July 23, 2021

Amber Rivers
Director, Office of Health Plan Standards and
Compliance Assistance
Employee Benefits Security Administration
US 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.

Submitted Electronically: www.regulations.gov

Dear Director Rivers:

UnitedHealthcare (UHC)) is writing in response to the Request for Information (RFI) on reporting of pharmacy benefits and prescription drug costs by health insurers and group health plans as required by the Consolidated Appropriations Act (CAA). The RFI was published by the Departments of Health and Human Services, Labor, and the Treasury (the "Departments") and the Office of Personnel Management (OPM) in the *Federal Register* on June 23, 2021 (86 FR 32813). The information submitted by insurers and plans will be used by the Departments to prepare annual public reports on prescription drug reimbursements, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases.

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, UnitedHealthcare 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.

UHC appreciates the opportunity to submit feedback and has provided specific comments and recommendations below in response to the RFI questions. We ask the Departments and OPM to consider the following policy perspectives as you develop the reporting standards through future rulemaking.

Concentrate on Information Needed for the Departments' Report – As noted, the information collected from insurers and plans will be used by the Departments to develop annual reports on prescription drug costs and premium impacts. As a result, the Departments should request data that is necessary to support those reports. For example, as discussed further below, certain information categories may go beyond what is needed to generate the Departments' reports and should not be required.

Use Uniform Industry-Supported Data Reporting Standards – The Departments' reports should reflect uniform data definitions and reporting formats allowing information to be easily compared across insurers and plans. For example, we recommend below that the Departments work with stakeholders to create reporting processes for insurers and plans using industry recognized standards such as the Fast Healthcare Interoperability Resources (FHIR) standards created by Health Level 7 (HL7).

Adopt Realistic Reporting Timeframes – The December 27, 2021 deadline for the initial insurer and plan report to the Departments raises a number of significant challenges. As discussed in the preamble to the Surprise Billing Part 1 Interim Final Rule, the Departments recognize that rulemaking may not be completed this year[1] and insurers and plans will need time to develop the information platforms and reporting mechanisms after those rules are finalized. We recommend below that insurers and plans first submit data no earlier than 12 months after publication of the final rule.

Focus on Data Submission by Insurers and Plans – We do not believe Federal Employee Health Benefits (FEHB) carriers should be included in the data submission and reporting process. In the CAA, Congress directed the Departments to collect information from and report on prescription drug benefits provided by health insurers and group health plans. FEHB carriers currently report prescription drug cost information to OPM and any additional data submission that may be necessary should be done in consultation with FEHB carriers pursuant to the annual contracting cycle.

The following are UHC's responses to the questions in the RFI.

General Implementation Concerns

What, if any, challenges do plans and issuers anticipate facing in meeting the statutory reporting obligations? For example, do plans or issuers currently have access to all the information they are required to report under PHS Act section 2799-10, ERISA section 725, and Code section 9825? If not, which statutory data elements are not readily accessible to plans and issuers, and how could plans and issuers obtain the information necessary to comply with the reporting requirements? Are there ways in which the Departments and OPM could structure the reporting requirements to facilitate compliance?

With the deadline for submission just months away, insurers and plans have numerous unanswered questions, and processes have yet to be defined, making it difficult to assemble the first report by the end of this year. To enable reporting, insurers and plans will need guidance detailing the report format, agency submission process, and data definitions. The Departments should give stakeholders sufficient time to provide comments on these issues through the rulemaking process.

There are a number of operational challenges with reporting group health plan information maintained by different entities, such as prescription drug rebates, wellness program costs, and enrollee premium amounts. As discussed below, different levels of information on prescription drug and other health care benefits and costs are maintained by the plan sponsor and plan services providers requiring the data to be aggregated prior to submission to the Departments.

[1] Departments of Health and Human Services, Labor, and the Treasury, *Surprise Billing Part 1,* 86 FR 36872, 36876 (July 13, 2021).

Given the operational challenges in pulling together data from multiple sources and business platforms and that it is unclear at this point how data will be defined or reported, UHC recommends the Departments establish the first reporting deadline no earlier than 12 months after the rules setting out the data elements, reporting formats, and submission process are finalized.

Are FEHB carriers (including those that are also issuers) able to report data separately for each FEHB plan?

UHC does not support requirements for FEHB carriers to submit data as part of this rulemaking on the CAA provisions. We recommend OPM work with FEHB carriers on any reporting requirements through the annual contracting process. The CAA did not require data submission by FEHB carriers and prescription drug and health cost information from carriers will not contribute to the Departments' reporting of prescription drug benefits and costs in the commercial market.

