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July 22, 2021

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

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

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

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

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

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

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

We appreciate the opportunity to respond to the Request for Information (RFI) from the Office of Personnel Management (OPM), as well as the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (collectively, the Departments) on Reporting on Pharmacy Benefits and Prescription Drug Costs, published in the Federal Register on June 23, 2021.

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

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

Section 204 of Title II of Division BB of the Consolidated Appropriations Act (CAA) requires group health plans and health insurance issuers offering group or individual health insurance coverage to submit to the Departments reports detailing top drivers of prescription drug costs, overall spending on health services and prescription drugs, and information about premiums and the impact of rebates and other remuneration on premiums and out-of-pocket costs. The Departments will release a bi-annual report on drug pricing trends, drug reimbursement, and the impact of drug prices on premiums.

While AHIP supports efforts to measure the impact of soaring drug prices on consumers' premiums and out-of-pocket costs, we urge the Administration to delay the enforcement of Section 204 and take the time necessary for full implementation to minimize administrative burden to plans and issuers. It is also critical that the Departments recognize the overall magnitude of challenges faced by plans implementing the No Surprises Act, along with other CAA transparency provisions when staging the implementation priorities of the Act. We therefore appreciate that the Departments are seeking public comment through a request for information in advance of future rulemaking. The overall requirements for Section 204 are multi-faceted, requiring data from multiple sources and require the development or modification of a complex reporting system and processes. Due to these complexities, we strongly recommend that the Departments delay implementation until one year after the reporting system is built and technical specifications are finalized, based on substantial stakeholder input.

In our comments we offer several areas where the Departments can implement alternative approaches to data reporting that will still provide the Departments the needed visibility into overall trends in medical and prescription drug costs while ensuring the reports are accurate and minimally burdensome for plans and the agencies. Accordingly, AHIP urges the Departments to require reporting at a higher, aggregated level than by each employer group or individual market plan – e.g., per line of business or by prescription drug formulary. This would significantly reduce administrative burdens on plans and issuers, reduce concerns about the privacy of enrollees, participants, and beneficiaries in small groups, while allowing the Departments to detect larger trends related to prescription drug prices.

As noted in our detailed comments that follow, some of the data elements mentioned in Section 204 are unavailable to plans and issuers, while some may reside with third-party vendors that also help administer the health plan's benefits. **Therefore, AHIP requests the Departments construct a data reporting system that allows plans, issuers, and employers to directly submit their portions of the required data and allow for null reporting values where they do not have access to such information.**

Finally, AHIP has concerns with OPM's proposal to extend the Section 204 reporting requirements to FEHB carriers given the complexity and burdens associated with the requirements described in other sections of our response to this RFI that are equally applicable to

these issuers. **We therefore recommend that OPM not pursue rulemaking to extend the Section 204 reporting requirements to FEHB carriers at this time.**

Our detailed recommendations on these and other matters raised in the RFI are included in the attached document. We would welcome the opportunity to discuss our recommendations as the Departments and OPM consider the implementation of Section 204.

Sincerely,

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

Attachment
AHIP Detailed Comments on the RFI

Overarching Recommendations

Reporting Timeframe:
To ensure a successful implementation of Section 204, we recommend the Departments delay the law's reporting requirements. The provisions of the No Surprises Act and the other transparency provisions of the CAA represent a significant regulatory undertaking for the Departments to promulgate and for plans to implement. As we have reviewed and discussed the Section 204 provisions with our members, we have discovered that obtaining and reporting the information required by the statute will be far more complicated than may have been initially thought by policymakers. We encourage the Departments and OPM to take the time necessary to construct and implement a reporting system that minimizes administrative burden for plans and ensures that collected data will be useful as the Secretaries' reports are written. Additionally, AHIP requests that the Departments and OPM consider the following when determining the implementation timeline:

- **A reporting system specific to Section 204's requirements will need to be built and users appropriately credentialed and trained to use it.** Currently, no reporting system exists to collect the required data, and any new system to be developed must also be thoroughly tested to ensure reliability and accuracy. Once a system is built, we anticipate time and extensive training will be necessary for plans and issuers to use the system. Further, staff will need to be credentialed to use the system, which may add to the time needed before a plan can submit its data.

