July 23, 2021

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RE: CMS-9905-NC

Dear Mr. Rettig, Mr. Khawar, and Ms. LaSure:

I am writing on behalf of the National Association of Health Underwriters (NAHU), a professional association representing over 100,000 licensed health insurance agents, brokers, general agents, consultants and employee benefits specialists. We are pleased to have the opportunity to respond to the "Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs" published in the *Federal Register* on June 23, 2021.

The members of NAHU work daily to help millions of individuals and employers of all sizes purchase, administer and utilize health insurance coverage. Our expertise lies in the technicalities of health-plan administration and the real-world challenges employers face therein. As such, our membership is very interested in the impact the new data-reporting requirements will have on group health plan sponsors. To develop our responses to the questions posed in your information request, NAHU assembled a representative group of members with direct experience in both group plan administration and health benefit plan compliance. Their thoughts on the issues posed by the implementation of these new reporting requirements are presented below.

A. General Implementation Concerns

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

The new reporting requirements will present significant challenges for all employers that sponsor group health insurance plans. We will provide additional detail about our compliance concerns in our answers to other questions, but the primary issues NAHU members see with meeting these statutory reporting obligations are:

- Most of the information to be disclosed is not available to a plan sponsor directly.
- Even though employers appear to bear full compliance liability, almost all data needs to be generated by vendors and then compiled by the plan.
- The compliance deadline is approaching rapidly, but there is no implementation guidance to date.
  How this data reporting could be completed without compromising the privacy of plan participants.

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?

Unfortunately, employer group health plan sponsors do not currently have access to most of the types of data that will need to be disclosed. In fact, for smaller employers with fully insured groups, this type of data is almost never disclosed to the group plan sponsor, even in de-identified form, because issuers claim that there is no valid business reason currently for fully insured plans to have this information and disclosing it would raise HIPAA privacy compliance issues.

Data will need to flow from both the pharmacy benefits manager(PBM) and the issuer or third-party claims administrators. Traditional self-funded groups may have access to some of the medical claims data needed (although this will vary by both the practices of their claims administrator and the current desires of the employer groups). However, carriers that offer fully-insured benefits do not make this much claims data available to employers of any size, and fully-insured group plans with less than 100 lives rarely get any, unless required by state law. In addition, in many benefits markets, it is common for employers of all sizes to opt for

a level-funded plan, which is technically a self-funded product, but operates much like a fully-insured group. These plans also typically get much less medical claims data than a traditional self-funded group.. PBMs already do not release all the types of data needed to employer plan sponsors, regardless of the group's size or funding structure. The new requirements would add even more data to the information that would need to be obtained.

The result of this is that PBMs, carriers and claims administrators will need to change established practices and release what they have historically viewed as contract-protected, proprietary and cost-sensitive data. Unless the Departments take action to ensure that vendors provide timely and accurate data to plan sponsors, they will be completely beholden to their insurance carriers, TPAs and PBMs without any assurance that they will receive the needed information in time to compile it and complete the reporting process on a timely basis. If vendors do provide the information needed, plan sponsors will still need to compile medical claims information, prescription drug data, plan details and premium information from multiple sources. They also will need to ensure that data is accurate and submitted appropriately, even though we do nt know what the submission process will be at present. In the best of circumstances, this work will probably need to be done over the course of many weeks.

In any case, plan sponsors will need time to develop processes to ensure the appropriate information is compiled and formatted according to any forthcoming submission guidance. In addition, compliance vendors need your Departments to provide system requirements and reporting formats as soon as possible if they are going to develop products to assist the employer community. We anticipate that many employers will utilize a vendor to complete and transmit their reports, just as they do for Form 5500 Reporting and IRC 6055 and 6056 reporting.

Given the volume of information that employer group plan sponsors need to begin the compliance process, the lack of availability of the data to plan sponsors currently, the need for implementation guidance, and the need for the creation of a disclosure submission infrastructure, NAHU members request an enforcement delay of at least one year.

A. General Implementation Concerns

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?

Yes, there are significant differences between each of the types of reporting entities. We have attempted to highlight some of the unique concerns for each below.

