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The Honorable Daniel R. Levinson
Office of Inspector General
U.S. Department of Health and Human Services
Room 5527, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: OIG-0936-P

Dear Inspector General Levinson:

The National Association of Specialty Pharmacy (NASP) is pleased for the opportunity to provide comments on the Office of Inspector General (OIG) Department of Health and Human Services (HHS) proposed regulation, "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" [84 Fed. Reg. No. 25, February 6, 2019; OIG-0936-P; RIN 0936-AA08]. NASP applauds the administration's continued efforts to lower out-of-pocket costs for beneficiaries under Medicare Part D. We encourage the continued adoption of policy reforms that work to lower costs for beneficiaries at the point-of-sale and reduce overall costs for the Medicare program. Representing specialty pharmacy, we also seek to ensure such reforms do all of the following: reduce both upfront drug costs and overall health care costs through appropriate medication access, monitoring, and adherence; recognize the need to improve the transparency of fees and ensure needed protections; ensure a competitive balance for pharmacies and adequate network standards under the Medicare Part D program; and support access to prescribed specialty medications that are frequently the only medication option to manage complex patient health conditions. Our comments focus on addressing each of these tenets as we contemplate implementation of the OIG rule's provisions.

NASP's members are committed to the practice of specialty pharmacy with a focus on the patients served to ensure better clinical outcomes while reducing overall healthcare costs. NASP defines a specialty pharmacy as a state licensed and registered pharmacy that is accredited by, or in the process of specialty pharmacy accreditation by an independent, third-party accreditor and solely or largely provides medications and patient medication management services to patients with serious health conditions requiring treatment with complex medication therapies. NASP represents the entire spectrum of the specialty pharmacy industry from the nation's leading independent specialty pharmacies and practicing pharmacists to small and mid-size pharmacy benefit managers (PBMs), pharmaceutical and biotechnology manufacturers of

specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; and technology and data management companies. With over 100 corporate members and 1,500 individual members, NASP is the unified voice of specialty pharmacy in the United States.

The proposed rule builds off of other critically important pending regulations that seek to reduce Medicare Part D out-of-pocket costs for beneficiaries, namely policy adjustments that would amend the definition of negotiated price and move all pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to the point-of-sale[1] to help ensure fair and transparent pricing. NASP commends the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for tackling this significant policy issue, which CMS data shows would have a limited impact on beneficiary premiums.[2] Premium increases would likely be far less significant given that some plan bids submitted by Part D plan sponsors understate in their submission an estimate of net plan liability. Also, any premium adjustment upwards would be more than offset by reductions in patient cost-sharing.[3] Amending the definition of negotiated price to move all DIR and other pharmacy price concessions to the point-of-sale ensures that beneficiaries get immediate reductions in the cost of their drugs and are no longer forced quickly into the catastrophic phase of the Part D benefit. Coupled with suggested reforms outlined in the Part D rule to standardize pharmacy performance metrics to appropriately assess and separately pay for quality based on the disease states being managed and drugs dispensed, HHS would further guarantee reduced costs to Medicare through improved medication monitoring and management. DIR reform at the point-of-sale and standardized performance metrics overseen by HHS are policy reforms that will generate an enormous return on investment under Medicare Part D. To immediately reduce out-of-pocket costs for seniors, it's critically important that these policies are finalized in 2019 and implemented for Calendar Year 2020. NASP remains committed to continuing to work with HHS-CMS to implement these important reforms.

Summary of NASP Comments

Proposed Regulation to Remove Safe Harbor Protection for Rebates Negotiated Price

Regulatory Implementation of New Safe Harbor Protection at Point-of-Sale

- Finalize pending and complimentary reforms to move all pharmacy price concessions, including direct and indirect remuneration (DIR) to the point-of-sale and establish standardized pharmacy quality metrics that are based on disease states being managed by a pharmacy and drugs being dispensed.
- The OIG/HHS must be prepared to make amendments to a final regulation to implement new safe harbor protections at the point-of-sale, issue formal guidance, and ensure an

[1] 83 Fed. Reg. 62152-62201 (November 30, 2018).
[2] 83 Fed. Reg. 62191-62192.
[3] Ibid.

oversight process is in place, given the significant operational changes that would need to occur.

Pharmacy Chargebacks

- The HHS should codify provisions in existing CMS guidance and manuals to protect pharmacies against reimbursement that is below a pharmacy's drug acquisition cost. Protections should also be put in place through the plan bid process that allow pharmacies to appeal when reimbursement is below a pharmacy's drug acquisition cost.

