155,000 churches, parishes, synagogues, and church-related organizations.

The plans of the Church Alliance's church benefits organizations ("denominational plans") are defined as "church plans" under section 3(33) of the Employee Retirement Income Security Act ("ERISA") of 1974 and section 414(e) of the Internal Revenue Code of 1986 ("Code"), as amended. In recognition that a church is not confined to the four walls of the church, these organizations carry out the broader mission of the denomination.

II. Background on Church Benefit Plans

A. Church Benefit Plans Generally

Church benefit plans have been in existence for decades and, in some cases, pre-date the enactment of the Code in 1913. Denominational plans are typically maintained by a separately incorporated church benefits organization for eligible employees of ministries in a denomination. In some cases, the sponsor is the church or denomination, not the benefits organization. The plans are generally multiple-employer in nature and provide retirement and welfare benefits to thousands (or, in the case of large denominations, tens of thousands) of clergy and lay workers working for different religious employers throughout the U.S.

Because denominational plans serve multiple employers, they provide efficiency, continuity, and consistency of employee benefits for ministers and lay workers as they move throughout the U.S. from one church or church-related organization to another within a denomination. Most participating employers are small, local churches with only a few employees. In many denominations, the local church's pastor may be that church's only employee. If there are other employees, they may be full or part-time workers who assist with administrative duties, although these duties are performed by volunteers in many churches.

In addition to serving churches, denominational plans also cover other nonprofit organizations associated with the denomination or church. Participating employers can include church-affiliated nursing homes, day care centers, seminaries, universities, elementary and secondary schools, food pantries, and other social services organizations. These organizations are essential to fulfilling the mission and ministry of the church and share common bonds of worship with the denomination. Individuals, such as self-employed ministers and missionaries, also may participate in denominational plans.

Denominations have been organized to reflect their own theological beliefs and church polity (the operational and governance structure of the denomination), which can give rise to unique challenges for denominational plans. Hierarchical structures, where the parent church organization sets policy for the entire denomination, operate in a manner similar to a large multiple employer plan. Hierarchical structures still will present unique challenges, though, because while policy may be set centrally, many decisions and processes impacting employee benefits are set and controlled locally, such as payroll, hiring, and termination. Other less hierarchical structures, including synodical or presbyterian structures (local or regional policy-making through representation from area churches) and congregational structures (voluntary cooperation among autonomous churches, or church conventions or associations) operate with less centralized policy decision-making, and can further divide various responsibilities and functions between the national plan and local employer, which can lead to greater regulatory compliance challenges. Moreover, in congregational structures the individual churches are the decision-makers, and are not subject to mandates from other organizations in the denomination.

B. Church Health Care Benefit Plans

Many church health plans have been in existence for over 50 years. Most denominations offer a nationwide plan (most often on a self-funded basis), which provides clergy and their families career-long, portable, comprehensive, and affordable medical coverage through a plan that reflects their denomination's beliefs. As workers move from one church to another, they often are able to continue coverage without impacting provider networks and existing contributions to annual deductibles and out-of-pocket maximums.

Notably, self-insured denominational health plans may fund their programs by averaging of contribution rates, so that larger, wealthier, and more-established churches effectively support smaller, poorer, or newer (i.e., evangelizing) churches. This averaging or community rating generally is for theologically-based reasons. However, in many denominations, the church benefits organization may not actually know the level of contributions that the local ministry pays on behalf of its employees, because there is no centralized human resource or payroll function. Similarly, the amount a minister or lay employee may be required to contribute towards the coverage may also vary by employing organization.

III. Statutory Exemption for Church Plans

A. Church Plan Exemption and the First Amendment

Congress has long acknowledged the unique organizational polities of America's churches, which reflect each denomination's or church's underlying theological tenets and religious beliefs. To this end, Congress has provided church plan exemptions, for example, when the requirements of federal law are recognized to have an adverse impact on a church benefits organizations' ability to continue to deliver their programs and to avoid government entanglement with religion in violation of the First Amendment.

By way of background, in 1974, when ERISA was enacted, church plans, including denominational plans, were exempted unless they affirmatively elected to be subject to ERISA. The exemption was granted to avoid government entanglement with religion in violation of the First Amendment. In exempting church plans, Congress recognized that examining the internal arrangements of churches constituted an unnecessary intrusion into religious activities. Since ERISA's enactment, Congress has repeatedly exempted non-electing church plans from certain employer group benefits plan disclosure and reporting requirements under the Code.

B. Church Plan Exemption from the Reporting Requirement

The Church Alliance believes that Congress similarly intended to exempt church plans from the Reporting Requirement. Specifically, Section 204 of Title II of Division BB of the CAA added parallel provisions at Section 2799A–10 of the Public Health Service Act ("PHSA"), Section 725 of ERISA, and Section 9825 of the Code for the Reporting Requirement. Incorporating parallel provisions to the three statutes was necessary to broadly cover group health plans given that each of those statutes has slightly different definitions of "group health plan," and, as such, applies to different types of group health plans. In this regard, Section 204(a) of the CAA amended Section 2799A–10(a) of the PHSA to provide, in pertinent part, as follows:

> ''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the Consolidated Appropriations Act, 2021, and not later than June 1 of each year thereafter, a group health plan or health insurance issuer offering group or individual health insurance coverage (*except for a church plan*) shall submit to the Secretary, the Secretary of Labor, and the Secretary of the Treasury the following information with respect to the health plan or coverage in the previous plan year: …." (emphasis added).

This PHSA language provides a statutory exemption for church plans, such that the Reporting Requirement does not apply to church plans under the PHSA. However, the PHSA does not apply to church plans that are self-funded group health plans. *See* Section 2722(a)(1)(B) of the PHSA. To provide an exemption for *all* church plans, the "(except for a church plan)" language or similar language should have been carried over to Section 9825(a) of the Code, which was added by Section 204(c) of the CAA.[1]

IV. Church Alliance Comments on the Departments' RFI

Given the above, the Church Alliance submitted comments on July 23, 2021, in response to the Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs ("RFI") published by the Departments at 86 Fed. Reg. 32813 on June 23, 2021. In its comments, the Church Alliance highlighted the ambiguity with respect to the applicability of the requirements, as well as the difficulty presented to sponsors of denominational plans to access the necessary data to comply with the requirements.

It is the Church Alliance's view that Congress intended to exempt all church plans from the Reporting Requirement. This is based in part on discussions with drafters of legislative text of the Lower Health Care Costs Act, which formed part of the basis for Division BB of the CAA, when that draft text only modified the PHSA. Accordingly, as part of its comments, the Church Alliance requested that the Department of the Treasury take a non-enforcement approach with respect to the Reporting Requirement under Section 9825 of the Code for church plans.

The Church Alliance is disappointed in the Department's definition of "group health plan" in the IFR that "includes both insured and self-funded group health plans, and includes private employment-based group health plans subject to ERISA, non-federal governmental plans (such as plans sponsored by states and local governments) subject to the PHS Act, and church plans subject to the Code."[2] Applying the Reporting Requirement to self-insured church plans creates the same entanglement issues as would have been created with insured plans that were exempted, and this inconsistency can be rectified with non-enforcement.

V. Executive Summary

The Church Alliance again requests that the Department of the Treasury take a non-enforcement approach with respect to the Reporting Requirement for church plans subject to the Code, to avoid

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[1] An exemption was not necessary in the language added to ERISA by the CAA because Section 4(b)(2) of ERISA provides that Title I of ERISA (which includes Section 725 of ERISA) does not apply to a church plan, as defined in Section 3(33) of ERISA, unless such a plan affirmatively elects to be subject to ERISA under Section 410(d) thereof.

[2] 86 Fed. Reg. 66662, 66665 (November 23, 2021).

governmental entanglement with religion, and to provide consistency with the church plan exemption from the Reporting Requirement for church plans subject to the PHSA.

If the Department of the Treasury chooses not to take that approach, further guidance will be necessary for compliance with the Reporting Requirement by church plans, as explained below. Church plans do not have the information needed to comply with the Reporting Requirements. Accordingly, in order to comply, church plans must either: (i) attempt to collect this information from potentially thousands of ministries, which for some denominations would be contrary to church polity and independence based on strongly-held religious beliefs, and would be a significant drain on resources; or (ii) submit the best data available, which may result in substantial inaccuracies.

To avoid entanglement or inaccurate reporting before further guidance is issued, we request that the Department of the Treasury temporarily forgo enforcing the Reporting Requirement on church plans, and/or provide a limited exemption for data that is unavailable to either the church plans or their third-party administrators ("TPAs"). The purpose of the IFR Section 204 reporting is to provide the Departments with information to draw conclusions about market trends for purposes of developing a meaningful and accurate section 204 public report.[3] The incremental data that would be reported by church plans would not impact the ability of the Departments to develop meaningful and accurate reports about health care prescription drug reimbursements, pricing trends, the impact of rebates, fees and other price concessions for purposes of its reporting and meeting its statutory requirements. On the other hand, the impact on church plans of enforcement prior to the issuance of necessary guidance would be substantial and unreasonably burdensome, and likely would result in the submission of inaccurate data.

Temporary non-enforcement and/or a limited exemption would be reasonable because many church plans do not fit within any of the market segments to be specified in the reporting, multi-state church plans do not fit the existing guidance for state aggregation, and many church plans do not know the average monthly contribution paid by employees, as explained below. Until further guidance is issued, we question whether it is possible for accurate data to be submitted on many church plans.

VI. Church Alliance Comments on the Department's IFR

A. Lack of Access to Information for Church Plans and Lack of Clarity for TPAs and pharmacy benefits managers ("PBMs") to Provide Data on Church Plans

As discussed in more detail in the Church Alliance's comments on the Departments' RFI, sponsors of denominational health plans have access to very little of the data that would be necessary to comply with the Reporting Requirement. Most denominational plan sponsors have access to the general enrollment information on the plan, such as the beginning and end dates of the plan year, the number of participants, beneficiaries, or enrollees, as applicable, and each state in which the plan or coverage is offered. However, denominational plan sponsors will not know the individual enrollees' health coverage

[3] "The Departments will issue biennial public reports on prescription drug pricing trends and the impact of prescription drug costs on premiums and out-of-pocket costs starting in 2023. These reports are expected to enhance transparency and shed light on how prescription drugs contribute to the growth of health care spending and the cost of health coverage." (See https://www.cms.gov/newsroom/fact-sheets/prescription-drug-and-health-care-spending-interim-final-rule-request-comments, last visited January 2, 2022.)

contribution amounts established by their individual employing organization, nor will they likely know the employer size and may not know the contribution amounts paid by employers.

The remaining data that would be necessary to comply with the Reporting Obligation is only accessible from records maintained by a denominational plan's TPA(s). A plan may use more than one TPA. For example, a plan may use separate TPAs for medical, mental health, wellness and pharmacy benefits. In addition, some plans use different TPAs for different geographical areas of the country given the geographically dispersed populations covered by denominational plans. Additionally, as described below, neither the TPAs nor the plans generally have information on the average monthly premium paid by employees and may not know the amount paid by employers.

1. Prescription Drug Costs

Much of the information requested by the Reporting Requirement relates to pharmacy benefits and prescription drug costs. A church health plan would need to request this data be provided by its PBM. Given that most PBMs are still assessing the Reporting Requirement and determining their capability to provide the necessary data, many church plan sponsors have not received confirmation from their PBM that they can provide the necessary data. In addition, many church plan sponsors have not yet received confirmation from their PBMs regarding fees that would be charged by the PBM to provide the required data. As noted above, many plans use separate TPAs for medical and pharmacy benefits, as well as wellness programs. In those cases, medical benefits and wellness program information would need to be requested from a different entity(ies), each which may charge a separate fee for this data.