  CMS has previously proposed interim use of the HIOS portal through which medical loss ratio (MLR) data is reported. AHIP believes this path forward presents many challenges and creates confusion and additional administrative burdens for plans, including self-funded plans that do not currently use or have access to the portal. If this interim step is used, plans would need to undergo the credentialing and training processes twice (once for the interim system and a second time for the permanent system).

- **Plans will need at least one year following the release of final technical specifications and reporting requirements before they are required to submit their data.** Given the uncertainty surrounding how reports will be submitted, the absence of other technical specifications including clarification of certain definitions in the statute, and the need to build out reporting functionality, it is not possible for initial reports to be submitted by the first deadline specified in the statute (December 27, 2021). Plans may need to update contracts or agreements with third-party vendors to fulfill the reporting requirements, which cannot be done until plans know what specific information they will need to obtain from their vendors

(and how). At minimum, plans will need one year after technical reporting specifications and the final Paperwork Reduction Act (PRA) package are released to negotiate contracts, build the necessary internal infrastructure to submit reports, and train on and credential the appropriate users in the designated reporting system.

Level of Data Collected

To facilitate collection, we recommend the Departments allow data to be aggregated and reported by market segment instead of at the highly granular plan or employer group level. Generally, if these data reports were collected at the individual health plan level, the amount of effort to make the required calculations (such as "top" drug lists) would be massive. This amount of effort would produce little additional value for the Departments or the public. Typically, the most expensive drugs and hospital costs are expensive no matter the specific employer or plan.

The administrative complexity of gathering the required data increases as the level of granularity specified increases. In other words, reporting at the plan/group level would be significantly more administratively complex than reporting at the market segment level. Further, the added complexity increases the opportunities for errors in collection and reporting of such data. The Departments should require plans to report by market segment (*e.g.*, individual, small group, large group). Reporting at these higher levels would allow the Departments to detect significant trends with respect to prescription drugs that are increasing consumers' premiums across all market segments.

It is also critical the Department's approach protects the privacy of individuals in small group plans. Reporting aggregated data at the market segment or formulary level will reduce any privacy concerns with compiling and submitting this information to the Departments. However, if this approach is not adopted, the Departments should establish minimum thresholds for reporting under Section 204 in order to protect the privacy of plan enrollees. For example, groups that have fewer than 20 enrollees should be exempted from the reporting requirements, and instances where reporting the data elements could reveal an individual's identity or health condition should not be reported.

What Data Is Collected

We recommend the Departments require plans to report only the data they currently maintain. Gathering and reporting the data required by Section 204 will be a complex undertaking for our members, even for the data they currently maintain or can access. Many do not currently store or have ready access to elements of the data required for submission by the statue, including data that is maintained by outside vendors that help manage a portion of the benefits, such as pharmacy benefit managers (PBMs) or third-party administrators (TPAs). Rather than requiring plans to renegotiate vendor contracts to access, store, and report the required data, the Departments should allow plans to report only the data they currently maintain and allow null reporting values in fields that they do not have data to fill.

If the Departments move forward with requiring all data detailed in the statute be collected, we recommend:

- Facilitating plan or issuer information collection from service providers: In order to expedite data collection by plans, the Departments should create and allow the use of segmentable templates. These templates would allow third-party vendors to submit the required information to plans in a format that can be efficiently incorporated into the plans' report submission.
- Allowing for phased implementation: As much of the data required by Section 204 is not currently maintained by plans, a phased implementation would allow earlier reporting and adjustments as more data is required. Again, many of Section 204's required data elements are not currently held by plans, but rather by outside vendors or employers. Other data elements are not captured at all, and if plans will be required to report this information, additional time will be needed for plans to develop processes and methods to gather and report that information. Rather than delay all reporting, a phased implementation could be created by the Departments to allow earlier reporting of data currently maintained by plans.