- Allow for the pilot testing of new chargeback systems prior to implementation to verify that new payment systems will not negatively impact cash flow to the pharmacies.

- Require that any chargeback process is consistent with federal prompt payment laws, requiring payment within 14 days, and establish appropriate oversight mechanisms.

- Ensure transparency for pharmacies within the new chargeback system so that a pharmacy understands the total due to the pharmacy at the time a drug is dispensed and to ensure a pharmacy can reconcile payments at the claim level. Establish an audit and reporting process to verify payment data accuracy.

Billing Corrections, Fees, and Pharmacy Reimbursement

- Establish regulatory protections against the retroactive reconciliation of claims and clawback of funds from pharmacies.

- Establish regulatory protections against the establishment of administrative or transaction fees on pharmacies associated with the new process for administering manufacturer reductions in price at the point-of-sale.

Safe Harbor Loopholes – Regulatory Protections and Market Oversight

- Eliminate regulatory loopholes to ensure that plan sponsors and PBMs that own their own specialty pharmacy business cannot conduct anticompetitive practices and utilize pricing negotiations with manufacturers to provide more advantageous pricing to their own entities in an effort to limit a pharmacy network and gain greater market share.

Value-Based Contracting Arrangements

- Consider appropriate regulatory protections to protect value-based contracting arrangements between drug manufacturers and Part D plan sponsors.

Indication-Based Formulary Design and Rebates at the Point-of-Sale – Complimentary Efforts and Considerations

- Consider how plan flexibility to allow indication-based formularies can support the OIG/HHS goal of further lowering beneficiary drug costs, especially high cost specialty drugs and the role specialty pharmacy can play to support the accuracy of such formularies.

NASP Comments on Proposed Regulation to Remove Safe Harbor Protection for Rebates

Impact on Pharmacy Distribution Channel

The proposed rule would eliminate current safe harbor protections for prescription drug rebates between manufacturers and plans or their pharmacy benefit managers (PBMs), moving toward a system of point-of-sale price reductions for beneficiaries enrolled in Medicare, Medicare Advantage, and Medicaid Managed Care. While NASP strongly supports the administration's goal of reducing patient out-of-pocket costs and changing the incentives within the current rebate system, we urge the OIG/HHS to exercise caution and careful oversight during implementation of the reforms outlined. NASP is concerned about shifts in behavior that could occur that would ultimately limit patient access to needed medications and reduce beneficiary and provider access to the pharmacy of their choice as a result of the rule's adjustments. The OIG/HHS must be prepared to make amendments to a final regulation, issue formal guidance, and ensure an oversight process is in place, given the significant operational changes that would need to occur to both meet the terms of the regulation and address the unintended changes that may occur as a result of the changes. The OIG/HHS should be prepared to monitor activities such as: significant changes in benefit offerings and formulary access by plans/PBMs, reimbursement to pharmacies below acquisition costs, and contract practices that limit competition and result in limited or closed networks.

The proposed rule would introduce new incentives into the market, adjusting how manufacturers and payers negotiate, potentially altering business practices and responsibilities for wholesalers, pharmacy benefit managers (PBMs) and health plans, and impacting contractual arrangements throughout the distribution channel. All stakeholders will need to re-orient entire business models and restructure operations to manage functions under a brand new system. Some suggested models of implementation would be more disruptive than others.

The rule provides a skeleton for the creation of a first-of-its-kind system, but it raises many questions about how the new system can be operationalized under an expedited time schedule. It is difficult to anticipate all of the ways the stakeholders in the pharmacy distribution channel will respond to the parameters outlined in the proposed rule. NASP is supportive of the bold

thinking and the critically important goals of changing drug pricing incentives and ultimately reducing beneficiary drug costs. However, we advise that in doing so, the OIG/HHS consider and ensure there are processes in place to monitor and respond to indirect effects of the rule that ultimately affect beneficiary cost via access to needed medications and the pharmacy of their choice to meet their health care needs.

Access to prescribed medications is critically important for patients on specialty drugs with complex medical conditions, and lack of affordability or sudden changes in formularies that prohibit access to medications can be life threatening. Net drug prices have previously had little to no transparency, and HHS' two proposals – to require pharmacy price concessions be moved to the point-of-sale and to require manufacturer rebates apply at the point-of-sale would bring new transparency into what has historically been a black box for seniors. NASP wants to ensure that in making regulatory adjustments to derive lowest price, HHS also ensures greater transparency within the market itself and that regulations can be adjusted upon implementation of reforms to protect against anticompetitive practices and gaming within the system.

