January 12, 2021

Demetrios Kouzoukas
Principal Deputy Administrator for Medicare and Director
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Cheri Rice
Deputy Director
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: 42 CFR Parts 1001 and 1003 (RIN 0936–AA10)

Dear Mr. Kouzoukas and Ms. Rice:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit, American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP is requesting CMS guidance that is necessary in order for NCPDP Standards to best support the Office of Inspector General (OIG), Department of Health and Human Services (HHS) Final Rule (RIN 0936-AA10) entitled "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements."

NCPDP's recommendation to support the intent of the new safe harbor protections, hereinafter, referred to as Point-of-Sale (POS) Rebates, requires additional guidance to which HHS' response within the Final Rule deferred our requests to the Centers for Medicare and Medicaid Services (CMS). Therefore, NCPDP is providing CMS a more detailed request outlining the technical and policy areas of concern where

guidance is needed for industry implementation of the Final Rule and to ensure alignment with CMS-related downstream processes.

As an ANSI-accredited Standards Developer (ASD), NCPDP must follow certain processes to make changes to its HIPAA-named standards. In order to associate a January 1, 2022, implementation date to the recommended changes to the Telecommunication Standard, additional CMS guidance and OIG's acceptance of our assumptions (outlined in NCPDP's January 12, 2021 letter to the OIG) must be available to the industry no later than **March 1, 2021.** This allows time for NCPDP to evaluate the guidance, complete the formal approval process for enhancements to the applicable standards and adhere to NCPDP's minimum 180-day implementation period.

The proposed technical solution to support POS Rebates within the existing Telecommunication Standard VD.0, named under HIPAA, leverages existing financial fields and pricing formulas. To comply with the rule, payers would leverage existing pricing fields, qualifiers and the pricing formula to communicate to the pharmacy the negotiated price that reflects the patient's cost savings from the POS Rebate. This solution, once approved through the formal NCPDP standard development process, will also make new standardized message code set values available to optionally communicate within non-financial fields that a rebate was applied.

- A payer's paid response to the claim request must contain the amount to be collected by the pharmacy based on the contracted negotiated price between the pharmacy and the payer/Pharmacy Benefit Manager (PBM). This would include:
    - Patient Pay Amount (505-F5) to reflect the patient's cost share adjusted to reflect applicable rebate savings passed onto the patient.
    - Total Amount Paid (509-F9) to reflect the balance of the negotiated price between the pharmacy and the payer/PBM.
- Optionally, the following additional detail may be returned:
    - Approved Message Code (548-6F)- A new paid claim value to specify the claim was subject to a Safe Harbor Rebate
    - Additional Message Information Qualifiers (132-UH):
        - A new value to specify the total amount of the rebate that is included in the contracted negotiated price to the pharmacy, provided it does not compromise proprietary trade agreements.
        - A new value to specify the total amount of the beneficiary's savings as a result of the rebate.

NCPDP is requesting CMS guidance relating to Medicare regulations and processes in order to address outstanding questions that present a barrier to implementation of the rule. Based on our interpretation of the Final Rule and the June 1, 2007, memo "Reporting Estimated Rebates Applied to the Point-of-Sale Price", we submit the following and ask CMS for confirmation of our assumptions:

- Prescription Drug Event (PDE) Reporting
    - The rebate amount should be reported on the PDE in the "Estimated Rebate at POS" field as specified in the 2007 guidance.
    - The modification of ingredient cost paid to reflect the rebate amount would be consistent with the 2007 guidance.

    - All subsequent PDE reported values would be calculated off the reduced ingredient cost paid as the 2007 guidance did not have a discount eligible cost.
    - Rebates are not expected to be paid in addition to coverage gap discounts.
    - The rebate amount cannot exceed the ingredient cost.
- Beneficiary Impacts:
    - There is no expectation that the pharmacy would need to communicate to the patient the actual dollar amount of the patient cost savings.
    - There is no expectation that the pharmacy would need to communicate to the patient that their prescription had a reduced cost share due to the POS Rebates.
    - There is no expectation that the Plan Sponsor would need to communicate the actual dollar amount of the patient cost savings directly to the patient on the Explanation of Benefits.
    - The existence of a rebate should be impacted by the information that is sent for Plan Finder.
- Real Time Pharmacy Benefits:
    - Price concession amounts would be reflected in real-time benefit tools (both prescriber-facing effective for 2021 and beneficiary-facing expected for 2022 or later) as the estimated patient financial responsibility.
    - The specific patient cost savings would not be identified in a distinct pricing field.
- Pharmacy Provider Impacts:
    - Current Direct and Indirect Remuneration (DIR) processes would leverage only the amount paid directly to the pharmacy by the PBM and not the ingredient cost paid field (which is increased by the rebate amount).
- Medicare as Secondary Payer (MSP):
    - MSP currently utilizes the NCPDP Other Payer Amount Paid (OPAP) Coordination of Benefits (COB) method. The method in which the rebate amount is communicated in the NCPDP transaction could impact how Part D plans will need to calculate the financials for both the NCPDP claim response and potentially the PDE. The rebate amount will not impact the MSP calculations.
    - Rebates should not apply to MSP claims.
- DIR, Negotiated Price, Contract Rates:
    - While the final rebate rule indicates there are no changes to pharmacy DIR, please confirm that all non-manufacturer elements of the DIR reporting guidance will remain as is.
    - For manufacturer rebates, plans anticipate the DIR reports will include retroactive post POS amounts, including those from litigation.
    - The rebate rule does not modify how plans report DIR at the 11-digit NDC level for the aggregate annual manufacturer's fee (Section 9008 of the ACA).
- Medicare Part D Program Type Impacts:
    - If the claim submitted under a Part D IIN (formerly BIN)/PCN is not covered under Part D but covered under the co-administered benefit (e.g., Medicaid (Medicare Medicaid Plan or Dual Eligible Special Needs Plans), Employer Group Waiver Plans, etc.) and a POS Rebate applies to the dispensed product, it is assumed the claim is exempt from the rule meeting Safe Harbor conditions.
- Chargeback Administrator:

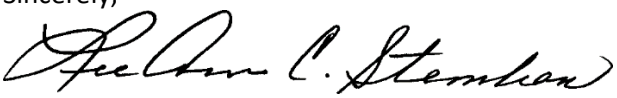
- Currently there is no requirement for a Chargeback Administrator.
- If a use case is identified involving a Chargeback Administrator that does not fit the proposed solution above, the use case should be brought to NCPDP for guidance and a potential technical solution. It is likely the technical solution would require a new version of the Telecommunication Standard, which would need to be named under HIPAA.
- Any Chargeback Administrator would be subject to HIPAA and prompt pay requirements currently required of other trading partners and business entities.

NCPDP respectfully requests CMS confirm, via guidance, the above assumptions comply with the intent of the Final Rule "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements".

It is important to note that CMS' guidance addressing the technical and policy areas of concern will be critical to ensure the proposed solution outlined above meets the POS Rebates claim adjudication and associated downstream reporting and financial calculation needs. Any delays beyond the March 1, 2021, requested date or substantial deviation from the proposed solution would impact the industry's ability to comply by January 1, 2022.

NCPDP looks forward to working with CMS to specify the additional standards guidance needed to bring forth a workable solution for the pharmacy industry within a reasonable timeframe.

Sincerely,



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