

October 17, 2014

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

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

Dear Ms. Johnson:

On behalf of the National Community Pharmacists Association (NCPA), I am pleased to share the following thoughts and recommendations in response to the *Proposed Guidance on Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions* released on September 29, 2014. 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.

NCPA Strongly Supportive of Revised CMS Definition of "Negotiated Prices"

NCPA commends CMS for its recent adoption of a new definition of "negotiated prices" in the Medicare Part D Final Rule that will require negotiated prices to be inclusive of all price concessions from network pharmacies except contingent price concessions that cannot be reasonably determined at the point of sale. In addition, the new definition also stipulates that additional contingent amounts such as incentive fees that increase prices are always excluded from the negotiated price. NCPA agrees that some Part D sponsors have manipulated the DIR reporting mechanism by reporting many pharmacy price concessions as DIR under the guise that such price concessions could not be determined at the point of sale. Such timing differential often has the result of CMS and the plan's enrollees paying higher monthly premiums and cost-sharing, however, such a plan may also owe a substantial year-end adjustment/risk-corridor payment to CMS due to substantial DIR.

NCPA Strongly Supportive of CMS Efforts to Standardize Reporting of Price Concessions/DIR

NCPA commends CMS in its efforts to standardize the reporting of price concessions and DIR. Inconsistency in the reporting of price concessions by Medicare Part D plans does not afford beneficiaries the ability to compare and contrast plans. NCPA is strongly supportive of the following statement found in the proposed guidance that speaks to the overall intent on the part of CMS to standardize reporting requirements for Part D participants in order to restore the integrity of the

reporting system itself. “The requirements for reporting price concessions apply regardless of how the price concessions are characterized by the Part D sponsor, the PBM, the pharmacy or any other entity and regardless of whether the price concession is calculated on a per-claim basis.” We feel that this is a critical statement that speaks to the heart of the problem that exists in the current system. PBMs characterize pharmacy price concessions in many different self-imposed ways primarily often via their manuals or contract addenda unilaterally imposed on pharmacies. Some of the terms used by PBMs of which we are aware include: “network access fees”, “administrative fees”, “technical fees”, “service fees”, “DIR fees”, “credentialing fees”, “post adjudication discounts”, and “network rebates.” These terms are not always indicative of what they encompass and whether they represent price concessions or fees for services provided by the PBM to the pharmacy or vice versa. If such amounts are not truly payments for services but price concessions, Medicare Part D plans should be deducting such amounts at the point of sale resulting in lower plan costs and beneficiary cost-sharing regardless of the term a PBM gives to such a concession. Negotiated price should include all fees over which the pharmacy has no control that impacts pharmacy compensation. Moving forward, CMS may wish to issue additional guidance to provide greater industry standardization on the characterization of price concessions and fees and could leverage the definition of “bona fide service fees” (and four-part test) referenced in the DIR Reporting Guide (taken from Medicaid Drug Rebate Program regulations at 42 CFR 414.802).

NCPA Strongly Supportive of Proposed Guidance on Pharmacy Price Concessions

The proposed guidance clarifies that pharmacy price concessions can be broken down into two categories—those that can be reasonably determined at point-of-sale and those that cannot. NCPA is strongly supportive of the proposed guidance that provides that “a determination at the point-of-sale includes an approximation of the price concession, even if the actual amount of the price concession is reconciled after the point-of-sale.” We agree with this approach and agree that PBMs that have worked in the Part D marketplace have ample experience with the types of price concessions and fees associated with the adjudication of claims that should enable them to “reasonably approximate” the appropriate amount. The guidance also provides a mechanism which would allow the difference between the approximation and actual final payment to be reported as DIR upon ultimate reconciliation.

Anticipated PBM/Plan Pushback on Proposed Guidance Not Persuasive

Inevitably there will be pushback on this proposed guidance from PBMs and plan sponsors who may claim that there are many different types of fees that cannot be “reasonably estimated” at the point of sale and even if they could theoretically be reasonably estimated, current claims adjudication systems are not capable of capturing and apportioning these fees on a per claim basis at the point of sale. However, it is an industry reality that the PBM business model is one in which most fees are already either charged or estimated on a “per click” or “per claim” basis. It is true that PBMs will need to re-program their claims adjudication systems in order to appropriately capture some price concession estimates in negotiated price at the point of sale. However, this guidance will not be in effect until benefit year 2016 which should provide these entities with ample time in which to implement

programming changes to existing claims adjudication systems to enable capture of price concession estimates at the point of sale.

The PBM industry also claimed that the mandatory maximum allowable cost (MAC) updates that were ultimately finalized in the Final Part D Rule would be “operationally infeasible.” We were pleased by CMS’ response to these concerns in the Final Rule in which it noted, “it does not make sense to us that part D sponsors/PBMs can manage the complexity in pharmacy reimbursement described in the comments, but cannot manage to modify that existing system”..... The proposed guidance also provides that for those price concessions that cannot be determined at point of sale, these amounts will be required to be reported in two new fields on the Summary DIR report. We would recommend that CMS in any final guidance make it mandatory that a Part D plan sponsor “shall provide” (rather than “can provide”) comments explaining why the price concessions could not be reasonably determined at point of sale.

Conclusion

In conclusion, NCPA is strongly supportive of the proposed guidance and commends CMS for its work on this issue designed to bring greater transparency and standardization to the reporting of price concessions and the overall treatment of costs in the Medicare Part D program. It is only when critical plan information is reported in the same manner for all plans that the federal government and beneficiaries alike will be able to conduct a true “apples to apples” comparison of the many different Part D plan options. We greatly appreciate the opportunity to provide comments on this proposed guidance.

Sincerely,

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