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July 23, 2021

Amber Rivers, Office Director  
Office of Health Plan Standards and Compliance Assistance  
Employee Benefits Security Administration  
U.S. Department of Labor  
200 Constitution Avenue NW, Room N-5653  
Washington, DC 20210

**Re: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs [CMS-9905-NC]**

Dear Director Rivers:

CVS Health appreciates the opportunity to respond to the Request for Information (“RFI”) Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs issued by the United States Office of Personnel Management (“OPM”) and the Departments of Labor, Health and Human Services and Treasury (“Departments”).<sup>1</sup>

CVS Health is the leading health solutions company that delivers care in ways no one else can. We reach people in more ways and improve the health of communities across America through our local presence, digital channels and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses and nurse practitioners.

Wherever and whenever people need us, we help them with their health – whether that’s managing chronic diseases, staying compliant with their medications, or accessing affordable health and wellness services in the most convenient ways. We help people 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.

We support OPM and the Departments’ thoughtful approach to implementing the prescription drug reporting requirements in Section 204 of Title II of Division BB of the Consolidated Appropriations Act of 2021 (“CAA”). We appreciate the Administration’s and Congress’ goal of increased transparency to better understand how high-cost drugs are increasing health care costs and to identify what drugs are the primary drivers of increased costs for plans and consumers. At CVS Health, we are also focused on consumer costs, and believe that consumers need meaningful, actionable information about their out-of-pocket costs so they can make informed decisions—we are dedicated to providing this information to our Caremark members and Aetna health plan enrollees through online consumer transparency tools. We recognize that the CAA transparency provisions are rooted in this same concern for consumer costs, and we particularly commend the focus of the legislation on sharing only aggregated and non-confidential, non-proprietary data to protect the competition that keeps costs as low as possible.

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<sup>1</sup> 86 *Fed. Reg.* 32813 (June 23, 2021).

**As you begin the process of rulemaking to implement the CAA, we ask you to consider the requirements of the various new health service and prescription drug reporting requirements in totality. The Transparency in Coverage final rule, the recent Notice of Benefit and Payment Parameters, and the CAA can and should be streamlined to focus on producing high value information that protects the confidentiality of the reported data and that gives covered entities appropriate time to implement the requirements.**

Specifically, health plans, pharmacy benefit managers (“PBMs”), and other stakeholders have concerns about the overlap of the CAA provisions with the machine-readable files (“MRFs”) requirements in the Transparency in Coverage final rule, and we believe the CAA—which was passed most recently and reflects the intent of Congress in this area—should control. There are numerous operational, technical, policy, and competitive concerns with the MRFs requirement found in the Transparency in Coverage final rule. In brief, the required data elements conflict with those in the CAA, they fall outside the scope of the authorizing statute and of the rule as proposed, and they create an overly burdensome process for the industry that will not produce meaningful consumer tools or an improved “shoppable experience” in healthcare for consumers focused on out-of-pocket costs. Moreover, the information will be disclosed publicly, and disclosing confidentially negotiated payments and other proprietary information risks distorting the market, undermining competition, and encouraging an unbalanced focus on cost at the expense of quality. Per the CAA, the intent of Congress is to protect proprietary information, yet recent rules seem inconsistent with this intent. Streamlining the various reporting requirements under the CAA and eliminating duplicative and unhelpful requirements will be better for consumers, for the industry, and for the federal government.

**We also urge the Departments to allow plans adequate time to fully implement and comply with the new requirements of Section 204.** The requirements are multi-faceted, requiring the development of a new, complex reporting system and processes. Due to these complexities, we strongly recommend the Departments delay implementation until final rules and guidance have been released, technical specifications are finalized, and the new reporting platform is built, all based on substantial stakeholder input.

A more detailed discussion of our recommendations is provided in the attached document.

CVS Health is committed to working with the Departments to formulate rules and policies that promote meaningful transparency in health care. We would be happy to respond to any follow-up questions you may have.