After the Departments and OPM finalize rulemaking and publish the reporting format and instructions, how much time will plans and issuers need to prepare their data and submit it to the Departments and OPM? What data sources are readily available and which data may take longer to compile? Are there operational, formatting, or technical considerations that the Departments and OPM should be aware of that may impact plans' and issuers' abilities to meet the statutory deadline for reporting?

As discussed, there are a number of key issues regarding the reporting formats, data definitions, and process that will need to be finalized which, in turn, impacts how quickly data can be submitted. These questions include the following:

- Will health insurers report for each legal entity or on another basis such as product, geographic area or market?
- Should self-insured group health plan sponsors report for each plan offered by the sponsor or could the information be combined for all plans offered by the sponsor?
- Is group health plan reporting determined by the situs of the employer or group plan or by the residence of the plan member?
- If the sponsor is part of a controlled employer group should the report be at the individual employer or controlled group level?
- Are reports on a plan or policy year basis or should data be submitted for calendar years?
- If data is submitted for plan or policy years, should the report reflect plan and policy years ending in the preceding calendar year?

Regardless of the ultimate decisions by the Departments on the data definitions and reporting formats, UHC recommends the first data submission be required no earlier than 12 months after the reporting rule is finalized.

Are there different considerations regarding data reporting by health insurance issuers versus group health plans that would affect their ability to comply with the statutory reporting obligations? Among group health plans, are there different considerations for reporting by fully-insured versus self-insured plans, or for insured plans with small group versus large group coverage? Are there different considerations for reporting FEHB carrier data versus other plans and issuers? Are there different considerations for reporting of premiums, spending, and other data by partially insured group health plans, such as those that utilize minimum premium, stop-loss, or similar coverage? Are there special considerations the Departments should consider for

multiemployer plans, or that OPM should consider for policies offered by FEHB carriers that are not issuers?

As discussed, there are a number of challenges in reporting group health plan data given the different places information may be maintained:

- Plan sponsor – The sponsor will have information on total premiums paid by the employer and employee and premium levels (e.g., individual vs. different types of family coverage) and details about the group health plan (e.g., plan year start and end dates and number of participants and beneficiaries).
- Health Care Spending Accounts – While we do not believe data on health care spending accounts, such as Health Reimbursement Arrangements, should be reported, this information may be maintained by a plan service provider such as a financial institution.
- Pharmacy Benefit Manager (PBM) – The PBM has information on the prescription drug costs, drug utilization, and any rebates paid by the prescription drug manufacturer.
- Third Party Administrator (TPA) – The TPA maintains information on the costs of other health care services required to be reported (hospital, provider/clinical, and "other" health care costs).
- Other entities – Other plan service providers may be involved in providing coverage and would have data specific to their services such as behavioral health and substance use disorder benefits and wellness programs.

What data reporting tools and systems should the Departments and OPM consider when deciding on the format of the data collection? What are the operational advantages and disadvantages of various reporting formats, such as Excel spreadsheets, fillable PDF forms, or flat files? How can the Departments and OPM reduce the need for manual data entry? What are the ways in which the Departments and OPM could implement the reporting requirements to facilitate compatibility with the systems most commonly used by plans and issuers?

UHC recommends that the initial reports be submitted using defined template layouts allowing data submission in an easily recognized file format such as Excel or Common Separated Values files. These formats facilitate uploading and sharing of large volumes of data that can be assimilated by the end user for analysis. We do not recommend using a fillable PDF file due to the complexity of the data being presented, the potential number of data elements, and data submission volume across health insurers and group health plans.

We also believe the Departments should work with stakeholders to develop uniform data definitions standards and reporting formats – for example, consider use of FHIR standards to enable electronic sharing of information with the Departments.

Are there state laws with similar reporting requirements that could serve as models for implementing the requirements under PHS Act section 2799A-10, ERISA section 725, and Code section 9825? If so, in what ways are these state laws directly comparable to PHS Act section 2799A-10, ERISA section 725, and Code section 9825, and what should the Departments and OPM consider when deviating from the state requirements?

Currently 23 states collect information on prescription drug benefits and costs either directly or as part of the required reporting for the state's All Payer Claims Database. However, all of these states utilize different data definitions, file formats, and report submission deadlines. As a result, UHC does not recommend using any of the current state reporting processes as a model for the data submission requirements. We ask that the Departments encourage states to align

their reporting requirements with those that will be adopted by the Departments for reporting prescription drug benefits and health care cost information at the federal level.

