EFFLUENT LIMITATIONS GUIDELINES FOR THE ELECTRIC POWER SECTOR
PROPOSED REGULATORY FRAMEWORK FOR PLANT RETIREMENTS

In the upcoming rulemaking to revise the Effluent Limitations Guidelines (ELG) rule, EPA should include special provisions on the treatment of existing electric generating units (EGUs) that are retiring over the next 10 to 12 years.

As discussed below, one provision would establish an exemption from the new effluent discharge limitations for those retiring EGUs with a remaining useful life of 8 years or less. An exemption for this category of retiring units is appropriate in order to avoid the stranded costs that would result from requiring these retiring units to make major capital investments for achieving compliance with the new discharge limitations for flue gas desulfurization (FGD) wastewater and bottom ash transport water under the upcoming ELG rulemaking.

Another provision would authorize EPA to establish a separate subcategory for those retiring EGUs with a remaining useful life that is greater than 8 years but less than 12 years. For this new subcategory of retiring EGUs, EPA would establish alternative effluent discharge limitations that would moderate the stringency of the limitations to ensure the reasonableness and economic achievability of the control requirements. These discharge limitations should be set on a case-by-case basis by the state or federal regulatory authority based on "best professional judgment" (BPJ) in order to reflect the unit's remaining useful life and other relevant source-specific factors for ensuring the establishment of reasonably achievable and cost-effective control levels for each affected EGU.

Key elements of the two proposed provisions for the regulation of retiring EGUs under the ELG rule are briefly discussed below.

EXEMPTION FOR NEAR-TERM RETIREMENTS

- EPA would establish an exemption for those retiring coal-fired EGUs with a remaining useful life that is 8 years or less from the promulgation date of the final ELG rule. Key elements of the retirement exemption include the following:
  - The owner or operator of the retiring EGU must make a federally enforceable commitment to retire the designated unit by no later than 8 years from the promulgation of the final rule.
  - To make an election to retire the unit, a letter must be submitted to the appropriate EPA and the state regulatory authorities within 2 years from promulgation date of the final rule.
  - The commitment to retire the unit would be irrevocable and become federally enforceable through the establishment of permit condition in the NPDES permit for the unit.
  - The permit condition to retire would be incorporated into the NPDES permit within 3 years from promulgation date of the final rule.
  - The effluent discharge limitations in existence prior to the 2015 ELG rule would continue to apply until the designated unit retires.

- The retiring unit must permanently cease commercial operations to generate electricity within 8 years from the promulgation date of the final rule.

- Assuming that EPA promulgates a final rule in November, 2020, the milestones for the implementation of the exemption would be as follows:

DATE	MILESTONE
November, 2020	EPA issues final ELG rule
November 2022	Owner or operator submits a letter making an irrevocable commitment to retire the designated existing EGU
November, 2023	The permit condition to retire the existing EGU is incorporated into the NPDES permit
November, 2028	The retiring unit permanently ceases commercial operations to generate electricity.

NEW SUBCATEGORY FOR LONGER-TERM RETIREMENTS

- EPA would establish a special new subcategory for those retiring coal-fired EGUs with a remaining useful life that is greater than 8 years but less than 12 years. In particular, the subcategory would apply to those existing units that are scheduled to be retired, but will need to operate over an extended time period that shall not exceed 12 years from the promulgation date of the final ELG rule.

- This subcategory of coal-fired units would be subject to a source-specific effluent discharge limitation based on a BPJ analysis that allows for the consideration of the remaining useful life of the unit and other unique design and operating considerations of the retiring unit. This approach makes sense because it avoids stranded costs by not requiring major capital investments that are going to be retired over the near term, while still requiring the installation of cost-effective control measures to limit discharges during interim period.
  - As a general matter, the effluent discharge limitation would be limited to those cost-effective measures for reducing pollutant discharges that do not require major capital investments. This would result in the establishment of an effluent discharge limitation that is less stringent than the new effluent discharge limitation that EPA will establish for units with a remaining useful life of greater than 12 years.
  - In the case of FGD wastewater, this effluent discharge limitation could be based on various less capital-intensive control options, such as physical and chemical treatment with the addition of specified chemicals to the ponds or FGD systems in order to precipitate metals and other constituents in the wastewater.
  - In addition, the setting of source-specific effluent limitations based on BPJ will allow the regulatory authority to consider other unique design and operating circumstances that will affect the performance and cost-effectiveness of the control options for reducing effluent discharges during the limited compliance period prior to retirement. Notable factors that should be considered in making the BPJ determination include the following:
    - Planned retirement date of the affected unit;
    - Size of the affected unit;

  - Projected annual capacity factor of the affected unit under current energy forecasts;
  - Projected dispatch of the affected unit, including the extent to which the unit is expected to cycle and follow load or be dispatched at a baseload steady-state under current energy forecasts;
  - Projected flow rates and discharge levels of the particular unit under projected utilization levels during the interim period; and
  - Other relevant unit-specific factors.

