January 29, 2015

Ms. Amanda Johnson
Director, Division of Payment Reconciliation
Centers for Medicare & Medicaid Services
7500 Security Blvd. C1-13-07
Baltimore, MD 21244

Re: Proposed Guidance on Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions

Dear Ms. Johnson:

The National Community Pharmacists Association (NCPA) appreciates the Centers for Medicare & Medicaid Services (CMS) providing an additional opportunity for stakeholders to provide input on CMS guidance that will implement the regulatory change to the definition of "negotiated price" as set forth in 42 C.F.R. § 423.100. NCPA represents the interests of pharmacist owners, managers and employees of more than 23,000 independent community pharmacies across the United States. Together they employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescription medicines.

Proposed Guidance to Standardize the Reporting of Price Concessions to Pharmacies In Medicare Part D Will Provide More Accurate Picture of True Cost of a Drug "Out the Door" of a Pharmacy to Beneficiaries, CMS and Public.

As set forth in our previous comments to CMS dated October 17, 2104 regarding your proposed guidance on DIR and pharmacy price concessions, NCPA is strongly supportive of the revised definition of "negotiated price" and CMS' proposed guidance to implement the revised definition of "negotiated price." We agree that some Part D plan sponsors (Sponsors) have manipulated how and when to report certain price concessions and payments to pharmacies related to drugs dispensed to Medicare Part D beneficiaries. Such manipulation has resulted in an unlevel playing field for pharmacies and Medicare Part D plans alike as the price of a drug out-the-door from a given pharmacy to a beneficiary can appear higher or lower on the Medicare Part D plan finder depending on how and when a Sponsor

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

accounts for certain payments and discounts provided to certain pharmacies participating in such Sponsor's pharmacy network. For instance, it is a common practice for Sponsors to provide an increase in reimbursement to certain preferred pharmacies for achieving certain performance measures, such as a set annual generic dispensing rate. However, historically many Sponsors have "elected" not to include such payments in their point of sale "negotiated prices." As a result, total reimbursement for a drug dispensed to a beneficiary at such a preferred pharmacy appears lower in both the individual Prescription Drug Event (PDE) and on the Medicare Part D plan finder than it actually is-- given the additional reimbursement paid to such a pharmacy at year-end for achieving the performance metric. This results in a misrepresentation to Medicare Part D beneficiaries of the actual cost of a drug out-the-door at such preferred pharmacies receiving such reimbursement increases related to performance metrics compared to pharmacies that have not negotiated or agreed to reimbursement tied to performance metrics. The change in the definition of "negotiated price" as well as CMS' proposed guidance to implement such change should serve to eliminate Sponsors manipulating the reporting timeframe for price concessions and payments to pharmacies, thereby making the reported cost of dispensing a pharmaceutical product in both individual PDE and on the Medicare Part D plan finder from Medicare Part D plan to Medicare Part D plan and from pharmacy to pharmacy more uniform. As a result, Medicare Part D beneficiaries will be able to make true "apples to apples" comparisons of the cost of a dispensing event in total—to the enrollee in terms of cost-sharing, as well as the Medicare Part D plan and CMS.

Proposed Guidance Would Have No Effect on Negotiations Between Plan Sponsors and/or their PBMs and Pharmacies: Sponsors/PBMs Would Still Be Free to Negotiate Any Reimbursement, Concessions or Pay Structure

The Pharmaceutical Care Management Association (PCMA), an industry group representing the interests of pharmacy benefit managers, suggested in its October 10, 2014 comments to CMS that CMS' proposed guidance to implement the changed definition of "negotiated price" is somehow contrary to the non-interference clause of the Medicare Prescription Drug, Improvement, and Modernization Act. We disagree. CMS is not inserting itself into negotiations between Sponsors and/or their pharmacy benefit managers and pharmacies by defining "negotiated price" and outlining

a uniform reporting timeframe and process by which to account for price concessions and payments to pharmacies any more than CMS is inserting itself into rebate negotiations between pharmaceutical manufacturers and Sponsors and/or their pharmacy benefit managers by providing plan design parameters for Medicare Part D plans or by regulating the minimum composition of plan formularies. Sponsors and/or their pharmacy benefit managers and pharmacies are still free to negotiate any reimbursement, concessions or pay structure they like just as pharmaceutical manufacturers and Sponsors and/or their agents are free to negotiate any rebate amounts, terms and conditions they choose. Moreover, CMS, as the agency delegated responsibility from Congress to oversee the Medicare Part D program, is charged with ensuring that all entities delivering the Part D benefit do so fairly, in accordance with the statutorily designed program requirements and do not manipulate or mislead beneficiaries. CMS' proposed guidance serves such purposes by ensuring consistent reporting by Sponsors such that there is a more uniform depiction of the cost of a drug out-the-door from a pharmacy presented to Medicare Part D beneficiaries, CMS and the public- at- large on an ongoing basis.