Sincerely,



Melissa Schulman  
Senior Vice President  
Government & Public Affairs

## Attachment

### CVS HEALTH RESPONSES TO THE REQUEST FOR INFORMATION

#### A. General Implementation Concerns

##### 1. Time Frames for Reporting

We understand the statutory time frame for reporting under Section 204 for was set for one year after enactment, which would be December 27, 2021, with reports required by June 1 of each year thereafter. However, as the RFI itself makes clear, there are still many unanswered questions regarding the reporting from a substantive, technical and operational perspective.

Even once these questions have been answered in the form of final regulations and final guidance (including the forms to be used and reporting instructions pursuant to an Information Collection Request process), plans, issuers and their vendors will require time to do the system build out to put the reporting infrastructure in place. This will require substantial lead time as these same entities are also having to expend significant time and resources on other transparency reporting requirements and interoperability mandates amidst ongoing resource shortages due to the pandemic. In addition, since the relevant data is likely to be held by a variety of entities on behalf of plans or issuers, time will be needed to renegotiate contracts between plans/issuers and the vendors holding the data to address the new reporting services. Data exchange agreements to protect the privacy, confidentiality and security of the data will also be required to be executed between the different vendors. This will take several months to complete, with the vendor-to-vendor agreements being negotiated only after the agreements with plans/issuers are in place.

In light of these considerations, CVS Health asks the Departments and OPM to allow at least one year following publication of final rules and guidance before requiring the first report. This is consistent with the time frames for reporting under the Transparency in Coverage and Pharmacy Benefit Manager (“PBM”) Transparency Reporting for qualified health plans (“QHPs”) requirements. We strongly urge the Departments and OPM not to consider requiring reporting prior to the issuance of final regulations and guidance, either on the basis of “good faith” compliance or reliance on proposed rules or draft guidance. Plans, issuers, and their vendors will be required to invest substantial resources in putting in place the necessary reporting processes from a technical, operational and compliance perspective, and it will be not only costly, but also confusing, to have to modify these as requirements change. No organizations should be required to comply with a law until they know what it entails. Given the many uncertainties and potentially different methodologies for reporting under Section 204, we also do not believe that “good faith” compliance will yield meaningful comparative data that will achieve Congress’ goals in enacting Section 204. Instead, it will serve only to impose additional burdens on reporting entities and expose them to additional compliance risks with no countervailing public policy benefits.

Regarding the plan year data for which reporting is required, we ask that reporting not begin until at least 9 months after the end of the plan year (or reporting period if other than plan year) in question. There are several steps in the process, each of which can take several months to complete before the information from a given plan year can be reported. First, it is necessary to wait until all end-of-year run out of claims has occurred; any claim adjustments, reversals and reconciliations are made; and rebates are collected. This usually takes at least three to four

months after year end. Once the data is finalized, it must be gathered, compiled, and, where required, analyzed. Data compilation alone will take several months as different data sets and elements are held by different parties, such as plans/issuers, TPAs, PBMs, and employers. Finally, reports prepared by vendors, such as PBMs, will need to be reviewed and approved by the plan or issuer, which is usually an iterative process taking at least two to three months, and potentially longer.

## **2. Reporting Tools and Formats**

The RFI asks about different reporting formats, how they can reduce the need for manual data entry, and ways to facilitate compatibility with the systems most commonly used by plans and issuers. We recommend the Departments and OPM consider a standard data flat file with a data layout to handle large datasets, since all reporting tools generally allow for flat file production. Flat files can also be transmitted easily as compared to Excel and PDF files. Data field formats should follow industry data standards to ensure consistency.

Whatever reporting formats are finalized and however the reportable data is defined, we urge the Departments and OPM to ensure that services or personnel are available to assist with data input challenges, technology issues, or other questions that arise during the reporting process.

### **B. Definitions**

#### **1. Rebates, Fees and Other Remuneration**

The RFI asks what items should be considered in defining the term “rebates, fees and other remuneration” and, in particular, whether it should include bona fide services fees and manufacturer copay assistance programs and coupon cards. Since Section 204 asks for this information with respect to the impact of prescription drug costs on premiums, it is clear that Congress is seeking information on only those rebates, fees and other remuneration from manufacturers that affect a plan or issuer’s drug costs, since it is only the plan or issuer’s drug costs that would have an impact on premiums. Broadening the term beyond these types of payments from manufacturers would exceed the Departments’ and OPM’s statutory authority.

