

## NCPA Lawsuit to End Pharmacy DIR Fees

**Background:** Pharmacy direct and indirect remuneration fees not included in “negotiated prices” at point-of-sale, known as pharmacy DIR fees, have continued to grow at an alarming rate and escalated over the last several years. This growth has significantly impacted patients’ pocketbooks and the viability of small business community pharmacies. CMS itself cited in a proposed rule, pharmacy DIR fees assessed against pharmacies participating in Medicare Part D Plans grew by 45,000 percent between 2010 and 2017<sup>1</sup>. This increase is unsustainable for the patients who rely on Part D prescription drugs and community pharmacies.

The Trump Administration had multiple opportunities to reform the flawed system that allowed Medicare Part D plans and their PBMs to pocket price concessions rather than passing them along to patients, but they failed to reform the broken system. CMS has said that the average growth of pharmacy DIR fees will increase approximately 10% per year.<sup>2</sup> Because the Administration failed to act and due to the ever-increasing pharmacy DIR fees that continue to be extracted from pharmacies, a lawsuit challenging the validity of pharmacy DIR fees is necessary to protect the downstream consumers.

**The Lawsuit:** This lawsuit has been filed against the U.S. Department of Health & Human Services (HHS), and specifically challenges the rulemaking promulgated through HHS. The lawsuit addresses an exception included in a CMS rule that states all negotiated prices must include price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale. HHS initially said the exception would address a very narrow set of circumstances, but instead, has opened a “pandora’s box” for Part D plans and their PBMs. Through this loophole, the Plans and PBMs have been able to extract exorbitant amounts of pharmacy DIR fees from pharmacies thus diverting price concessions to their own benefit and allowing PBMs yet another stream of revenue. The lawsuit is challenging the rule on several grounds:

- 1. The rule’s definition of “negotiated price” violates the plain language and intent of Congress when they passed legislation creating the Medicare Part D program.**
- 2. The rule is invalid as arbitrary and capricious.**
  - In 2014 CMS said that the “reasonably determined” exception leading to DIR fees would be “narrow,” but comment letters showed that not to be the case.<sup>3</sup> A recent study showed that pharmacy DIR fees have increased 1600% since 2015, with \$4 billion in DIR fees being squeezed from pharmacies in 2017 alone.
- 3. The Final Rule Was Not Adopted Through Proper Notice-and-Comment Rulemaking.**
  - The proposed rule defined negotiated prices to include all price concessions from pharmacies and did not discuss or address any exceptions. In the final rule, without giving interested parties notice or the opportunity to comment, CMS created the exception for price concessions that could not be reasonably determined at the point of sale.

**Relief Sought:** The goal of this lawsuit is to strike down a massive loophole in the Medicare rules which Part D plans and their PBMs have used to pocket billions of dollars at the expense of patients and small business community pharmacies.

---

<sup>1</sup> The Centers for Medicare and Medicaid Services (CMS) November 30, 2018 proposed rule, “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,” (CMS-4180-P), can be found at <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf>

<sup>2</sup> Id.

<sup>3</sup> See 79 Fed. Reg. at 29,878