601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004
T 202.778.3200
F 202.331.7487
ahip.org

July 28, 2022

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer

RE: Prescription Drug and Health Care Spending (CMS-10788) —AHIP Comments

Dear Sir or Madam:

Thank you for the opportunity to provide additional comments on the 30-day Paperwork Reduction Act (PRA) notice for the collection of Prescription Drug and Health Care Spending data (CMS-10788; OMB: 0938-1407; OMB: 0938-1405) by the Office of Personnel Management (OPM), as well as the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (collectively, the Departments).

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

AHIP appreciates the Departments' substantive engagement of stakeholders and your responsiveness to our feedback and comments throughout the implementation process. In particular, we appreciate the Departments' understanding the difficulty of collecting data when a contractual relationship began before the passage of the Consolidated Appropriations Act (CAA), as reflected in the decision not to pursue enforcement action against plans and issuers unable to obtain data on premium amounts paid by employers and members. We also appreciate the Departments' decision to move pharmacy data and medical data out of files D2 and D6, respectively, which will prevent overlap and duplicate reporting in those files. Below, we offer additional comments and technical questions on the most recent version of the reporting instructions (dated June 29, 2022) and other related reporting materials.

Premiums Paid by Employers and Members
AHIP's members appreciate the Departments' decision not to take enforcement action against plans and issuers who are unable to access and report the amounts of premium paid by employers and members for the 2020 and 2021 reference years only. However, our members report that

many of their contracts for the 2022 and 2023 reference years were signed before the Departments published the interim final rule with comments in November 2021. As plan years may not follow the calendar year, a contract for a plan year spanning July 2022-June 2023 may have been signed the preceding fall. Further, while plans and issuers are actively working to contact clients to request this and other required information, our members report that some clients have not been responsive or have not provided useable information, meaning that plans and issuers may need to estimate for the 2022 and 2023 plan years. AHIP urges the Department to extend the delay in enforcement action for this information to the 2022 and 2023 reference years, after which the requirements for the submission of this information can be included in client contracts.

For plans and issuers who have been able to collect the information, our members report persistent collection challenges, noting that the amounts can vary based on several factors, such as the classification or type of employee or how long someone has worked for that employer. Recognizing this complexity, AHIP recommends the Departments allow issuers to report an average percentage of premium paid by the employer, which could be more feasibly collected from groups while still providing the Departments meaningful information on the breakdown of the member's share.

Form 5500 Plan Number

In our comments on the interim final rule and PRA package, AHIP provided feedback from our members concerned about finding and reporting the Form 5500 Plan Number. As plans have begun searching for this information and/or requesting the information from plan sponsor clients, they have reported difficulties identifying these numbers for group health plans. Plan administrators must request and collect the information from their clients, build storage for the new data, and ensure the values are in a reportable format. As Form 5500 is filed by employers, insurers, even when acting as a third-party administrator, are generally unfamiliar with the form, and as with premium amounts, the information has been difficult to collect, particularly if the client relationship no longer exists or if the client's business ceased operations or was acquired by a new entity.

AHIP members have additionally raised concerns about ensuring the correct number is reported, as Form 5500 may be filed up to seven months following the end of the plan year (or longer if an extension is granted). As the RxDC reporting is due on June 1, our members are concerned that the numbers they include in their reporting may not match what the employer ultimately reports on the form. AHIP appreciates any clarification and guidance the Departments can provide to address these potential conflicts.

Given that the statute does not require the Form 5500 Plan Number to be collected, AHIP requests that the Department remove this reporting requirement from the RxDC reporting. Should the Departments decline to remove this requirement, AHIP urges the Departments to

delay enforcement action on reporting this information to provide the time necessary to build the collection and reporting infrastructure and to include the information disclosure in client contracts. As with premium amounts, AHIP recommends this delay for the 2020, 2021, 2022, and 2023 reporting years.

Section 3.4 of the Reporting Instructions

AHIP is concerned about the Departments' directions in Section 3.4 of the Reporting Instructions (and the associated footnote) to transmit aggregated reports to multiple vendors to allow entities to fill in their own data if a vendor is not able to complete an entire file. AHIP's members are concerned about the operational realities of transmitting their large data files to disparate entities for completion. We are also concerned about sensitive financial information being revealed to third parties in the process of transmitting this file to multiple reporting entities.

AHIP agrees with the Departments that reporting aggregate data is preferred and will yield the most comprehensive and useful data on prescription drug and health care spending. However, the inclusion of data points that originate from multiple sources in single files creates an operational challenge for reporting entities, and we are concerned the added cost and difficulty may result in some groups choosing to submit their own unaggregated reporting. Files D1 and P2 both present this concern; for example, file D1 requires that the reporting entity (most likely a TPA or ASO) include costs specific to a single group health plan that the vendor submitting on their behalf neither collects nor knows, such as the total costs of providing and maintaining coverage, including claims costs, administrative costs, ASO and other TPA fees, and stop-loss premiums. Some of this information, such as what other (possibly competing) vendors charge plans for services, is not appropriate to be shared between vendors.