Definitions

What considerations should the Departments and OPM consider in defining "rebates, fees, and any other remuneration"? Should bona fide service fees—for example, administrative fees, data sharing fees, formulary placement fees, credits, and market share incentives—be included in this definition?

There are generally two levels of rebates, fees, and other renumeration that may be paid by a prescription drug manufacturer. The manufacturer may pay rebates or fees to a plan service provider such as a PBM and the PBM may share all or part of that renumeration with the plan. UHC recommends that group health plans submit data on rebates, fees, and other remuneration they receive from the service provider and not report any renumeration paid by a prescription drug manufacturer to a service provider that is not passed along to the plan.

We believe this approach is consistent with the CAA requirement for 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 would not impact premiums and are not directly connected to drugs prescribed to plan enrollees.

How should manufacturer copay assistance programs and coupon cards be accounted for?

In general, manufacturer copay assistance or coupon program payments paid by a manufacturer are used by the consumer at the pharmacy point of sale to reduce their out-of-pocket costs and are not indicated separately on the claim submitted to the insurer or plan. The fact that part of the member's cost-sharing represents a payment from the manufacturer is not known to the insurer or plan. As a result, UHC recommends that these payments not be reported.

How should copay accumulator programs be accounted for?

As noted, payments by prescription drug manufacturers to consumers are typically reflected on the pharmacy submitted claim as a member cost-sharing payment and the fact that the payment may originate from another source is not indicated. As a result, the insurer or plan does not have access to the amount of the manufacturer copay assistance or coupon program payment and would be unable to report this data to the Departments.

What considerations should the Departments and OPM take into account in defining the term "pharmacy"? Are there different considerations for retail pharmacies versus mail order or specialty pharmacies? Are there different considerations for prescription drugs dispensed in an inpatient, outpatient, office, home, or other setting?

Insurers and plans should not be required to separately report data for retail, mail-order, and specialty pharmacies. Insurers and plans may adopt different definitions and payment approaches for each pharmacy category. As a result, the data should be aggregated and reported for all transactions covered under the pharmacy benefit, regardless of the type of pharmacy.

In addition, drugs dispensed in an inpatient setting, outpatient facility, physician office or home care are typically covered under the medical benefit and not pharmacy coverage and should not be reported. These costs are not easily extracted from medical claims and may not be priced on a per drug dispensed basis (e.g., drugs administered in an inpatient setting may paid as part of the overall per diem or a case rate and not separately distinguished in the course of care).

What considerations should the Departments and OPM take into account in defining the term "prescription drug." Should prescription drugs be identified by National Drug Codes (NDCs)? Are there other prescription drug classification systems that should be considered, such as the first nine digits of the NDC, the RxNorm Concept Unique Identifier (RxCUI), or the United States Pharmacopeia Drug Classification (USP-DC)? How does the choice of prescription drug classification influence plan and issuer operational costs?

UHC recommends that information on prescription drugs be submitted using the National Drug Code (NDC) – for example, in reporting the 50 prescription drugs with the greatest increase in plan expenditures over the plan year. Insurers and plans use and are familiar with the NDC classifications, which makes the results easier to provide, and ensures comparability across all data submitter. We recommend using the first nine digits of the NDC as it is a standard that can be used by all insurers and plans for reporting.

The other two classification systems discussed in the RFI (RxCUI and USP-DC) are not used by all insurers and plans. Insurers and plans would need to adopt these classification systems for data submission and will incur up-front costs, training, and testing to use the systems. In addition, requiring insurers and plans to adopt new classifications systems would add to the time to implement the new reporting provisions.

Should there be different definitions of "prescription drug" for different elements of the PHS Act section 2799A-10, ERISA section 725, and Code section 9825 data collection, such as the 9-digit NDC for identifying the 25 drugs with the highest rebates and the RxCUI for identifying the 50 most costly drugs?

One uniform standard – the 9-digit NDC – should be used for all reporting of prescription drug data.

What classification systems do plans and issuers currently use for internal needs and compliance with reporting requirements other than those under PHS Act section 2799A-10, ERISA section 725, and Code section 9825?

Currently, the only consistent reporting classification system across all insurers and plans is the NDC.