Fully Insured Group Plans vs. Self-Funded Plans
All group health plan sponsors will struggle more with this reporting requirement because they will need to gather data that they do not have access to currently from multiple sources. In theory, a fully insured plan issuer could compile the medical plan claims data relatively easily and disclose it to group clients in ready format, but this is not a common market practice today. Currently, fully insured and level-funded service agreements with issuers do not address the disclosure of such data, and modifications will need to be made for the coming plan years. Given that these agreements are largely contracts of adhesion, particularly with smaller employer groups, the employers will be reliant on how, when and what their issuer will be willing to share.

A self-funded plan will need to ask its TPAs to provide the medical claims data and will likely need to alter existing service agreements with the TPA to ensure that they do so. While these contracts are generally more flexible, TPAs are already taking steps to shield themselves from liability relative to this data reporting.

Both fully insured and self-funded plans will struggle with the prescription drug claims data gathering process and will be at the mercy of their PBM to provide data. The prescription data in the market today is much more opaque than what is available to certain self-funded groups on the medical claims front. It does not appear that most PBMs are eager to release the needed data. Since there is some common ownership between select issuers and PBMs, those entities may do better with data sharing. However, even an issuer that shares common ownership with a PBM may struggle with data gathering since these entities operate on a separate basis currently.

Level-funded plans often operate in a similar fashion to the fully insured small employer market and in terms of data, somewhere in the middle between traditional self-funded plans and groups with a fully insured group health plan contract. In general, these plans have far less access to claims currently than a traditional self-funded plan.

Small-Group vs. Large-Group Plans
Small employers will find this requirement extremely difficult to meet, but it will be a struggle for larger employers too. There are over 2.5 million private employer-sponsored plans in existence in the United States, and most of these are fully insured group plans that incur less than 100 lives. These entities currently do not

typically have access to any tier one or tier two medical claims data and it is unclear how they will compel their insurance carriers and PBMs to release the data needed for reporting.

Partially Self-Insured vs. Fully Self-Funded

A plan's use of stop-loss insurance does not have an impact on claims-data access when it comes to self-funded plans. Instead, the variables are the vendor partners utilized by the plan and the employers themselves. Some employers contract with their TPA and other partners to provide specific data, and others do not. The smaller the employer is, in general, the more difficult it is to obtain granular data as opposed to summarized loss information. As a result, different types of vendors cater to the various types of employer plan sponsor needs. Some provide more analysis of claims data and others provided summarized data only to lower administrative costs on the plans they service.

Multi-Employer Plans Arrangements vs. Single Employer Groups

A challenge unique to all kinds of multi-employer arrangements will be: Who is the plan sponsor and which entity will need to do the reporting? Or will each employer need to report on an entity basis? This is a common source of confusion with both Form 5500 disclosures and IRC 6055 and 6056 reporting, and we anticipate that it will be the same for the new disclosure requirements. Clear guidance and direction to address this concern is needed. Also, it is important to keep in mind that a multi-employer plan is not always a neat arrangement where there is a logical responsible party who can take charge of an overall filing. . While requiring entities to report on a distinct basis may be more burdensome for the employers, it would create simple accountability boundaries. Also, given the sensitivity of the data to be disclosed, it would be helpful if the Departments addressed privacy concerns and the need to insulate data between the different employers involved.

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?

Most employers will likely use professional compliance vendors that have significant system capabilities for their report completion and transmission, just as they do for Forms 5500 and IRC 6055 and 6056 reporting and disclosures. However, there will also be employers that do not, especially the smallest of business entities. Whatever file formats and submission methodologies the Departments develop, there should be a method for smaller employers to easily self-file.

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?

While there are reporting requirements for fully insured health insurance issuers that might overlap, there are no state-reporting requirement direct equivalents for employer group health plan sponsors.

Employers have recently needed to report group health plan information to certain states to help enforce the state's individual health insurance mandate. These states do not make paper-filing options available and require data submissions to be in file formats that are not typically used by employers. As such, virtually all employers struggle to submit data and need to use vendors for submissions. Some of these states have a self-fill PDF option for small employers, but some employers find this system hard to use and some states do not make this system available until very close to the submission deadline. An easy-to-use self-file option for small employers would be appreciated. Allowing for paper filings would also help smaller employers comply.

B. Definitions

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?

NAHU members believe that the need for clear rules and instructions on what information will be required, as well as protections for group plan sponsors who have tried but cannot get adequate or any data from their vendor partners, is more important than these definitions.

