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RE: CMS-9905-NC

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Thank you for the opportunity to provide input to help you achieve your objectives regarding the Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs.

OneDigital is the nation's leading health, retirement/wealth, and HR advisory firm focused on empowering business growth for employers of all sizes and has consistently led as a workplace ally for over 20 years. Headquartered in Atlanta, OneDigital's more than 100 offices and 2,400+ business strategists serve the needs of over 85,000 employers across the nation.

Our service staff and large team of insurance professionals, licensed throughout all 50 states, assist our small group and large group clients with education, consultation, plan design and selection, compliance with federal and state laws and regulation, and implementation of group health insurance and employee benefits solutions. This response focuses primarily on our expertise and experience with pharmacy and prescription drugs as a component of employer-sponsored health plans and their dynamics within the broader pharmacy and prescription drug marketplace.

A. General Implementation Concerns

1. *What, if any, challenges do plans and issuers anticipate facing in meeting the statutory reporting obligations?*

Plan administrators of employer-sponsored plans are not one of the parties that determine the procurement, pricing, and delivery of prescription drugs. They rarely have access to setting or negotiating discount arrangements or have bargaining power to enter into special arrangements with pharmacies or

manufacturers.

Employers are completely reliant on third parties/pharmacy benefit managers (PBM) to design, implement, and manage the prescription drug provisions of their benefits plan. As a result, all data known regarding utilization, pricing, discounts, rebates, etc. originates from the PBM. Employers could comply with most of the reporting provisions regarding the actual plan of benefits but would need to rely solely on the PBM for the remainder of the reporting requirements of PHS Act section 2799A-10, ERISA section 725, and Code section 9825. Of further note, PBMs typically do not include the level of detail required by these reporting rules in the rebate and disclosure information provided to employer-sponsored plans. Among the reasons for the lack of details are contractual provisions between the PBM, manufacturers, pharmacies, and other third parties that restrict the disclosure of competitive and confidential information.

Rebate information is very limited. Often it is just a dollar amount with little back-up information. In addition, the information is often proprietary and governed by contract between the parties. Employers generally only receive a fraction of the rebates. There are also "rebate aggregators" and those are often owned by pharmacies or pharmacy plans. These entities often take portions of the overall rebate prior to the plan's involvement. In this case, the employer-sponsored plan would then underreport since they would have no knowledge of the gross amount of the rebate.

Further, it is difficult to tell how much of the total rebate is related to a specific drug and its usage. The Consolidated Appropriations Act, *Sec. 201. Increasing Transparency by Removing Gag Clauses on Price and Quality Information,* rightly prohibits plans from entering into agreements with providers, networks, TPAs and other service providers from entering into agreements that prevent the plan from providing or sharing certain information. This clause should extend to the aggregators and all the contracts between all parties. This rule can encounter issues under contractual confines and the right to protect trade secrets. Many contracts with smaller self-funded employers involve third parties.

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

We believe PBMs do have the capability.

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?*

Less than 5% of employer-sponsored health plans will have access to all the information. Reliance on third parties and PBMs to provide the information back to the health plan will result in extended timelines. Requirements and deadlines to gather final information will be contingent on the PBM's and third parties' requirement to disclose the information to the health plans.

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?*

Group health plans are consumers and have no control over these elements other than negotiating their contract provisions. Small group premium and claim expenses are aggregated and, as such, are allocated by credibility considerations – any discounts or rebates will be applied to the pool rather than individual employer accounts, etc. – based on overall experience. Therefore, individual employer health plan sponsors in the small group market will not be able to provide any meaningful data associated with their specific plan.

It will be difficult for fully-insured carriers to produce the same data elements and information since they do not have access to the same information or the same sources. Additionally, there are different players in each market involved in the process from manufacturing to retail.

Separate reporting of fully-insured vs self-funded, even for entities who handle both, will help analyze factors that affect each market differently, e.g. state laws and regulations, pooling, operational elements, type of discount arrangements and volume.

5. *What data reporting tools and systems should the Departments and OPM consider when deciding on the format of the data collection?*

Pre-defined formats, with clear definitions for data elements, are necessary to ensure validity of data. A uniform process and entry are key. A centralized reporting portal, equipped to accept data elements, will be necessary to ensure consistency.

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?*

We recognize the growing number of states that now, or will soon, require specific licensure, data, reporting, disclosures and notices for PBMs. See TN HB1398 and GA SB 313 Law Text.

