April 8, 2019

Mr. Aaron Zajic
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue SW
Washington, DC 20201

Re: OIG-0936-P

Dear Mr. Zajic:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-accredited Standards Development Organization (SDO) consisting of more than 1,600 members 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) Proposed Rule (file code OIG–0936–P) entitled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees". Specifically, NCPDP is submitting comments on the following topic areas:

I. Program and Legal Requirements – NCPDP Supported Transactions
II. Approaches to support the proposed definition of a chargeback
III. Applicability of the proposed safe harbor to claims with 100% beneficiary cost sharing and other types of claims that might raise additional questions
IV. NCPDP Registry of Pharmacies
V. Estimates of implementation burden in the Regulatory Impact Analysis

I. Program and Legal Requirements – NCPDP Supported Transactions

The OIG and HHS solicit comments on how the proposed changes to certain safe harbors would relate to existing program and legal requirements:

> *To address the Department's concerns with the current rebate system, the Department proposes to eliminate safe harbor protection for manufacturer reductions in price on prescription pharmaceutical products to Medicare Part D plans operating under section 1860D–1 et seq. of the Act, and Medicaid MCOs, as defined under section 1903(m) of the Act. In conjunction with this amendment, the Department is proposing a new safe harbor that would protect manufacturer point-of-sale reductions in price on prescription pharmaceutical products to a plan sponsor under Medicare Part D, a Medicaid MCO, or a PBM acting under contract with either, that would be*

applied at the point-of-sale to benefit the beneficiary, the plan, and, by extension, the Government. Finally, the Department is proposing a new safe harbor to protect certain fixed service fees that pharmaceutical manufacturers pay to PBMs. ***We are interested in and solicit comments on how these proposals, individually and/or collectively, would align or conflict with program requirements and any legal requirements (e.g., antitrust laws) that may apply to affected parties****.[Emphasis added]*

Among the program and legal requirements that Part D sponsors and Medicaid Managed Care Organizations (Medicaid MCOs) must comply with are those of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA requires the adoption of standards for certain electronic healthcare transactions between covered entities, including claims transmission; payment and remittance advice; claim status; patient eligibility: premium payments; enrollment, and disenrollment; and referral certification and authorizations.

Under HIPAA, the National Committee on Vital and Health Statistics (NCVHS) must recommend standards and operating rules to the Secretary of HHS, following review and approval of standard updates from the applicable Designated Standards Maintenance Organizations (DSMO). The DSMO for retail pharmacy transactions is NCPDP. Thus, industry stakeholders convene at NCPDP meetings to establish the industry standards used to adjudicate claim transactions at the point-of-sale. The current version of the NCPDP standard approved by HHS is the Telecommunication Standard Version D.0, and any changes in business models must be able to be transacted in accordance with this version. This means only certain limited types of modifications may be made in the near-term, following due process and consensus agreement, including reasonable timeframes for implementation. By near-term we mean the changes do not require a new version of the NCPDP Telecommunication Standard, but additional expedited code values are required.

The following comments represent NCPDP's interpretation of the proposed rule and how price reductions negotiated between manufacturers and applicable plan sponsors/PBMs could be both applied at the point-of-sale and reimbursed to dispensing pharmacies consistent with the current approved standard **with or without certain modifications**. In the interest of clear communication, we have utilized the same terminology as in the NPRM. Appendix A was also included to portray the same information utilizing NCPDP format and field names.

II. Approaches to support the proposed definition of a chargeback within the claim adjudication process

The OIG and HHS solicit comments on the proposed definition of a "chargeback" that would meet the second criterion of a new safe harbor:

Second, the reduction in price could not involve a rebate, as defined in 42 CFR 1001.952(h), unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or a series of chargebacks, or the rebate is required by law. We propose to define a ''chargeback'' as a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product. For example, when a pharmacy dispenses a drug to a beneficiary that is reimbursed by a particular Part D plan or Medicaid MCO, the total payment to the pharmacy (i.e., cost-sharing from the beneficiary, payment from the Part D plan or Medicaid MCO, and any chargeback) will be at least equal to the price agreed upon between the

manufacturer of that drug and the Part D Plan or Medicaid MCO, or a PBM acting under contract with either. We solicit comments on this definition.