AHIP recommends that each reporting entity be responsible for reporting the data they administer and maintain regardless of whether it is in a single file or represents only a partially completed file. Our members are extremely concerned about gathering and reporting data from other unaffiliated entities, especially when the data is financial or competitively sensitive in nature. AHIP believes this approach would ensure the data for each plan are reported completely without duplication, while being reported by the entity that owns or is the "source of truth" for the data.

Due Date for Future Reporting

AHIP remains concerned about the June 1 deadline for submitting the required data for 2022 and future reference years. We note that some of the reporting relies heavily on MLR reporting, which is due on July 31 for the prior calendar year. Additionally, the "Total Spending" and "Rx Spending" reporting elements are to represent claims net of state/federal reinsurance and risk adjustment payments. However, that information for the 2021 plan year was not issued until June 30, 2022. In future years, it is likely that the information may routinely be reported after the June 1 RxDC filing deadline. In our comments on the interim final rule and PRA package, we noted

that plans could have as little as 61 days to validate and produce their annual reports, as they must report claims for care received in the reference year but paid through March 31 of the following year. These factors mean that the reported data may not be fully aligned with other data submissions, such as for MLR reporting, and the overall quality and accuracy of the data may suffer as a result. AHIP encourages the Departments to use enforcement discretion to allow reporting entities to submit information up to nine months following the end of the reference year to ensure the completeness and to maximize the validity of claims data.

Spread Pricing
AHIP reiterates our strong opposition to the inclusion of spread pricing in the reporting instructions, as the statute includes no mention of this information in the enumerated and extensive list of reporting elements plans and issuers must report. The statute requires reporting on rebates, fees, and other remuneration from manufacturers to the extent those transfers impact premiums. The statute in no way suggests that plans and issuers should report, nor the Departments collect and analyze, spread amounts. AHIP urges the Departments to remove all references to spread amounts in the reporting instructions.

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

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

AHIP also recommends clarification that plans and issuers need only report information in this field to the extent that such amounts are known to the plan or issuer. Thus, the description of the field should state "*To the extent known,* report billed amounts that were (1) not applied to a member's deductible or out-of-pocket maximum, (2) not paid by the plan, issuer, or carrier, and

(3) not included in Total Spending." As stated above, there may be multiple instances where a given patient's health care expenditures are not reported to the plan or issuer, and therefore would not be known. The addition of this language will enable plan and issuer compliance, despite the challenges.

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

However, even with clearer definitions, AHIP remains concerned that combining all the listed categories into a single total will result in the larger data element ("Amounts Not Applied to Deductible or Out-of-Pocket Maximum") being misinterpreted in the Department's required report on the Section 204 data.

Capitation and Bundled Payments

The updated guidance for RxDC reporting will require splitting of bundled payments (including per diem rates and DRG payments) into new spending categories for "medical benefit drugs" and "medical benefit drugs estimated amounts." In addition, capitation spending is required to be allocated to different spending categories through estimations.

AHIP is concerned that attempting to disaggregate bundled payments and capitation amounts by spending category is unnecessary and creates additional complexity and reporting burden on plans with no clear benefit. AHIP recommends removing the medical benefit estimated breakout by spend category, as well as the capitation breakout by spend category.

Safe Harbor for Additional Changes to the Reporting Instructions

In order to meet the initial reporting deadline, reporting entities must begin building these reports using the updated guidance issued on June 29, 2022. Should the Departments make further changes to the reporting instructions or data file formats, reporting entities will likely be unable to incorporate any modifications to the data files in time for the December 27, 2022 reporting deadline. AHIP urges the Departments to provide a safe harbor and allow reporting entities to adopt changes made in response to stakeholder comments in the first report following the December 27, 2022 submission.

Technical Questions
We offer the following additional technical questions:

- How to mark the new "Included in D1-D8" fields in the Plan List reports. Should plans mark such field as included (i.e., mark a "1"), even when the actual dollar value for that field is $0? How should it be answered if one entity is completing P2, but another entity is completing (and possibly aggregating) one or more of the D files?

- For the year-over-year increases, we assume the first year to report this information is the 2021 reference year since the initial reference year is 2020. We recommend this is confirmed in the final PRA package.

AHIP appreciates the opportunity to provide feedback on the collection of Prescription Drug and Health Care Spending data. If you have any questions or need additional information, please contact Meghan Stringer at mstringer@ahip.org. We welcome the opportunity to discuss these issues as the Departments and OPM continue their work.

Sincerely,

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