Applicability to FEHB Plans

We recommend the Departments not extend the Section 204 requirements to carriers participating in the Federal Employees Health Benefits (FEHB) program at this time. Although Congress did not apply the CAA's reporting requirements to FEHB carriers, OPM is seeking comments on applying Section 204 to carriers participating in the FEHB program. AHIP has concerns with OPM's proposal:

- **Applying Section 204 to FEHB carriers is duplicative of existing reporting requirements.** OPM already requires FEHB carriers to report aggregate pharmacy cost and utilization data to OPM pursuant to the requirement that carriers "furnish such reasonable reports as the Office determines to be necessary to enable it to carry out its functions under this chapter" (Section 8910 of the FEHB Act (5 U.S. Code § 8910)). We believe that extending Section 204 reporting requirements to FEHB carriers would create unnecessary burdens on carriers given the duplicative nature of the information being collected and reported and the potential need for a second, parallel system to collect and report the same data.

- **Stakeholder concerns should be addressed, and reporting requirements and specifications should be finalized before OPM considers extending Section 204's requirements to FEHB carriers.** Given the complexity and burdens associated with Section 204 reporting requirements described in detail in other sections of our response to this RFI, we recommend that OPM not pursue rulemaking to extend the Section 204 reporting requirements to FEHB carriers at this time. We believe that issues and concerns raised by AHIP, our members, and other stakeholders should be fully addressed, and reporting

requirements and specifications should be finalized prior to consideration of extending the Section 204 reporting requirements to FEHB carriers.

- **OPM should align its existing pharmacy cost and utilization data reporting requirements with the final Section 204 reporting requirements issued by the Departments.** If OPM decides to pursue rulemaking to require FEHB carriers to comply with Section 204, OPM should align its existing pharmacy cost and utilization data reporting requirements with the final Section 204 reporting requirements issued by the Departments. This approach would minimize unnecessary burdens and costs and would utilize an already-existing platform for FEHB carriers to report this data.

AHIP Responses to the Solicitation of Comments

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?**

Reporting system
Currently, no reporting system exists to collect the required information. Once a system is built, we anticipate time and extensive training will be necessary for plans and issuers to use the system. Further, staff will likely need to be credentialed, which may add to the time needed before a plan can submit its data.

CMS has previously proposed interim use of the HIOS portal through which MLR data is reported. AHIP believes this path forward presents many challenges and creates confusion and additional administrative burdens for plans, including self-funded plans that do not currently use or have access to the portal. If this interim step is used, plans would need to undergo the credentialing and training processes twice (once for the interim system and a second time for the permanent system).

Report timing
The annual reporting under Section 204 must be completed by June 1 for the preceding plan year. However, additional time is needed between the end of a plan year and the reporting deadline. This time lapse is necessary to process claims and calculate rebates and to maximize the validity of that data. AHIP recommends the reporting deadline fall no earlier than nine months after the end of a plan year.

Data availability/accessibility
Most health plans do not maintain all the data outlined in Section 204 of the No Surprises Act on their own servers. Additionally, some of the required data elements may not be available to or obtainable by plans.

- **Data held by multiple vendors.** Many plans use third-party vendors, such as Pharmacy Benefit Managers (PBMs) or third-party administrators (TPAs), to manage a portion of covered benefits. These third-party vendors maintain their own records

and data relating to the portion of benefits they manage. As a result, health plans may have to renegotiate contracts and build and maintain new data storage infrastructure if they are required to complete all reporting. This would also require additional administrative burden to aggregate data from vendors, and then build and submit the reports. For example, a plan's contracted PBM may have better access to the data necessary to report on elements 4, 5, 6, 7(A)(iii), 7(B)(i), 9 and 10.[1]

- **Considerations for Self-funded plans.** AHIP's members frequently serve as third-party vendors for self-funded plans, which may contract with multiple, unrelated vendors. In considering which entities will be responsible for submitting required information, AHIP asks the Departments to consider that these vendors often have a contracted relationship with the plan, but no relationship with each other. As such, vendors should not be responsible for negotiating contracts with or submitting data from other third-party vendors.

- **Unobtainable or unavailable data.** Some of the required data elements may not be available to or obtainable by plans or issuers. Examples include:

  - **Employer/employee premium contributions.** Plans do not know the division between an employer's and an employee's premium contributions. For fully insured plans, only the average premium amount is known or can be derived. This would impact data element 8.