NCPDP has reviewed the proposed rule specifically as it relates to new safe harbor for price reductions on prescription pharmaceutical products that meet certain new proposed criteria. We outline two "approaches" representing three "methods" for point-of-sale transactions we believe may be consistent with the conditions of this proposed safe harbor rule. NCPDP is also submitting comments on the OIG's terminology and intent regarding the definitions of total payment and chargeback as they relate to the NCPDP Telecommunication Standard Version D.0. The approaches being proposed by NCPDP are based on assumptions outlined in this document.

Of the three methods outlined below, two itemize the chargeback amount in point-of-sale transactions, (allowing visibility to the discount for administration purposes) and one method does not. One of these three methods allow an entity other than the PBM to administer the chargeback. Two methods will require certain near-term modifications to the standard. One method requires no modification to the standard but requires the PBM to be the chargeback administrator and does not itemize the discount amount in point-of-sale transactions.

If the proposed rule is finalized and if these approaches are consistent with the finalized definition of chargeback, these approaches would allow for either the plan sponsor or its contracted PBM or a third-party entity (or entities) to pay the dispensing pharmacies (indirectly) on behalf of the manufacturer relying on calculations performed and reported in the claim generated at the point-of-sale.

Approach 1: PBM administered

- Approach 1/Method 1: This method would be used if the plan (or its PBM) functions as the chargeback administrator, responsible for the full payment of the chargeback to the dispensing pharmacy. The pharmacy would receive one payment and remittance from the plan (combined but separately identifiable (benefit liability amount plus chargeback amount)). This method will require the addition of new pricing qualifiers to the existing HIPAA named standard. This is a near-term standards modification process.

- Approach 1/Method 2: This method would function similarly to the first method, having one payment to the dispensing pharmacy by the PBM for both the benefit liability and the chargeback amount in the point-of-sale transaction. However, unlike Method 1 the chargeback amount would not be visible to the pharmacy. This method will not require any modifications to the existing HIPAA named standard.

Approach 2: Non-PBM administered:

- Approach 2/Method 3: This method would be used if an entity other than the plan (or its PBM) functions as the chargeback administrator responsible for administering the chargeback payment to the dispensing pharmacy. In this method, the pharmacy would receive two remittances, one from the plan (benefit liability amount) and one from the chargeback administrator (chargeback amount). This method will require the addition of new pricing qualifiers to the existing HIPAA named standard. This is a near-term standards modification process.

In all three methods, the final cost sharing of the beneficiary reflects the result of the chargeback amount being applied as proposed in the rule. In the current NCPDP Telecommunication Standard

Version D.0, there are no pricing fields to communicate to the beneficiary the cost sharing difference as a result of the chargeback amount being applied.

NCPDP requests OIG and HHS review these methods and provide guidance in any final rule confirming whether these methods would support the proposed definition of a chargeback and satisfy the proposed criteria for the new safe harbor. Such guidance may avoid the need for over 1,000 Part D and Medicaid MCO plan sponsors, pharmacy benefit managers, manufacturers or potential intermediaries to individually seek opinions from the OIG.

In the following discussion, we use these terms:

- "PBM" to mean the entities contracted to administer pharmacy benefits.
- "Chargeback" to mean a reduction in price from a manufacturer that meets the three proposed criteria under the new safe harbor: that is,
    - (1^{st}) it is fixed (not variable in relation to list price) and disclosed in advance in writing;
    - (2^{nd}) the full value of the reduction in price is provided to the dispensing pharmacy; and
    - (3^{rd}) is completely reflected in the price the dispensing pharmacy charges to the beneficiary at the point-of-sale.
- "Chargeback amount" to refer to the fixed amount that meets the definition of a chargeback and is the negotiated reduction in price.
- "Net Cost" in the same manner that HHS employs on page 2341 of the proposed rule, i.e., the PBM contracted rate with the pharmacy (including ingredient cost, dispensing fee and other components that attribute to contracted rate) minus the negotiated discount (chargeback) amount.

