KAISER PERMANENTE®

July 23, 2021

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Attention: Request for Information Regarding Reporting on
Pharmacy Benefits and Prescription Drug Costs
200 Constitution Avenue NW, Room N-5653
Washington, DC 20210

Submitted electronically to www.regulations.gov

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

To Whom It May Concern:

Kaiser Permanente appreciates the opportunity to comment on the above-captioned Request for Information (RFI) issued jointly by the Office of Personnel Management (OPM) 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 12.4 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. The goal of the RFI is to seek input regarding the implementation and related impact of 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"), with which the Departments and OPM "intend to analyze trends in overall spending on prescription drugs and other health care services by plans and issuers and to publish the analysis in the required reports…to enable plans and issuers

[1] 86 Fed. Reg. 32813 (June 23, 2021).
[2] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., 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.

to ultimately negotiate fairer rates and lower costs for participants, beneficiaries, and enrollees."[3] We offer our response to particular questions where further clarity and direction will be most impactful to producing meaningful reporting submissions considering the significant amount of data generated from our internalized pharmacy system. We also support the comments and responses to additional RFI questions submitted by America's Health Insurance Plans (AHIP).

A. General Implementation Concerns

1. *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?*

Response:
Many plans and issuers may not have access to the information necessary to report "the average monthly premiums paid by participants, beneficiaries, and enrollees and paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable."[4] The amount of premium paid by employers on behalf of their employees varies widely and that information is typically held by the employer groups and not the issuer. Issuers generally only have access to the entire premium amount billed to the employer group. Therefore, we recommend OPM and the Departments require plans and issuers to report the total average monthly premium, without breaking this amount down further. Reporting the total average monthly premium will still allow OPM and the Departments to identify material cost trends, while creating a reporting structure that reflects the data available to plans and issuers.

4. *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 take into account for multiemployer plans, or that OPM should take into account for policies offered by FEHB carriers that are not issuers?*

Response:
For those entities that intend to report information on behalf of their self-insured group health plan clients, it will be important to clarify the reporting requirements related to average monthly premiums. Since self-insured group health plans do not pay a monthly premium for coverage as compared to their fully-insured counterparts, we recommend that OPM and the Departments

[3] 86 Fed. Reg. 32814 (June 23, 2021).
[4] *Id*.

permit premium equivalence reporting for self-insured plans. A premium-equivalent rate would allow for more consistent and comparable reporting between fully-insured and self-insured plans, as it would best reflect the claims expenses, expected medical trend, and other costs that are generally represented by a monthly premium.

5. *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?*

Response:
To facilitate a more efficient submission process, we recommend using a Comma-Separated Values (CSV) text file for the submission. CSV files are generally more straightforward, allowing easier input and manipulation, resulting in manageable file sizes. Other options, such as fillable PDF forms would take significantly more time for data input. Overall, CSV files are a more convenient, effective way of importing and exporting the necessary data.

6. *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?*

Response:
Several state legislatures have enacted similar pharmacy benefit and prescription drug cost reporting requirements. We recommend and support the approach taken by Washington State in implementing its reporting requirements with respect to the level at which reports are generated. Similar to the CAA's requirement for plans and issuers to submit "certain information with respect to the health plan or coverage for the previous plan year,"[5] Washington State requires reporting "for each health plan [the issuer] offers in the state."[6] Regulators in Washington State determined that having issuers generate reports at the market level (i.e., individual market, small group market, large group market) would be the best way to gather meaningful data "for each health plan" offered in the state.[7]

We recommend that OPM and the Departments adopt a similar methodology as used by Washington State regulators by having plans and issuers compile reports at the market level for each state or region. If plans and issuers are required to report at a more granular level, this will require significantly more time and resources to parse out the data, without any additional benefit. Reporting at the market level will allow OPM and the Departments to identify material trends more easily with respect to utilization, spending, and costs.

[5] 86 Fed. Reg. 32814 (June 23, 2021).
[6] RCW 43.71C.020.
[7] See *Washington State Health Care Authority Carrier Data Submission Guide (December 22, 2020)* at https://www.hca.wa.gov/assets/DPT-submission-guide-carriers.pdf.