The Departments and OPM should therefore define the term to mean only those fees or payments by drug manufacturers that affect the plan’s or issuer’s drug costs, and should explicitly exclude bona fide service fees and other payments by manufacturers, such as coupons and copay assistance programs, that do not affect the prescription drug costs of the plan or issuer. Manufacturer copay assistance programs and coupon cards reduce enrollee cost sharing, rather than the costs of plans or issuers, and therefore should also be explicitly excluded from the definition. This is consistent with the Departments’ position with respect to the calculation of the commercial medical loss ratio (“MLR”), which similarly seeks to determine the drug costs incurred by a plan or issuer. In that case, the Departments agreed with comments that manufacturer coupons and similar items do not reduce plan or issuer drugs costs and therefore explicitly excluded “any remuneration, coupons, or price concessions for which the full value is passed on to the enrollee” from the definition of “prescription drug rebates and other price concessions.”<sup>2</sup>

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<sup>2</sup> See definition of “prescription drug rebates and other price concessions” in 45 CFR 158.103. See also 85 Fed. Reg. at 24259 (“*Comment: Several commenters requested that HHS clarify that the definition of prescription drug rebates and other price concessions at § 158.103 excludes prescription drug coupons and similar items that benefit enrollees directly at the point of sale, since these items do not reduce*”).

For consistency, the Departments and OPM should define “bona fide service fees” in the same way as that term is defined for Part D purposes (42 CFR 423.501), the QHP transparency requirements (45 CFR 184.50(a)(2)(i)) and for commercial MLR purposes (45 CFR 158.103).

## 2. Pharmacies

The RFI requests information on defining “pharmacies,” and specifically, whether different considerations apply for retail versus mail pharmacies and for prescription drugs dispensed in an inpatient, outpatient, office, home, or other setting. Section 204 requires reporting with respect to the “pharmacy benefits” and asks about drugs dispensed by “pharmacies.” The Departments and OPM should therefore limit reporting to drugs dispensed by pharmacies under a pharmacy benefit. This does not include drugs dispensed in inpatient settings, physicians’ offices, or other non-pharmacy settings. It also does not encompass dispensing by pharmacies as part of the medical benefit. This is also clear from the Section 204 requirement to provide a breakdown of spending for “health care services,” which clearly distinguishes spending for prescription drugs from other categories, namely, hospital, clinical and other medical services.

Regarding the definition of “pharmacy,” it is not clear that a definition is needed for this term, given its plain and well-understood meaning. Thus, for example, there is no definition for the term in the Part D regulations, which use the term repeatedly. However, to the extent the Departments and OPM believe that a definition is necessary to provide clarity or avoid confusion, the term could simply be defined as an entity licensed as a pharmacy under applicable state law. Section 204 does not call for, nor do we see any need to, distinguish between different types of pharmacies for purposes of the Section 204 reporting.

## 3. Prescription Drug

The RFI asks what considerations should be taken into account in defining the term “prescription drug,” and specifically, whether prescription drugs should be identified by National Drug Codes (“NDCs”), the RxNorm Concept Unique Identifier (“RxCUI”), or the United States Pharmacopeia Drug Classification (“USP-DC”).