Approach 1/Method 1: PBM functions as Chargeback Administrator/chargeback amount is visible

HHS seems to suggest that the pharmacy can adjust the cost sharing on its own. (*"For example, if the discounted rate is set in advance, at the time of dispensing the pharmacy would have the necessary information to appropriately charge a beneficiary who owes coinsurance, even if the manufacturer ultimately tenders the dispensing pharmacy a payment through a chargeback to reflect this negotiated price with the payor.*" [p.2349]). However, this is not the case. While the chargeback amount may be fixed in advance, the cost sharing is not. Cost sharing must be calculated by the PBM at the time of adjudication based on its contracted rate with the pharmacy and the beneficiary's applicable formulary, benefit design and level of benefit accumulators at that point in time. Only the PBM has the information necessary to perform this calculation.

NCPDP's assumption is that in order for manufacturer discounts to be fully reflected in the price on which the beneficiary's cost sharing is calculated (3^{rd} criterion), the PBM must adjudicate the claim based on the net cost of the drug product. When the benefit design includes a deductible or coinsurance, the net cost of the drug would be used as the basis for the calculations, not the list price as occurs today. This would reduce beneficiary coinsurance and the total cost reported by the plan sponsor to the Part D program.

It is NCPDP's understanding that plan designs not based solely on coinsurance may not reduce beneficiary cost sharing at the point-of-sale. NCPDP seeks confirmation of this understanding.

NCPDP's assumption is that in order to meet the 2^{nd}criterion of a chargeback, which is to provide the full value of the discount to the pharmacy, the total amount due must also include the full chargeback

amount within the paid claim response to the pharmacy (and the subsequent remittance). This will be true even when there is no adjudicated plan liability for the drug at net cost. NCPDP believes this would satisfy the proposed requirement "*total payment to the pharmacy for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product".* NCPDP seeks confirmation that this interpretation is consistent with the OIG's intent.

We note this chargeback amount can be included in the total amount paid to the pharmacy without affecting the beneficiary calculations to meet the 3rd criterion, that the price the pharmacy charges to the beneficiary at the point-of-sale is based on adjudication of the benefit at net cost. In this case, the chargeback is paid to the pharmacy by the PBM serving as the chargeback administrator, and the chargeback amount is included in the claim response transaction as a separately identifiable component of the payment fields. This delineates the amount the pharmacy will receive that is part of the benefit liability from the chargeback amount. Thus, in this method the discount amount is both included and explicitly itemized in the claim at the point-of-sale (and becomes a chargeback amount due) separate, and distinct from the plan amount due which is based on the net cost of the drug. Because it is separately identified in the claim response at the point-of-sale, the chargeback amount due can be tracked by the pharmacy for claim reconciliation, financial accounting, coordination of benefits (COB) with downstream payers, and any audit or program integrity purposes. A simplified example is shown below.

Exhibit 1. **Approach 1/Method 1:** PBM functions as Chargeback Administrator/chargeback amount is visible

COINSURANCE EXAMPLE	**CURRENT STATE**		**FUTURE STATE**	
Pricing Component	**Status Quo Formula**	**Old Calc**	**Approach 1, Method 1 Change in Formula**	**New Calc**
WAC		$100.00		$100.00
Wholesaler acquisition cost	WAC minus 2%	$98.00	WAC minus 2%	$98.00
Pharmacy acquisition cost	WAC[1]	$100.00	WAC	$100.00
Plan/PBM Contracted Rate with pharmacy	1.2x WAC minus 15% + $2.00 dispensing fee	$104.00	1.2x WAC minus 15% + $2.00 dispensing fee	$104.00
Rebate (current state)	30% WAC	$30.00		
Chargeback administered by **Plan/PBM** (future state)			Per unit x #units	$30.00
Net drug cost to Payer/PBM at point of sale	NA	NA	PBM contracted rate with pharmacy less chargeback	$74.00
Patient Pay (Coinsurance)	25% of pharmacy POS payment	$26.00	25% of net drug cost	$18.50

[1] Total WAC for the prescription

Plan liability (based on benefit only)	Benefit - patient pay (75% of negotiated price)	$78.00	Benefit - patient pay (75% of net drug cost)	$55.50
Pharmacy POS payment (all payors)		$104.00		$104.00
PAYMENT SOURCES TO PHARMACY				
Plan payment	Plan liability only	$78.00	Plan liability + chargeback	$85.50
Patient Pay		$26.00		$18.50
Non-Plan payment		$0.00		$0.00
Total payment		$104.00		$104.00