What considerations should the Departments and OPM take into account in defining the term "therapeutic class"? How do plans and issuers currently classify prescription drugs by therapeutic class?

Insurers and plans have adopted different definitions for therapeutic classes. While there are different classification systems available, requiring insurers and plans to adopt a specific set of definitions will result in additional costs for systems changes, training, and reporting. As a result, UHC recommends that reporting by therapeutic class be phased in to allow insurers and plans sufficient time to implement any new standard required by the Departments for reporting. As an alternative, insurers and plans could initially report data with their standard therapeutic class definitions to allow the Departments to determine if there is a methodology being used by

the majority of the insurers and plans. This approach would allow for future standardization with the least disruptive impact on insurers and plans.

Does the classification method rely on proprietary software, and how would the choice of therapeutic classification method influence plan and issuer operational costs?

Depending on the required reporting methodology, insurers and plans may need to invest in new licenses and adopt system upgrades to support reporting by therapeutic class. UHC is recommending that reporting by therapeutic class be phased in. As an alternative, insurers and plans could initially report data with their standard therapeutic class definitions to allow the Departments to determine if there is a methodology being used by the majority of the insurers and plans. This approach would allow for future standardization with the least disruptive impact on insurers and plans.

What considerations should the Departments and OPM take into account in defining "health care services"? 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)? Or would it be preferable to disaggregate by particular services (for example, by Current Procedure Technology code)? In what ways could this definition help reduce burdens or increase the utility of data reporting?

We recommend giving insurers and plans flexibility to determine how best to group non-prescription drug benefit costs for the submission of data for hospital care, medical and clinical services, and other health care costs such as wellness programs. Insurers and plans currently may treat certain services differently (e.g., day treatment programs for behavioral health or substance use disorders may be considered either inpatient or outpatient care depending on the terms of the benefit plan). Creating a new classification system for reporting will have significant impacts on the implementation of the reporting requirements by insurers and plans with little resulting benefit for the Departments' report.

Entities That Must Report

Are there special considerations for certain types or sizes of group health plans, such as individual coverage health reimbursement arrangements and other account-based plans, that make it challenging or not feasible for these plans to satisfy the reporting requirements? What are those specific challenges? If exemptions are provided for certain plans, how might that affect the value of the required public analysis?

The Departments' report is intended to provide the public with an overall view of prescription drug reimbursements, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases. The Departments should weigh the costs and complexity of the required level of data submission against the benefits in reporting the impact of drug costs on health care spending. In particular, we suggest the following:

- Insurers should report aggregated data at the legal entity level and not by specific plan or coverage type.
- Group health plans should report aggregated data for all plans offered by the sponsor.
- Data should be reported at the state level based on the situs of the legal entity or plan sponsor.
- Reporting should not be required for health care spending accounts such as HRAs.

Should the Departments expect that self-insured and partially-insured group health plans will contract with third-party administrators or other service providers to submit the required data on

their behalf? Is there any relevant information or data that may be helpful in determining how widespread this approach may be?

Most plans rely on one or more service providers to assist with providing health coverage under the benefit plan to participants and beneficiaries and it should be expected the plan sponsor may use a service provider to submit data to the Departments. As discussed, the plan will likely require coordination of data from the plan sponsor and other service providers such as a PBM.

Are there ways for issuers and plan service providers to submit data on behalf of multiple plans and coverage options, consistent with the statutory requirements? What benefit would there be to issuers and plan service providers having the ability to submit aggregated data as opposed to reporting information separately for each group health plan, to the extent consistent with the statutory requirements? What considerations exist with respect to issuers that participate in the FEHB Program submitting FEHB-specific data separately as opposed to including FEHB data in their general book of business?

The reporting obligation applies directly to the plan sponsor and they should have flexibility to determine how best to meet those requirements. In some cases, they will rely on a service provider to collect and submit data or they may choose to directly report the information to the Departments. We believe separate reporting by multiple service providers on behalf of a single plan will be operationally challenging for the plan and service providers and for the Departments. As a result, we do not recommend requirements for a plan and its service providers to submit separate reports to the Departments.

What role, if any, will Pharmacy Benefits Managers (PBMs) play in furnishing necessary information to plans and issuers, or to the Departments or OPM? If permitted, would plans and issuers rely on PBMs to help satisfy their reporting obligations, such as by retaining PBMs to conduct some or all of the reporting? Could PBMs obtain all the information required to be reported, including general information on the plan or coverage, such as the number of participants, beneficiaries, and enrollees; each state in which the plan or coverage is offered; monthly premiums paid by employers and by participants, beneficiaries, and enrollees; total spending on health care services broken down by type; and the impact on premiums of prescription drug rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers? If not, would allowing separate reporting forms, modules, or data collection systems for PBMs and issuers and plan administrators to report such information be administratively and operationally feasible? How would separate reporting forms change the costs or burdens associated with compliance?