Pharmacy Chargebacks

To address the difference between a pharmacy's acquisition cost and the manufacturer-plan negotiated discounted price at the point-of-sale, the rule proposes to implement a chargeback process. A chargeback is proposed as "a payment [that] is 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."[4] The rule further explains that under this process, the total payment to the pharmacy would include cost sharing from the beneficiary, payment from the Part D plan or Medicaid MCO, and the chargeback. NASP agrees with the OIG/HHS that any new chargeback process or any other similar mechanism to rectify payment to pharmacies must support appropriate and accurate pharmacy reimbursement. However, we believe that additional regulatory protections will be necessary as such a process is stood up to ensure that pharmacies are reimbursed in full, at a level not below their acquisition costs, and that the information associated with a chargeback is easily accessible and transparent and can be reconciled to the claim level to maintain system integrity.

A new chargeback system must achieve two critical objectives: reimbursement transparency and mechanisms to ensure reimbursement is not below the cost of drugs dispensed. To date, due to current DIR fees, there has been little-to-no transparency for pharmacies under the Part D payment system with final reimbursement often being far below a pharmacy's net costs. Specialty pharmacies are unable to provide the extensive care management services needed to

[4] 84 Fed. Reg. 2363.

support medication therapy and oversight if reimbursement is below cost. The net effect of unreasonable reimbursement is restricted pharmacy networks as pharmacies cannot accept network terms, limiting beneficiary and provider access to a pharmacy needed to support beneficiary needs. NASP offers the following recommendations to the OIG/HHS for addressing this significant issue:

- Require Part D plans and Medicaid MCOs to outline in their submitted plan year bids a process to facilitate appeals from pharmacies, particularly appeals in relation to the plan's reimbursement falling below a pharmacy's drug acquisition costs.
- Ensure that the Complaints Tracking Module (CTM)[5] in place today for Part D plans is utilized to provide timely response to pharmacy complaints, including complaints regarding reimbursement being below a pharmacy's costs. The CTM currently allows for the receipt of provider and pharmacy complaints and outlines a process for timely response. NASP asks that CMS clarify in revised guidance on the CTM that plans are to be responsive to complaints addressing reimbursement falling below cost in relation to lowest price under negotiated price as defined.

The proposed rule does not stipulate what type of entity would serve as the administrator of the chargeback process, instead requesting feedback on how a system could be administered through a wholesaler or PBM. Rather than focus on which type of entity should serve as the chargeback administrator, NASP believes the OIG's/HHS's focus must be on how a new, first-of-its-kind chargeback system can be appropriately operationalized under the expedited timeframe proposed in the rule and what resources, oversight, and accountability processes will be in place to appropriately handle and protect the integrity of this process. No such process exists today, and significant efforts must be conducted to stand up such a process.

Operationalizing a Chargeback System – Pilot Testing Needed

At a minimum, operationalizing a chargeback system will require investment in existing or the building of new data management systems, personnel to manage and oversee the process, and new technology systems for pharmacies, payers, PBMs, manufacturers, wholesalers and possibly others. It will be necessary for the OIG/HHS to allow for the pilot testing of chargeback systems prior to implementation to verify that select entities can appropriately administer this new type of chargeback process for the 2020 plan year and that point-of-sale pharmacy software vendors can make the requisite changes to support pharmacies to transact a new three-part reimbursement system and capture payment from a plan, payment from a plan member, and payments from the chargeback process. It is critically important that the OIG/HHS verify that such a financial flow is feasible and also that a chargeback system will not negatively impact cash flow to the pharmacies under the new system, which would have catastrophic consequences for pharmacy participation in networks, and as a result, beneficiaries accessing

[5] Centers for Medicare and Medicaid Services. Complaints Tracking Module (CTM) Standard Operating Procedures: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/UpdatedGuidanceStandardOperatingProcedures.pdf .

their drugs in a timely manner or at all. NASP urges the OIG/HHS to run pilot tests with prospective chargeback administrators utilizing different types of pharmacy providers, including independent specialty pharmacies, community pharmacies, and chain pharmacies, as the operations and resources by pharmacy type can vary considerably. It's important to ensure that patient access to all types of pharmacy entities is not disrupted due to financial turmoil that would result from an unworkable chargeback process that disrupts cash flow to the pharmacies in a given network, threatening network participation.