*Note: Based on a 30-unit example/prescription

It is presumed when the PBM functions as the chargeback administrator, PBMs and manufacturers continue to use the existing processes, modified as needed, to seek reimbursement of the chargeback funds from the manufacturers in accordance with trading partner agreements. This process is somewhat analogous to the current Part D coverage gap discount program financial flows, but with PBMs rather than CMS handling the reimbursement request process. However, with the coverage gap discount, that amount is not separately identifiable from the plan benefit liability, whereas in this method, the chargeback is separately identifiable.

This method will require the addition of new values to uniquely identify chargeback amounts, so they can be tracked and handled appropriately. In accordance with NCPDP procedures, the expedited standards development process could be initiated but only upon issuance of a final rule establishing the urgency. If the outlined approaches meet the needs as defined in the final rule, NCPDP estimates a minimum of 10-12 months from the date of a final rule for the ANSI-accredited process to be completed and the official NCPDP documents to be published. Additional time will be needed for modification of industry operations to support disclosure of the chargeback amount in financial transactions. These changes impact all entities using the NCPDP Telecommunication Standard.

The following chart identifies high-level impacts of Approach 1/Method 1:

Implementation considerations	**Impact?**
Requires changes to the NCPDP Telecommunication Standard Version D.0	Yes
Timeframe for standards changes	Near-term[2]
The chargeback amount is available in claim response	Yes
Ability for non-PBM administration	No
Impact to financial fields in the NCPDP Telecommunication Standard Version D.0	Yes
Impact to sales tax basis if based on ingredient cost	Yes, State dependent, e.g., Illinois
Harmonization of code sets between NCPDP and other HIPAA named standards development organizations to clearly identify chargeback amounts in the remittance advice	TBD. Although Pharmacy receives one remittance advice for one claim, NCPDP has not assessed the impact of the proposed changes on all standards that

[2] Changes do not require a new version of the NCPDP Telecommunication Standard, but additional expedited code values are required.

	may be necessary to conduct business under the proposed safe harbor.

Approach 1/Method 2: PBM Functions as Chargeback Administrator/chargeback amount is not visible on the claim

As described under Method 1, the Part D or Medicaid MCO claim must initially be processed by the PBM. In order for the manufacturer discount to be completely reflected in the price the pharmacy charges to the beneficiary at the point-of-sale (3rd criterion), the PBM must adjudicate the benefit (cost sharing) at the net cost of the drug product. When the benefit design includes a deductible or coinsurance, the 100% or lower coinsurance percentage would be applied to the net cost of the drug, rather than to the full Plan/PBM contracted rate with the pharmacy as occurs today. This would reduce the beneficiary coinsurance and the gross cost of the drug to the plan sponsor and the Part D program.

Method 2 does not include a discrete field for the chargeback amount for point-of-sale visibility to this value. However, the chargeback amount will still be transferred to the dispensing pharmacy along with the plan payment due based on the net cost of the claim. The plan sponsor/PBM combines the full amount of the discount and the benefit liability in a single field in the paid response to the pharmacy (and the subsequent remittance) without affecting the adjudication of the benefit at net cost. We assume this will continue to satisfy the 2ndcriterion to provide the full value of the discount to the pharmacy, as the transaction incorporates that amount in the paid response to the pharmacy and the subsequent remittance without affecting the adjudication of the benefit at net cost.

Since the chargeback amount is not reported in a discrete field, there is no need to modify the standard. All adjustments to compute the differences in payment responsibility among plan, patient and manufacturer are managed by the PBM back-end systems. The absence of the discrete chargeback field reduces the risk of reverse engineering proprietary contractual pricing. Since changes are not required to the standard for Method 2, this would be the quickest standard implementation approach.