2. Market Segment/Employer Size

For all of the TPAs with information on self-insured health plans, data is to be reported by market segment, and many church health plans do not neatly fit into any of the specified market segments, since they are multiple employer plans and the employers vary in size. Moreover, denominational church benefits organizations have varying approaches to offering group health plans to their individual church or church-associated employers, typically driven by the underlying polity of the denomination, which is based on religious belief. This means that one denominational church benefits organization may be managing each of its eligible employers' self-funded individual employer plans, sponsored by the individual employers. Another denomination's church benefits organization may be managing plans for its eligible employers on a synod, conference or other denominational regional governing body plan basis, with the regional group as the sponsor. A third model exists where the denomination sponsors the same plan designs for all the individual employers in the denomination and administers those designs centrally as a single plan.

Therefore, the TPAs cannot simply assume that the benefits organization is the plan sponsor (treating that organization as the "employer" and basing market segment on that) or assess the market segment based on the number of plan members. In addition, the TPAs generally do not have information about the sizes of the various employers participating in the denominational church plan because they are processing claims and administering the program as if the plan was a large single employer plan. Finally, since the church benefits organization generally does not have payroll information, it also does not have accurate information about employer size. Thus, reporting from a TPA or PBM by market size would be next to impossible without significant input from each church or other ministry, which would put significant strain on the ministry, church benefits organization, TPAs and PBMs.

3. State Level Reporting

Similarly, the guidance on state aggregation for multi-state self-insured church plans generally does not fit. Often this coverage is provided through a group trust with multiple employers in multiple states, so the guidance for group trusts to report based on where the employer has its principal place of business does not work. Even if the church benefits organization would be interpreted as akin to an association, that guidance only applies if the association qualifies as an employer under ERISA or has no principal place of business, and church plans are not subject to ERISA, but the benefits organizations have principal places of business. Also self-insured church plans are not multiple employer welfare arrangements ("MEWAs") so those aggregation rules do not apply.

Depending on the denomination, the group health plan managed by the church benefits organization may exist at the individual employer level, a regional level or the denominational level. It is unclear whether the IFR requires a denominational benefits organization that administers individual employer-level plans to be attributed to the state where the individual employer has its principal place of business and how the regional-level plan would aggregate by state.

4. Conclusion

Thus, self-insured church plans will neither be able to report on their own, nor do their TPAs have the guidance to report information accurately on their behalf. TPAs will only be able to report the data as part of a large single employer market segment and on the basis of the state of the church benefits organization's principal place of business (though much of the enrollees' data has no bearing to the state of the church plan benefits organization's principal place of business). The Church Alliance believes the value for government reporting purposes is de minimis at best and could in fact have a skewing effect. While we agree that this irregularity will not have an outsized impact on the top 50 lists and trends in a state, it nonetheless demonstrates the futility of the church plan reporting for purposes of Section 204, at least before further clarifying guidance is issued.

B. Monthly Premium Reporting

Reporting the average monthly contributions for health coverage paid by participants, beneficiaries, and enrollees and paid by participating employers on their behalf presents a unique challenge to denominational church plans, which does not exist with a typical single employer and many other multiple employer group health plans.

The governance structures of the Church Alliance members range from purely hierarchical churches to independent churches or denominations that are congregational in nature. The governance structure of a denomination often determines how direct the relationship between each church and the denominational plan is and may affect the way contributions for coverage are established. As a result, the "average monthly premiums" paid by participants, beneficiaries, and enrollees, as well as employers in some denominations, under a self-insured church health plan is not usually known by the church benefits organization.

In some denominations, the church plan invoices a regional sub-unit of the denomination for an established contribution. These intermediate bodies, such as a diocese, presbytery, or state convention, may alter the method of sharing costs among participating churches. Sometimes contributions set by the church plan are blended to remove any perceived barriers to appointment/employment at a particular

church due to a clergyperson's family size. For example, assume a state conference pays the denominational plan $7,000 to cover single clergy and $13,000 to cover clergy with families. The conference blends the rates and charges each church $10,000 for coverage. The denominational plan will not know the actual contribution amount charged to the churches' employees or to the church. Some denominations and intermediate church bodies cross-subsidize churches through contribution structures. They may charge higher contribution rates to churches with larger memberships, greater revenue (giving), or more assets, and in turn charge a reduced contribution rate to smaller, rural or underprivileged churches. This cross-subsidization often serves the mission of these denominations.

Some denominational plans charge a contribution for coverage that is a fixed percentage of a clergyperson's, or an employee's, compensation. In other cases, the contribution under the health plan may be combined with the contribution to the church pension plan to set one benefits coverage contribution for the church. In addition, in some cases, an intermediate body may combine health plan contributions with other general church remittances for participating churches. Yet other denominational plans assess a contribution amount that is blended among a variety of health and welfare products. These contributions may also be varied within a denomination (e.g., in order to reflect mission needs and church values).

Requiring denominational plans to obtain this information would be unduly burdensome on the denominational plan and on churches, and contrary to church polity and belief in some denominations, dwarfing any possible public benefit from the information, and therefore it would be of questionable constitutionality. The independence of individual churches in some denominations is strongly based on religious beliefs, so requiring the disclosure of this information from churches would violate the separation of church and state. Therefore, a limited exemption from this reporting requirement is warranted for church plans. Alternatively, the reporting format and guidance should allow the submission of an answer such as "unknown" in the field for average monthly premium paid by employees.

VII. Conclusion

As highlighted above, it is the Church Alliance's view that Congress intended to exempt all church plans from the Reporting Requirement. The unique characteristics of church plans cry out for an exemption from the Reporting Requirement. In the alternative, temporary non-enforcement and/or a limited scope exemption for church plan reporting is warranted until such time as practical guidance is issued that would improve the accuracy of the data reported for church plans and reduce the substantial administrative and financial burdens that the Reporting Requirement imposes on denominational plans. The Church Alliance appreciates the opportunity to comment on the Departments' IFR with respect to prescription drug and health care spending. As the Departments navigate these issues, the Church Alliance looks forward to the opportunity to work together and requests that the Departments consider the special considerations of church health plans and the difficulty in obtaining the required information. Please consider the Church Alliance as a resource and do not hesitate to contact us if you have any questions.

Sincerely,

Karishma S. Page
Partner, K&L Gates LLP
On behalf of the Church Alliance

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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January 24, 2022

The Honorable Xavier Becerra
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The Honorable Marty Walsh
Secretary of Labor
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The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, NW
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Director Kiran Ahuja
Office of Personnel Management
1900 E Street, NW
Washington, D.C. 20415

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

RE: Interim Final Rules with Request for Comments (IFC) and Paperwork Reduction Act (PRA) Materials Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (CMS-9905-IFC, CMS-10788)

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

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide comments on the IFC regarding Reporting on Pharmacy Benefits and Prescriptions Drug Costs included in Section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021 (CAA) as issued in the Federal Register on Nov. 23, 2021 (86 Fed. Reg. 66662).

BCBSA is a national federation of 35 independent, community-based and locally operated Blue Cross and Blue Shield companies (Plans) that collectively provide health care coverage for one in three Americans. For more than 90 years, Blue Cross and Blue Shield companies have offered quality health care coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

We appreciate the opportunity to provide comments and recommendations as the Departments of Health and Human Services, Labor, and Treasury (the Departments) and the Office of Personnel Management (OPM) develop this reporting requirement. BCBSA supports a reporting system that is administratively efficient, protects proprietary and confidential information, and reduces burden on the Departments, OPM and reporting entities. We appreciate the inclusion of several BCBSA recommendations in the IFC and the PRA materials to meet these objectives including:

- Delaying implementation to allow reporting entities to submit data for 2020 and 2021 by Dec. 27, 2022
- Allowing reporting by line of business (LOB) rather than at the group health plan level

- Creating a reporting system allowing health insurance issuers, employers and pharmacy benefit managers (PBMs) and other third-party entities to submit data in a way that would protect competitively sensitive information

- Providing detailed definitions of terms for reporting prescription drug data, aligning with medical loss ratio (MLR) definitions and processes when appropriate, to ensure consistency in reporting across reporting entities

In addition, BCBSA recommends the following to support accurate, efficient and consistent reporting:

- Releasing the final templates and instructions as soon as possible in the first quarter in 2022 to allow adequate time for reporting entities to meet the Dec. 27, 2022, reporting deadline

- Moving the June 1 reporting deadline to Sept. 30 in subsequent years to allow claims run off, rebate calculation and data validation for maximum accuracy

- Sunsetting existing OPM prescription drug reporting standards to minimize compliance costs and avoid unreasonably excessive costs of duplicative reporting standards, as OPM is requiring Federal Employees Health Benefits (FEHB) carriers to report under Sec. 204

- Removing drug manufacturer cost-sharing assistance to patients as a part of Total Spending reporting, as issuers and PBMs do not have the capability to track the vast majority of manufacturer cost-sharing assistance or "coupons"

- Revising the reporting requirement to only require reporting group health plan premiums as total premiums, rather than premiums paid by employer vs premiums paid by participants, beneficiaries and enrollees

- Holding "open office" sessions with plans and issuers to review and discuss these reporting requirements, providing the Departments and reporting entities the opportunity to share solutions as BCBS Plans prepare to implement the Sec. 204 reporting requirement. CMS engaged in similar stakeholder outreach for the insurer machine-readable file requirements under the Transparency in Coverage Final Rule.

We appreciate your consideration of our recommendations. We look forward to continuing to work with the Departments on implementation issues under the CAA. If you have any questions, please contact me at 202.626.4814 or at kris.haltmeyer@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Legislative and Regulatory Policy
Blue Cross and Blue Shield Association

I. §§ 26 CFR 54.9825–4T, 29 CFR, 2590.725–2, and 45 CFR 149.720. Reporting requirements related to prescription drug and health care spending (temporary).

Issue:

The Departments are releasing regulations and draft reporting templates and instructions for compliance with the first reporting deadline of Dec. 27, 2022.

Recommendation:

BCBSA urges the Departments to release the final templates and instructions as soon as possible in the first quarter of 2022 to allow adequate time to meet this deadline.

Rationale:

We appreciate the Departments' decision to delay enforcement of the reporting requirements. BCBS Plans remain concerned about the timeline for implementation. Health plan teams have other significant regulatory reporting commitments, including the Transparency in Coverage machine-readable files and operationalizing other No Surprises Act provisions that have direct consumer impact. Final templates and instructions are needed as soon as possible to allow time for reporting entities to review the Departments' standards, aggregate data from various sources, test the templates for data submission and submit the final reports, as well as identify, train and credential employees on the reporting requirements.

Recommendation #2:

BCBSA calls on the Departments to provide for a safe harbor for good faith compliance, at least for the first submission.

Rationale #2:

We appreciate the release of the Reporting Instructions, templates and therapeutic class crosswalk for Sec. 204 reporting. However, plans and issuers do not have the level of detail on the file layout that they need to adequately satisfy the requirements, and questions remain regarding whether plans and issuers have access to the data needed to comply with the requirements, as noted in these comments. There also are complexities for certain market segments, particularly *self-funded plans offered by large employers*, where multiple reporting entities will be submitting data for the same group health plan. A safe harbor for good faith compliance will provide assurances to reporting entities bearing compliance risk.

Recommendation #3:

After the initial Dec. 27, 2022, reporting deadline, BCBSA urges moving the June 1 reporting deadline to Sept. 30.

Rationale:

To ensure completeness of pharmacy claims, we recommend the Departments modify the reporting deadline so that it is at least nine months after the end of a plan year. The five-month lapse between the end of the plan year and the June 1 reporting deadline is too short and does not provide enough time to close out claims and calculate and reconcile rebates to maximize the validity of that data.

