July 23, 2021

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue NW, Room N-5653
Washington, DC 20210

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

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Office of Personnel Management, the Internal Revenue Service of the Department of the Treasury, the Employee Benefits Security Administration of the Department of Labor, and the Centers for Medicare & Medicaid Services of the Department of Health and Human Services. NCPA recognizes the importance of ensuring consistent reporting on pharmacy benefits and prescription drug costs by health plans and pharmacy benefit managers (PBMs).

NCPA represents America's community pharmacists, including 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $74 billion healthcare marketplace, employ 250,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of community and long-term care pharmacies.

NCPA is encouraged by the direction of Congressional action to interject more publicly available transparency into pharmacy benefits and drug costs. NCPA will provide responses to selected questions from the Request for Information (RFI) which we feel we have the most direct knowledge of and on which we can provide information.

General Implementation Concerns

Question 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?

NCPA responds to the agencies that pharmacy benefit managers (PBMs), by the nature of their relationship with the health insurance plans covered under these provisions, have such data elements for prescription drug data readily available for inspection and reporting to the agencies with jurisdiction in order to comply with the Congressional mandate set forth within section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021.

NCPA encourages the agencies to be diligent in structuring reporting requirements to encapsulate sufficient data to make accurate determinations of compliance.

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?

NCPA suggests to the agencies that the rules for reporting data mirror requirements already set forth in Medicare Part D. For these requirements, plans have until the last Monday in August to report for the January 1 to June 30 period and the last Monday of February for July 1 to December 31[1] to report to CMS all enrollment and disenrollment data. Requiring a report to be filed by the last Monday of February for the preceding year complies with the statutory deadline and is congruent with existing obligations.

Question 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?

NCPA encourages the agencies to review the following states which have implemented similar provisions as models for implementation of the requirements:

- Alabama - Requires a PBM to notify its clients that the client can request the PBM to prepare an annual report which discloses the following with respect to that client:
    - The aggregate amount of all rebates that the PBM received from manufacturers on behalf of the client;

[1] https://www.cms.gov/files/document/cy2021-part-d-reporting-requirements-120920.pdf

  - The aggregate amount of the rebates that the PBM received from manufacturers that did not pass through to the client;
  - If the PBM engages in spread pricing, the aggregated amount of the difference between the amount paid by the client for prescription drugs and the actual amount paid to the pharmacy.
- Maine - Requires a carrier to ensure that its contract with its PBM requires that the PBM acts as the carrier's agent and owes a fiduciary duty to the carrier that obligates the PBM to act prudently and solely in the best interest of the carrier in its management of activities related to the carrier's prescription benefits, account for and disclose to the carrier all compensation that it receives so that the carrier may apply it either to directly reduce members out of pocket costs or to reduce premiums.
- Massachusetts - Requires that a Medicaid MCO's contract with its PBM requires the PBM to:
  - Identify all sources and amounts of income, payments and financial benefits related to the provision and administration of pharmacy benefit management services on behalf of the managed care provider including, but not limited to, pricing discounts, rebates, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements or other benefits; and
  - Disclose to MassHealth the sources and amounts of all income, payments and financial benefits received by the PBM.
- Michigan - Requires a PBM contracting with a Medicaid MCO to use the reimbursement methodology required by the state Medicaid agency and move to a transparent pass-through pricing model, in which the PBM discloses the administrative fee as a percentage of the professional dispensing costs to the state Medicaid agency and limits an increase in such fees to no more than the rate of inflation. By January 15 of each fiscal year, the PBM must submit to the Medicaid agency:
  - The total number of prescriptions dispensed
  - The aggregate WAC for each drug on its formulary
  - The aggregate amount of rebates, discounts, and price concessions that the PBM received for each drug on its formulary (including utilization discounts that the PBM receives from a manufacturer)
  - The aggregate amount of administrative fees that the PBM received from all pharmaceutical manufacturers.
  - The aggregate amount of WAC and rebates, discounts and price concessions that were retained by the PBM and not passed through to the Medicaid agency or the Medicaid health plan
  - The aggregate amount of reimbursements the PBM pays to network pharmacies
- North Dakota - Requires PBMs, drug manufacturers, and health insurers to file annual reports with the Insurance Commissioner with certain drug level pricing, rebate, drug spend, and utilization data.

  Additionally, the Insurance Commissioner will publish the reports on a publicly available website (protecting trade secret, proprietary, commercial, financial, and confidential information of any pharmacy, PBM, wholesaler, or hospital).

  If the Public Employee Retirement System contracts with a PBM or provides drug coverage through a self-insurance plan, the PBM must disclose to the Board all rebates and other fees that

provide the PBM with sources of income under the contract, including related contracts the PBM has with third parties, such as drug manufacturers.