  - **Employer contributions to an Individual Coverage HRA (ICHRA).** A plan cannot determine whether or how much an employer contributes to an ICHRA used to purchase coverage in the individual market (this would impact reporting on element 8). Such information would need to be collected by another entity, such as the state's exchange, and shared with plans. Regardless, the impact of pharmacy trends would be reflected in reporting for the individual market. It would not be feasible to report pharmacy or other information for the ICHRA itself. These plans are merely funding mechanisms for individual coverage, which can be obtained from multiple issuers, and do not include benefits, pharmacy or otherwise, in and of themselves.

  - **Impact of coupons on out-of-pocket (OOP) costs for prescription drugs.** With respect to OOP costs for prescription drugs, plans do not always know if an enrollee chooses to pay with a manufacturer coupon or copay assistance. This would impact reporting on element 7(B)(ii).

[1] See Appendix for enumerated data elements.

- **Church plan identification.** Section 204 exempts church plans from its reporting requirements. However, some plans do not maintain data distinguishing church plans from other plans. In order to exclude church plans' data, they would have to contact all non-ERISA groups, create a system to track responses, and build data storage for the information. Such an undertaking would be complex and burdensome and could not be done in order to meet the first reporting cycle obligation.

Report Structure

AHIP believes the heavy administrative burden placed on plans to gather, store, and report the required data outweighs the benefits derived from receiving the data. However, the Departments can tailor the reporting system to reduce this burden.

- **Construct a data reporting system that allows the use of segmentable templates.** These templates would allow third-party vendors to submit the required information to plans in a format that can be efficiently incorporated into the plans' report submission.

- **Establish a process to identify data that plans cannot obtain or that is exceptionally difficult to obtain and provide limited carve-out exceptions for that data.** The Departments should work with plans to identify and provide limited carve-out exceptions for data that cannot be obtained or that is exceptionally difficult to access. While some blanket exceptions are appropriate (such as employer/employee premium contributions), other carve-outs may be needed in particular, unique instances. Addressing these narrower circumstances will reduce the overall time and administrative costs to implement while preserving the quality and utility of the data collected.

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

   [AHIP has no response to this question.]

3. **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?**

The relative availability and accessibility of required data will differ widely between plans. Plans that contract with third-party vendors to administer various benefits will need to negotiate receipt of or access to data.

No contracts or agreements can be negotiated until plans know what specific information they will need to obtain from their vendors. At minimum, plans will need one year after technical reporting specifications and the final PRA package are released to negotiate contracts and build the necessary internal infrastructure to submit reports.

As previously noted, requiring plans to aggregate data held by multiple vendors that help manage aspects of the plan's benefits will require them to build and maintain new data storage infrastructure. Plans would also have to aggregate data from their vendors and then build and submit the reports.

With respect to specific sources of data, our members have expressed concerns about translating their existing prescription drug data into required formats and classifications, such as therapeutic classes. Additional time may be necessary for plans to determine appropriate identifiers and cross-walk their claims to the required format.

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?**

Premium amounts

In the employer market, per-enrollee premiums are relevant only for fully-insured plans. For self-funded plans, a calculation to determine a premium equivalent will be necessary to report premium costs. Employees' premium contributions are not known for either fully-insured or self-funded plans.

Drugs covered under the medical benefit

If the Departments determine that plans must submit data for drugs covered under the pharmacy benefit, as well as drugs covered under the medical benefit (*e.g.*, those administered in physicians' offices), the data sets for those drugs may be administered by

separate entities (such as a PBM and a TPA). As previously noted, self-funded plans would need to collect and combine the sets of data.

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?**

   According to our members, flat text or CSV files are preferred. The state of Minnesota uses Excel files for its prescription drug reporting, though that reporting is very simple and does not generate large files.

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?**

   AHIP recommends that current state law reporting requirements not serve as models for reporting at the federal level. In existing state laws that involve prescription benefit reporting, the parameters for requested data vary significantly, as do the requirements for who reports the information and to whom. Although there are laws that involve reporting of prescription benefit information, none of the existing state laws are sufficiently similar to Section 204 to serve as a true model for implementation. Nevertheless, our members noted the following state requirements and related information that may be of interest for the Departments' general awareness:

   - **California.** The statute for the reporting requirements is at Insurance Code Section 10123.205.
   - **Connecticut.** The statute for the reporting requirements is at Section 38a-479qqq.
   - **Minnesota.** The statute for the reporting requirements is at Sec. 62K.07 MN Statutes (Subdivision 2).
   - **Texas.** The statute for reporting requirements is at Texas Insurance Code 1369.503.
   - **Utah.** The statue for reporting requirements is at Utah Code Section 31A-48-103.
   - **Washington.** Washington State has reporting requirements, and regulators agreed that reporting should occur at the line-of-business level, as reporting at the plan level

is not reasonable/feasible nor would it produce meaningful data.[2]

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?**

   The Departments should consider aligning the definition of rebates with 45 CFR 158.103, which many plans already use for MLR reporting. Creating a separate definition could be confusing for plans as they work to comply with reporting requirements across several statutes.

   As noted previously, plans do not always know when an enrollee utilizes a manufacturer assistance program, such as a coupon card, at the point-of-sale. Further, pharmaceutical manufacturers use coupons and other assistance programs to hide from consumers the true cost of their drugs and game the system, ultimately increasing costs for all plan enrollees in the form of higher premiums. Creating a system that facilitates this gamesmanship undermines the original intent of Section 204.

2. **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?**

   AHIP recommends the Departments define "pharmacy" broadly. In the preamble to the Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards, published in the Federal Register on May 5, 2021, CMS noted that while there are several different types of pharmacies, they generally are all licensed as a pharmacy by the state and dispense medication to the general public. CMS also recognized that data related to specific types of pharmacies is not currently captured by plans and thus cannot be reported.

   Many of our members provide coverage for prescription drugs under two benefits: the

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

pharmacy benefit (where patients receive self-administered medications dispensed from a pharmacy) and the medical benefit (where medical providers administer medications to patients, such as in a physician's office). However, there is variability across plans, and many define the medical and pharmacy benefits differently.

According to some of our members, separating out prescription drug spending from claims under the medical benefit would be a complex process. Further, providers have up to one year following the administration of a drug to file the claim, which would make reporting complete data under Section 204 difficult.

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?**

   AHIP recommends that all definitions of "prescription drug" be consistent across all categories for reporting under Section 204. The definition should indicate that the drugs are non-compound, legacy drugs. Indicators, such as RxCUI or USP-DC would not be appropriate for this type of data.

   We urge the Departments to avoid using a classification system that would result in the "top 50" and "top 25" lists (elements 4, 5, 6, and 9(B)) being populated by multiple entries of a single drug's various formulations and dosages. While AHIP does not have a specific recommendation for a classification system, we note that systems such as National Drug Codes (*e.g.*, NDC-9) and Medispan's Generic Product Identifier (*e.g.*, GPI-8) have varying levels of granularity. The Departments could also provide instructions and mapping for consolidating same-drug codes into a single entry for reporting, though we note that this would create an additional administrative step, creating the need for clear instructions and the time necessary to implement.

4. **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? 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?**

AHIP recommends that all definitions of "prescription drug" be consistent across all categories for reporting under Section 204. The definition should indicate that the drugs are non-compound, legacy drugs. Having varying definitions across the data elements could hinder the Departments from drawing meaningful conclusions, particularly in the "top 25" and "top 50" listings.

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?**

   "Therapeutic class" (element 9(A)) definitions are not intrinsic to claims, but rather come from external data vendors, and our members report using a variety of vendors with differing classification systems. AHIP recommends the Departments create a new, or reference an existing and commonly-used mapping file or cross walk claims codes to facilitate data consistency.

6. **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?**

   Each item under element 7(A) needs a clear definition, ensuring that the categories are discrete from one another and do not overlap. Additional clarification is needed on whether the costs under 7(A) include the cost to both the plan and the beneficiary or just the cost to the plan.

   For element 7(A)(iv), clarity is needed for what items and services should be included in the reporting of "other medical costs". Under the same element, "wellness services" should include only services offered by the plan that generate a claim. Wellness programs and services offered by an employer, including those programs that reward participation with reductions in health coverage premiums, should not be included, as plans do not have access to that information or data.

   If the intent of reporting for element 7 is to compare categories of spending, then disaggregating claims by service is unnecessary and creates additional reporting burden on plans with no clear benefit. AHIP recommends allowing plans to aggregate data at the highest possible levels to reduce reporting burdens and to keep the focus on the high

costs of prescription drugs.