Exhibit 2. Approach 1/Method 2 – PBM Functions as Chargeback Administrator/chargeback amount is not visible on the claim

COINSURANCE EXAMPLE	**CURRENT STATE**		**FUTURE STATE**	
Pricing Component	**Status Quo Formula**	**Old Calc**	**Approach 1, Method 2 Change in Formula**	**New Calc**
WAC*		$100.00		$100.00
Wholesaler acquisition cost	WAC minus 2%	$98.00	WAC minus 2%	$98.00
Pharmacy acquisition cost	WAC[3]	$100.00	WAC	$100.00
Plan/PBM Contracted Rate with pharmacy	1.2x WAC minus 15% + $2.00 dispensing fee	$104.00	1.2x WAC minus 15% + $2.00 dispensing fee	$104.00
Rebate (current state)	30% WAC	$30.00		

[3] Total WAC for the prescription

Chargeback administered by **Plan/PBM** (future state)			Per unit x #units	$30.00
Net drug cost to Payer/PBM at point of sale	NA	NA	PBM contracted rate with pharmacy less chargeback. Note: Amount not itemized in claim but included here for illustration.	$74.00
Patient Pay (Coinsurance)	25% of pharmacy POS payment	$26.00	25% of net drug cost	$18.50
Plan liability (based on benefit only)	Benefit - patient pay (75% of negotiated price)	$78.00	Benefit - patient pay (75% of net drug cost)	$55.50
Pharmacy POS payment (all payors)		$104.00		$104.00
PAYMENT SOURCES TO PHARMACY				
Plan payment	Plan liability only	$78.00	Plan liability + chargeback	$85.50
Patient Pay		$26.00		$18.50
Non-Plan payment		$0.00		$0.00
Total payment		$104.00		$104.00

*Note: Based on a 30-unit example/prescription

The following chart identifies high-level impacts of Approach 1/Method 2:

Implementation considerations	**Impact?**
Requires changes to the NCPDP Telecommunication Standard Version D.0	No
Timeframe for standards changes	Immediate[4]
The chargeback amount is available in claim response	No
Ability for non-PBM administration	No
Impact to financial fields in the NCPDP Telecommunication Standard Version D.0	None
Impact to sales tax basis if based on ingredient cost	None
Harmonization of code sets between NCPDP and other HIPAA named standards development organizations to clearly identify chargeback amounts in the remittance advice.	TBD. Although Pharmacy receives one remittance advice for one claim, NCPDP has not assessed the impact of the proposed changes on all standards that may be necessary to conduct business under the proposed safe harbor.

[4] No additional changes to code sets are required.

Approach 2/Method 3 Non-PBM Entity Functions as the Chargeback Administrator

As described under Approach 1, in order for the manufacturer discount to be fully applied to claims for Part D and Medicaid MCO beneficiaries at the point-of-sale (3rd criterion), the PBM must adjudicate the claim based on the net cost of the drug product. When the benefit design includes a deductible or coinsurance, the net cost of the drug would be used as the basis for the calculations, not the list price as occurs today. This would reduce the beneficiary cost sharing and the gross cost of the drug to the plan sponsor and the Part D program.

It is NCPDP's assumption that subsequent payment of the chargeback amount to the dispensing pharmacy may be administered and/or paid by a third party acting on the manufacturer's behalf. In this case, the chargeback is paid indirectly by the manufacturer via a third-party intermediary and represents a second payment source to the pharmacy.

Approach 2 assumes an entity functioning as the chargeback administrator is utilized to meet the 2nd criterion of a chargeback and enables the provision of the full value of the discount to the pharmacy. The PBM must also *itemize* the chargeback amount in the paid response to the pharmacy. Thus, in contrast to Approach 1, the itemized chargeback amount would not be included in the financial amount due from the PBM, and the pharmacy provider must account for a separate receivable from the chargeback administrator. The pharmacy provider must receive payment from the chargeback administrator and then reconcile the payment with the original claim. The amount can be conveyed in a separate field on the claim that establishes the chargeback amount due from the chargeback administrator on behalf of the manufacturer. The outstanding chargeback must then be separately tracked by the pharmacy for appropriate claim reconciliation, financial accounting (in particular the establishment of a second separate receivable balance from the manufacturer), COB, and any audit or program integrity purposes.

To enable full tracking by the pharmacy, we request the final rule require the chargeback administrator to furnish along with the chargeback payments, electronic remittance advices in the NCPDP Pharmacy Reference Guide to the X12/005010X221 Health Care Claim Payment/Advice (835) document with all chargeback amounts detailed at the claim level including the claim reference number.