The Departments and OPM should use a definition that best captures the information sought by Congress through Section 204. Since Section 204 seeks information that sheds light on “prescription drug pricing trends,” including through identifying the top drugs accounting for plan or issuer drug costs and therefore premiums, we do not believe that reporting at the NDC level will provide the type of information intended by Congress. This is because manufacturers often have multiple NDCs for the same drug or trade name to account for different forms, dosages, and strengths, with the result that reporting by NDC could result in the same or only a handful of drug names being identified. This would not provide meaningful information to the Departments or OPM to help identify the drugs accounting for the most drug costs or contributing to the most to drug price trends as intended by Congress. Reporting at the NDC level would therefore need

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*issuers’ drug costs and may not be known to issuers. Response: We agree with the commenters and clarify that it was never our intent to include prescription drug coupons and similar items that benefit enrollees directly at the point of sale in the definition of prescription drug rebates and other price concessions at § 158.103. Accordingly, we are modifying the proposed definition of prescription drug rebates and other price concessions in this final rule to clarify that this term excludes any remuneration, coupons, or price concessions for which the full value is passed on to the enrollee, such that no other entity receives any portion of the coupon payment, remuneration, or price concession.”)*

to be aggregated to the drug or trade name level to show the impact on prescription drug costs and premiums of a particular drug as Section 204 clearly intends.

Instead, CVS Health recommends that the Departments and OPM require reporting using the generic product identifier (“GPI”) at the GPI-6 level. This will allow the Departments and OPM to see more clearly and easily which drugs, by name, cost the most, which brand drugs the most frequently dispensed, which drugs accounted for the greatest increase in plan expenditures, and which yielded the greatest rebates and other price concessions. While reporting using the RxCUI and USP-DC could be accommodated, reporting at the GPI-6 level is likely to yield the most useful information to the Departments and OPM.

#### **4. Therapeutic Class**

The RFI asks what considerations should be taken into account in defining the term “therapeutic class,” and how plans and issuers currently classify prescription drugs by therapeutic class. There are many therapeutic class classifications used in the market today. We therefore recommend that the Departments consider allowing reporting of therapeutic class information using any one of the recognized industry standards, which the Departments and OPM could then crosswalk to a standardized classification of their choosing. Alternately, the Departments and OPM could seek multi-stakeholder input on whether reporting using the therapeutic class classification chosen by the Departments and OPM is feasible if the Departments and OPM make available a crosswalk based on GPI code.

#### **5. Health Care Services**

The RFI seeks input on defining “health care services,” and whether it is preferable to define the term as a service or bundle of services necessary to treat an illness (for example, by Diagnosis Related Group code). We are without a clear understanding of how the reporting system will be set up or how the information will be used and do not have a clear response to this definitional question at this point in the process. Please also see our response in Section B.2 on the definition of “pharmacy.” CVS Health recommends that CMS convene a multi-stakeholder process to address specific issues like this, where PBM and health plan interactions are entwined. A separate, focused, multi-stakeholder approach will allow experts to explore definitions and operational approaches to ensure alignment across entities, operational feasibility, and data accuracy.

### **C. Entities Required to Report**

#### **1. Reporting Level**

The RFI asks whether there are ways to submit aggregated data as opposed to reporting information separately for each group health plan, to the extent consistent with statutory requirements, and whether this would be of benefit to plans and issuers. We believe that reporting data at the employer or issuer level would both comply with the statutory reporting requirements as well as meet Congress’ goals in enacting Section 204. We also believe this would significantly reduce the administrative burden.

As Section 204 itself states, the information reported is ultimately to be used to make available a public report, aggregated so that no drug or plan specific information is made public, and that report will provide information on prescription drug coverage, pricing trends, and impact on premiums. Given the purpose of the report and that Section 204 states explicitly that it will show

only aggregate data, we do not believe that it is necessary for reporting to be at the plan level. In addition, while section 204 requires that information be reported for each group health plan or issuer, it does not state that this reporting must be done separately for each group health plan, and reporting at the employer level for group health plans would be most consistent with reporting at the issuer level. Therefore, as long as the information required by Section 204 for each group health plan is included in the report, we believe it would comply with the statutory requirements.

Reporting at an aggregate level will allow the Departments and OPM to identify patterns and trends more easily and with less need to manipulate the data. In addition, there are generally few, if any, significant differences in drug costs, drugs dispensed or impact on premiums between different plan options provided by an employer or issuer. Reporting at the employer or issuer level, will also reduce privacy concerns and administrative burden without in any way reducing the value or insights derivable from the data. Indeed, as stated above, it should provide more meaningful information to the Departments and OPM and enhance the public report ultimately produced.