C. Entities That Must Report

1. **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?**

   As noted previously, a plan cannot determine whether or how much an employer contributes to an Individual Coverage HRA (ICHRA) used to purchase coverage in the individual market. That information would need to be collected by the state's exchange and shared with plans. Regardless, the impact of pharmacy trends would be reflected in reporting for the individual market. It would not be feasible to report pharmacy or other information for the ICHRA itself. These plans are merely funding mechanisms for individual coverage, which can be obtained from multiple issuers, and do not include benefits, pharmacy or otherwise, in and of themselves.

2. **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?**

   Many self-funded employer plans contract with a third party to provide administrative services for the plan. Clarity is need about which entity (the plan or the TPA/ASO) is responsible for reporting to the Departments. Additionally, guidance is needed to address reporting responsibilities in situations where multiple third parties administer different parts of a plan. For example, a TPA might administer a plan's medical benefits, while a separate PBM administers the drug benefit. As noted previously, a reporting system that allows that the use of segmentable templates would facilitate reporting the required data and would reduce administrative burden.

3. **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?

As noted previously, data submission templates could be segmentable to allow third-party vendors to submit data to plans more easily.

Generally, if these data reports were collected at the group health plan level, the amount of effort to make the required calculations (such as "top" drug lists) would be massive. The amount of effort would produce little additional value for the Departments or the public. Typically, the most expensive drugs and hospital costs are expensive no matter the specific employer or plan.

The administrative complexity of gathering the required data increases as the level of granularity increases. In other words, reporting at the plan/group level would be significantly more administratively complex than reporting at the market segment level. The Departments should require plans to report by market segment (e.g., individual, small group, large group) or by formulary. Reporting at these higher levels would allow the Departments to detect significant trends with respect to prescription drugs that are increasing consumers' premiums across all market segments.

4. **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?**

Many of AHIP's members contract with PBMs to administer their pharmacy benefit. Generally, PBMs – not the plans – maintain the data related to drugs covered under the benefit. Plans would need to renegotiate contracts with their PBMs to access much of the data elements required to be reported under Section 204.

As noted previously, a reporting system that uses segmentable templates would facilitate

reporting the required data and would reduce administrative burden.

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?**

   There is no consensus on the definition of a "brand" prescription drug. Additional clarity will be needed and the codes for those drugs would need to be identified by the Departments.

   AHIP recommends the Departments use a determination based on the total number of claims. Other alternatives, such as days' supply, would be extremely complicated for plans to determine and report.

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?**

   AHIP recommends the Departments measure increases in plan expenditures by the absolute increase in dollars. One plan noted that Minnesota uses absolute increases in dollars in its reporting. If the intent of collecting this data is to look at which drugs are driving increases in health expenditures, then the increase in dollars will reveal that information.

3. **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?**

   AHIP recommends <u>against</u> using RxCUI for reporting under Section 204. Using RxCUI would be complicated for plans, and the Departments would need to provide mapping to

ensure consistency in matching the data.

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

   [AHIP has no response to this question.]

5. **What considerations are important for plans and issuers in determining the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year? 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? If a price measure is used, which price measure should be used and why?**

   As previously noted, the five-month lapse between the end of the plan year and the required June 1 reporting is too short. Additional time is needed between the end of a plan year and the reporting deadline. This time lapse is necessary to process claims and calculate rebates and to maximize the validity of that data. AHIP recommends the reporting deadline fall no earlier than nine months after the end of a plan year.

   AHIP supports measuring rebates by using the total dollar amount. Our members report that lower levels or alternate measures would increase complexity and reporting burden. Ultimately, the focus should be on aggregate trend analysis, rather than focusing on specific rebates.

6. **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?**

   As noted previously, separating drugs administered through the medical benefit would be complex and burdensome for plans. Additionally, differentiating between settings of care will be difficult for plans. Further, we recommend the following for data element 7:

   - *Hospital costs* refer to services with a uniform billing (UB) claim form
   - *Health care provider and clinical service costs* refer to services with a health

insurance claim form (a "HCFA 1500" or "CMS 1500" form), with:
  - *Primary care* referring to where the provider of a service is a primary care clinician (e.g., general practitioner, family practice, family nurse practitioner) and
  - *Specialty care* referring to all other practitioners
- *Other medical costs, including wellness services* refer to all other claims not included in other categories of data element 7.