As discussed, a group health plan may use different service providers – such as a PBM – to administer benefits and each service provider will have distinct datasets needed by the plan for reporting purposes. The plan sponsor should have the flexibility to decide how best to submit data, including having one service provider collect and report information from the applicable vendors. As discussed, we do not support separate reporting by each service provider.

Information Required to be Reported

What considerations are important for plans and issuers in determining the 50 brand prescription drugs that are most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each drug?

Brand drugs may fall into different categories depending on the dosage or type (e.g., extended release). The Departments should adopt clear definitions for brand drugs, and the appropriate level of reporting using NDC 9.

Should the determination be based on the number of claims, the number of days' supply, or something else?

The determination of the most frequently dispensed drugs should be based on the number of pharmacy claims submitted. Submitting data using other methodologies such as the number of days or dosage per prescription increases the complexity of reporting without adding materially to the information required for the Departments' reporting.

Should the unique number of participants, beneficiaries, or enrollees that received a prescription be taken into account, and, if so, how?

We recommend reporting based on the number of claims. Pulling in additional detail complicates the data submission and adds marginal value to the information that will be used in the Departments' report.

What considerations are important for plans and issuers in determining the 50 prescription drugs with the greatest increase in plan expenditures?

UHC recommends the Departments adopt clear definitions for what is a brand drug, and the level of reporting for brand drugs.

Should the increase 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?

The increase in prescription drug costs should be measured based on absolute increase in dollars over the reporting period, but only for drugs that had activity in the prior year. This approach eliminates including new drugs for the first reporting year.

What factors should the Departments and OPM consider in selecting an approach?

As noted, we do not believe new drugs should be included for the first reporting year. If drugs newly introduced into the market are included, the Departments should provide clear guidance on drug definitions and how to account for the costs during the initial reporting year.

If the Departments and OPM define the increase in proportion to the change in overall spending, should the increase be measured in comparison to total spending or only to spending on prescription drugs?

The increase in prescription drug costs should be measured against prior year spending on prescription drugs and not in comparison to other health care cost trends. Pricing trends for other health care costs such as inpatient care may be driven by other factors than those applicable to pricing for prescription drugs. For example, the COVID-19 pandemic is impacting healthcare spending for certain types of episodes of care (e.g., treatment of pneumonia), but may not have a comparable effect on prescription drug pricing. Comparing prescription drug cost trends to other health care costs does not provide useful information unless additional detail on overall health care impacts are available to provide context.

If the top prescription drugs are identified by RxCUI (or any classification other than NDC), is it feasible for plans and issuers to report the required information separately by NDC for each NDC associated with the given RxCUI?

We do not support reporting for the top 50 prescription drugs by RxCUI and separately by NDC associated with the given RxCUI due to the volume of data. As discussed above, we recommend reporting by NDC only.

Which 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?

UHC recommends tying data elements to the prescription drug level. It may be necessary in certain situations to allocate pricing or other information – for example, where the insurer or plan receives a fixed amount rebate per brand drug prescription. In that case, the rebate value is allocated to each prescription for a brand drug which will not indicate the drugs that had the most rebates. In this situation, we recommend allocating the rebates across all of the brand prescription drug claims.

If an amount must be allocated, what allocation method(s) are preferable, and why?

Amounts should be allocated proportionately over the impacted population.

What considerations are important for plans and issuers in determining the 25 drugs that yielded the highest number of rebates and other remuneration from drug manufacturers during the plan year?

Insurers and plans generally negotiate prescription drug rebates with a service provider such as a PBM and may have different approaches with respect to rebates. For example, an insurer or plan may choose to give up rebate value in exchange for reductions in expenses and, as a result, may not have any data to report. In other situations, the insurer or plan may be paid a fixed rebate for all brand scripts, so data for the top 25 drugs would be based on volume and not reflect the total amount of rebates paid in connection with a specific drug. As a result, a certain amount of variability in the rebate results based on the contract arrangement between the plan and the PBM should be expected.