## **2. Role of PBMs**

The RFI asks about the role of PBMs in furnishing the information required to be reported and if plans and issuers would rely on PBMs to help satisfy their reporting obligations. The RFI also asks whether PBMs obtain all the information required to be reported. CVS Health thus recommends that the Departments and OPM allow, but not require, PBMs and other vendors to assist plans with reporting. Most employers and issuers utilize PBMs to manage their drug benefits, and therefore, they will look to PBMs to provide much of the prescription drug information required by Section 204. However, Section 204 also requires reporting on information that is not known or held by PBMs, such as expenditures on other types of health services and information on premiums.

Some of the information required for reporting will be held by PBMs for plans, and it is possible, and even likely, that plans that utilize PBMs will ultimately contract with their PBMs to assist in the preparation of the information required to be submitted pursuant to Section 204. However, PBMs will not have all of the required data (e.g., employer contributions toward member/employee premiums, number of members per plan), so it would not be appropriate to make PBMs the reporting entity. Rather, consistent with the statute, the Departments should allow plans and issuers the flexibility to contract with vendors to perform the reporting on their behalf.

The reporting portal and specifications should be designed from a technical and operational perspective to allow for the greatest flexibility in data submission. Specifically, the Departments and OPM should be able to accept reports from plans and issuers and/or their service providers, including PBMs, and it should be possible for different entities (whether the plan/issuer or a specific service provider) to submit different data elements on behalf of a particular plan or issuer. This will allow plans and issuers to contract with service providers in a way that works best for them and their service providers, and that takes into account the different information held by each. Separate reporting forms or modules that would allow the submission of different information by different parties on behalf of a plan or issuer should achieve this flexibility.

## **D. Information to be Reported**

### **1. 50 Brand Prescription Drugs Most Frequently Dispensed by Pharmacies**

The RFI asks whether the determination of the most frequently dispensed drugs should be based on the number of claims, the number of days' supply, or something else. In order to ensure consistent measurement, metrics on drugs dispensed must account for drugs with varying days' supply. If only one metric will address drug frequency, then we recommend using total day supply. Alternately, a 30-day equivalent of the total day supply could be used, which would be derived by dividing the total day supply by 30 days.

## **2. 50 Prescription Drugs with the Greatest Increase in Plan Expenditures**

The RFI asks whether the increase in plan expenditures be measured based on the absolute increase in dollars, percentage increase in price, the increase relative to another measure (such as overall spending by the plan or issuer) or something else. We recommend using the absolute increase in dollar spending over time. A percentage increase in price should not be used as this would result in reporting drugs with low utilization in the base year. This is because these drugs will show the largest percentage increase in plan expenditures over time.

## **3. Identification of Top Prescription Drugs by RxCUI**

The RFI asks whether, if RxCUI or any classification other than NDC is used to identify top drugs, it is feasible for plans and issuers to report the required information separately by NDC for each NDC associated with the given RxCUI. We believe it would be feasible to do so, however, as explained above, we believe reporting by GPI at level 6 would be the better prescription drug classification to use.

## **4. Allocation to Prescription Drugs or Drug Classes**

The RFI asks what data elements can be directly tied to a specific prescription drug or class of prescription drugs, and which data elements must be allocated among prescription drugs or prescription drug classes. Drug spend and rebates are tied directly with specific drug or drug classes and can be reported at the drug level. Premiums are plan level amounts which can only be reported at the plan level.

## **5. Drug Costs by Setting of Care**

The RFI asks whether prescription drug spending information should be collected separately based on the setting of care. Section 204 requires reporting of plan expenditures on health services broken down by four categories, one of which is prescription drug costs. There is nothing in Section 204 requiring that prescription drug costs be broken down by setting of care (as is the case, for example, with respect to clinical services, which Section 204 explicitly states must be broken down by primary and specialty care). Therefore, we do not believe Congress intended or that there is a need to break down prescription drug costs by setting of care. In addition, as discussed earlier, based on the data elements and public report required by Section 204, as well as the references to "pharmacy benefits," it is clear that in referring to prescription drugs costs, Congress meant the pharmacy benefit. Drugs dispensed as part of a hospital stay or clinical services would be included within those health service categories.