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?**

   As noted previously, the Departments should require plans to report by market segment (e.g., individual, small group, large group) or by formulary. Reporting at these higher levels would allow the Departments to detect significant trends with respect to prescription drugs that are increasing consumers' premiums across all market segments.

   Reporting aggregated data at the market segment or formulary level will reduce any privacy concerns with compiling and submitting this information to the Departments. However, if this approach is not adopted, the Departments should establish minimum thresholds for reporting under Section 204 in order to protect the privacy of plan enrollees. For example, groups that have fewer than 20 enrollees should be exempted from the reporting requirements, and instances where reporting the data elements could reveal an individual's identity or health condition should not be reported.

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?**

   [AHIP has no response to this question.]

9. **Should the Departments and OPM collect information on rebates, fees, and any other remuneration at the total level or broken out by relevant subcategories? For example, in the PBM Transparency for Qualified Health Plans (QHPs) data collection, 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?

As with overall reporting, AHIP recommends the Departments aggregate this data at the highest possible level to reduce operational and administrative complexity. Requiring reporting for any set of subcategories would increase the burden on plans.

10. **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?**

    AHIP is not aware of any such payments at this time.

11. **Are there types of rebates and price concessions that are passed directly to the participant, beneficiary, or enrollee? If so, how should they be treated? Should they be included or acknowledged in this data collection?**

    AHIP understands that a small number of plans may have point-of-sale rebate arrangements for a select set of drugs. However, these generally rare arrangements should not be separated from the general data collection under Section 204.

E. Coordination with Other Reporting Requirements

1. **Are there opportunities to remove other reporting requirements applicable to plans and issuers or to leverage or combine those requirements with the reporting requirements under PHS Act section 2799A-10, ERISA section 725, and Code section 9825 to reduce administrative burdens or costs associated with complying with the new requirements? For example, the Departments are aware that there may be some overlap between the data subject to collection under PHS Act section 2799A-10, ERISA section 725, and Code section 9825 and the data subject to collection in the PBM Transparency for QHPs data collection, which requires issuers of QHPs or their PBMs to report prescription drug information to HHS.**

   AHIP agrees that there is potential overlap with the PBM Transparency for QHPs data collection and recommends that the requirement be removed entirely or that the Departments deem compliant QHP issuers who comply with the reporting requirements under Section 204.

F. Public Report and Privacy Protections

1. **In what ways can the Departments and OPM facilitate use of the reports by a variety of interested parties, such as government entities, academics, industry entities, and consumers and their advocates?**

   [AHIP has no response to this question.]

2. **Should OPM issue a public report specifically for FEHB carriers?**

   [AHIP has no response to this question.]

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?**

   As recognized in the statute, many plan years outside of the individual market do not coincide with the calendar year. While many of our members prefer reporting by calendar year, for those plans that do not match the calendar year, their latest end date should be during the preceding calendar year.

   As previously noted, the five-month lapse between the end of the plan year and the required June 1 reporting is too short. Additional time is needed between the end of a plan year and the reporting deadline. This time lapse is necessary to process claims and calculate rebates and to maximize the validity of that data. AHIP recommends the reporting deadline fall no earlier than nine months after the end of a plan year.

4. **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?**

   [AHIP has no response to this question.]

5. **Should the public report include a comparative analysis of prescription drug costs for plans and issuers, relative to costs under Medicare or in other countries?**

[AHIP has no response to this question.]

G. Regulatory Impact Analysis

1. **What benefits, costs, and other impacts do plans, issuers, or other stakeholders anticipate from the reporting requirements of PHS Act section 2799A-10, ERISA section 725, and Code section 9825?**

   AHIP's members believe that the reporting requirements under Section 204 will increase the compliance costs, as they must collect and compile information from disparate sources to align with requirements as defined by the Departments. We are concerned that the Departments create even more granular reporting requirements under Section 204, thus magnifying the increase in administrative burden and compliance costs.

2. **Are there benefits to academics or other researchers? How will consumers benefit?**

   [AHIP has no response to this question.]