- The owner or operator of the retiring EGU must make a federally enforceable commitment to retire the designated unit within 2 years from the promulgation date of the final rule.
  - To make an election to retire the unit, a letter must be submitted to the appropriate EPA and the state regulatory authorities within 2 years from promulgation date of the final rule.
  - The commitment to retire the unit would be irrevocable and become federally enforceable through the establishment of permit condition in the NPDES permit for the unit.
  - The permit condition to retire would be incorporated into the NPDES permit within 3 years from promulgation date of the final rule.

- The deadline for compliance with the alternative effluent discharge limitation for this new subcategory of retiring EGUs would be 5 years from the promulgation date of a final rule. An extension of up to two years may be obtained if additional time is needed to achieve compliance with the alternative limitation.
  - The effluent discharge limitation with the specified compliance deadline would be incorporated as a permit condition into the NPDES permit at the same time that the federally enforceable requirement to retire the unit (*i.e.*, 3 years from the promulgation date of a final rule.)
  - The retiring unit must permanently cease commercial operation to generate electricity within 12 years from the promulgation date of the final rule.

- Assuming that EPA promulgates a final rule in November, 2020, the milestones for the implementation of the requirements for this new subcategorization of retiring units would be as follows:

DATE	MILESTONE
November, 2020	EPA issues final ELG rule
November 2022	Owner or operator submits a letter making an irrevocable commitment to retire the designated existing EGU
November, 2023	The permit condition to retire the existing EGU is incorporated into the NPDES permit
November, 2025	The retiring unit must begin to comply with the alternative discharge effluent limitation established for retiring units unless it obtains an extension of up to two years.
November, 2032	The retiring unit permanently ceases commercial operations to generate electricity.

NCPA's Minimum Requirements on the Proposed Rule Regarding the Rebate Safe Harbor

HHS' OIG has published a proposed rule that seeks to prohibit rebates paid by manufacturers to plans under Medicare Part D and Medicaid MCOs from the discount safe harbor. This means that kickbacks given to PBM's would be prohibited under the law. The proposed rule, instead, creates a new safe harbor that allows for point-of-sale price reductions from manufacturers to plans. By moving manufacturer rebates to the point of sale, this proposal intends to reduce list prices and lower patients' out-of-pocket drug costs.

NCPA has spent a great deal of time and effort analyzing and speaking to stakeholders on the implications of this proposed rule for community pharmacies, including but not limited to potential legal, commercial, financial, and regulatory impacts. Based on our analysis, NCPA has prepared the following "Minimum Requirements" for NCPA to provide support for finalization of the proposed rule. NCPA encourages your organization to utilize these Minimum Requirements in your own comments to the proposed rule.

Public comments are due on April 8, 2019.

Minimum Requirements:

Contingent on NCPA's support for the proposed rule, listed below are the following Minimum Requirements for independent community pharmacies:

1. Fix Pharmacy DIR:
    - A system contemplated by this rule shall not go into effect without, at a minimum, finalization of the CMS proposed rule on pharmacy price concessions, 83 Fed. Reg. 62,152 (Nov. 30, 2018).

2. Timeliness of payments:
    - Independent community pharmacies shall, at a minimum, be paid in full for the total and final reimbursement, including any chargeback amounts, for a drug product consistent with protections provided under the Medicare Part D prompt pay rules, 42 C.F.R. § 423.520.

3. Transparency:
    - Independent community pharmacies shall have at the point of sale full visibility, in the approved claim, to the total and final reimbursement due the pharmacy.
    - Independent community pharmacies shall have at the point of sale full visibility to the existence and total and final amount of any chargeback amounts due.

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- Independent community pharmacies shall receive claim-level detail in electronic remittance advices that substantiate the total and final reimbursement of payor amounts and chargeback amounts.

