**Statement for the Record: Brian Hose, Pharm.D.**
**Pharmacy Owner and National Community Pharmacists Association Member**
**National Regulatory Fairness Hearing**
**U.S. Small Business Administration**
**August 19, 2019**

Representatives of the Small Business Administration and Office of the National Ombudsman:

Thank you for conducting this hearing focusing on regulatory fairness and the impact of certain regulations on small businesses in the United States. My name is Brian Hose. I have been a community pharmacist since 2006 and currently am the pharmacist-owner of Sharpsburg Pharmacy in Sharpsburg, Maryland. We are located in a small rural community where we are one of only a handful of small local businesses and are the only healthcare provider. I am here on behalf of myself, my small business community pharmacy, and the National Community Pharmacists Association (NCPA). NCPA represents America's community pharmacists, including 22,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in care coordination and ensuring patients have immediate access to medications in both community and long-term care settings. Together they represent a $76 billion healthcare marketplace, employ 250,000 individuals on a full or part-time basis, and provide pharmacy services to millions of patients every day.

My testimony today will focus on the retroactive, arbitrary, and unpredictable nature of direct and indirect remuneration fees, also known as pharmacy DIR fees or pharmacy price concessions, in the Medicare Part D program. Specifically, my comments will focus on how the Centers for Medicare and Medicaid Services' regulatory action in 2014 has had a dire impact on my small business community pharmacy and many other community pharmacies like my own. I will also address CMS' recent inaction on a proposal earlier this year that would have provided

much-needed relief from pharmacy DIR fees to small business community pharmacies across the country.

I'm sure that DIR fees are a new concept to many of you at this hearing. It certainly was for me a few years ago as insurers rolled these fees into their Medicare Part D contracts. Pharmacy DIR fees come in all shapes and sizes, but the common thread of all these fees is that they are assessed retroactively against a pharmacy. The easiest way that I can explain one type of pharmacy DIR fee is through the following example: Imagine that you are a sub-contractor that works on building a home for a family and is paid $50,000 for your materials and labor. The project is completed on time and the family is very happy with your work and their new home. At some point over the next several months to a year, the general contractor reaches into your bank account and removes a fee for every piece of lumber you used on the project just for the privilege of working on the home. In the worst example for my store, one plan took back 32% of what I was paid for generic medications in a calendar year. In our $50,000 example above, that would have cost you $16,000 in pharmacy DIR fees out of your original payment.

Other types of pharmacy DIR fees are based on unstandardized quality and performance metrics that I do not have the actual ability to influence at my pharmacy. This is because the quality and performance metrics in today's Medicare Part D program are meant to measure Part D plans, not my individual community pharmacy. What's worse, these kinds of pharmacy DIR fees always mean that a retroactive penalty will be assessed against my pharmacy. I have never been paid a positive amount for achieving quality or performance metrics despite my concerted and tireless efforts. My experience with these types of pharmacy DIR fees is not an anomaly.

On the whole, the current retroactive, arbitrary, and unpredictable nature of all pharmacy DIR fees eliminates a pharmacy's ability to account for profit or loss at the per-prescription level. A pharmacy is reimbursed at the negotiated price with a PBM/plan sponsor absent any retroactive pharmacy DIR fees, and such reimbursement may appear adequate and appropriate at the point of sale. Then, months later a PBM/plan sponsor withholds a large amount, suddenly making the previously reported reimbursement on the claim inadequate and perhaps lower than cost. The pharmacy is not able to forecast or model for this withholding, often not knowing the total pharmacy DIR fee in advance. In most instances, pharmacies cannot even allocate the aggregate withholding to the individual claim level of a prescription. Thus, the retroactive nature of pharmacy DIR fees is untenable for small business community pharmacies. Personally, these unpredictable reductions in payment have led to cutbacks in staffing, pay freezes, the loss of our community residency training program, and decreases in the level of service that we are able to provide to our patients and our small community.

In 2014, CMS attempted to amend its regulation that allows for retroactive pharmacy DIR fees by proposing that all pharmacy DIR fees should be assessed at the point of sale. That meant that the current retroactive nature of the fees would be eliminated, and pharmacies would finally be able to determine the impact of the fees to their store up front instead of months later. In CMS' final rule, however, they created a loophole that allows PBMs/plan sponsors to only include pharmacy DIR fees that could be "reasonably determined" at the point of sale, and the rest can still be applied retroactively. This loophole has had a dire impact on community pharmacies.

In fact, recent CMS estimations state that pharmacy DIR fees have grown an extraordinary 45,000 percent between 2010 and 2017, with the steep increase occurring between 2013 to 2017

where the fees increased from $229 million in 2013 to $4 billion in 2017. Internal NCPA numbers have found that pharmacy DIR fees impact on average approximately 1.5-3.5% of total revenue of a community pharmacy, which is roughly $88,500/per store on an annual basis. What's more concerning, is that there is some evidence that an uptick in community pharmacy closures in certain states with a high Medicare population correlates with the increase of pharmacy DIR fees.

Early this summer, CMS once again attempted to address pharmacy DIR fees by proposing to close the "reasonably determined" loophole and require PBMs/plan sponsors to assess all pharmacy DIR fees at the point of sale. Unfortunately, CMS declined to act on its proposal and did not include the change in a final rule. This inaction was a huge loss to our industry and our patients who continue to pay more at point of sale.

In conclusion, I believe that CMS should swiftly review all input received from stakeholders and expeditiously finalize, through rulemaking procedures, a rule to assess all pharmacy DIR fees at point of sale. At a minimum, CMS should hold plans accountable and standardize performance-based programs that are, today, arbitrarily and inconsistently imposed on community pharmacies and give the pharmacy profession meaningful control over these metrics to best serve the patient. The future of small business community pharmacies depends on these actions.