B. Definitions

1. *What considerations should the Departments and OPM take into account 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? Are there additional fees that the Departments and OPM should include in this definition? How should manufacturer copay assistance programs and coupon cards be accounted for? How should copay accumulator programs be accounted for?*

Response:
The Departments and OPM should consider that there are various drug purchasing models that plans and issuers may use, including the integrated model used within Kaiser Permanente. Through our integrated model of care, Kaiser Permanente internally performs many major functions of the prescription drug benefit and care delivery supply chain. We are typically the provider, health plan, and pharmacy for our members. For most of our business, we negotiate pricing for drugs directly with manufacturers, purchase drugs directly on behalf of our owned and operated pharmacy operations, and set and manage our own formulary with the full engagement and cooperation of our PMG physicians, whose prescribing and drug selection decisions are free of individual financial conflict. As a result, we experience best-in-class levels of prescription drug use management, which allows us to achieve significant price discounts when we directly purchase drugs, rather than primarily through rebates.

While we receive some rebates from manufacturers, discounts realized at the time of our purchase constitute the large majority of our price concessions from manufacturers. As we work to implement these reporting requirements, it will be necessary for OPM and the Departments to clarify whether "rebates, fees, and any other remuneration" will include concessions realized at the time of purchase by issuers that are direct purchasers of drugs. To better support OPM's and the Departments' overall trend analysis, we recommend including total, aggregated manufacturer concessions realized at the time of purchase by issuers that are direct purchasers of drugs in the definition of "rebates, fees, and any other remuneration." Capturing both manufacturer concessions realized by issuers at the time of purchase, if the issuer is purchasing drugs directly, and post-sale manufacturer concessions at a total, aggregated level, will offer a more complete landscape of manufacturer pricing practices.

While using a definition of "rebates, fees, and any other remuneration" that requires only reporting post-sale manufacturer concessions would more closely align with the traditional rebate structure used by most issuers, groups and their Pharmacy Benefit Managers (PBMs), this reporting structure could omit a significant amount of value realized at the time an issuer directly purchases drugs from the manufacturer.

3. *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?

Response:
OPM and the Departments should identify prescription drugs using only National Drug Codes (NDCs) across all the reporting requirements. NDCs are universal among plans and issuers and requiring the use of other prescription drug groupers or identifiers will result in additional time and resources to complete reporting, as further mapping would be needed to correctly match the identifier with the corresponding drug. Consistently using NDCs across all reporting requirements will avoid the complexity associated with tracking and verifying multiple identifiers.

We recognize, however, that a single drug may have multiple NDCs to account for various dosages or delivery methods, which could impact how the data are presented in the required reporting lists of 50 or 25 drugs. For these lists, if only NDCs were used, the same drug might appear multiple times within a list, albeit with different dosages or different delivery methods. For example, an NDC associated with a 20 mg tablet of atorvastatin and an NDC associated with a 40 mg tablet of atorvastatin might appear on the same list. Depending on OPM and the Departments' intent, this may or may not be a desired outcome. If this outcome is not desired, OPM and the Departments could devise a methodology for further consolidating the list by drug name or another alternative identifier.

Additionally, we recommend using a consistent definition of "prescription drug" across all reporting requirements. The definition should indicate the drug is a non-compounded, legend drug, and it should be limited to drugs prescribed for outpatient use and dispensed through an outpatient pharmacy, excluding provider-administered or inpatient drugs. Provider-administered drugs are usually covered under the enrollee's medical benefit, rather than their prescription drug benefit, and there is additional complexity and difficulty associated with compiling data for inpatient or provider-administered drugs. Furthermore, limiting the definition of "prescription drug" to those drugs prescribed for outpatient use and dispensed through an outpatient pharmacy would align with similar reporting requirements found in other states.[8]

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

Response:
When defining the term "therapeutic class," we recommend that OPM and the Departments use the AHFS Pharmacologic-Therapeutic Classification as developed and maintained by the American Society of Health System Pharmacists (ASHP). In addition to being widely accepted[9], Kaiser Permanente uses this classification for our Medicare Part D and commercial formularies.

[8] See *Washington State Health Care Authority Carrier Data Submission Guide (December 22, 2020)* at https://www.hca.wa.gov/assets/DPT-submission-guide-carriers.pdf; Va. Code Ann. § 38.2-3407.15:6(B)(1) (effective January 1, 2022); Cal. Health & Safety Code § 1367.243(2).
[9] Medicare Prescription Drug Benefit Manual, Ch. 6, 30.2.1 (Rev. 18, January 15, 2016).