II. §§ 26 CFR 54.9825-6T, 29 CFR 2590.725-4, and 45 CFR 149.740. Required information.

Issue:

The Departments plan to include drug manufacturer cost-sharing assistance, to the extent known by the reporting entity, in reporting of "total annual spending." Reporting entities must identify drug manufacturer cost-sharing assistance to patients when information is available to the issuer/PBM.

Recommendation #1:

BCBSA recommends removing the reporting of drug manufacturer cost-sharing assistance as a part of *Total Spending* reporting.

Rationale:

Issuers and PBMs do not have the capability to track the majority of manufacturer cost-sharing assistance or "coupons." Some issuers and PBMs can capture the use of manufacturer coupons when drugs are dispensed at a specialty pharmacy or delivered via mail-order pharmacy. However, issuers and PBMs are often unable to capture when consumers use a coupon at a retail pharmacy (let alone the source of the coupon). If the Departments retain this reporting element, drug manufacturer cost-sharing assistance data reporting will be inconsistent across reporting entities due to differing capabilities to capture such amounts. Second, manufacturer cost-sharing assistance totals will grossly underestimate actual dollars spent by manufacturers. Including incomplete dollar amounts in the Sec. 204 public report will give a false picture of actual manufacturer financial incentives used to steer patients to their high-cost drugs, thus downplaying the severity of the problem.

Recommendation #2:

CMS should explore mechanisms by which it can require full transparency and reporting from drug manufacturers on drug manufacturer cost-sharing assistance to patients.

Rationale:

Due to the inability of issuers and plans to capture complete data, a more stable, consistent approach would be to put the onus on manufacturers for industry-level reporting of cost-sharing assistance. More and more manufacturers are using coupons to steer patients to their high-cost drugs even when less expensive and equally effective drugs are available. Drug manufacturers often provide patients with discount coupons to help offset the patients' out-of-pocket costs for medication. While these discounts help individual patients, they allow manufacturers to increase drug prices leading to higher premiums for all enrollees. A manufacturer reporting process would provide a better understanding of the breadth and scope of drug manufacturer cost-sharing assistance and would contribute to the overall objectives of the Sec. 204 public report to understand "prescription drug pricing trends."[1]

Issue:

The Departments are calling on plans and issuers to submit the average monthly premium amounts separated by payments made by employers and payments made by participants, beneficiaries and enrollees.

Recommendation #1:

We call on the Departments to revise this reporting element and require reporting total premiums only.

Rationale:

We believe revising this reporting requirement is needed given the inability of plans and issuers to obtain premium amounts paid by employers vs. participants, beneficiaries and enrollees. BCBS Plans have reviewed data that is accessible to their companies, and Plans do not have access to the data needed to satisfy this requirement.

Today, only employers maintain data on the "average monthly premium" paid by employer versus employees. In general, issuers and third-party administers (TPAs) receive all funding for a group health plan directly from the health plan sponsor, but they do not know what portion comes from the employer versus the employee. Employers with self-funded coverage collect premiums from enrollees and pay claims, but the TPA does not see the costs paid by the employee.

It would be a very difficult task to collect, store and develop reporting on the premium paid by employer/employees from all employer accounts (small, mid-sized, large, self-funded), as

[1] P.L. No. 116-260

that is not collected from employers by plans. We recommend the Departments rely on other internal agency data or external research for the data under subsection (a)(8) (e.g., KFF Employer Health Benefits Survey or Form 5500s). This approach would reduce compliance burden on employers, plans and issuers, but would still produce valuable data for the Sec. 204 public report.

Recommendation #2:

Should the Departments go forward with this reporting element, we recommend that reporting on amount of premium paid by employer versus participants, beneficiaries and enrollees not begin until the 2023 plan reference year, with reporting in 2024. BCBSA recommends that the Departments only require reporting on the total premium for plan years 2020, 2021 and 2022.

Rationale:

BCBSA has concerns with this requirement, as we have noted in past comments to the Departments in the Recommendation #1 above. Meeting this reporting requirement retrospectively for 2020, 2021 and 2022 will be extremely difficult, as this information is not readily available to issuers. BCBSA does not oppose reporting total average monthly premium amounts, but separating premium amounts by employer share and enrollee share will be burdensome, if not impossible, for past reference years. Obtaining this information poses challenges, particularly for groups that have terminated their coverage with an insurer. Without active contracts, issuers cannot require employers to share this information. Delaying this reporting requirement to reference year 2023 enables proactive agreements to be made between issuers and employer sponsors and allows issuers to build the infrastructure needed to collect and store this information in a reportable repository.

Recommendation #3:

BCBSA urges the Departments to only require reporting of premium information that plans and issuers can obtain.

Rationale:

Plans and issuers can request detailed premium cost breakdowns from employer-sponsored plans, but, ultimately, should not be held responsible if the employer does not comply.

Issue:

The Departments are calling for reporting of premium amounts for the individual market (excluding the student market).

Recommendation:

BCBSA recommends providing clarity as to how issuers must report premiums for marketplace products when a consumer receives advanced payment tax credit (APTC) subsidies.

Rationale:

Clarification is necessary for premium data to be consistent across issuers and usable by the Departments.

III. Overview of the Interim Final Rules – Office of Personnel Management – Authority for Data Collection

Issue:

OPM is extending the Sec. 204 reporting requirement to FEHB carriers.

Recommendation:

We call on OPM to sunset the existing FEHB pharmacy data collection and submission process as updated under Carrier Letter 2020-17.

Rationale:

OPM has already established robust FEHB pharmacy benefit data reporting standards, which are not entirely consistent with the pharmacy benefit data reporting standards established under Sec. 204. To minimize compliance costs and avoid the incurrence of unreasonably excessive reposting costs by FEHB carriers, we strongly urge OPM to sunset the existing reporting requirements.

We strongly discourage OPM from requiring FEHB carriers to continue to comply with OPM's current pharmacy data reporting requirements and, in addition, comply with the reporting requirements established under Section 204. By sunsetting the existing prescription drug reporting standards, OPM will align its requirements with the intent of the IFC to identify methods to reduce administrative burden and costs.

IV. Definitions (26 CFR 54.9825-3T, 29 CFR 2590.725-1, 45 CFR 149.710)

Issue:

The IFC defines *Prescription Drug Rebates, Fees, and Other Renumeration* to include bona fide service fees. The Departments only require reporting of the total amount of bona fide service fees. They do not require the fees to be reported separately for each therapeutic class or drug.

Recommendation #1:

BCBSA recommends excluding bona fide services from the definition of *Prescription Drug Rebates, Fees, and Other Renumeration* for the purposes of this reporting requirement.

Rationale:

Bona fide services fees are fair market value payments provided for services performed and for which fees are not passed on, in whole or in part, to a client or customer of the entity. Including these fees in the definition of *Prescription Drug Rebates, Fees, and Other Renumeration* for the purposes of this reporting requirement would be inconsistent with the definition of rebates and fees used elsewhere, such as in MLR reporting and qualified health plan (QHP) PBM reporting. The inconsistency may create confusion and lead to inconsistent reporting practices among plans and PBMs.

Further, obtaining this data would be burdensome and repetitive of existing reporting requirements. Issuers do not readily have access to bona fide service fee payment data. Therefore, gathering this information would require an extra step to obtain the data from PBMs, who are already subject to reporting requirements.

Recommendation #2:

If the Departments require disclosure of total bona fide services fees, BCBSA recommends that qualitative descriptions of payments, as opposed to quantitative amounts, satisfy this requirement.

Rationale:

Bona fide service fees are not related to specific prescriptions in all cases. Some fees are related to a general contract between a PBM and a drug manufacturer. A qualitative report on such fees would suffice for content for the Sec. 204 public report.

V. Prescription Drug Data Collection (RxDC) Reporting Instructions

Issue:

The Departments propose to require plans and issuers to report the total annual spending on health care services, based on the statutory categories: *(1) hospital costs; (2) health care provider and clinical service costs, for primary care and specialty care separately; (3) costs for prescription drugs; and (4) other medical costs, including wellness services.* The proposed reporting instructions provide broad category definitions via lists of services.

Recommendation:

BCBSA recommends the Departments define the health care cost categories more specifically by national billing code standards rather than a list of services. Further, categorization of services into primary and specialty care should be defined by provider taxonomy. For this reporting element, we recommend:

- *Hospital costs* refer to services with a uniform billing (UB) claim form
- *Health care provider and clinical service costs, for primary care and specialty care separately* refer to services with a health insurance claim form (a "HCFA 1500" or "CMS 1500" form), excluding lab and radiology services
    - Primary Care and Specialty Care categorization should be mapped to specific provider taxonomies, to be defined by CMS
- *Costs of prescription drugs* refer only to drugs covered under the pharmacy benefit
- *Wellness services* refer to services managed by the insurer or TPA
- *Other medical costs* refer to all other claims not included in a category above (named *Other Clinical Health Care Services and Equipment* in the Reporting Instructions).

Rationale:

Specifically defining health care cost categories using national code sets provided by the Departments would create consistency in categories between reporting entities, ultimately improving the usability of the data and aligning information with the objectives of the reporting requirement. Also, it would reduce the administrative burden and duplication of effort that would occur as each reporting entity interprets the list of services under each category independently.

Moving lab and radiology costs to *Other Clinical Health Care Services and Equipment* will avoid variation in methods of linking the lab and radiology services to the primary or specialty care spending categories across reporting entities. Linking lab and radiology claims to a specific primary or specialty care visit presents a challenge, especially if the lab or radiology service occurred on a different date than a primary or specialty care visit.

Issue:

On table P2 of the Reporting Instructions' Appendix A, the Departments include a requirement for plans and issues to report *Form 5500 Plan Number*.

Recommendation:

We recommend this data field be removed, or at least delay reporting until the 2023 reference year.

Rationale:

While TPAs and issuers may assist employers by providing information for the Form 5500, the Form 5500 Plan Number is not a value received or stored. We believe removal of this

field would not disrupt reporting as there will be other identifies for the employer such as the federal employer identification number (FEIN).

If the requirement remains, it should be delayed until the 2023 reference year. Obtaining this information poses challenges, particularly for groups that have terminated their coverage. Without active contracts, issuers cannot require employers to share this information. Delaying this reporting requirement to reference year 2023 enables proactive agreements to be made between issuers and employer sponsors and allows issuers to build the infrastructure needed to collect and store this information in a reportable repository.

Issue:

The Departments intend to build a data collection system to allow multiple reporting entities to submit different subsets of information with respect to the same plan or issuer. Should a plan or issuer enter a written agreement with a third party (e.g., PBM) to submit some or all data and the other party fails to submit, the plan or issuer will be in violation of the reporting requirement.

Recommendation:

BCBSA urges the creation of a notification system for plans and issuers when third parties submit data. This can be achieved through modifications to the file layout to include identifying information at the group health plan level, such as the name and the FEIN. A notification system will allow the plan or issuer to verify receipt of data from third-party reporting entities when such entities submit data on the same group health plan(s).

Rationale:

Under the Departments' proposal, fully insured and self-funded group health plans, as well as health insurance issuers offering group or individual health coverage, may enter into written agreements to require third parties (e.g., issuers, third-party administrators (TPAs), PBMs, etc.) to report in compliance with the IFC. However, the issuer or plan bears the compliance risk should a third party fail to report some or all of the data under this requirement.

It would be measurably helpful for plans and issuers to gain more insight into the data submitted by third-party entities on group health plans. We have concerns about the ability of PBMs, TPAs, employer groups and other entities who may need to submit data to satisfy these reporting requirements, and about the challenges associated with ensuring data from these various sources are as accurate and complete as possible. A notification system will allow the issuer or plan to manage compliance risk and ensure data reporting is submitted under deadlines congruent with written agreements with third parties.