- South Dakota - Requires a health insurer to make available to the public on a website, free of charge and without conditions, a machine-readable prescription drug file that includes:
    - A health insurance oversight identifier or employer identification number;
    - The NDC and the proprietary and nonproprietary name assigned to the NDC by the FDA
    - A negotiated rate that is:
        - Reflected as a dollar amount by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;
        - Associated with the national provider identifier, tax identification number, or place of service code; and
        - Associated with the last date of the contract term;
    - Historical net prices that are:
        - Reflected as a dollar amount by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;
        - Associated with the national provider identifier, tax identification number, or place of service code; and
        - Associated with the ninety-day time period that begins one hundred eighty days prior to publication date of the machine-readable file for each provider specific historical net price that applies to each NDC.
- Virginia - Requires the Department of Health to collect, compile, and make available on its publicly available website aggregate, de-identified information about prescription drug prices submitted by health carriers, PBMs, wholesale distributors, and manufacturers.
  Carriers must report utilization data, percent increase in annual net spending after accounting for rebates, discounts, and other price reductions, percent increase in premiums, percentage of specialty drugs with utilization management requirements, premium reductions attributable to specialty drug utilization management.
  PBMs must report its aggregate rebates, aggregate rebates distributed to each plan, aggregate rebates passed on to members at the point of sale.
  PBMs must offer a carrier or health plan the option of extending point of sale rebates to members.
- West Virginia - Requires PBMs report to the Insurance Commissioner at least annually:
    - The aggregate amount of rebates received by the PBM
    - The aggregate amount of rebates distributed to each health plan or covered entity contracted with the PBM;
    - The aggregate amount of rebates passed on to members of each plan or covered entity at the point of sale that reduced the members' applicable deductible, copayment, coinsurance, or other cost sharing amount;
    - The individual and aggregate amount paid by the health plan or covered entity to the PBM for pharmacist services itemized by pharmacy, by product, and by goods and services;
    - The individual and aggregate amount a PBM paid for pharmacist services itemized by pharmacy, by product, and by goods and services.
- Wisconsin - Requires a PBM to report to the Department of Insurance annually with the aggregate rebate amount that the PBM received from all manufacturers but retained and did not pass through to health plans and the percentage of the aggregate rebate amount that is retained rebates (limited to contracts held with pharmacies in WI).

Definitions

Question 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?

NCPA urges the agencies to broaden the proposed definition within the RFI to include any remuneration including direct and indirect remuneration (DIR), rebates, fees, and other revenues generated by the PBM as part of the prescription drug plan as well as revenue derived from any inhouse discount cards which may be used by patients.

NCPA cautions the agencies on previous attempts by the PBMs to attempt to mask incoming revenue associated with prescription drugs as service fees. Previously, the HHS Office of Inspector General found that PBMs were claiming certain fees as bona fide service fees[2] and were therefore not reported to Medicare Part D plans or to CMS, provided they were paid at fair market value. However, the contracts between the Part D plans and the PBMs had only limited information about these bona fide service fees, and neither CMS nor the Part D plans were able to verify whether claimed bona fide service fees should actually have been considered rebates.

NCPA urges the agencies to adopt a requirement that fees meet the Bona Fide Service Fee (BFSF) Test used in the Medicaid program to determine if a fee should be treated as a fee versus a price concession or some other form of revenue. The BFSF Test is a four-part test that is well understood by PBMs as it has long been utilized under the Medicaid Drug Rebate Program and was adopted into the Medicare Part D program in the DIR fees reporting context, and therefore incorporation of the BFSF Test should not be burdensome for PBMs.

Question 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?

NCPA urges the agencies to use an expansive view of "pharmacy" to capture as much data as possible, including any PBM-owned pharmacies. In fulfilling the directive from Congress, the

[2] United States Department of Health and Human Services Office of Inspector General. (2019). Reasonable assumptions in manufacturer reporting of AMPs and best prices. Retrieved from https://oig.hhs.gov/oei/reports/oei-12-17-00130.pdf

reporting should be agnostic to pharmacy types – including, but not limited to, specialty and mail order - and require any transaction based upon the fulfillment of a properly authored prescription from a provider included.

Question 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?

NCPA urges the agencies to utilize the existing National Drug Codes (NDC), which provides the most universal means to identify prescription drugs. In their own reporting requirements, many states utilize the NDC for identified prescription drugs. Congruency across state and federal reporting requirements will ensure timely and accurate data reporting.

Entities That Must Report

Question 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?

NCPA recognizes the ability of PBMs to be a manager of prescription drug data which would be part of the reporting requirements. Under existing federal and state mandates, PBMs are already responsible for maintaining the information. Also, rebates and price concessions are contractual agreements between pharmaceutical manufacturers, the PBMs, and dispensing pharmacies.

Information Required to be Reported

Question 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?

NCPA wishes to raise the issue with the agencies regarding the potential discrepancies between mail order and traditional retail pharmacy. Mail order allows for a longer supply, up to 90 days, for an individual prescription which might reduce the number of claims – rather than a traditional 30-day supply. NCPA urges the agencies to adopt a standard which properly accounts for these fundamental differences – whether that is a 30-day supply or total number of units of dosage for each prescription.

Question 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?

NCPA requests that the agencies adopt a gross to net pricing model to account for all rebates and price concessions for any given prescription. Any determination in selecting an approach should not be solely based on the list price or pharmacy reimbursement.

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?

NCPA urges the agencies to consider the inclusion of pharmacy direct and indirect renumeration (DIR) fees in their calculations of renumeration. These fees are assessed post point of sale and collected by the PBMs after the prescription is dispensed – and the inclusion of DIR fees would increase the transparency of the financial operations of the PBMs and the costs associated with prescription drugs.

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,[1] 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?

NCPA urges the agencies to adopt consistency across all federal programs where plans are required to report on data on prescription drugs. We recognize the information necessary to be captured is in the hands of the PBMs and recommend any requirements extended to plans require the assistance of PBMs for compliance. NCPA remains concerned about the ability of the PBMs to mask or report incomplete data and deceive the agencies in reporting if there are different requirements depending on the insured patients on a particular plan.

Conclusion

NCPA greatly appreciates the opportunity to share our views on the Reporting on Pharmacy Benefits and Prescription Drug Costs. NCPA looks forward to continuing to work with the Office of Personnel Management and the Departments of Treasury, Labor, and Health and Human Services as well as other interested stakeholders to develop workable reporting requirements on prescription drugs. Should you have any questions, please contact me at ronna.hauser@ncpa.org or (703) 838-2691.

Sincerely,

Ronna B. Hauser, PharmD
Senior Vice President, Policy & Pharmacy Affairs