4. Financial viability:
   - Independent community pharmacies shall assume no monetary liability for implementation of a system contemplated by the proposed rule. For example, should fees transpire from the operation of such system, such fees shall not be paid by pharmacies.
   - Independent community pharmacies' total and final reimbursement shall not be affected by the negotiated rate between the plan/PBM and manufacturer under a system contemplated by the proposed rule. Instead, pharmacies shall be made whole under such system based on a pharmacy's drug acquisition cost, the pharmacy's contracted rate between the pharmacy and plan/PBM, and a patient's out-of-pocket payment.

5. Agency oversight:
   - A system contemplated by this rule shall not go into effect without relevant regulatory action from relevant agencies to ensure appropriate oversight and alignment of such system in applicable government programs.

6. Small business protections:
   - A system contemplated by this rule shall not go into effect without implementation of small business community pharmacy protections, including but not limited to: right to appeal, inquire about missing payments, utilize audit processes, and engage in dispute resolution.
   - Independent community pharmacies shall be held harmless from activity of other parties in violation of the Anti-Kickback Statute.

7. Opportunity to choose business partners:
   - Independent community pharmacies shall have the opportunity to do business with any trading partner in the supply, billing, or reconciliation chain in a new system contemplated by this rule.

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

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By electronic submission

April 8, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Room 600E
Washington, DC 20201

The Honorable Daniel R. Levinson
Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue SW
Room 5527
Washington, DC 20201

Re: *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, OIG-0936-P

Dear Secretary Azar and Inspector General Levinson,

The National Community Pharmacists Association ("NCPA") appreciates the opportunity to comment on The Department of Health and Human Services-Office of Inspector General's ("HHS-OIG") proposed rule titled, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, OIG-0936-P (the "Proposed Rule").[1] 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 ensuring patients have immediate access to medications in both community and long-term care settings.[2] Together, our members represent a $76 billion healthcare marketplace, employ 250,000 individuals, and provide pharmacy services to millions of patients every day. Our members are small business owners who

[1] 84 Fed. Reg. 2340 (Feb. 6, 2019).
[2] *NCPA 2018 Digest by Cardinal Health* (2018).

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are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and long-term care independent pharmacies.

NCPA shares the administration's goal to lower drug prices for American patients and asserts that community pharmacies are uniquely positioned to aid the administration in accomplishing such goal. In fact, the proposal to require manufacturer price reductions at the point of sale featured in this Proposed Rule is closely aligned with NCPA's continuous advocacy efforts to secure a policy to assess all pharmacy price concessions at the point of sale. Both policy changes have the potential to lower drug prices, decrease out-of-pocket costs for patients, and reduce government drug spending in federal health care programs.[3]

However, while NCPA supports the spirit of this Proposed Rule and emphasizes that community pharmacies will play a key role in effectuating such a change, NCPA must secure minimum requirements from the administration before giving our support, given the significant questions surrounding how to operationalize a system contemplated under this Proposed Rule. NCPA offers the following comments to outline these necessary minimum requirements to ensure community pharmacies are securely positioned to aid the administration in accomplishing our shared goal to lower drug prices.[4]

Executive Summary

Over the past year, NCPA has stood with the administration in its efforts to lower drug prices for American patients. Last summer, NCPA offered support for many of the administration's policy considerations outlined in HHS' *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*.[5] NCPA supported the administration's proposal to prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, which is the very proposal reflected in this Proposed Rule. Importantly, NCPA supported the administration's efforts to abolish so-called "gag clauses" or provisions that impede a pharmacists ability to ensure that patients pay the lower cost for drugs.[6] Just this fall pharmacists from NCPA's leadership stood behind the President as he signed two pieces of legislation into law that prohibited pharmacist gag clauses in Medicare and private health plans.[7] The force of these laws has provided for the freer flow of information between pharmacists and their patients. NCPA celebrates this success along with the administration while acknowledging that there is still more work to be done.

Thus, NCPA continues to stand with the administration in its efforts to lower drug prices. Earlier this year NCPA, industry stakeholders, and patients provided resounding support for a proposal from

[3] 84 Fed. Reg. 2340, 2352.
[4] *NCPA 2018 Digest by Cardinal Health* (2018).
[5] 83 Fed. Reg. 22692 (May 16, 2018).
[6] NCPA Comments to *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, CMS-2018-0149 (July 16, 2018), *available at* http://www.ncpa.co/pdf/ncpa-comments-to-blueprint.pdf.
[7] *NCPA Leaders Attend White House Signing of "Gag Clause" Ban* (Oct. 10, 2018), *available at* https://www.ncpanet.org/newsroom/news-releases/2018/10/10/ncpa-leaders-attend-white-house-signing-of-gag-clause-ban.