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January 24, 2022

VIA ELECTRONIC SUBMISSION TO www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9905-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Interim Final Rules with Comments Regarding Prescription Drug and Health Care Spending; File Code CMS–9905–IFC

To Whom It May Concern:

Cigna welcomes the opportunity to respond to the interim final rules with comments on prescription drug and health care spending transparency (the "IFR") issued by the U.S. Departments of Health and Human Services, Labor, Treasury, and the Office of Personnel Management (the "Departments"). Cigna provides perspective in this comment letter on implementation considerations for the data submissions required under Section 204 of Title II of Division BB of the Consolidated Appropriation Act, 2021 ("Section 204"), and the associated impact on group health plans and health insurance issuers. Cigna supports the Departments' goal of lowering health system costs and its pursuit of consumer-facing transparency for plan and issuer participants, beneficiaries and enrollees.

Cigna Corporation is a global health service organization dedicated to helping people improve their health, well-being, and peace of mind. Our subsidiaries are major providers of medical, pharmacy, dental, and related products and services, with over 175 million customer relationships in the more than 30 countries and jurisdictions in which we operate. Within the United States, Cigna provides medical coverage to approximately 14 million Americans in the commercial group health plan market, predominantly in the self-insured segment. We also provide coverage in the individual Affordable Care Act insurance segment in several states, both on- and off-Exchange, to about 235,000 people. Additionally, we serve more than 4.5 million people through our Medicare Advantage, Medicare Prescription Drug Program and Medicare Supplemental products. In all of the segments we serve, Cigna is focused on creating products and services that support a quality, affordable, equitable, and sustainable health care system for all Americans.

With that context as background, Cigna offers the following comments on the IFR.

* * *

Cigna supports the goal of providing transparency to consumers through the sharing of meaningful, actionable information that encourages informed health care choices and competition. Providing our customers with convenient access to personalized information about the cost and quality of care has long been one of our principal priorities. Consistent with Cigna's aim of making health care affordable, predictable and simple for our customers, we designed and have been offering industry-leading tools to help our customers make informed health care decisions, including the ability to view real-time cost-sharing information for prescription drugs and more than 1,000 medical procedures. Cigna therefore has supported the Departments' focus on guaranteeing all Americans access to personalized information about the cost of medical services before seeking care.

However, we continue to be concerned that the Transparency in Coverage rule requirements associated with the public posting of machine-readable files are likely to sow consumer confusion or misinformation, and we are concerned about unintended consequences. These well-intended provisions actually may increase consumer and patient frustration, worsen challenges to affordability, and hinder innovation.

In contrast to the Transparency in Coverage rule's machine readable file requirements, Section 204 is designed to shed light on drivers of health care spending through plan and issuer reporting of *aggregated* data to the Departments. Furthermore, Section 204 requires the Departments *to protect confidential and proprietary data* from public disclosure. This policy approach to transparency will enable the Departments, and eventually the public, to understand how certain prescription drugs are increasing costs for patients, plans, and issuers, without unnecessarily requiring disclosure of sensitive information that could lead to consumer confusion. Cigna therefore supports the Departments' overarching public policy goals of Section 204.

Notwithstanding, Cigna has recommendations regarding the Departments' Section 204 IFR and associated guidance on information collection on the following topics: (I) application to expatriate health plans; (II) spread pricing information; and (III) reporting timeline.

I. Application to Expatriate Health Plans

Consistent with the treatment of expatriate health plans under other U.S. statutes and regulations, we respectfully request the Departments affirm that expatriate health plans are exempt from the reporting requirements under Section 204, as provided by the Expatriate Health Coverage Clarification Act. Section 204's focus on domestic U.S. prescription drug and health care spending clearly did not contemplate global health care coverage. From a price, transparency, and affordability perspective, plans providing health coverage across both international and domestic markets operate in a system that is dramatically different from domestic plans and issuers. Inclusion of data from these carriers will yield skewed results and risks rendering the data collected under Section 204 less meaningful and useful.

For example, expatriate health plans set premiums based on both U.S. claims expenditures and international claims spending. It is not possible to parse domestic U.S. impact on premiums from non-U.S impact on premiums. For purposes of Section 204 reporting, expatriate plans can report domestic U.S. claims spending and pharmaceutical spending, but it will not be possible to separately report increases or decreases in premiums attributable only to domestic claims data. Because expatriate health plan data points are so different, the reporting of expatriate health plan data under Section 204 will yield data that could be misleading regarding the impact of domestic spending on premiums.

In recognition of these unique issues presented by expatriate health plans, the Departments have already excluded expatriate health plans from the Transparency in Coverage rule. The Departments should similarly exclude expatriate health plans from Section 204 reporting requirements.

II. Spread Pricing Information

The required reporting of spread pricing under Section 204 data collection is not required by statute or regulation, and the policy rationale for requiring such reporting through Departmental guidance is unclear.

Because spread pricing is only one financing approach among many that is made available for PBM clients to use, and it neither increases nor decreases prescription drug spending, Cigna recommends that spread pricing not be included in Section 204 reporting because it is not required in statute or regulation. In addition, such reporting will provide an incomplete understanding of PBM arrangements with employers, health plans, and pharmacies.

III. Reporting Timeline

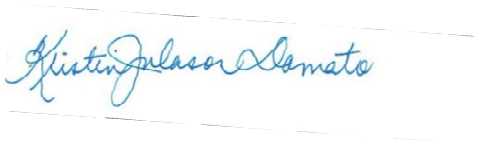
As we noted in Cigna's comments in response to the Section 204 request for information, we recommend that the Departments consider the challenges of timing data submission given the desire of all parties to report accurately on an annual basis. Time is needed after the end of the reporting period to process claims and calculate rebates and to ensure the validity of the data. We note that the June 1 reporting date does not provide sufficient time to process the data for Section 204 reporting. Although June 1 is the date specified in statute, the practical reality of challenges with this timeframe may yield incomplete information. Cigna appreciates that the Department will allow for updates to the data beyond the June 1 date, however subsequent updates impose administrative burden over time.

Cigna recommends that the Departments use their enforcement discretion to move the reporting deadline from June 1 to August 1 (or later). In the alternative, we recommend reporting of health plan spending based on when claims are paid, instead of incurred. This would enable more complete plan reporting because payments in a given year will require neither an extended run-out period, nor subsequent updates due to claims processing timelines.

* * *

Thank you for your consideration of these comments. Cigna would welcome the opportunity to discuss these issues with you in more detail at your convenience.

Respectfully,



Kristin Julason Damato

Submitted electronically via regulations.gov

January 24, 2022

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Re: Prescription Drug and Health Care Spending (CMS-9905-IFC)

Dear Deputy Director Wu and others:

CVS Health appreciates the opportunity to comment on the Interim Final Rule (IFC) implementing Section 204 of the Consolidated Appropriations Act, 2021 (CAA). We believe that Section 204 represents the best reflection of Congressional intent to create insight into the costs associated with prescription drug and health care spending. It represents a much more thoughtful approach than proposals focused on publicizing plan cost data that will create no actionable information for consumers and at the same time undermine competitive markets.

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses and nurse practitioners. Our unique health care model gives us an unparalleled perspective on how systems can be better designed to help consumers navigate the health care system – and their personal health care – by improving access, lowering costs, and being a trusted partner for every meaningful moment of health. And we do it all with heart, each and every day.

Below we provide some specific feedback on the Section 204 implementation both in the IFC and related Information Collection Request (ICR) documents from CMS,[1] designed to bring the regulation in line with the statutory language, standardize requirements in order to keep data useful, and limit unnecessary administrative burdens that will increase costs without providing clearer information.

I. The Agencies Should Align Definitions and Data Elements to Reflect the Statutory Requirements

The CAA was very specific in its data disclosure requirements of plans and issuers. The statute includes ten explicit data categories to be collected by the agencies.[2] These requirements provide more than sufficient clarity as to what entities must collect and report. However, some of the definitions and data elements in the IFC go far beyond the text of the statute, and even create entirely new requirements with no statutory underpinning. Data elements not authorized by the statute should be removed from the rule and from the file templates in the guidance before any submissions are required.

Pharmacy Reimbursement and Plan Cost Information

The most glaring new extra-statutory requirement from the agencies is the requirement for plans and issuers to disclose "the difference between the amounts that the plan or issuer pays a pharmacy benefits manger (PBM) and the amount the PBM pays the pharmacy. The statute limits disclosure to "rebates, fees and any other remuneration paid *by drug manufacturers* to the plan or coverage or its administrators or service providers with respect to prescription drugs prescribed to enrollees."[3] The IFC and ICR also require issuers and plans to report on the application of any rebates at the point-of-sale (POS) for the plan members.[4] However, there are no requirements anywhere in the statute for disclosure of fees or remuneration from pharmacies, plan sponsors, or any other participants in the pharmaceutical supply chain other than drug manufacturers, and no requirement to report rebates passed through to members at POS.

[1] CMS Form Number CMS-10788
[2] 42 USC 300gg-120(a)(1)-(10)
[3] 42 USC 300gg-120(a)(9) (emphasis added)
[4] See proposed 45 CFR 149.740(b)(7)(ii) and CMS Form Number CMS-10788 at 7.1

Beyond exceeding the scope of the statute, these requirements do not further the goals of Congress as reflected in the Section 204 required reporting. The other data elements already require plans and issuers to disclose the effect of manufacturer payments on premiums. Examining pharmacy reimbursement rates in comparison to PBM charges to plans and issuers provides no additional information on the effects on premiums or member out-of-pocket (OOP) costs, as pharmacy reimbursement is not a factor used in those calculations.

These requirements exceed the Congressional mandate in both letter and spirit. The statute explicitly calls for payments by "drug manufacturers" and makes no mention of payments to pharmacies or enrollees. By requiring these additional data elements in the face of the specific and explicit statutory language otherwise, the agencies are exceeding their authority. Therefore, the agencies should remove these data elements from the reporting requirements prior to the submission deadlines for the first reference year.

Bona Fide Service Fees

The requirement to report bona fide service fees also directly contradicts the requirements of the statute. The statute requires reporting of the impact on premiums of any "rebates, fees and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers *with respect to prescription drugs prescribed to enrollees in the plan or coverage."*[5] Bona fide services, in contrast, are defined in the IFC to mean:

> fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the plan or issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of *the manufacturer that the manufacturer would otherwise perform* (or contract for) in the absence of the service arrangement, and *that are not passed on in whole or in part to a client or customer of the entity*, whether or not the entity takes title to the drug.[6]

Since bona fide service fees are, by definition, for services performed for a manufacturer and are not passed through to the plan or issuer, they have no impact on drug costs or premiums and are not paid "with respect to prescription drugs" prescribed for a plan or issuer's enrollees. The Departments appear to try to justify the requirement to report bona fide service fees on the basis that they are not explicitly excluded by the statute.[7] However, for this to be a basis for including them, they must first fall within the data

[5] 42 USC 300gg-120(a)(9) (emphasis added)

[6] 86 Fed. Reg. at 66668.

[7] See 86 Fed. Reg. at 66669 ("The Departments note that section 9825(a)(9) of the Code, section 725(a)(9) of ERISA, and section 2799A–10(a)(9) of the PHS Act require plans and issuers to report rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees, as applicable, in the plan or coverage, and do not provide for the exclusion of bona fide service fees or any other fees.")

required to be reported by the statute, since there is no need to exclude them otherwise. Since the statutory language is clearly limited to requiring reporting of payments by manufacturers that affect a plan or issuer's drug costs and bona fide service fees, by definition, do not affect a plan or issuer's drug costs, bona fide service fees are clearly not included. Therefore, there is no need for the statute to exclude them. Indeed, if the statute did exclude them, it would suggest that Congress believed that the language could otherwise be read to include them.