Should rebates and other remuneration be measured by total dollar amount? Should rebates and other remuneration be measured in comparison to another measure, such as total spending on a drug or a unit price?

UHC recommends that insurers and plans report the total dollar amount of rebates, fees, and other remuneration and not be required to measure the amount in comparison to other prescription drug spending or unit pricing.

PHS Act section 2799A-10, ERISA section 725, and Code section 9825 require plans and issuers to report total spending on health care services separately for hospital costs, health care provider and clinical service costs (for primary care and specialty care separately), prescription drug costs, and other medical costs, including wellness services. Which cost elements should be included in each category? Should the Departments and OPM collect prescription drug spending information separately based on the setting of care?

Prescription drug costs paid under the insurer or plan pharmacy benefit should be the focus of the report. Drugs that are covered under a medical benefit should be reported within the

medical cost reporting and not broken out by site of care. As discussed, insurers and plans take different approaches on how drugs administered as part of the medical benefit are reimbursed and the data on prescription drug costs may be difficult to extract from the medical claims submitted to the insurer or plan.

Should the Departments collect information separately by market, state, or employer size? If so, are there data elements that must be allocated among the categories? What allocation methods should be used? Are there differences in the capacities of different size entities to comply with the Departments' and OPM's reporting requirements, or in the costs and burdens of compliance?

As discussed above, we support reporting at the legal entity level by state. The volume of the data submission would be significant and require more time to process if a greater level of reporting detail is required.

Should the Departments and OPM collect information on rebates, fees, and any other remuneration at the total level or broken out by relevant subcategories?

We suggest insurers and plans report total rebates, fees, and any other renumeration received from a PBM. In some situations, rebates, fees, and other renumeration may be combined into a single amount for purposes of reporting by the PBM per their contract with the insurer or plan and would not be available by subcategories.

For example, in the PBM Transparency for Qualified Health Plans (QHPs) data collection,1 PBMs will report information for retained rebates, rebates expected but not yet received, PBM incentive payments, price concessions for administrative services from manufacturers, all other price concessions from manufacturers, amounts received and paid to pharmacies, and spread amounts for retail and mail order pharmacies. Should the Departments use the same or similar subcategories for the reporting requirements under PHS Act section 2799A-10, ERISA section 725, and Code section 9825?

We do not support data submissions by insurers or plans at this level of detail. The reporting required for QHP data collection is appropriate for PBMs because the PBM has the contract with manufacturer and can provide specific details on the rebates including what amounts, if any, are passed on to the insurer or plan. Each insurer and plan can only report regarding the information that is included in rebates or other remuneration paid under their particular contract with the PBM. As a result, the insurer or plan should only report the total amount of rebates, fees, and other remuneration received by the insurer or plan. This information would highlight the overall impact of rebates and other payments on health care spending.

Are there types of payments that flow from plans, issuers, or PBMs directly to drug manufacturers? If so, how should these payments be treated? Should they be netted against rebates and other price concessions that are received from drug manufacturers?

We are not aware of any such payments.

Public Report and Privacy Protections

Should OPM issue a public report specifically for FEHB carriers?

As discussed above, UHC does not support data submission by FEHB carriers under this CAA provision. If OPM believes the collection of prescription drug information is necessary it should work with the carriers through the contracting process.

Would the Departments' and OPM's reports have greater value and utility if data were collected on a calendar year basis, by plan or policy years, or by some combination, to the extent consistent with the statutory requirements?

UHC supports reporting on a calendar year basis. The complexity of trying to report by plan year will increase the administrative burden of compliance without providing any significant value to the Departments' reporting. We also note that there is typically a runout period for rebates, fees, and other renumeration paid by a PBM or other service provider to an insurer or plan. We recommend that the data submitted by insurers and plans reflect payments received as of the end of the calendar year preceding the reporting year (e.g., data reported to the Departments by insurers and plans on June 1, 2023 will reflect payments or claims through the end of 2022).

Are there any examples of similar reports published by state agencies? If so, what are any strengths or limitations of the reports published by the state agencies that would be relevant to the Departments and OPM? In what ways should the Departments and OPM consider adapting or differentiating the process under PHS Act section 2799A-10, ERISA section 725, and Code section 9825 from any similar state reporting processes?

As noted, state have adopted different data definitions, reporting processes and timelines for prescription drug data. We do not recommend use of any state data until the reporting processes and data definitions are standardized across all state data submission platforms.

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

Sincerely,

Chris McCartney Harris, Sr. Director
UnitedHealthcare