3. **What data, research, or other information is available to help quantify the benefits, costs, and other impacts of the reporting requirements? Are there existing data, research, or reporting analogues that could be extrapolated from to predict market impacts?**

   [AHIP has no response to this question.]

4. **What actions could the Departments and OPM take to minimize the compliance costs of the reporting requirements?**

   Create segmentable templates that allow third-party vendors to submit data to plans more easily. Instead of requiring each plan to receive, store, and aggregate the required data, the Departments should create and allow the use of segmentable templates. These templates would allow third-party vendors to submit the required information to plans in a format that can be efficiently incorporated into the plans' report submission.

   Establish a process to identify data that plans cannot obtain or that is exceptionally difficult to obtain and provide limited carve-out exceptions for that data. The Departments should work with plans to identify and provide limited carve-out exceptions for data that cannot be obtained or that is exceptionally difficult to access. While some blanket exceptions are appropriate, other carve-outs may be needed in particular, unique instances. Addressing these narrower circumstances will reduce the overall time and

administrative costs to implement while not reducing the quality or utility of the data collected.

Clarify the level at which plans are expected to report data. The administrative complexity of gathering the required data increases as the level of granularity increases. In other words, reporting at the plan/group level would be significantly more administratively complex than reporting at the market segment level. The Departments should require plans to report by market segment (*e.g.*, individual, small group, large group) or by formulary. Reporting at these higher levels would allow the Departments to detect significant trends with respect to prescription drugs that are increasing consumers' premiums across all market segments. Additionally, within the data elements, the Departments should require reporting at the highest possible levels and avoid requiring reporting on subcategories.

5. **Operationally, which types of employees will be necessary to ensure compliance with the reporting requirements? Will staff specialized in medical billing coding be needed for the purpose of reporting?**

   According to our members, the following additional types of staff would likely be necessary:
   - Subject matter experts in impacted business areas,
   - Data analysts with a broad array of analytics expertise, and
   - Reporting developers.

6. **Will new or additional technology be needed for the collection, maintenance, or storage of the data to be reported?**

   Most health plans do not maintain all the data outlined in Section 204 of the No Surprises Act on their own servers. Many use third-party vendors, such as PBMs or TPAs, to manage a portion of covered benefits. These third-party vendors maintain their own records and data relating to these benefits. Requiring each health plan to report all the data elements listed in Section 204 would require plans to build and maintain new data storage infrastructure, aggregate data from its vendors, and then build and submit the reports.

7. **Will there be coordination costs or benefits from simultaneously complying with state regulations that require the reporting of medical services costs or prescription drug costs?**

   AHIP believes that aligning and streamlining the Section 204 requirements with other state reporting requirements could reduce compliance costs. However, without a better

understanding of what the Departments will require of plans under Section 204, the extent to which burden and costs would be reduced is unclear.

8. **Would greater alignment with other Federal reporting requirements reduce associated compliance costs, and if so, how?**

   AHIP believes that aligning and streamlining the Section 204 requirements with other federal reporting requirements could reduce compliance costs. However, without a better understanding of what the Departments will require of plans under Section 204, the extent to which burden and costs would be reduced is unclear.

Appendix: Required data elements under Section 204 of the No Surprises Act

(1) The beginning and end dates of the plan year.

(2) The number of enrollees.

(3) Each State in which the plan or coverage is offered.

(4) The 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each such drug.

(5) The 50 most costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug.

(6) The 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year.

(7) Total spending on health care services by such group health plan or health insurance coverage, broken down by—

(A) the type of costs, including—

(i) hospital costs;

(ii) health care provider and clinical service costs, for primary care and specialty care separately;

(iii) costs for prescription drugs; and

(iv) other medical costs, including wellness services; and

(B) spending on prescription drugs by—

(i) the health plan or coverage; and

(ii) the enrollees.

(8) The average monthly premium—

(A) paid by employers on behalf of enrollees, as applicable; and

(B) paid by enrollees.

(9) Any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, with respect to prescription drugs prescribed to enrollees in the plan or coverage, including—

(A) the amounts so paid for each therapeutic class of drugs; and

(B) the amounts so paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year.

(10) Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration described in paragraph (9).