The fact that Congress did not see the need to explicitly exclude bona fide service fees further supports the position that they are not, nor were ever contemplated as being, included within the data required to be reported. The Departments acknowledge as much, stating "the Departments recognize that bona fide service fees may not always be intended to directly affect the cost or utilization of specific prescription drugs, and generally are not passed through to plans and issuers or to participants, beneficiaries, and enrollees. Therefore, the Departments will require reporting of only the total amount of bona fide service fees, but will not require these fees to be reported separately for each therapeutic class or for each drug on the top 25 list."[8] As noted above, by their definition of bona fide service fees in the regulation, the Departments ensure that such fees do not "directly affect" the cost or utilization of specific prescription drugs and that they are not passed through to plans or issuers.

Since the reporting of bona fide service fees is not authorized by the statute, this data element should be removed from the reporting requirements prior to the submission deadlines for the first reference year.

Fees and Remuneration from Non-Manufacturers

Similar to the requirements related to pharmacy reimbursement, the IFC and ICR require additional disclosures of remuneration paid by other supply chain entities not included in the statute. The only entities whose payments are included *anywhere* in the statutory requirement are drug manufacturers. However, the ICR requires additional disclosures around arrangements with "pharmacies, wholesalers, and other entities." By including transactions associated with other supply chain entities, the ICR goes far beyond the authorizing statute. Additionally, th Departments completely exclude these entities as filers, an implicit recognition that they were never meant to be included in the first place.

These requirements are not only excluded from the statute but also sweeping and vague. Any disclosure requirements related to non-manufacturer rebates, fees, or remuneration should be removed prior to submission deadlines.

[8] 86 Fed. Reg. at 66669.

Excess Data Elements
There are also several other data elements that exceed the statutory authority in Section 204. A number of these present significant policy concerns and/or logistical hurdles detailed below. We have included an appendix of these data elements by form at the end of these comments. However, one in particular warrant specific mention:
Manufacturer Assistance Programs: The statute exclusively refers to remuneration paid between manufacturers and *the plan.* However, the ICR includes reporting of manufacturer cost-sharing assistance provided to the plan member or pharmacy. As detailed below, the plan rarely has insight into these transactions

- **Recommendation:** Prior to enforcement for any reporting requirements under Section 204, the agencies should remove data elements currently included in the IFC and ICR that require entities to report information not authorized by the statute. These elements go far beyond the statutory authority created under Section 204, and cannot be expected from filers.

II. The Agencies Should Clarify Responsibility for Data Elements that Cannot Reliably Be Collected from Plans and Issuers

The rule clearly allows for plans, issuers, PBMs and Third Party Administrators (TPAs) to report the required data elements. CVS particularly appreciates the ability for PBMs and TPAs to separately submit their own data independent of plans and issuers for ease of reporting. However, there are certain elements that will create significant logistical burden for these entities to report because they are the function of private decisions made by plan sponsors or third parties with no reporting responsibilities.

Member Contributions
The statute includes two specific instances requiring plans and issuers to disclose plan member costs, specifically related to premiums paid by members and spending on prescription drugs by enrollees. Unfortunately, no one reporting entity is likely to have this information, if any of them do at all.

With regards to premium contributions made by members, in many instances the PBM or issuer will not have direct access to the contribution amount by member. Different plan sponsors elect different levels of premium contributions for their members, and often rely on separate vendors for payroll deductions attributed to premiums. For that reason, the PBM or issuer may not have this information.

Additionally, with regards to member spending on prescription drugs, the PBM may have access to member contributions, but may not be aware of other reimbursements from the plan. Because the system requires each reporting entity to submit separate forms, there may be no reliable way to cross reference the claims between the PBM and plan or issuer.

In both instances, the agencies should consider providing attestation forms for the reporting entities to attest that they do not have this information, in which case the reporting entity should not be subject to enforcement action for failing to report it.

Rebate, Fee, and Other Remuneration Attribution to Premiums and Enrollee Cost-sharing

Similar to member OOP costs and premium contributions, PBMs and issuers may not have direct access to the use of rebates, fees, and other drug manufacturer remuneration on enrollee costs such as premiums or cost sharing obligations.

In some instances, when elected by a plan sponsor, a PBM may apply rebates from manufacturers on a specific transaction at the point of sale (POS). However, in most other instances these rebates are paid in lump sums to plan sponsors, who subsequently use them as one source of funds used to determine premiums, cost-sharing, and maximum OOP figures.

In addition, the ICR does not provide any productive way to attribute those dollars to premiums or OOP costs paid by members. Any metric that specifically assigned rebate dollars to any one element of coverage would be completely arbitrary, and fail to provide any meaningful insight.

Additionally, due to the dual reporting mechanism included in the ICR, there is no effective way for PBMs and plan sponsors to communicate on how to report these data elements.

Ultimately, the best way for the agencies to collect this information is through qualitative descriptions from plan sponsors. In instances where a PBM or TPA is administering a self-funded plan, the PBM/TPA should be allowed to provide attestation that they have requested such a qualitative response from the sponsor. These qualitative responses can include aggregate rebate dollars in comparison to member cost sharing and premium contributions as a total percentage of funds in the plan.

Manufacturer Assistance Programs

As noted previously, manufacturer assistance programs and coupons are not identified in the statute as the types of funds to be reported. However, the agencies included manufacturer assistance program funds to be reported as part of total spending.[9]

These programs are not reported to PBMs, issuers, or plan sponsors. In fact, they are often designed to completely elude data collection by reporting entities. For that reason, if the agencies wish to collect information on manufacturer assistance programs, they

[9] 86 Fed. Reg. at 66675.

should provide an opportunity in the reporting system for manufacturers to report this information. However, it is unlikely that manufacturers will be able to attribute these funds to individual plans, as these assistance programs often encourage patients to move to options outside the plan's traditional benefit structure.

Wellness Services

The rule requires disclosure of costs associated with wellness services, including those that are designed to provide incentives to improve member health and are not billed as a claim. Only costs that may be included as quality improvement expenses for purposes of calculating of Medical Loss Ratio are to be included here. Due to the broader behavioral goals of such programs, it is likely that data between insurers and even between individual plans will be far from standardized and difficult to analyze. Some programs are best estimated by operational costs, such as employee hours. Others may have an estimated total premium discount impact, but will be subject to member participation that could vary dramatically.

Ultimately, it is best that these services be described qualitatively to allow the agencies the opportunity to best evaluate them.

Principal Place of Business

For some self-funded plans, it may be difficult for PBMs and TPAs to identify a principal place of business. An individual employer may identify their primary place of differently, such as the state of incorporation or the location of a specific corporate office.

In these instances, PBMs and TPAs should be permitted to provide an attestation acknowledging the limitations of the location they have reported.

- **Recommendation:** The agencies should provide flexibility in instances where reporters cannot reasonably be expected to have or be able to calculate the data elements as required in the IFC. In instances where information would need to be verified by a plan sponsor, reporting entities should be permitted to provide attestations that they made reasonable efforts to verify. In other instances, where calculations would be arbitrary, lack standardization, and fail to provide meaningful information, the agencies should request qualitative reporting.

III. The Agencies Should Ensure All Necessary Resources Are in Place Before Enforcement

Finally, while the agencies provided some clarity around the logistical processes around reporting, some additional functionality is still necessary.

Drug Totals Dual Reporting Capability
The ICR notes that entities will be able to report separately through the Health Insurance Oversight System (HIOS), which is greatly appreciated. Still needed though is a system to coordinate between plans, issuers, PBMs, and TPAs. Currently there are no notification systems to ensure that all parties have reported, and ultimately could create the risk of duplicate reporting and clerical errors leading to missing reports.

Due to this restraint, filers will ultimately not be able to report many of the data elements included in the ICR. Metrics such as rebate attribution to member contributions and cost sharing require the plan sponsor or issuer to receive data from the PBM in order to make further calculations. Without allowing for filers to communicate on individual forms included in the ICR there will likely be significant confusion around responsibility for individual elements that require coordination between the PBM and the plan. Additionally, the ICR documents state that multiple reporting entities should not submit the same data file for a plan, issuer, or carrier. However, certain elements, such as the "Spending by Category" data file and the Narrative Responses, request information not in the possession of the PBM, who would likely be submitting the relevant form for drug-related data elements. Therefore, the requirement increases the potentially burdensome and unreliable transfer of information between parties.

- **Recommendation:** The agencies should provide, at minimum, six months after the development of dual reporting mechanisms that allow for communication between the issuers, PBMs, plans and plan sponsors. All filers will require time to build systems to communicate between plans, issuers, PBMs, TPAs, and plan sponsors.

Thank you again for the opportunity to respond to the newly finalized rule and guidelines. We understand the agencies' goals in further exploring the drug supply chain, and would be happy to provide technical assistance to clarify any feedback in this response. Please do not hesitate to reach out for any further information or clarity. I can be reached at Melissa.Schulman@cvshealth.com.

Sincerely,

Melissa Schulman
Senior Vice President
Government & Public Affairs
CVS Health

APPENDIX
Data Elements Exceeding Statutory Authority

ICR File	Data Element	Rationale
D2	Disallowed amounts for non-covered services or for prescription drugs not on a plan or coverage's formulary	(a)(1)-(10) only refer to plan spending, and do not cover non-covered drugs or services
D2	Cost-sharing amounts not applied to the deductible or OOP maximum	(a)(1)-(10) do not include any elements related to deductibles or OOP maximums
D3	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or administrator, and does not include transfers from a manufacturer to a member or pharmacy
D4	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or administrator, and does not include transfers from a manufacturer to a member or pharmacy
D5	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or administrator, and does not include transfers from a manufacturer to a member or pharmacy
D7	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or administrator,

		and does not include transfers from a manufacturer to a member or pharmacy
D8	Manufacturer Cost Sharing Assistance by Drug	(a)(9) only refers to transfers between manufacturers and a plan or administrator, and does not include transfers from a manufacturer to a member or pharmacy
D6	Bona Fide Service Fees as a Separate Element	(a)(9) only refers to transfers between manufacturers and a plan or administrator that are related to a member prescription. Bona fide service fees are not reasonably related and are not included in (a)(9) separate from total rebates, fees, and other remuneration.
D7	Net Transfer of Remuneration from Manufacturers to Plans/Issuers/Carriers/PBMs by Therapeutic Class	(a)(9)(A) only requires a total transfer figure
D7	Net Transfer of Remuneration from Pharmacies, Wholesalers, and Other Entities to Issuers/Plans/Carriers/PBMs	(a)(9) only refers to transfers between manufacturers and a plan or administrator, and does not include transfers between other entities
D7	Restated Prior Year Rebates, Fees and Other Remuneration	(a)(1)-(10) only refer to reporting for individual years

D8	Restated Prior Year Rebates, Fees and Other Remuneration	(a)(1)-(10) only refer to reporting for individual years
D8	Net Transfer of Remuneration from Manufacturers to Plans/Issuers/Carriers/PBMs by Drug	(a)(9)(B) only requires a total transfer figure
D8	Net Transfer of Remuneration from Pharmacies, Wholesalers, and Other Entities to Issuers/Plans/Carriers/PBMs	(a)(9) only refers to transfers between manufacturers and a plan or administrator, and does not include transfers between other entities
D6, D7, D8	Definition of "rebates retained" to include rebate guarantees made by a PBM or TPA to the plan or issuer	(a)(9) only refers to rebates, fees, and other remuneration paid by the manufacturers, and does not reference private guarantees made by a PBM or vendor, which is a separate agreement with the plan.