Some involved vendors will not want to disclose fee data to group plan sponsors, and they will have a very strong business reasons behind their reluctance. Will there be any consequences for vendors that refuse to disclose fee data? At minimum, NAHU members believe the Departments should impose a good-faith compliance standard for group plan sponsors, as they will have no way to compel vendors to cooperate.

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?

Pharmacy data will come from different sources. In-patient prescriptions will be part of the plan's medical claims data, whereas retail, mail-order and specialty drug claims data will come from the PBM and, in some cases, a separate specialty pharmacy. NAHU members suggest that the Departments define pharmacy claims on a site-of-claims basis and limit it to retail, mail-order and specialty drug claims. Such a differentiation will both simplify the data-collection process and avoid any duplication between medical and prescription drug claims data.

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 nine-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?

NAHU members support the use of consistent definitions.

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?

These definitions are determined by the PBMs and may be proprietary to them. This is not something an employer plan sponsor would be able to control. All classifications used will stem from each PBM.

What considerations should the Departments and OPM take into account in defining "healthcare 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?

Employer plan sponsors will be bound by how the data is given to them by their claims payer(s) and will have no way to control if they will provide it by DRG or CPT code or another means. Employers should have flexibility to use and submit the healthcare services claims data as presented to them by their claims payers.

C. Entities That Must Report

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

NAHU members have a significant concern about the privacy issues associated with this level of data reporting. As already noted in responses to other questions, the degree of claims-related data addressed by this requirement is not typically made available to group health plan sponsors. Even if data is de-identified, issuers have not typically found that plan sponsors have a legitimate plan operational need for this data, particularly at the small-group level, and have historically refused to provide it, citing HIPAA privacy concerns. Given the granularity of the data to be reported by each group, it is hard to imagine how PHI disclosures could be avoided.

In addition, employment discrimination concerns could apply. In a smaller group, plan participants may not take more than 50 prescription drugs total. This requirement includes, among other things, the disclosure of: (1) the 50 drugs prescribed most frequently along with the total number of prescriptions filled for each; (2) the 50 drugs the plan spent the most on and the amount spent for each; and (3) the 50 drugs that increased the most in cost relative to the prior plan year and the change in expenditure for each drug relative to the prior plan year. With this type of data in hand, it would be natural for employers to speculate or even accurately guess the prescriptions taken by various employees and their dependents, provoking significant privacy and human resources concerns.

Additionally, NAHU members believe that any regulations should limit disclosures to the overall group health plan, rather than to individual plan components. For example, even though integrated Health Reimbursement Arrangements, FSAs and ICHRAs that only reimburse individual coverage premiums are all group health insurance arrangements, they all are coupled with other plans and therefore should not need to do distinct reporting. In addition, HSAs and QSEHRAs are not group health plans, so employers would not have the data needed to report.

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?

Yes, our membership expects third-party administrators and PBMs will be asked to provide data to group plan sponsors, and that the plans will either contract with their TPA to compile the data and transmit it (with the TPA typically contracting this out to a third-party vendor) or the employer plan sponsor will aggregate data

and then rely on a third-party compliance vendor for completion and submission. This is the typical process used for both Form 5500 and IRC 6055 and 6056 reporting, and we expect that vendor reliance will be similar for this requirement.

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?

Prescription drug data is going to come from different sources. In-patient prescriptions will be part of the plan's medical claims data, whereas retail, mail-order and specialty drug claims data will come from the PBM and, in some cases, a separate specialty pharmacy. NAHU members suggest that the Departments define pharmacy claims on a site-of-claims basis and limit it to retail, mail-order and specialty drug claims. Such a differentiation will both simplify the data-collection process and avoid any duplication between medical and prescription drug claims data.

What role, if any, will 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 healthcare 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?

PBMs will play a critical role in providing prescription drug claims information to both employer plan sponsors and health insurance issuers. Without the direct cooperation of the PBM, it will be impossible for a group health plan sponsor to gather the data necessary to fulfill this compliance obligation.

If PBMs were to agree to do the reporting directly for an employer, it would certainly simplify matters for the group plan sponsor. One consideration would be if the PBM would need to provide group-specific data, or if aggregate data would be permitted. Depending on how the reporting data was prepared (aggregate or group-specific) and then disclosed to the plan sponsor it could also eliminate some of the privacy concerns created by giving employers access to this level of prescription drug claim details.