## **6. Collection of Data Separately by Market, State or Employer Size**

The RFI asks whether information should be collected separately by market, state, or employer size and, if so, if there are data elements that must be allocated among the categories and what

allocation methods should be used. We do not support, nor does the statute authorize, breaking down the data reported by market, state, or employer size. Even without considering allocation issues, this would add greatly to the administrative burden on plans and issuers and their vendors, since the data is not collected or maintained on this basis. Had Congress desired or intended this type of break down, it could easily have asked for it, as it did explicitly for the spending on health care services to be broken down by various categories provided in Section 204.

## **7. 25 Drugs that Yield Highest Rebates and Impact on Premiums**

The RFI asks about considerations in measuring the impact of drug manufacturer rebates on premiums and out-of-pocket costs, and what analyses plans and issuers currently perform in this regard. Our health plans do not calculate premiums in this manner. Instead, plans look at all the factors that will influence the projected costs for a particular customer and then develop an appropriate premium based upon those factors. In addition, neither plans nor their vendors track or have the information necessary to adequately report or calculate the percentage of premium[s] paid by employers versus members/enrollees.

## **8. Information on Rebates and Other Remuneration**

The RFI asks whether information on rebates, fees, and any other remuneration should be collected at the total level or broken out by relevant subcategories, and whether the same or similar subcategories should be used as for the PBM Transparency Reporting for QHPs. Section 204 does not require reporting by subcategory, nor is this necessary to achieve Congress' intent in enacting Section 204. As discussed above, Section 204 requires the reported information in order to generate an aggregate report on drug coverage and drug price trends. As such, there is no need or mandate to breakdown the reporting by subcategories. In addition, Section 204 requires reporting only of payments from manufacturers, not other parties, that affect drug costs. The reporting categories for the PBM Transparency Reporting for QHPs in Section 1150A of the Social Security Act, are different from, and broader than, those required by Section 204, including items such as the difference between the amount PBMs charge plans or issuers and pay pharmacies. Therefore, it would not only be unnecessary and inappropriate, but also go beyond the statutory authority in Section 204 to require reporting by subcategories similar to those used for the PBM Transparency Reporting for QHPs, or to require reporting by any subcategories at all.

## **9. Payments to Manufacturers**

The RFI asks whether there are any payments that flow from plans, issuers, or PBMs directly to drug manufacturers and, if so, whether these payments should be netted against the payments from manufacturers. Section 204 seeks information on drug costs and payments from manufacturers that affect drug costs, such as rebates, which may or may not occur. If plans or issuers agree to make payments to manufacturers that result in increases in plan drug costs, such as rebate adjustments, then these should be netted against payments from manufacturers so as to accurately capture drug costs. However, there is no basis under Section 204 to collect information about any other payments that may flow between plans, issuers, and their vendors and manufacturers.

## **E. Coordination with Other Reporting Requirements**

The RFI asks whether there are opportunities to remove other reporting requirements applicable to plans and issuers or to leverage or combine those requirements with the reporting requirements under Section 204 to reduce administrative burdens or costs associated with complying with the new requirements. CVS Health appreciates the Departments' and OPM's recognition of the multiple, overlapping, and sometimes contradictory reporting requirements applicable to prescription drug costs. Since Section 204 is the most recent and clearest expression of Congressional intent on this issue, it should form the framework and parameters for any other prescription drug reporting requirements. We therefore recommend that the Departments utilize the Section 204 reporting requirements to obtain information on drug costs and pricing trends, instead of creating other drug cost reporting requirements that are not specifically called for by statute. In particular, we urge the Departments to rescind the machine-readable file requirement of the Transparency in Coverage final rule. This requirement has no statutory basis, is extremely onerous and, far from leading to greater meaningful transparency or improved consumer understanding of the factors driving drug costs, will undermine competition and lead to higher prices overall.