Purchaser Business Group on Health

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Via www.regulations.gov

Hon. Janet L. Yellen
Secretary of the Treasury
RIN 1545-BQ10/1545-BQ27/REG-117575-21
Department of the Treasury
1500 Pennsylvania Avenue
Washington, DC 20220

Hon. Martin J. Walsh
Secretary of Labor
RIN 1210-AC07, EBSA
Department of Labor
200 Constitution Ave. NW, N-5653
Washington, DC 20210

Hon. Xavier Becerra
Secretary of Health and Human Services
CMS-9905-IFC
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Hon. Kiran Ahuja
Director
RIN 3206-AO27
Office of Personnel Management
1900 E Street NW
Washington, DC 20415

RE: OPM/Treasury/Labor/HHS Notice of Interim Final Rules, File Code CMS-9905-IFC, and Treasury Notice of Proposed Rulemaking, REG-117575-21, Both Titled "Prescription Drug and Health Care Spending," 86 Fed. Reg. 66662 and 86 Fed. Reg. 66495 (November 23, 2021)

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

The Purchaser Business Group on Health (PBGH) appreciates the opportunity to comment on the proposed Interim Final Rules implementing Sec. 204 of the Consolidated Appropriation Act on Prescription Drug and Health Care Spending. We applaud the departments for addressing prescription drug costs and transparency. Affordability is a critical issue for consumers and employer purchasers. PBGH is a not-for-profit public benefit organization consisting of large public and private purchasers of health care. Together our members spend nearly $100 billion each year to provide health care coverage for about twelve million Americans.

PBGH is cognizant of the potential administrative burden for reporting these data and believes that the regulations can help streamline reporting process and enhance the likelihood of providing meaningful and actionable information by setting forth data specifications applicable to all suppliers. Purchasers rely on health plans, pharmacy benefit managers and additional parties to provide comprehensive prescription drug benefits to their members. Even as purchasers work diligently to assure high quality

and affordable benefits for their members, there are many hidden rebates, administrative fees, market access fees and other remuneration that are embedded in prescription drug pricing that are not visible to purchasers.

Addressing Complex Ownership and Business Relationships

There has been recent growth in the formation of Group Purchasing Organizations and expansion of wholesale aggregators that introduce an additional layer of middlemen and costs for drug acquisition. Despite their core business focused on the US drug supply chain, many of these entities are headquartered outside of the United States, whether designed to optimize tax benefits or escape regulatory oversight. Regulations implementing Sec. 204 and similar transparency requirements should require prescription drug suppliers to disclose detailed pricing information on rebates, administrative fees any other transactional fees when the supplier relies on any third parties between the pharmaceutical manufacturer and ultimately the delivery of medications to the patient. **These transparency requirements should extend to contracted suppliers and in particular, any subsidiary corporations in which there may be a mutual or indirect ownership interest, including corporate entities headquartered outside the United States.**

Assuring Appropriate Granularity in Reporting

PBGH supports efforts to identify and describe the highest cost drugs, as required in Sec. 240. Such drugs are often medical specialty drugs that are billed through a doctor's office or hospital and paid through the medical benefit. Many of these drugs are billed through J-codes or the Healthcare Common Procedure Coding System (HCPCS) that are commonly used for billing Medicare & Medicaid patients. Purchasers are often challenged by use of generic non-specified codes such as J3490 that limit transparency into high-cost drugs and the potential for identifying opportunities to support affordability and competition through adoption of biosimilar medications. Instead, **we recommend the IFR be amended to capture National Drug Codes (NDC) for medical specialty drugs, improving our collective ability to improve value and access.**

To optimize the utility of reported data and mitigate the administrative burden of collecting drug cost information, updated regulations should specify that the top 50 drugs be counted based on the NDC, a unique 11-digit, 3-segment number. This universal product identifier provides information identifying the labeler, the product, and the commercial package size**. PBGH recommends that the top 50 drugs be defined and counted based on the first two segments, with itemized reporting on the third segment based on all packages dispensed.** Given the diverse combinations of specific strength, dosage form (i.e, capsule, tablet, liquid) and formulation of a drug for a specific labeler, the top 50 drug list could reflect only 10 branded drugs as currently defined in the IFR. Ultimately, the number of top volume drugs may need to be

increased from 50 to provide meaningful benchmarking information that is actionable by purchasers to improve value and reduce consumer out-of-pocket costs.

Temporary Enforcement Discretion for Employers Acting in Good Faith

While Sec. 204 of the CAA places responsibility for reporting on plan sponsors, much of the required information is held by third parties, which have historically limited the ability of plan sponsors to access the necessary data. In early efforts to obtain required prescription drug cost data, many employers have expressed difficulty obtaining the requisite reporting from their suppliers. **We recommend that the Administration use enforcement discretion for a transitional period to recognize best efforts that purchasers are undertaking to access required data.** Ultimately, we believe it may be necessary for the Administration to directly require third party entities to report on required data.

Thank you again for the opportunity to provide our perspective on this vital rule. Please contact Shawn Gremminger, Director of Health Policy, at sgremminger@pbgh.org, for further information.

Sincerely,

/s/

William Kramer
Executive Director, Health Policy

UPMC LIFE CHANGING MEDICINE

UPMC Health Plan
Legal Services Department

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January 24, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
Attention: **(CMS-9905-IFC)**
200 Independence Ave., SW
Washington, D.C. 20201

Submitted electronically via http://www.regulations.gov

Re: Prescription Drug and Health Care Spending (CMS-9905-IFC)

Dear Secretary Becerra,

UPMC Health Plan and the integrated companies of the UPMC Insurance Services Division (collectively, "UPMC") are pleased to submit the following comments in response to the Departments of Health and Human Services (HHS), Labor, the Treasury, and the Office of Personal Management (collectively, "the Departments") **Prescription Drug and Health Care Spending Interim Final Rules with Request for Comments,** as published in the Federal Register at 86 FR 66662 (the "IFC").

UPMC offers a wide range of commercial group and individual, Medicare, Medicaid, CHIP, and ancillary coverage products to consumers in Pennsylvania, West Virginia, and Ohio. Since beginning operations in 1996, UPMC has been recognized for its dedication to quality and the provision of outstanding customer service across its product lines, which collectively provide commercial or government programs coverage to more than 4 million members. UPMC has offered consumers a variety of coverage options as a QHP issuer since the launch of the Marketplace in 2014, and currently provides coverage to approximately 113,000 Marketplace enrollees. In several Pennsylvania counties, UPMC is the only QHP issuer currently offering a product through the Marketplace.

We thank the Departments for providing QHP issuers and other stakeholders an opportunity to comment on reporting requirements under the Consolidated Appropriations Act, 2021 (CAA). UPMC supports the Departments in their ongoing efforts to improve transparency and lower the price of prescription drugs. It is with this support in mind that we respectfully offer the following comments on selected provisions of the IFC.

Reporting on Pharmacy Benefits and Prescription Drug Costs RFI

The Departments previously sought feedback on new requirements under the CAA for group health plans and issuers offering group or individual health insurance to report

certain pharmacy benefits and drug costs on an annual basis in the **Reporting on Pharmacy Benefits and Prescription Drug Costs RFI (RIN 0938-AU66)**. In our response to the RFI, UPMC offered several recommendations that we believed would implement the reporting requirements of the CAA in an efficient and effective manner.

In the IFC, the Departments have chosen to defer enforcement with respect to reporting for the 2020 and 2021 reference years data until December 27, 2022, specify that plans and issuers are permitted to have third parties submit information on their behalf, establish that reporting entities are able to aggregate data at the state and market level, and stated the Department's intent to establish a data collection system that will allow multiple reporting entities to submit different subsets of the required information for a single plan or issuer. We believe that these policies will promote consistency and reduce administrative burden for reporting entities and help facilitate the Department's objectives of identifying excessive pricing of prescription drugs and reducing out-of-pocket costs for prescription drugs for consumers. We thank the Departments for finalizing these provisions in the IFC.

Premium Amounts

The IFC implements provisions of the CAA that require plans and issuers to report the average monthly premium paid by employers on behalf of participants, beneficiaries, and enrollees, as well as the average monthly premium paid by participants, beneficiaries, and enrollees. UPMC is concerned that plans and issuers are not well-positioned as the source of certain information that would be required for compliance with these new reporting requirements. Specifically, although issuers know the premium charged to employers on a "per member per month" basis, information about individualized and/or relative employee- and dependent-specific shares of monthly premium, including any employer contributions to the same is held by employers and is not customarily shared with issuers. Even to the extent such information could be shared, there is no uniform agreed-upon format or data standard by which issuers could systematically ingest this information from thousands of distinct employers. In the absence of a compelling enforcement mechanism on the part of issuers as a service provider, we are concerned with the real possibility that a significant portion of employers will not provide the information necessary for compliance with the reporting requirements.

Given that plans and issuers are not the primary holders of employer/employee premium data and there is no obvious, standardized methodology to establish this type data exchange, it is not practicable or equitable that they should be the responsible reporting entity for this information. Accordingly, we ask that the Departments rescind the requirement that plans and issuers report the division of the monthly premium amount paid by employers and employees. Should the Departments continue to require the reporting of this data by issuers, we ask that the Departments establish a safe harbor for good faith compliance through the reporting of that information, which

is available to issuers, at least until such time as a standardized means of electronic reporting of such information can be established.

We again thank the Departments for affording plans, issuers and other stakeholders the opportunity to provide input on their implementation of new reporting requirements under the CAA. We appreciate your consideration of our comments and look forward to continued collaboration with the Departments in the future.

Respectfully Submitted,

Kyle Levin
Director of Public Policy
UPMC Health Plan

American Diabetes Association®
Connected for Life

January 24, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Attention: File Code: CMS–9905–IFC

Submitted via www.regulations.gov

Re: Prescription Drug and Health Care Spending

Dear Administrator Brooks-LaSure:

The American Diabetes Association (ADA) is pleased to submit comments in response to the Interim Final Rule with Comment (IFC) entitled: "Prescription Drug and Healthcare Spending" under the Consolidated Appropriations Act of 2021, as published in the *Federal Register* on November 23, 2021.

About ADA

The ADA is a nationwide, nonprofit, voluntary health organization founded in 1940 and made up of persons with diabetes, healthcare professionals who treat persons with diabetes, research scientists, and other concerned individuals. The ADA's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. The ADA, the largest non-governmental organization that deals with the treatment and impact of diabetes, represents the 122 million individuals living with diabetes and prediabetes, and has more than 500,000 general members, 15,000 health professional members, and more than one million volunteers. The ADA also reviews and authors the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes[1] and publishes the most influential professional journals concerning diabetes research and treatment.[2]

[1] American Diabetes Association: Standards of Medical Care in Diabetes 2022, Diabetes Care 45: Supp. 1 (January 2022).
[2] The Association publishes five professional journals with widespread circulation: (1) Diabetes (original scientific research about diabetes); (2) Diabetes Care (original human studies about diabetes treatment); (3) Clinical Diabetes (information about state-of-the-art care for people with diabetes); (4) BMJ Open Diabetes Research & Care (clinical research articles regarding type 1 and type 2 diabetes and associated complications); and (5) Diabetes Spectrum (review and original articles on clinical diabetes management).

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American Diabetes Association.
Connected for Life

The ADA would like to thank the Centers for Medicare and Medicaid Services (CMS), along with the related agencies focused on this rule, for its continued commitment and attention to getting at the root causes of the ever-increasing cost of health care in the United States. As you are aware, the cost of health care is one of the most consequential issues for the diabetes community today – and is among the greatest barriers to the health and well-being for Americans living with this illness. The ADA remains equally focused on both lowering the cost of drugs and devices at the pharmacy counter, as it is the systemic costs, more broadly. We look forward to seeing plans and issuers' submissions on prescription drug pricing and other health spending, required in this rule, in the upcoming years.