the administration to change the current assessment of pharmacy price concessions (also known as pharmacy direct and indirect remuneration or pharmacy DIR) in Medicare Part D.[8] This Proposed Rule states that patients win when manufacturer price reductions are applied at the point of sale, but patients also win when all pharmacy price concessions are assessed at the point of sale. In fact, CMS recently estimated that beneficiaries would save $7.1 to $9.2 billion over 10 years resulting from reduced patient cost-sharing if pharmacy price concessions are assessed at the point of sale.[9] Community pharmacists continue to support CMS' proposed rule to eliminate retroactive pharmacy DIR and standardize pharmacy quality measures and urge the administration to finalize the proposal to go into effect for contract year 2020. NCPA also continues to support the total elimination of pharmacy DIR in the Medicare Part D program in the same spirit this Proposed Rule seeks to eliminate the pharmacy benefit manager ("PBM") kickbacks that exist today.

NCPA seeks future opportunities to work with the administration in its efforts to lower drug prices, including support on the Proposed Rule that is the subject of these comments. However, as NCPA continues to express to the administration, our members need support to eliminate the barriers that inhibit their patient relationships. To do this, community pharmacies need to compete in an environment that is transparent, unbiased, and has aligned incentives that best serve the interests of our patients, which is continually threatened by the tactics of PBMs. Community pharmacies also need to compete in transparent government programs that do not disproportionately punish small businesses for operating in these programs.[10] Approximately 36 and 17 percent of prescriptions in independent community pharmacies are covered by Medicare Part D and Medicaid, respectively,[11] and these government programs continue to account for more than half of all prescriptions sold in community pharmacies. Still, misaligned incentives punish small business community pharmacies for serving patients in these programs.

Specifically in the Medicare Part D program, pharmacy price concessions, net of all pharmacy incentive payments, grew an extraordinary 45,000 percent between 2010 and 2017.[12] What's more, what are meant to be performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased on average nearly 225 percent per year between 2012 and 2017 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates. The extraordinary growth of these price concessions is not an anomaly: PBMs have developed business models that utilize pharmacy DIR fees to siphon money from

[8] 83 Fed. Reg. 62,152 (Nov. 30, 2018).
[9] *Id.*
[10] Under the current system, there is a disconnect between estimated DIR in Part D bids and DIR reported annually by plan sponsors at the end of the year. The DIR projected in bids is an estimate made in early June of the preceding year and so is subject to errors in estimation. However, CMS does not have a formal process for checking on the reasonableness of DIR projected in the bids as compared with subsequent actual results. We contend that due to lack of oversight plans are using DIR, and more narrowly pharmacy price concessions, to "game the bids."
[11] NCPA focuses largely on how the Proposed Rule could impact the operation of Medicare Part D. NCPA will discuss the Proposed Rule's impact on Medicaid Managed Care in section II. of these comments.
[12] *Id.* at 62,174.

pharmacy businesses while simultaneously "gaming" the Medicare Part D bid process.[13] In fact, a recent *Wall Street Journal* article found that health insurers kept $9.1 billion in excess payments from Medicare in the years 2005-2016 by inaccurately estimating the prescription drug benefits they proposed to offer to beneficiaries in their Medicare Part D bids and that the lack of transparency in U.S. healthcare allowing such games is driving up spending.[14] Without intervention, the extraordinary extraction of pharmacy DIR fees from small business community pharmacies will not stop and could make it economically unfeasible for community pharmacies to continue to provide services to these vulnerable patient populations..

While NCPA urges CMS to fix pharmacy DIR immediately, NCPA continues to support alternative methods to change the pharmacy payment model that would allow community pharmacies to compete in a transparent and unbiased environment that has aligned incentives to serve today's Medicare Part D patients. As Secretary Azar was able to personally witness during his visits to community pharmacies in Pittsburgh and New Orleans this past October and February, respectively, our pharmacies do more than dispense. They know their patients and provide valuable products and services that stave patients from hospital and emergency room readmissions. It is for these reasons that NCPA members are increasingly joining together to demonstrate that value by becoming members of the Community Pharmacy Enhanced Services Network ("CPESN®"), a clinically integrated network of community pharmacies that coordinates patient care with physicians, care managers, and other patient care teams to provide medication optimization activities and enhanced services for high-risk patients. CPESN now has 47 networks in 44 states across the United States.[15] CPESN is setting the tone for a future that combats today's misaligned incentives as community pharmacies in this network work directly with payers to add enhanced services into contracts that lower medical and drug costs for patients.[16] CPESN will play a critical role in changing the pharmacy payment model, and NCPA encourages policymakers to consider this initiative as the administration looks for alternative methods to lower drug prices and overall healthcare costs for patients.