PBMs would not be able to compile the required medical claim and plan-specific details required for complete reporting. If that will be required, then the employer plan sponsor would still need to coordinate reporting elements amongst third parities and provide some of their own data.

Other concerns related to the possibility of segmented reporting by claims-paying plan vendors (namely the PBM and the health insurance issuer or TPA) are cost, quality and liability. There is no doubt that if PBMs, issuers and TPAs are permitted or required to do segmented reporting on behalf of a plan, there will be associated costs passed on to the employer and ultimately plan participants, particularly if they need to provide group-specific rather than aggregated data. How much these costs will be, and if plan sponsors will have any control of this spend, is a question that warrants significant consideration.

In addition, if the relevant vendors did the reporting for plan sponsors, there would need to be protections for employers relative to the timeliness and quality of the data provided by the vendors. Given that it is impossible for employer plan sponsors to compile this data independently, there is no good way for a plan sponsor to perform quality control. However, employer plan sponsors are ultimately liable for the reporting, so a safe harbor and liability shield for them would be critical. Such a safe harbor would need to come from your Departments as employer plan sponsors will not be in the position to obtain adequate indemnification via vendor contracts. In fact, the opposite will likely be true, in that PBMs and other vendors will be extremely likely to build liability protections for themselves into standard health plan contracts.

D. Information Required to Be Reported

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

The number of days of supply would be the most accurate measure. It is also data that a PBM should be able to provide to a plan sponsor.

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?

Group health plan sponsors will ultimately be the most interested in the overall increase in price measured in dollars per unit. This is also data that a PBM should be able to provide to a plan. However, NAHU members are not sure what the Departments want to do with the data you intend to collect. We believe the ultimate purpose of the data-collection effort should drive your collection request. Our membership also believes that a clear explanation of the purpose of the data-collection effort, as well as thorough directions about how the data should be collected and presented by plan sponsors, will be critical to a good data yield and adequate compliance.

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?

Employer group plan sponsors will be entirely dependent on their PBMs for reporting data, so all requirements should be based on what they can and will provide.

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?

Employer group plan sponsors will be entirely dependent on their PBMs for reporting data, so all requirements should be based on what they can and will provide.

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?

Employer group plan sponsors will be entirely dependent on their PBMs for reporting data, so all requirements should be based on what they can and will provide. However, NAHU members note that the percentage of unit price and total amount measures when evaluated on a standalone basis are insufficient data sources. Both measures would be helpful if viewed side by side. However, if the Departments would like to access either type of data, or both types, you will need to compel disclosure by the PBMs since we believe they may be reluctant unwilling to disclose it to plan sponsors otherwise.

PHS Act section 2799A-10, ERISA section 725 and Code section 9825 require plans and issuers to report total spending on healthcare services separately for hospital costs, healthcare 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?

NAHU members believe tracking contracted and non-contracted payment for each would be appropriate cost elements to track. For prescription-drug data, NAHU members feel it would be far more efficient for all involved if the data collection mandated a separation of prescription-drug costs provided through the plan's medical benefit (which will generally be prescriptions given by a provider in a healthcare facility) and prescriptions filled through a retail, mail-order or specialty pharmacy.

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?

If the Departments are considering making modifications to the data-collection requirements and enforcement mechanisms by different population segments, then there would be a benefit to collecting data separately by those groupings. For example, the amount of data group plan sponsors will have access to depends on the size and funding mechanism of the employer group, with larger, self-funded plans having the ability to access more (although not all) of the data required.

If the Departments are not planning to issue reporting modifications to meet the needs of the various reporting entities, then NAHU members do not see the benefit of separate data-collection efforts.

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?

Most group plan sponsors do not have access to this data currently. Small groups, fully insured groups of any size, many level-funded groups of all sizes, and self-funded groups that do not work with a particularly transparent PBM will not have access to this data. Therefore, very few perform any type of analyses.

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?

Very few group plan sponsors have access to any of this data now, and those that have access to some will not have complete access to all of the data elements described. Employer group plan sponsors will be entirely dependent on their PBMs for reporting data, so all requirements should be based on what they can and will provide. Keeping data categories as similar as possible so that additional work is not required would be hugely beneficial to group plan sponsors.