Americans with diabetes spend two and a half times more on health care than those who do not have diabetes; they account for $1 in every $3 spent on prescription drugs, 25 cents of every dollar spent on health care; and one in four insulin-dependent Americans report rationing their insulin supply due to financial difficulty.[3] The cost of living with diabetes is not only high, but also continues to rise – since 2014, insulin list prices have surged by more than 50 percent, while list prices for non-insulin diabetes medications have spiked by over 75 percent – a much steeper increase than costs for all drugs, which increased by just 30 percent over the same period.[4]

The nation's pharmacy benefit manager (PBM)-centric system raises costs and restricts choice, by incentivizing higher list prices, resulting in increased costs to patients, but manufacturers, middlemen, and payors all bear a share of the responsibility for the unsustainable cost of diabetes drugs and devices.

A June, 2021 article from the *Journal of the American Medical Association* looked at whether prescription drug rebates were associated with increased out-of-pocket costs. Researchers looked at estimated rebates for 444 unique branded drugs with prescriptions filled by 38,131 unique individuals. They found that increased rebate sizes were associated with increased out-of-pocket costs for those with Medicare,

[3] American Diabetes Association, "Economic Costs of Diabetes in the US in 2017," *Diabetes Care* 41, no. 5 (2018): 917-928, https://care.diabetesjournals.org/content/41/5/917; Sarah Stark Casagrande and Catherine C. Cowie, "Health Insurance Coverage Among People With and Without Diabetes in the US Adult Population," *Diabetes Care* 35, no. 11 (2012): 2243-2249, https://care.diabetesjournals.org/content/35/11/2243; U.S. Centers for Medicare and Medicaid Services, "National Health Expenditure Data – Historical," NHE Tables, December 16, 2020, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical; American Diabetes Association, "The Cost of Diabetes," https://www.diabetes.org/resources/statistics/cost-diabetes; Darby Herkert et al., "Cost-Related Insulin Underuse Among Patients with Diabetes," *JAMA Internal Medicine* 179, no. 1 (2019): 112-114, https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717499.

[4] Amanda Nguyen and Katie Mui, "The Staggering True Cost of Diabetes," GoodRx Research, April 2020, https://www.goodrx.com/blog/wp-content/uploads/2020/04/Diabetes-Cost-White-Paper.pdf.

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commercial insurance, or no insurance at all. Additionally, associations between rebates and out-of-pocket costs were associated with simultaneous increases in list prices. The findings also suggest that while drug manufacturers may increase list prices in order to offer larger rebates to insurers, such increases were associated with increased out-of-pocket costs, especially among individuals without insurance.[5] With 98% of people with diabetes depending on prescription drugs, almost all of them are at the mercy of this inequitable system. Furthering the case for this, is the disproportionate number of low-income, underserved Americans who live with diabetes. Shifting economics between other industry stakeholders does not ensure any reduction in cost to patients, something on which we remain steadfast.

The American Diabetes Association appreciates the attention CMS is paying to this vital issue and remains encouraged by the prescription drug pricing policies set forth by the Administration over the past year that affects the nation's entire patient population, as well as the 122 million Americans with diabetes and prediabetes.

We stand ready to provide assistance to the agency as it implements this rule and formulates additional pricing and payment policies. Should you have any questions or seek additional information regarding these comments, please reach out to me at: lfriedman@diabetes.org.

Sincerely,

Laura Peck Friedman

Laura P. Friedman
Vice President, Regulatory Affairs

[5] Kai Yeung, PharmD, PhD, Kaiser Permanente Washington Health Research Institute, *JAMA Network Open,* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780950

ERIC | THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

Mercer

January 24, 2022

Submitted Electronically via: www.regulations.gov

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

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

To Whom It May Concern:

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

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

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

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

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

Additional Plan Types That Should be Considered Exempt

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

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

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

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

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

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

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

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

Definition of Rebates, Fees, and Any Other Remuneration

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

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

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

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

Definition of Prescription Drug

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

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

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

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

Definition of Health Care Services

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

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

Impact of Mergers, Splits, and Similar Transactions

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

Hospital and Provider Reporting

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

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

Data Submission Requirements

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

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

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

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

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

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

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

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

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

Conclusion

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

James Gelfand
Executive Vice President, Public Affairs
The ERISA Industry Committee

David Dross
Drug Pricing & Policy Leader
Mercer

NATIONAL COORDINATING COMMITTEE FOR MULTIEMPLOYER PLANS

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MICHAEL D. SCOTT
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January 24, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services

Mr. Ali Khawar
Acting Assistant Secretary, Employee Benefits Security Administration
U.S. Department of Labor

The Honorable Lily Batchelder
Assistant Secretary (Tax Policy)
U.S. Department of Treasury

Submitted electronically via www.regulations.gov

Re: Prescription Drug and Health Care Spending Interim Final Rules with Request for Comments CMS–9905–IFC (86 FR 66662 (November 23, 2021))

Dear Secretary Becerra, Assistant Secretary Batchelder, and Acting Assistant Secretary Khawar:

The National Coordinating Committee for Multiemployer Plans (NCCMP) appreciates the opportunity to submit comments concerning the above referenced interim final rules with request for comments (IFC), which implement the requirement in the Consolidated Appropriations Act, 2021 (the "CAA") that group health plans submit significant information to the Departments concerning prescription drug costs and the impact on plan expenses. Our comments focus on four issues: (1) the need for sufficient time for implementation; (2) the definition of "premium amount" for self-funded plans; (3) application of the provisions relating to prevention of duplication to as applicable to self-funded plans; and (4) the aggregation rules and the need for plans to have access to plan-specific data.

Background on the NCCMP and Multiemployer Plans

The NCCMP is the only national organization devoted exclusively to protecting the interests of the job-creating employers of America and their labor partners, as well as the more than 20 million active and retired American workers and their families who rely on multiemployer retirement and health and welfare plans. The NCCMP's purpose is to assure an environment in which multiemployer plans can continue their vital role in providing retirement, health, training, and other benefits to America's workers and their families.

The NCCMP is a non-partisan, nonprofit, tax-exempt social welfare organization established under Internal Revenue Code ("IRC") Section 501(c)(4), with members, plans and contributing employers in every major segment of the multiemployer universe. Those segments include the airline, agriculture, building and construction, bakery and confectionery, entertainment, health care, hospitality, longshore, manufacturing, mining, office employee, retail food, service, steel,

and trucking industries. Multiemployer plans are jointly trusteed by employer and employee representatives.

The CAA includes multiple new obligations on group health plans, including the prescription drug reporting requirements that are the subject of the IFC. As the Departments consider final regulations, we encourage consideration of the fact that burdensome costs can undermine the goal of providing high quality health care. Multiemployer health plans are essentially pools of workers' earnings held in trust under federal law for the exclusive purpose of providing benefits to plan participants and beneficiaries. The trust funds are funded entirely by collectively bargained employer contributions for which covered workers explicitly trade off wages through the bargaining process. In a very direct sense, workers pay for their health coverage. If a trust fund's costs increase, despite the trustees' best efforts at cost containment, the burden falls directly on the workers, as trustees may be faced with the need to reduce benefits or adjust eligibility rules to address new costs. The benefits of any new mandates concerning prescription drug reporting and related administrative requirements must be carefully weighed against the costs to ensure that workers continue to receive real value for their health care dollars.

SPECIFIC COMMENTS

1. General Implementation Issues

We appreciate the Departments' decision to exercise discretion to defer enforcement in connection with the December 27, 2021 and the June 1, 2022 deadlines for data submissions for the 2020 and 2021 reference years, respectively. Enforcement action should not be taken against a plan for failure to report before December 27, 2022. In light of the fact that plans will need additional reporting instructions, we suggest that the Departments continue to defer enforcement for at least the first reporting year, as long as the plan sponsor is attempting to comply in good faith, due to the fact that the reporting rules, process, and systems will take time to understand and implement.

The preamble to the IFR states that additional instructions will be available to plans implementing the reporting obligations of the CAA. We urge the Departments to provide these additional instructions in a timely manner and on a public website easily accessible by plan sponsors. Previously, much of the information concerning transparency and instructions have been placed on websites not easily available to plan sponsors which are designed for programming or technical assistance. Guidance should be issued in regulatory or subregulatory forms that are easily accessible to plan sponsors and their professional administrators. Guidance should not be issued in formats or forums where plan sponsors do not participate, e.g., guidance should not be issued through systems such as the HIOS system which group health plan sponsors are not able to regularly access. Because plan sponsors have the ultimate responsibility for compliance, all instructions should be made available in a clear and consistent manner designed for the plan sponsor community.

2. Definition of Premium Amount for Self-Funded Plans

The IFC defines the term Premium Amount for self-insured group health plans as follows:

To accurately capture the concept of premiums and the full costs of maintaining health coverage with respect to self-funded group health plans and other arrangements that do not rely exclusively or primarily on premiums, in these interim final rules, the term ‘‘premium amount’’ with respect to these plans includes premium equivalent amounts that represent the total cost of providing and maintaining coverage, such as the cost of claims, administrative costs, and stop-loss premiums.

Based on this definition, it appears that plan sponsors could use the cost of COBRA continuation coverage as the premium amount. We request confirmation that plan sponsors would not be in violation of the requirement if they use the COBRA continuation premium for the premium amount for self-insured plans for reporting purposes.

3. Prevention of Duplication and Application to Self-Funded Plans

We support the provision in the IFC providing that fully-insured plans satisfy the reporting requirements if the plan requires the health insurance issuer offering the coverage to report the required information, pursuant to a written agreement. In this situation, the insurance issuer, not the plan would be responsible for compliance.

We recommend that a similar approach would be appropriate for self-funded plans, particularly because under the current aggregate reporting approach in the IFC (discussed below), the plan sponsor is unable to verify whether the information reporting by its reporting entities (i.e., its PBM, TPA, or other administrative service provider) is accurate. Similar to the provision in the IFC for self-insured plans, we recommend that the Departments provide that if a self-funded plan has delegated reporting responsibility to a reporting entity in writing, and the reporting entity has made an error in reporting, the plan would not be responsible for the error if the plan has acted in good faith in delegating responsibility, has monitored the reporting obligation, and has taken appropriate steps to assure that the information is timely reported to the best efforts of the plan sponsor. Specifically, if the plan sponsor has been informed by the reporting entity that information was reported to the government in a timely manner in accordance with the written agreement, the plan sponsor should not be found to be in violation of the requirement if there is an error in reporting.

4. Aggregate Reporting Rules Should Allow Plans to Have Access to Their Own Plan Level Data

The IFC states that the Departments have determined that plans and their reporting entities may submit the majority of the reportable information on an aggregate basis. The only plan-level information collected will be identifying information, plan year dates, the number of participants and states in which coverage is offered. Data of self-funded plans would be aggregated according to the TPA that acts as a reporting entity for the plan.

The Departments discuss the reason for aggregate information collection largely in the context of the Departments' ability to prepare the statutorily-required report on prescription drug spending. The Departments state, "Plan-specific lists might have some value for plans, but for purposes of the Departments' analysis of the data for the [CAA] section 204 public report, there is no compelling policy reason to require plans and issuers to engage in a complex and burdensome allocation exercise, particularly because lists based on allocation calculations would not provide useful information about any specific plan." The Departments also state that plans may need to revise their service agreements with TPAs to address liability for and accuracy of the information that the TPA or PBM reports and the ways in which the plan can review such reporting to confirm its accuracy. However, if the regulations permit aggregate reporting without the ability of plans to review plan-specific information, plans cannot confirm the accuracy of the reports.

