

May 16, 2016

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

***RE: Proposed Medicare Part D Direct & Indirect Remuneration (“DIR”) Reporting Requirements for 2015***

Dear Ms. Johnson:

On April 27, 2016, the Centers for Medicare & Medicaid Services (CMS) published the *Proposed Medicare Part D DIR Reporting Requirements for 2015* (the Proposed 2015 DIR Report), which sets forth certain changes and clarifications to the Summary and Detailed DIR reporting requirements for calendar year 2015. CMS specifically requested feedback from the National Community Pharmacists Association (NCPA) on the 2015 DIR Report that are we providing in this letter. In addition, twenty-one other industry stakeholder organizations (as listed below) including state pharmacy organizations, drug wholesalers, pharmacy buying groups/cooperatives and Pharmacy Services Administrative Organizations (PSAOs) have elected to sign on in support of these comments as well.

The NCPA represents the pharmacist owners, managers, and employees of more than 22,000 independent community pharmacies across the United States. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines. Independent pharmacists are small business entrepreneurs and multifaceted health care providers who represent a vital part of the United States' health care delivery system.

So-called “DIR Fees” imposed on pharmacies participating in their networks by Medicare Part D plans and their pharmacy benefit managers (PBMs) are confusing and misleading to pharmacies and beneficiaries alike. NCPA has long advocated for transparency around the existence and amount of “DIR Fees” and for inclusion of such fees in the “negotiated price” of prescription drugs paid for by Medicare Part D plans and in the Prescription Drug Event (PDE) records submitted to CMS on an ongoing basis.

While we continue to urge CMS to finalize its *2015 DIR Report on Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions* released on September 29, 2014, that would affect CY 2016 reporting, we commend CMS for the Proposed 2015 DIR Report, specifically the addition of the two new reporting fields aimed to capture “DIR Fees” charged pharmacies—“DIR #8 – Generic Dispensing Incentive Payments and Adjustments” and “DIR #9 – Other Pharmacy Incentive Payments and Adjustments.” We believe that the addition of these two new fields will provide greater insight into the different types of and sheer magnitude of pharmacy DIR Fees.

**We do wish to make the following comments with respect to the Proposed 2015 DIR Report:**

1. With respect to the fields DIR #8C and DIR #9C (Additional Comments), we feel strongly that Part D sponsors should be required to complete these fields with specific information regarding the Generic Dispensing Incentives, or Other Pharmacy Incentive Payments, as applicable, and describe precisely what those fees or incentives represent. It would also be appropriate to require the entity completing the report to explain why these particular fees cannot be reasonably estimated prior to the POS and included in the “negotiated price.”

2. The Column Description for field DIR #9 should be revised to include additional examples of what may qualify as “Other Pharmacy Incentive Payments and Adjustments.” We suggest that the following fees be listed as examples of “Other Pharmacy Incentive Payments and Adjustments”: preferred pharmacy fees; fees related to extended supply rates; and fees imposed based on qualitative measures, often in comparison to other pharmacies’ participation in a PBM’s network.

3. Finally, we urge CMS to create an additional and separate reporting field that addresses so called “Effective Rate True-Ups” whereby any amount that accounts for differences between the adjudicated rate indicated to the pharmacy at the point of sale and the contracted/effective rate paid to the pharmacy for drugs is reported. The proposed guidance does include such “effective rate” reconciliation amounts in DIR #9. However, given the prevalence of these arrangements and the disruption in the Medicare Part D pharmacy marketplace they are causing—we feel strongly that there should be a separate field to capture these amounts. There are various effective rates set forth in Medicare Part D plan sponsor and PBM agreements with network pharmacies as well as PBM manuals,

including generic and brand effective rates as well as comprehensive or “overall” effective rates for total prescriptions dispensed to a Medicare Part D plan’s enrollees by a given pharmacy. Again with the addition of this new field, we would recommend that entities completing the report explain why these specific fees cannot be reasonably estimated prior to the POS and included in “negotiated price.” Particularly with regard to this specific “type” of DIR fee, the “fee” is the result of a reconciliation between the adjudicated rate indicated to the pharmacy at the point of sale (or MAC) rate and the contracted/effective rate (usually a discount off AWP). Precisely because of the fact that AWP values are publicly available and MAC values are set by the Plan/PBM, it should not be a problem to estimate these at point of sale.

The NCPA and the undersigned organizations thank CMS for the opportunity to comment on these important issues. We hope the information captured in the 2015 DIR reports about “DIR Fees” is insightful to CMS and persuades CMS to finalize its guidance for Part D sponsors on reporting direct and indirect remuneration (DIR) data for contract year CY 2016 and beyond.

Sincerely,

The National Community Pharmacists Association

Academy of Independent Pharmacy (GA)

American Pharmacy Cooperative, Inc.

Astrup Drug, Inc.

Burlington Drug Company

CARE Pharmacies Cooperative, Inc.

Elevate Provider Network

Federation of Pharmacy Networks

Georgia Pharmacy Association

Independent Pharmacy Cooperative

Keystone Pharmacy Purchasing Alliance, Inc.

Louisiana Independent Pharmacies Association

National Alliance of State Pharmacy Associations (NASPA)

Northeast Pharmacy Service Corporation

PBA Health

Pharmacy Productions, Inc. d/b/a/ QualityCare Pharmacies

Philadelphia Association of Retail Druggists

PPOK RxSelect Pharmacy Network

Rochester Drug Cooperative, Inc.

RxPlus Pharmacies

Smart-Fill Management Group

Southern Pharmacy Cooperative