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?

There are rebates and price concessions that are passed directly to plan participants, but they would be difficult, if not impossible, to track accurately since the full price of the drug is what is billed back to the plan. If an individual pays less because of a coupon, manufacturer rebate or other discount, an employer group plan sponsor or issuer would not know. Additionally, there are services like independent PBMs, such as GoodRX, that work outside of the plan and are rarely submitted as an out-of-network claim. As such, NAHU members do not recommend the inclusion of such data in any collection and reporting effort.

E. Coordination with Other Reporting Requirements

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.

For group health plan sponsors, there are no other directly comparable reporting requirements. There will be some overlap for group health plans required to submit Form 5500, but that is a small fraction of the approximately 2.3 million group health insurance plans subject to ERISA. In addition, some of the new group health plan transparency requirements will overlap, but it is not clear to NAHU members how those requirements and this one could replace one another.

For group health insurance issuers offering fully insured coverage subject to state insurance regulation, there are some state-level reporting requirements that could overlap. However, this reporting obligation will not replace those requirements, and could actually result in an increased administrative burden for these issuers.

F. Public Report and Privacy Protections

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?

For employer-sponsored plans, a plan-year collection window, with data reporting required within a certain point following the conclusion of the plan year, similar to the Form 5500 reporting window, would be the easiest and most efficient method. However, this method would conflict with the statutory date of June 1 of each year.

Requiring all plans to utilize the calendar year for data collection would be mm-calendar-year plans, especially if the plan changed its funding structure, design, issuer or PBM with its new plan year.

A potential solution would be to stagger group health plan reporting based on plan year using two fixed dates, just as is done now with PCORI fee payment. However, instead of using October 1 and July 31 like the PCORI fee, the Departments could use the statutory dates of June 1 and January 1. For the first year, plans or policies that ended in the months of July to December of that year would be required to report their past year's claims data by June 1 of the following year. The next year, all plans would report, but those plans whose policy or plan years ended in the later half of the year would report their second year of data, and those with plan or policy years that end between January and June would report their first year of data.

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?

We are not aware of anything like what is envisioned by these requirements that encompass fully insured and self-funded group health plan data. Some states require carrier-specific fully insured data collection, but those requirements do not apply to employer-sponsored group health plans.

G. Regulatory Impact Analysis

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?

For employer-sponsored plans, the administrative burdens, costs and HIPAA privacy and ERISA compliance risks posed by these new reporting requirements cannot be understated. There are approximately 2.3 million group health insurance plans in the United States that are subject ERISA that will be bound by these new reporting requirements. The vast majority of these plans are sponsored by small employers.

NAHU members universally report that none of their employer clients had any idea about this looming obligation until their NAHU member health insurance advisor alerted them. Now that they know, these employers have no idea how they will get their vendor partners to assist them and meet their obligations, and these entities only represent a fraction of those who will need to comply.

Our membership is worried that the combined lack of knowledge about these new obligations, the limited availability of data to plan sponsors, and absolute need for vendor assistance to fulfill the requirements sets plan sponsors up for failure. An employer's overall ability to comply, as well as the quality of the information given and the timeliness of the data, will be dependent on multiple third parties. There will be no means available for plan fiduciaries to exert quality control. All of these factors create an ERISA risk, so it is imperative that the Departments act to educate and assist plan sponsors with these new responsibilities, as well as provide them with compliance relief.

While plans do have contracts with issuers, PBMs and third-party administrators, these agreements are largely contracts of adhesion. There is little practical hope that employers will be able to compel cooperation from their vendors. Furthermore, employer plan sponsors are not in the position to seek indemnification from those that will need to assist them in these efforts. In fact, the vendors are far more likely to impose clear liability restrictions on their group plan clients to protect themselves than the other way around.

NAHU members also have significant concerns about the privacy liability and discrimination risks posed by these new requirements. As envisioned by the statute, group health plan sponsors will need to have access to very detailed claims data. Particularly for smaller groups, it will be hard to truly de-identify this information. The inability to truly de-identify this type of data is why health insurance issuers routinely refuse to give claims information to groups of less than 100 individuals. The new requirements create a plan operations reason for smaller employers to get the data according to the HIPAA privacy rules, but these smaller entities are in no way prepared for the HIPAA compliance obligations that come with access to this information. In addition, NAHU members are concerned about both actual potential employment discrimination that could stem from

the release of such granular data to group plan sponsors, as well as the potential new risk of employer discrimination charges from disgruntled employees.