Pharmacy Chargebacks and Prompt Payment

A final regulation must also require that any chargeback process is consistent with federal prompt payment laws, requiring payment within 14 days. Oversight by the OIG/HHS and the ability for pharmacies to address delays in payment with a process for accountability, including penalties to be applied when wrongdoing occurs, will be essential.

The OIG/HHS must ensure that a chargeback administrator does not intentionally or unintentionally delay payments to pharmacies. In the competitive specialty pharmacy marketplace, a PBM that owns a specialty pharmacy and also serves as a chargeback administrator could seek to obtain a market advantage by delaying chargeback payments to independent specialty pharmacies in a given network. The resulting impact on an independent specialty pharmacy's ability to maintain operations in the absence of reimbursement would threaten the pharmacy's ability to remain in network and meet beneficiary and prescribing clinician needs.

Ensuring transparency exists for pharmacies within the new chargeback system is paramount to its success. The total due to the pharmacy, inclusive of any payment related to manufacturer price concessions, must be known by the pharmacy at the time a drug is dispensed. Pharmacies must be able to track and account for the collection of open receivables to protect against extreme financial risk. The chargeback process will require a mapping of an individual beneficiary's particular plan(s), drug formulary(ies), individual drugs purchased off that formulary, the application of discount or rebate arrangement for each drug purchased, and deductible, copayment, and other pertinent information. NASP requests that OIG/HHS ensure that an audit and reporting process is in place to appropriately verify data accuracy as the system gets underway and continues forward. Given the number and type of fluctuations that will occur with the data (e.g., beneficiaries changing plans; anticipated formulary adjustments, etc), it will be necessary that data adjustments can occur in real time and that data accuracy is checked and verified. Pharmacies will need line item visibility in the adjudication and remittance processes that are auditable down to the claim level to ensure that the pharmacy can reconcile payments and are made whole on all drugs dispensed.

Billing Corrections, Other Fees, and Pharmacy Reimbursement

As a new process for the billing of claims is initialized to provide beneficiaries the benefit of a rebate at the point-of-sale, there will likely be occasional errors in calculation. For example, there may be a situation where a beneficiary was initially provided a rebate at the point-of-sale, but later determined to be ineligible for the rebate due to an error made by the PBM at the time of claim adjudication. When such billing errors occur, pharmacies should not be subject to retroactive reconciliation of claims and the clawback of funds. The liability for such errors in calculation of the drug cost must not be placed on the pharmacy.

Pharmacies must also not be responsible for or directly charged administrative or transaction fees associated with the process for administering manufacturer reductions in price at the point-of-sale. The complete and final reimbursement to the pharmacy must be equal to the full contracted reimbursement amount agreed upon by the pharmacy and the Part D plan sponsor and their PBMs.

Safe Harbor Loopholes – Regulatory Protections and Market Oversight

NASP agrees with HHS's concern about the potential for certain types of discounts to be used as a loophole to funnel remuneration to PBMs and plans, disregarding the restrictions on rebates and the regulation's requirements for point-of-sale reductions for beneficiaries. Some specialty pharmacies are under common ownership and control by PBMs and/or plan sponsors. NASP is concerned that a PBM/plan sponsor could potentially offer a manufacturer favorable formularies or other coverage support for its products in exchange for a purchase discount, instead of a rebate. There must be protections in a final regulation to ensure that arrangements for manufacturer price concessions are not more favorable for PBM/plan-affiliated specialty pharmacies than they would be when the same drug is dispensed by a network specialty pharmacy. Reforms to the system must not result in a deliberate pricing disadvantage for network specialty pharmacies that are unable to influence formulary placement, allowing PBM/plan-owned specialty pharmacies to gain a market advantage. Providing regulatory protections against such practices is all the more important when addressing pricing for drugs where there are limited drug alternatives for patients, such as those with rare and other specialized conditions. Specialty pharmacies provide medication and services that are tailored to managing these unique populations. Network adequacy and ensuring that the contracting negotiations and practices that result from reforms to the system do not violate any willing pharmacy requirements is essential to ensuring access to these medications for patients.

Value-Based Contracting Arrangements

Value-based contracts between drug manufacturers and plans are utilized today to expand patient access to new therapies when such therapies prove to have a clinical or financial benefit. Specialty pharmacies often play an important role in the data collection process used to assess the success of newer therapies administered through such value-based contract

arrangements, as the specialty pharmacy works closely with patients to manage their ongoing therapies.

