



January 12, 2021

Stewart Kameen  
Office of Inspector General  
Department of Health and Human Services  
330 Independence Avenue SW  
Washington, DC 20201

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

Dear Mr. Kameen:

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 submits these comments in response to 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 previously submitted comments on the proposed rule and requested OIG and HHS review NCPDP's proposed methods and provide additional guidance on whether these methods supported the intent of the new safe harbor protections, hereinafter, referred to as Point-of-Sale (POS) Rebates. The Final Rule did not specify whether any or all of the methods proposed by NCPDP would comply with the new POS Rebates rule. The Final Rule did, however, defer our requests for additional clarification and guidance to Centers for Medicare and Medicaid Services (CMS). Therefore, CMS is copied on this correspondence. In addition, NCPDP will send CMS a more detailed request outlining the technical and policy areas of concern where guidance is needed for industry implementation of the Final Rule.

As an ANSI-accredited, HIPAA-named ASD, NCPDP must follow certain processes to make changes to its HIPAA-named standards. In order to implement changes by January 1, 2022, complete, clarifying guidance must be made 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.

NCPDP's proposed solution to support POS Rebates within the existing Telecommunication Standard VD.0 named under HIPAA is based on the following interpretations of the Final Rule:

- The rule is focused on the POS Rebates contained in the contractual agreements between drug manufacturers, Medicare Part D and other federal program plan sponsors and their pharmacy benefit managers (PBM).
- The pharmacy is not a party to these agreements and therefore not directly affected by the safe harbor rules.
- Reduction of price due to the rebate must be reflected in the cost share to the beneficiary to be a rebate protected under the new safe harbor provisions.
- The full negotiated price is reimbursed to the pharmacy, i.e., the pharmacy is made whole to the contracted rate with their trading partner.

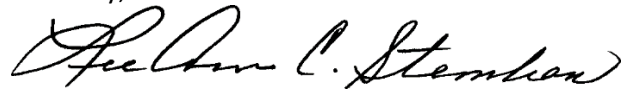
The proposed technical solution to support POS Rebates within the existing Telecommunication Standard VD.0 named under HIPAA leverages existing financial fields and pricing formulas. To comply with the rule, payers would leverage existing pricing fields, qualifiers and the pricing formula in the standard 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 standards 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/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.

It is important to note that CMS' guidance to 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. NCPDP will be working closely with CMS to meet the necessary timelines and objectives. Any delays beyond the March 1, 2021, requested date or substantial deviation from the proposed solution may compromise the NCPDP standards development timeline and would affect the industry's ability to comply by January 1, 2022.

NCPDP respectfully requests the OIG, HHS and CMS confirm the NCPDP proposed solution complies 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".

Sincerely,



Lee Ann C. Stember  
President & CEO  
National Council for Prescription Drug Programs (NCPDP)  
9240 E. Raintree Drive  
Scottsdale, AZ 85260

For direct inquiries or questions related to this letter, please contact:

Margaret Weiker  
Vice President, Standards Development  
NCPDP  
[standards@ncdpd.org](mailto:standards@ncdpd.org)

cc: NCPDP Board of Trustees

Demetrios Kouzoukas, Principal Deputy Administrator for Medicare and Director  
Centers for Medicare and Medicaid Services

Cheri Rice, Deputy Director  
Centers for Medicare and Medicaid Services