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

While there is no way to fully minimize the cost impact and administrative burdens these new requirements will place on all employers who sponsor group health insurance for their employees and their dependents, the following actions would be a helpful start:

- The development of clear implementation rules that recognize that group health plan sponsors do not have access to all needed data currently and will need to rely on third parties to compile accurate data and submit it appropriately and in a timely manner.
- Recognition that the vast majority of group health plans that will be subject to these requirements are sponsored by small businesses with limited financial and human resources at their disposal for compliance purposes.
- Consideration of a long-standing enforcement delay or exemption for small-group health plan sponsors, such as the Form 5500 exemption for group health plans with less than 100 participants on the first day of the plan year.
- Consideration of different reporting standards for group health plans that offer fully insured coverage as opposed to self-funded coverage.
- Crafting federal rules in such a way that compel vendors to assist group health plan sponsors with their data-collection and reporting responsibilities.
- Allowing entities like third-party administrators and health insurance issuers to assist with reporting by providing aggregated data to plan sponsors, similar to what was allowed by the recent surprise-billing IFR to implement the qualified payment amount requirements for self-funded plans.
- An enforcement delay of at least one year after the publication of final implementation rules.
- An enforcement safe harbor for group health plan sponsors for at least the first year of compliance.
- A reliable good-faith compliance standard for group health plan sponsors that does not renew on an annual basis, but instead is clearly established for the foreseeable future.
- Prioritization by the Departments to educate plan sponsors about the new disclosure requirements.

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?

From an employer group health plan perspective, the employees charged with performing human resources and benefit-administration functions will assume responsibility for this reporting, if the employer has any

employees in this role. Many small businesses do not have employees available to perform functions like this type of reporting. NAHU members anticipate that many employer plan sponsors will lean on their health insurance agent or broker to assist with compliance, and most employers will likely outsource the actual report compilation and submission, just as many do with Form 5500 filing and ACA reporting today. NAHU members also note that any employers that are already aware of these looming requirements, no matter what their size or group plan funding structure, are hoping that their health insurance carriers and third-party administrators will provide ready assistance in completing this reporting. However, based on our membership's observation of the industry's response to these new requirements and other requirements that stem from the No Surprises Act, we are not confident that many carriers, TPAs and PBMs will be able and/or willing to provide the kind of ready assistance that employers are hoping for, particularly without imposing a significant cost on plan sponsors.

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

Yes, there will be new technology needs associated with this reporting, which is one of the reasons why vendor assistance will be critical and employers are likely to outsource reporting compilation and submission to third parties. Additionally, the development of technology to submit and compile these reports could be complicated and pricy, depending on federal receipt specifications that still need to be developed.

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?

No, NAHU members do not believe that state-level reporting will be easy or cost-efficient to coordinate, since there will be multiple sets of reporting rules to follow. Also, state-level reporting only applies to health insurance issuers. Employer group plan sponsors are not subject to state-level reporting requirements so there is no opportunity for efficiency.

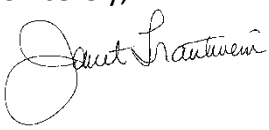
Would greater alignment with other federal reporting requirements reduce associated compliance costs and, if so, how?

Greater alignment with the Form 5500 filing requirements would probably yield the greatest operational and cost efficiencies. The type of vendors most likely to want to branch into providing this type of reporting assistance to group health plan sponsors are those firms that are already providing Form 5500 filing assistance to group plans. For these firms, alignment in the submission process would lead to technological savings and efficiencies. Additionally, such alignment would benefit the group plan sponsors that are already subject to the Form 5500 filing requirements. However, it is important to keep in mind that the overwhelming majority

of group plan sponsors that could be required to fulfill this new compliance obligation are exempt from the Form 5500 requirement today.

Thank you for the opportunity to provide input on the new reporting requirement for group health plan sponsors established by PHS Act section 2799- 10, ERISA section 725 and the Internal Revenue Code section 9825. If you have any questions about our comments or need more information, please do not hesitate to contact me at (202) 595-0639 or jtrautwein@nahu.org.

Sincerely,



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