NCPDP did not evaluate the full impact to the HIPAA named X12 835 transaction. However, we recognize the possibility that X12 may require time to adapt their 835 transaction to accurately reflect the chargeback amount paid.

Exhibit 3. Approach 2/Method 3 Non-PBM functions as Chargeback Administrator

COINSURANCE EXAMPLE	**CURRENT STATE**		**FUTURE STATE**	
Pricing Component	**Status Quo Formula**	**Old Calc**	**Approach 2/ Method 3 Change in Formula**	**New Calc**
WAC*		$100.00		$100.00
Wholesaler acquisition cost	WAC minus 2%	$98.00	WAC minus 2%	$98.00
Pharmacy acquisition cost	WAC[5]	$100.00	WAC	$100.00

[5] Total WAC for the prescription

Plan/PBM Contracted Rate with pharmacy	1.2x WAC minus 15% + $2.00 dispensing fee	$104.00	1.2x WAC minus 15% + $2.00 dispensing fee	$104.00
Rebate (current state)	30% WAC	$30.00		
Chargeback administered by **Manufacturer**			Per unit x #units	$ 30.00
Net drug cost to Payer/PBM at point of sale	NA	NA	PBM contracted rate with pharmacy less chargeback	$74.00
Patient Pay (Coinsurance)	25% of pharmacy POS payment	$26.00	25% of net drug cost	$18.50
Plan liability (based on benefit only)	Benefit - patient pay (75% of negotiated price)	$78.00	Benefit - patient pay (75% of net drug cost)	$55.50
Pharmacy POS payment (all payors)		$104.00		$104.00
PAYMENT SOURCES TO PHARMACY				
Plan payment	Plan liability only	$78.00	Plan liability only (chargeback from another source)	$55.50
Patient Pay		$26.00		$18.50
Non-Plan payment		$0.00	chargeback	$30.00
Total payment		$104.00		$104.00

*Note: Based on a 30-unit example/prescription

Similar to the Method 1, Approach 2/Method 3 requires the addition of new values to uniquely identify chargeback amounts, so they can be tracked and handled appropriately. In accordance with NCPDP procedures, the expedited standards development process can be initiated, but only upon issuance of a final rule establishing the urgency. If the outlined approaches meet the needs as defined in the final rule, NCPDP estimates a minimum of 10-12 months from the date of the final rule for the ANSI-accredited process to be completed and the official NCPDP documents to be published. Additional time is needed for modification of industry operations to support disclosure of the chargeback amount in financial transactions and incorporate a multi-payer remittance process. In addition, trading partner agreements may need to be modified to support accountability for the new payment flows. It is important to note these changes to the standard impact all covered entities.

The following chart identifies high-level impacts of Approach 2/Method 3:

Implementation considerations	**Impact?**
Requires changes to the NCPDP Telecommunication Standard Version D.0	Yes
Timeframe for standards changes	Near-term[6]

[6] Changes do not require a new version of the NCPDP Telecommunication Standard, but additional expedited code values are required.

The chargeback amount is available in claim response	Yes
Ability for non-PBM administration	Yes
Impact to financial fields in the NCPDP Telecommunication Standard Version D.0	Yes
Impact to sales tax basis if based on ingredient cost	Yes, State dependent, e.g., Illinois
Harmonization of code sets between NCPDP and other HIPAA named standards development organizations to clearly identify chargeback amounts in the remittance advice.	Yes, pharmacy receives two remittance advices for a single claim. One from the payer/PBM and one from the manufacturer's chargeback administrator.

III. Applicability of the proposed safe harbor to 100% cost sharing claims, and other types of claims that raise additional questions

100% Cost-Sharing Claims: Claims that result in a beneficiary cost sharing of 100% due to a deductible phase or coinsurance benefit design, would not need special treatment under the approaches outlined above. This is because the discount will be fully applied during the adjudication of the claim to arrive at the net cost, therefore, the coinsurance and claim amount will be fully reduced by the discount amount. Referring to the examples in the previous illustrations, if the claim is in the deductible phase under the status quo, the 100% cost sharing would be $104. Under either of the approaches outlined above, the cost sharing would be based on the net cost of the drug, or $74 and the pharmacy reimbursement would include the discount amount.