D. Information Required to be Reported

1. *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? Should the determination be based on the number of claims, the number of days' supply, or something else? Should the unique number of participants, beneficiaries, or enrollees that received a prescription be taken into account, and, if so, how?*

Response:
To facilitate a more straightforward reporting process, we recommend solely using the total number of claims as the basis for determining the 50 brand prescription drugs that are most frequently dispensed, without further stratification for other categories such as number of days' supply. This will streamline the reporting process and minimize administrative burden by reducing the variables by which plans and issuers will need to sort and compile data.

2. *What considerations are important for plans and issuers in determining the 50 prescription drugs with the greatest increase in plan expenditures? 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? What factors should the Departments and OPM consider in selecting an approach? 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?*

Response:
When determining the 50 prescription drugs with the greatest increase in plan expenditures, we recommend measuring the increase by the absolute increase in dollars. This approach is straightforward, and as compared to other approaches, the data can be more easily mapped to drug NDCs, which will reduce the administrative burden associated with compiling and preparing the reports.

7. *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?*

Response:
As described earlier, we recommend and support the approach taken by Washington State in implementing its similar reporting requirements with respect to aggregating data. Washington State determined that having issuers generate reports at the market level (i.e., individual market, small group market, large group market) would be preferred over reporting information separately for each group health plan or with respect to employer size.[10] Reporting at the market level will

[10] See *Washington State Health Care Authority Carrier Data Submission Guide (December 22, 2020)* at https://www.hca.wa.gov/assets/DPT-submission-guide-carriers.pdf.

aid in identifying material trends with respect to utilization, spending, and costs.

8. *What considerations are important for plans and issuers in measuring the impact of drug manufacturer rebates on premiums and out-of-pocket costs? What quantitative or qualitative analyses might plans and issuers perform? What analyses do plans and issuers currently perform?*

Response:
As described above, it is important to consider that integrated systems like Kaiser Permanente purchase drugs differently than other plans and issuers. Under our integrated model, Kaiser Permanente purchases most of our own drugs through our pharmacy operations, and therefore negotiates drug prices directly with manufacturers in most cases. For drugs purchased and used by our own pharmacy operations, we do not use PBM services for negotiating pricing with manufacturers or any formulary creation or management services. In these instances, we achieve the majority of our drug price savings through upfront price concessions at the time of purchase rather than through rebates.

The savings we achieve through our upfront pricing concessions from manufacturers help offset costs and are important considerations as we develop our premiums and drug pricing for our members and groups. Due to the level of integration of our operations, however, we are unable to precisely account for how the price concessions we receive from drug manufacturers are reflected in member premiums.

To ensure that effective and efficient drug purchasing models like ours can comply with the reporting requirements while still achieving the intent of the statute, we recommend OPM and the Departments allow for plans and issuers to provide a qualitative description explaining how "rebates, fees, or other remuneration" paid by drug manufacturers are used to reduce premiums and overall out-of-pocket costs for their enrollees. OPM and the Departments can then aggregate the responses and provide a summary generally of how issuers and plans use their savings to support their enrollees. We suggest having the qualitative description focus on how the total amount of "rebates, fees, or other remuneration" paid by manufacturers influences overall out-of-pocket savings for enrollees, rather than trying to analyze the impact on a drug-by-drug basis. A granular drug-by-drug analysis will make it difficult to identify material, high-level trends.

F. Public Report and Privacy Protections

3. *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? If data were to be collected by plan or policy year, are there any considerations the Departments and OPM should take into account when determining the plan or policy year effective dates for reporting periods? For example, what is the last plan or policy year end date that should be included in data submitted by June 1 of each year?*

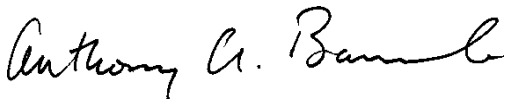
Response:
Kaiser Permanente recommends that data be collected on a calendar year basis, with the policy

end date for the reporting period being December 31 of the preceding year. Reporting on a calendar year basis will facilitate identifying and compiling data and help remove the variability associated with policies issued mid-year.

Conclusion

Kaiser Permanente looks forward to working with OPM and the Departments to ensure the forthcoming regulations and processes for data submission support fair and effective compliance. 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,



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Senior Vice President
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