

June 1, 2017

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 2016

Dear Ms. Johnson:

On May 17, 2017, the Centers for Medicare & Medicaid Services (CMS) published the *Proposed Medicare Part D DIR Reporting Requirements for 2016* (the Proposed 2016 DIR Report), which sets forth certain changes and clarifications to the Summary and Detailed DIR reporting requirements for calendar year 2016. CMS specifically solicited comments on the Proposed 2016 DIR Report, which the National Community Pharmacists Associations (NCPA) is providing in this letter.

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.

As CMS is aware, the imposition of so-called “DIR Fees” levied on pharmacies participating in their networks by Medicare Part D plans and their pharmacy benefit managers (PBMs) have exploded in recent years. We know CMS, the Medicare Payment Advisory Commission and members of Congress share concerns that Medicare Part D plan sponsors and their PBMs are utilizing such fees to manipulate

premium amounts in their annual bid submissions for various reasons. NCPA shares these concerns and finds that DIR Fees are undermining independent pharmacy profitability and in many instances threatening the existence and survival of independent pharmacies. In addition, the proliferation of these post point-of sale price concessions are having a detrimental effect on beneficiaries and the Medicare program alike. Part D beneficiaries—due to higher cost sharing—are driven into the donut hole and out of the donut hole into the catastrophic coverage phase of the Part D benefit faster resulting in the Medicare program paying more for Medicare Part D beneficiary drug costs. 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, we commend CMS for the Proposed 2016 DIR Report specifically the 2 fields aimed at capturing DIR fees charged or paid to pharmacies—“DIR #8 – Amounts Received from Pharmacies” and “DIR #9 – “Amounts Paid to Pharmacies.” We strongly support this modification in how pharmacy DIR information is collected; specifically making a distinction between price concessions received from pharmacies and incentive payments paid to pharmacies by Medicare Part D plan sponsors. This delineation will also shed much needed light on plan sponsor/PBM pharmacy quality measures in the Part D program. Based on our discussions with NCPA members, as pharmacy quality programs are currently operating, they bear no resemblance to the Medicare Star Ratings system under which Part D plans are evaluated and eligible for bonus payments (MA-PD) based on performance. As currently operating, pharmacies that exhibit exceptional performance simply owe less pharmacy concession amounts to the plan/PBM—we have not heard of pharmacies being eligible for bonuses or incentive payments under such programs.

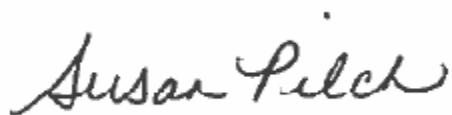
Additionally, NCPA would recommend that CMS include an additional field or fields that would further delineate DIR amounts charged or paid to non-retail pharmacies—specifically mail order and specialty pharmacies. This additional information would provide CMS with greater insight into how these fees are being applied across the Part D pharmacy marketplace.

We commend CMS for incorporating NCPA's suggestion from our prior year's comments and requiring Medicare Part D plan sponsors who report any amounts in column DIR #8 or #9 to complete fields DIR #8C and DIR #9C (Additional Comments). Specifically, fields DIR #8C and DIR #9C will require Medicare Part D plan sponsors to detail the metrics by which pharmacy performance was assessed. NCPA suggests that CMS request plan sponsors to attach program documents/contract excerpts describing these arrangements. By requiring plan sponsors to detail the metrics by which pharmacies were assessed, CMS will learn more about the various types of DIR Fees and be better positioned to evaluate why such Medicare Part D plan sponsors concluded that the amount of such fees cannot be reasonably determined or estimated prior to the point of sale.

NCPA urges CMS to consider requiring Medicare Part D plan sponsors to explain why these particular fees cannot be reasonably estimated at the point of sale based on historical data/trends or otherwise and included in the "negotiated price" in DIR #8C and DIR #9C (Additional Comments) as well. NCPA has long held that virtually all pharmacy price concessions could be reasonably estimated by plans/PBMs. 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

The NCPA thanks CMS for the opportunity to comment on these important issues. We hope the information captured in the 2016 DIR reports about "DIR Fees" is insightful to CMS and persuades CMS to finalize its *2015 DIR Report on Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions* for future plan years.

Sincerely,

A handwritten signature in cursive script that reads "Susan Pilch".

Susan Pilch, J.D.

Vice President, Policy and Regulatory Affairs