The aggregation approach chosen by the Departments will result in plans having liability for reporting but having no access to the data being reported. Multiemployer plans have increasingly attempted to obtain access to prescription drug benefit data from their pharmacy benefit managers (PBMs). The reporting requirement represented an opportunity to increase transparency between PBMs and plans by requiring plans to provide information which must be obtained from their PBM. Increased access for plans to their own plan data, including regarding rebates, has been an important goal of sponsors for employment plans health plans, including multiemployer plan sponsors.

We believe that the focus **solely on the Departments'** desire for data is seriously misplaced and the statement that there is "no compelling policy reason" to allow plan access to specific data widely misses the mark. First of all, this position is surprising and questionable as statutory interpretation based on the multiple references in the statute to plan specific data. From a policy perspective, transparency is about more than just aggregate level data. While that type of data certainly may have value, that is by no means the only purpose. As already noted, plan sponsors, including multiemployer plan sponsors, have been struggling for some time to obtain access to data from their PBMs in order to help improve quality, outcomes, and efficiency for plan participants. These goals -- improving quality, outcomes, and efficiency, are shared goals among policy makers, as reflected in numerous places, including recently the bi-partisan health care provisions in the CAA. The Departments have also recognized these goals in other areas. Failing to ensure that plans have access to their own data is a blow against these policy goals, and a missed opportunity to enhance transparency as well as to ensure that Trustees can fulfill their fiduciary duty through the management of plan assets, which includes plan data. Further, we question the legality of imposing sanctions on plans when they do not have access to the information needed to ensure compliance. For all these reasons the IFC should be modified to align with both the statutory provisions and purposes of the law.

Specifically, the regulation should be modified so that, in order to take advantage of the benefits of aggregate reporting to the Departments, the reporting entity (TPA or PBM) must make plan-level detail available to plan sponsors upon request. This change would permit the plan to review

what has been submitted on its behalf and, importantly, use that information as it continues its attempts to provide cost-effective prescription drug benefits to the plan's participants and beneficiaries within the strict financial controls in place under the plan's current funding arrangement through its participating employers. This rule would also implement the statutory requirements for plan reporting of plan data.

CONCLUSION

The NCCMP looks forward to continuing to work with the Departments on this matter. Thank you for considering these comments. If you have any questions or would like to discuss these comments further, please contact Mariah Becker (202.756.4637 or mbecker@NCCMP.org).

Regards,

Michael D. Scott
Executive Director

January 24, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9905-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Prescription Drug and Health Care Spending (CMS-9905-IFC)

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Office of Personnel Management, the Internal Revenue Service of the Department of the Treasury, the Employee Benefits Security Administration of the Department of Labor, and the Centers for Medicare & Medicaid Services of the Department of Health and Human Services on the interim final rules with request for comments. NCPA continues to recognize the importance of ensuring consistent reporting on pharmacy benefits and prescription drug costs by health plans and pharmacy benefit managers (PBMs).

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $67 billion healthcare marketplace, employ 215,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

NCPA has been encouraged by the direction of Congressional action to interject more publicly available transparency into pharmacy benefits and drug costs. However, NCPA is cautiously optimistic that increased transparency, as required by section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021, will motivate fair dealing by the pharmacy benefit managers (PBMs) and the health insurance plans.

Definitions of Rebates, Service Fees, and Other Remuneration

As the Agencies continue to refine the reporting requirements for these plans, NCPA appreciates the agencies broad proposed definition within the interim rule to include any remuneration including rebates, fees, and other revenues generated by the PBM. However, the agencies fail to specifically mention direct and indirect remuneration (DIR), which impacts pharmacies as well as a source of revenue for the PBMs. Additionally, NCPA cautions the agencies on previous attempts by the PBMs to attempt to mask incoming revenue associated with prescription drugs

as service fees and other administrative fees. Previously, the HHS Office of Inspector General found that PBMs were claiming certain fees as bona fide service fees[1] and were therefore not reported to Medicare Part D plans or to CMS, provided they were paid at fair market value. However, the contracts between the Part D plans and the PBMs had only limited information about these bona fide service fees, and neither CMS nor the Part D plans were able to verify whether claimed bona fide service fees should actually have been considered rebates.

While NCPA appreciates the reporting of bona fide service fees, the rule only contemplates fees paid by the manufacturers and does not include fees paid by pharmacies as price concessions. Therefore, NCPA continues to urge the agencies to adopt a requirement that fees meet the Bona Fide Service Fee (BFSF) Test used in the Medicaid program to determine if a fee should be treated as a fee versus a price concession or some other form of revenue. The BFSF Test is a four-part test that is well understood by PBMs as it has long been utilized under the Medicaid Drug Rebate Program and was adopted into the Medicare Part D program in the DIR fees reporting context, and therefore incorporation of the BFSF Test should not be burdensome for PBMs.

Conclusion

NCPA greatly appreciates the opportunity to share our views on the Prescription Drug and Health Care Spending. NCPA looks forward to continuing to work with the Office of Personnel Management and the Departments of Treasury, Labor, and Health and Human Services as well as other interested stakeholders to develop workable reporting requirements on prescription drugs as required by Congress. Should you have any questions, please contact me at ronna.hauser@ncpa.org or (703) 838-2691.

Sincerely,

Ronna B. Hauser, PharmD
Senior Vice President, Policy & Pharmacy Affairs

[1] United States Department of Health and Human Services Office of Inspector General. (2019). Reasonable assumptions in manufacturer reporting of AMPs and best prices. Retrieved from https://oig.hhs.gov/oei/reports/oei-12-17-00130.pdf

CHCC

CORPORATE HEALTH CARE COALITION

January 24, 2022

Office of Personnel Management (OPM)
Internal Revenue Service, Department of Treasury
Employee Benefits Security Administration, Department of Labor
Centers for Medicare & Medicaid Services, Department of Health and Human Services

Delivered electronically via https://www.regulations.gov

RE: Interim Final Rule with Request for Comment Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs [CMS-9905-IFC]

The Corporate Health Care Coalition (CHCC) appreciates the opportunity to comment on CMS 9905-IFC, the Interim Final Rule concerning the implementation of the prescription drug and health care spending transparency provisions of Section 204 of the No Surprises Act, contained in the Consolidated Appropriations Act of 2021 (P.L. 116-260).

CHCC is comprised of companies from industries that compete in the global marketplace and sponsor self-insured health plans for the benefit of our employees and other beneficiaries. CHCC member companies are committed to providing access to affordable, quality health care benefits. We offer market-leading health and well-being benefits to recruit and retain top talent, but even more importantly, to maintain a healthy and productive workforce, which is key to any company's success. Collectively, CHCC member companies provide health benefits for nearly 5 million Americans across every state in the nation.

As self-funded health plan sponsors, CHCC member companies tailor health and well-being benefits to the needs of our workforce, while providing nationwide benefits for plan participants. CHCC member companies are constantly looking to innovate to improve plan participants' health, reduce health care costs for all, and use our leverage as payers to improve the health care system.

CHCC believes that increased transparency in the health care system, particularly as it relates to prescription drug costs, is a critical component to addressing the rising cost of health care. Because health care is localized, companies often partner with a variety of different vendor partners to ensure the best overall delivery of health care services for their employees in any given location. As such, the required reporting will present some significant challenges and additional costs for employers, as outlined below.

Timing of Reports

CMS 9905-IFC states that, with respect to plan years 2020 and 2021, the reports for these plan years are to be submitted on December 27, 2022. For subsequent plan years, the

submission date will occur every June following a given plan year. CHCC appreciates the discretion used by the Department to delay the reporting requirements for the 2020 and 2021 plan years. We believe, however, that the need for additional clarity regarding the reporting requirements and their operationalization merits a further delay for the first reports under this regime, for the 2020 and 2021 plan years.

We also note that the reference year is defined as calendar year versus plan year. This raises complications for plan sponsors that do not operate on a plan year, which is common in several industries due to higher business volume requiring attention and employee time later in the year. Data will not be comparable or consistent given plan sponsors often make adjustments to plan design and other aspects of their plans annually.

Aggregation of Data at the State Level

CMS 9905-IFC proposes that data should be reported on an aggregated/state and market-level instead of on the plan level. As proposed, the only plan-level information that will be required to be collected is identifying information for plans and issuers, such as the beginning and end date of the plan year, the number of participants covered on the last day of the reference year, and each state in which the plan is being offered. CHCC companies are concerned about the ability to track data - such as claims, premiums, contributions, and rebates - at the state level, which is not current practice. Many of our companies have national plans that span all, or nearly all, 50 states, often with multiple vendor parties. Under this proposal, employer plan sponsors would be required to separate our national plans into as many as 50 different state reporting structures, which is a significant and burdensome undertaking. We also believe it will be very difficult to track the impact of rebates on premiums on a state-by-state basis. Further, rebates are paid to employer health plans in arrears and health plan premiums are set prospectively. This will create a mismatch of data during the reporting period which may skew the data that this proposal aims to provide. We question whether this will provide useful and reliable data. *Therefore, CHCC requests additional guidance on how plan sponsors will be required to demonstrate, and be evaluated on, the impact of rebates on premiums and out of pocket costs.*

Determining the Top 50 Costliest Drugs

Plan sponsors are required to report the 50 most frequently dispensed brand prescription drugs, the 50 costliest prescription drugs by total annual spending, and the 50 prescription drugs with the greatest increase in plan or coverage expenditures. Given the complexities mentioned above with multiple vendor partners in many states, many companies will have to invest heavily in costly data-intensive resources to comply with the requirements. There will be scenarios where drugs in the top 50 of any given state could be split between several medical and pharmacy plans, and ensuring the top 50 drugs will be reported at the state level could be very complex. Additional time may be needed to comply, as plan sponsors identify and engage third parties to set up the system, gather the data and produce the first report period for 2020 and 2021.

Drugs Included in a Plan's Medical Coverage

CHCC notes the difficulty plan sponsors have in determining what portion of a bundled payment is attributable to prescription drugs. Therefore, we appreciate that while drugs covered under a plan's medical coverage are still included in the reporting requirements, plan sponsors will only have to report total spending. *CMS 9905-IFC proposes a safe harbor for plan sponsors who are unable to determine what portion of a bundled payment is attributable to prescription drugs but demonstrate a good faith effort, which CHCC supports.*

Reporting Entities

In most cases, large, multi-state employer plan sponsors, such as those represented by CHCC, contract with multiple pharmaceutical benefit administrators and third-party administrators to administer multiple, sometimes hundreds of, prescription drug and medical plans across the country. Many of the data elements required as part of Section 204 are collected by these entities, rather than the plan sponsor. In most cases, the plan sponsor does not have access to this data. CHCC supports providing flexibility in the data collection system to allow multiple reporting entities to submit different subsets of required information rather than one entity collecting and submitting the required information. *While we feel it is appropriate to hold employers accountable to ensure their self-funded vendor partners submit data, employers should not be held accountable for the quality or accuracy of the data provided. Safe harbors should be developed where employers taking good faith actions to comply are not held responsible, where vendor partners are struggling to produce data in the manner required. CHCC encourages regulators to engage and consult plan sponsors, their PBMs, and third-party administrators, early in the enforcement process, to gain a full understanding as to why full compliance may have fallen short.*

Conclusion

CHCC believes that access to cost and quality data can help provide important insights as we continue our efforts as plan sponsors to offer employees and their families access to high-quality, affordable care. We appreciate the opportunity to provide feedback on CMS 9905-IFC and thank you in advance for your consideration of our comments.

Sincerely,

The Corporate Health Care Coalition