Standardizing the Timing of Reporting Would Not Require Immediate Payment of Performance-Based Reimbursement

Furthermore, in its October 10, 2014 comments, PCMA seems to confuse the CMS-proposed reporting timeframe for pharmacy performance-based reimbursement and price concessions with the payment timeframe for such performance-based reimbursement and price concessions. Nothing in CMS' proposed guidance suggests that a Sponsor and/or its pharmacy benefit manager must pay performance-based reimbursement to a pharmacy or credit a price concession immediately following the dispensing event or any other set timeframe merely because such payment or concession can reasonably be determined at the point of sale, and, therefore, must be included in "negotiated price." Rather, under the revised definition of "negotiated price" and CMS proposed guidance implementing such revised definition, any price concessions or payments that can reasonably be determined at the point of sale, through approximation or otherwise, must be reported in the PDE record for such dispensing event. The payment timeframe for such enhanced reimbursement or price concession is subject to the arms-length negotiations of the pharmacy and the Sponsor and/or its pharmacy benefit

manager. It is true that if a given Medicare Part D plan utilizes percentage-based co-insurance that an enrollee's co-insurance obligation must be based on the "negotiated price," which would include the performance-based reimbursement or price concessions reasonably determined, through approximation or otherwise, at the point of sale. However, an enrollee's co-insurance could be based on the "negotiated price" while the payment to the pharmacy immediately following the dispensing event is based on what is contractually required to be paid to the pharmacy by the Sponsor and/or if pharmacy benefits manager at such time.

Some Sponsors utilize a similar approach today with the coverage gap discounts paid by pharmaceutical manufacturers for branded drugs, remitting coverage gap discounts to dispensing pharmacies at a different time than the Medicare Part D plan's portion of the dispensing pharmacy's reimbursement, all of which is driven by the terms of the Sponsor and/or its pharmacy benefit manager's contract with the pharmacy. Furthermore, practically speaking, the overwhelming majority of Medicare Part D plans utilize an actuarially equivalent design to the standard Medicare Part D benefit which employs flat dollar co-payments in lieu of percentage-based co-insurance. So, in most instances while the total price of a drug dispensed to a Medicare Part D beneficiary out-the-door reported to CMS in PDE records and on the Medicare Part D plan finder may change given the revised definition of "negotiated price" and CMS' guidance implementing such revised definition, in the most instances an enrollee's cost-sharing obligation for a Part D drug will not change despite the change in definition of "negotiated price" given the fact that the overwhelming majority of Medicare Part D plans utilize flat-dollar co-payments and not co-insurance based on "negotiated price."

The Use of Historical Experience to Approximate Income and Outlay is Routinely Used by "Prudent Businesses" and Federal Agencies

In CMS' November 5, 2014 correspondence, CMS specifically asks for examples of the types of pharmacy price concessions and incentive payments that cannot reasonably be determined at the point of sale. NCPA believes that most, if not all, pharmacy price concessions and payments can be reasonably determined through approximation or otherwise, at the point of sale. NCPA surmises that most, if not all, stakeholders would agree with NCPA's assertion. In fact, PCMA seems to agree with

NCPA assertion as in PCMA's October 10, 2014 comments to CMS it states that "[p]rudent businesses approximate anticipated income and outlay, such that the effect of every price concession is 'approximated' by each sponsor. Moreover, virtually every approximation is at least in part based on recent experience, since recent experience is at least a partial indicator of future outcomes." The concept of using historical experience to approximate a liability, reimbursement or cost on an ongoing basis is not novel to federal government agencies. For instance, the Internal Revenue Service requires individuals to pay quarterly estimated taxes and permits individuals to utilize 110% of their prior year's tax liability as the basis for the quarterly estimates in order to avoid a failure to pay penalty. CMS could adopt similar guidance here and require Sponsors to include concessions and performance-based payments in the "negotiated price" and report such amounts on an ongoing basis in PDE and on the Medicare Part D plan finder tool in lieu of DIR to the extent the amounts can reasonably be approximated at the point of sale based on at least one year of historical data.

Conclusion

We greatly appreciate the opportunity to provide additional comments on CMS' proposed guidance implementing the revised definition of "negotiated price." We truly believe that standardizing how and when payments or price concessions given to pharmacies by Medicare Part D plans are reported allows for a more consistent picture of the total cost of a drug out-the- door from a pharmacy under a given Medicare Part D plan to all Medicare stakeholders—plans, CMS and beneficiaries—from plan-to-plan and pharmacy-to-pharmacy. This method allows beneficiaries to more easily compare plans and also levels the playing field for all Medicare Part D plans and pharmacies committed to delivering the Medicare Part D benefit to such beneficiaries. Please let us know if you have any questions or if we can be of further assistance.

Sincerely,

Susan Pilch, J.D.
Vice President, Policy and Regulatory Affairs