The proposed rule states that the OIG/HHS does not intend for the proposed safe harbor adjustments to have any effect on existing value-based contract arrangements that exist between manufacturers, plans/PBMs and others in the distribution channel.[6] However, the OIG/HHS also does not propose to provide a separate safe harbor to protect such arrangements, and with the rule's proposed adjustments to safe harbors for rebates, there is concern as to whether sufficient protection would exist for value-based contracts going forward. These contract arrangements assess drug performance to support the setting of drug prices. NASP supports the OIG's/HHS's efforts to reduce drug costs for beneficiaries, and believes moving toward a system of payment based on value has merit and can serve as another mechanism for lowering drug costs, particularly for patients on specialty medications with limited drug options or generic substitutions. NASP asks that the OIG/HHS consider appropriate protections to support such contracting practices going forward.

Indication-Based Formulary Design and Rebates at the Point-of-Sale – Complimentary Efforts and Considerations

In addition to pending rules that seek to derive lowest price at the point-of-sale, there are other pending or actual reforms that HHS has considered or initiated that could have complex and/or complimentary interactions with changes to the Part D rebate system outlined in the proposed rule. One such reform of interest to specialty pharmacy is indication-based formulary design in Part D. Indication-based formularies have the potential for lowering beneficiary drug costs and ensuring access to specialty drugs, particularly high cost specialty drugs that have material variance of clinical efficacy across FDA-approved indications and/or have different levels of competition within a clinical indication. In August 2018, CMS announced new guidance,[7] providing additional flexibilities in the Medicare Part D program to allow for indication-based formulary design beginning in CY 2020. Beginning in 2020, Part D plan sponsors will have the option of implementing indication-based formularies, tailoring and negotiating formulary coverage of drugs based on specific drug indications rather than covering a drug for every indication approved by the FDA. In addition, manufacturers are already offering different levels of rebate for the same product based on the indication for which the product is being used. Under CMS' approved guidance, if a Medicare Part D plan sponsor chooses to tailor on-formulary coverage to certain indications, it will also be required to ensure there is another therapeutically similar drug on the formulary for non-covered indications.

Specialty pharmacies in the U.S. have a large potential role to play in ensuring that any indication-based formulary model can be appropriately established in working with Part D plan

[6] 84 Fed. Reg. 2348.
[7] Centers for Medicare and Medicaid Services. "Indication-Based Formulary Design Beginning in Contract Year (CY) 2020." August 29, 2018: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-Aug-29th.pdf.

sponsors. Specialty pharmacies often serve as intermediaries between manufacturers and patients and physicians and patients, ensuring that patients understand and comply with their drug regimens in an effort to maintain their health and reduce overall health care costs. These pharmacies have access to coding and clinical data and, as such, are uniquely positioned to be a data source for Part D plan sponsors to capture and transmit diagnosis codes at the time of adjudication. ICD-10 coding information provided by the treating physician to the pharmacist, along with additional medical information that may be of importance in determining a point-of-sale rebate, could be included in specialty pharmacy data systems.

For such a system to be effective nationwide, and to ensure correct and complete data can be collected and utilized to support an indication-based formulary and accurate point-of-sale rebate chargebacks, it is essential that a robust network of specialty pharmacies be involved in the data collection and transmission system that would be needed. Utilizing plan sponsor-owned specialty pharmacies alone to achieve the data collection system would threaten beneficiary access and be grossly insufficient in achieving the goal of obtaining the complete patient-provider data information needed to appropriately determine or verify drug indications.

HHS should ensure that a plan is in place to support the resources required to stand up any new robust data capabilities between pharmacies and the Part D plan sponsors they contract with, and that resources are available to appropriately compensate specialty pharmacies that serve in this capacity. Specialty pharmacies across the country have the expertise, access and the ability to transmit in real time the data needed to support HHS' goal of reducing drug costs at the point-of-sale.

Conclusion

We thank the OIG/HHS for the opportunity to comment on the proposals included in the proposed rule. NASP looks forward to continuing to work with the administration to support policy reforms that will reduce costs to Medicare beneficiaries and the broader Medicare program for specialty drugs and ensure access to the specialty drugs and services needed to improve health and reduce overall healthcare costs. If we can provide additional information, please contact me at 703-842-0122 or sarquette@naspnet.org.

Sincerely,

Sheila M. Arquette, R.Ph.
Executive Director