Usual & Customary (U&C) Claims: Because the discount will be fully applied in the adjudication of the claim to arrive at the net cost, the coinsurance and relevant claim amounts will be fully reduced by the chargeback amount and the pharmacy reimbursement would include the discount amount..

Paper Claims - Direct Member Reimbursement (DMR)/Universal Claim Form (UCF): None of the methods outlined in these comments would apply in the case of a paper claim since the discount was not applied during the adjudication process.

Claims where the ingredient cost is less than the rebate:
This business case has not yet been thoroughly evaluated by NCPDP to determine all potential impacts. NCPDP requests the OIG recognize the patient liability amount after application of the chargeback, cannot be a negative value. A negative patient liability amount would result in the pharmacy refunding monies to the patient before they have been collected from the PBM or chargeback administrator as well as compromising downstream payers. NCPDP's assumption is if the value of the chargeback exceeds the amount of the ingredient cost this excess value would not be covered under safe harbor. NCPDP seeks confirmation of this understanding.

IV. NCPDP Registry of Pharmacies

As a service to its members, NCPDP maintains and publishes a registry of pharmacies and providers which is used throughout the healthcare industry to support the adjudication of claims. If the chargeback administrator is an entity other than the PBM, this registry could be expanded to include chargeback entity information at the pharmacy level similar to the manner in which payment addresses are maintained.

V. Estimates of implementation burden in the Regulatory Impact Analysis

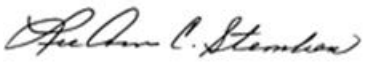
NCPDP believes the resources, time and burden identified in the NPRM are significantly under-stated. Approach1/Method 1 and Approach 2/Method 3 require changes to financial fields in the standard and associated calculations, which typically require greater implementation resources than would Approach 1/Method 2.

In closing, these comments represent NCPDP's interpretation of the proposed rule and how three methods consistent with the current adopted HIPAA standard can support arrangements permissible under the new point-of-sale safe harbor. NCPDP wishes to emphasize that the ordering of the three methods is arbitrary and not intended to convey preference or priority.

NCPDP appreciates the opportunity to provide input on this important rulemaking. We stand ready to assist HHS and the OIG in understanding the impact of the proposed rule on HIPAA standard transactions and to efficiently support the implementation of the final rule when issued. Please contact us if you have questions or require further clarification.

For direct inquiries or questions related to these comments, please contact:
Margaret Weiker, Director, Standards Development
National Council for Prescription Drug Programs
NCPDP
Email: mweiker@ncpdp.org

Sincerely,



Lee Ann Stember
President & CEO
NCPDP
9240 East Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000, ext. 108
(602) 321-6363 cell
lstember@ncpdp.org

cc: NCPDP Board of Trustees

Appendix A. View of Financial Fields within the NCPDP Transaction Layout

		Current Day	Approach 1/Method 1 (Single Payer)	Approach 1/Method 2 (Single Payer)	Approach 2/ Method 3 (2 Payers)
5Ø5-F5	Patient Pay Amount	$20.80	$14.80	$14.80	$14.80
5Ø6-F6	Ingredient Cost Paid	$102.00	$72.00	$102.00	$72.00
5Ø7-F7	Dispensing Fee Paid	$2.00	$2.00	$2.00	$2.00
563-J2	Other Amount Paid Count				
564-J3	Other Amount Paid Qualifier		XX - Manufacturer Chargeback Amount **Paid**		XX - Manufacturer Chargeback Amount **Payment Pending**
565-J4	Other Amount Paid		$30.00		$30.00
5Ø9-F9	Total Amount Paid	$83.20	$89.20	$89.20	$89.20
522-FM	Basis of Reimbursement Determination	01-AWP	XX -Contract Rate - Chargeback Amount	01-AWP	XX -Contract Rate - Chargeback Amount
572-4U	Amount of Coinsurance	$20.80	$14.80	$14.80	$14.80
	POS Sell Price Amount	**$104.00**	**$104.00**	**$104.00**	**$104.00**

Items in red represent near-term NCPDP Telecommunication Standard changes and the field where the chargeback amount would be conveyed.