B. Definitions

Our recommendations regarding the establishment of definitions include the following:

1) "Rebates", "fees", and "any other remuneration"
    a. All "pharma-based revenues" must be included regardless of naming convention, i.e. rebate vs coupon vs discount. Currently, these are not uniform and specific names may preclude the inclusion of some of these revenues. Therefore, use of a generic term, like "revenues" with examples may result in more inclusive results.
    b. Copay assistance cards - cards where the member does not pay for the medication, should grant the ability to put that money against the plan cost rather than the out-of-pocket for the members since the member does not bear the cost. This allows for members on specialty to have an unfair advantage in using the coupon to meet their deductible or OOP obligations potentially allows for free healthcare.

2) "Pharmacy" –
    a. All pharmacies bill in a standard format so they should have uniform requirements and do not require any special handling.
    b. The cost of doing business is much higher for a mail or specialty where shipping, handling, and other aspects increase the cost to deliver so those payments and contracts should reflect that variance.

3) "Prescription drug" - We recommend using the NDC and removing OTC products since each plan defines OTC differently. Therefore, its inclusion would skew results and findings.

4) "Prescription drug" for reporting purposes – Currently, rebate details are not applied at the drug level with the majority of employers so greater clarity needs to exist to be able to comply with this requirement. Subsequently, reporting should then consider at the GPI level as the same drug in 2 package types and NDC would show up potentially different spots on that list.

5) "Therapeutic class" – This is dependent on the PBM reporting systems. It is not standardized though the overlap is reasonable.

6) "Health care services" – It is unclear whether any health plan gathers and tracks information accurately and with any regularity, related to a therapeutic class, DRG, or underlying CPT code. Pharmacy dispensed as part of a provider facility, e.g. inpatient hospital or ambulatory surgical

facility, may be the exception. Outside of these providers, this information would seem to reside with the pharmacies where prescription and diagnosis are paired.

7) One additional challenge of note is the fact that some pharmacy expenses run through the health plan and some run through the pharmacy plan. This may challenge the reporting results. Costs may look very different between health plans and pharmacies.

C. Entities That Must Report

As detailed in the responses above, few health plans have access to the level of detail required under these reporting regulations. Reliance would be on the third party or PBM to provide the information required. PBMs are the entities that contain the complete set of data elements required.

It is our recommendation that PBMs provide reporting in a standard format for all health plans. The most direct and expeditious method would be for PBMs to report the information directly to the Departments and provide disclosure of the information to each health plan. The alternative would be for PBMs to provide information uniformly to all health plans, which would add to the reporting timeline.

D. Information Required To Be Reported

- Determining drugs most frequently dispensed - Top 50 brands by total ingredient cost as the plan cost will vary based on plan design and member cost sharing.
- Determining drugs by highest volume – The highest rebates by drug at the GPI level possibly. This will be heavily weighted on more expensive drugs especially on specialty. Various types of drugs are significant cost drivers and if coupled with other drugs may skew results. For that matter, we recommend that biologics be listed separately.
- Determining drugs by greatest increase in plan expenditure - PBM support would be needed for most employers but the increase should be at total drug cost level. There will always be outlier claims where the patient is new to therapy or new to that plan creating increase flags. Orphan drug expenditures may further skew this data set.

E. Coordination with Other Reporting Requirements

To the extent applicable, based on which entities must report, consolidation with other reporting obligations makes sense. Limiting the number of reporting events will help to promote efficiency and keep costs lower since this new element would then only provide an incremental cost rather than another full vendor engagement cost.

F. Public Report and Privacy Protections

We believe a meaningful public report will compare the following pricing information per drug:

- Manufacturer (represented as a range);
- Medicare;
- Private plans; and
- Other countries

G. Regulatory Impact Analysis

There is a cost to any entity required to build and provide additional information. From an employer perspective, health plan reporting, including Employer Shared Responsibility reporting under the ACA §6055 and §6056, Form 5500, etc. each add expense to the health plan since it must employee vendors and

partners with expertise, technology, and manpower to fulfill the requirements. The same can be said for requirements to health insurance issuers and the PBMs.

Each new layer of administration results in additional costs that the entities end up passing, directly or indirectly, back to the plan sponsor and plan participant in the form of higher cost sharing in the purchase of the coverage or cost-share on claims incurred, e.g. deductible, copayments, and coinsurance.

The most expensive and inefficient method is to require the reporting from the employer-sponsored health plan since they do not currently have access to most of the data. The best method of limiting the overall cost of the reporting is to limit reporting to only those entities who have the data readily available, namely, PBMs.

In closing, we feel it may be beneficial to work with PBMs to understand the data they have and then determine what information is missing from that data set. The next step could be to work with industry representatives on ways to procure the remaining data.

OneDigital values the opportunity to provide this feedback and offers its services to you as you work through the comments. Let us know if we can be of any assistance to you in this process. Please feel free to contact me at (770) 296- 7254 or abechtold@onedigital.com.

Sincerely,

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