<u>This Proposed Rule, however, seeks to combat high drug prices in government programs by effectuating a system by which manufacturer price reductions are applied at the point of sale.</u> Once

[13] In fact, the Medicare Payment Advisory Commission ("MedPAC") identified that plan sponsors generally have an incentive to receive price concessions in the form of DIR rather than higher point-of-sale discounts, all else being equal. This is due to the timing of when these price concessions are made or reflected in the costs, and which parties share in the costs at different stages. MedPAC stated that "it is reasonable to ask if there is a financial advantage to a plan's bidding approach," or in other words, using various factors to "game" the bidding process. MedPAC, *Sharing Risk in Medicare Part D* (Mar. 5, 2015), *available at* http://www.medpac.gov/docs/default-source/meeting-materials/march-2015-meeting-presentation-sharing-risk-in-medicare-part-d-.pdf?sfvrsn=0. OIG has identified similar games are being played when Part D plan sponsors underestimate rebates in their bids. *See* OIG, Concerns with Rebates in the Medicare Part D Program (Mar. 2011), *available at* https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.

[14] Joseph Walker & Christopher Weaver, *The $9 Billion Upcharge: How Insurers Kept Extra Cash From Medicare*, WALL ST. J. (Jan. 4, 2019), *available at* https://www.wsj.com/articles/the-9-billion-upcharge-how-insurers-kept-extra-cash-from-medicare-11546617082.

[15] CPESN, *available at* https://www.cpesn.com/.

[16] *Id.*

applied, these point-of-sale reductions would effectively base a patient's out-of-pocket cost on the "net price" of a drug and prevent backend kickbacks from manufacturers to PBMs.[17] This proposal is a step in the right direction to change the pharmacy payment model as it relates to a patient's drug spend. It is NCPA's understanding, however, that in order to facilitate a system contemplated by the Proposed Rule, a pharmacy's reimbursement would be subject to certain chargebacks from the manufacturer to the pharmacy, either directly or indirectly, to make the pharmacy whole.

To this end, NCPA has evaluated two business models that could emerge as a system under this Proposed Rule: 1) Plan/PBM Administered Model; and 2) Non-PBM Administered Model. After our analysis and given the significant problems that community pharmacies have endured under current relationships with PBMs, NCPA advocates for a Non-PBM Administered Model to remedy the non-transparent and biased environment that has misaligned incentives that hinder patient care in today's healthcare system. In supporting such a model, NCPA must secure the following necessary minimum requirements for independent community pharmacies:

1. **Fix Pharmacy DIR**

   - A system contemplated by this Proposed Rule shall not go into effect without, at a minimum, finalization of the CMS proposed rule on pharmacy price concessions, 83 Fed. Reg. 62,152 (Nov. 30, 2018).

2. **Timeliness of Payments**

   - Independent community pharmacies shall, at a minimum, be paid in full for the total and final reimbursement, including any chargeback amounts, for a drug product consistent with protections provided under the Medicare Part D prompt pay rules, 42 C.F.R. § 423.520, and will earn interest on chargebacks due based on the LIBOR rate the day of the transaction.

3. **Transparency**

   - Independent community pharmacies shall have at the point of sale full visibility, in the approved claim, to the total and final reimbursement due the pharmacy.

   - Independent community pharmacies shall have at the point of sale full visibility to the existence and total and final amount of any chargeback amounts due.

   - Independent community pharmacies shall receive claim-level detail in electronic remittance advices that substantiate the total and final reimbursement of payor amounts and chargeback amounts.

[17] 84 Fed. Reg. 2340, 2352.

4. **Financial Viability**

- Independent community pharmacies shall assume no monetary liability for implementation of a system contemplated by the Proposed Rule. For example, should fees transpire from the operation of such system, such fees shall not be paid by pharmacies.

- Independent community pharmacies' total and final reimbursement shall not be affected by the price reduction agreed upon between the plan/PBM and manufacturer under a system contemplated by the Proposed Rule. Instead, pharmacies shall be made whole under such system based on the pharmacy's contracted rate negotiated with the plan/PBM.

5. **Agency Oversight**

- A system contemplated by this Proposed Rule shall not go into effect without relevant regulatory action from relevant agencies to ensure appropriate oversight and alignment of such system in applicable government programs.

6. **Small Business Protections**[18]

- A system contemplated by this Proposed Rule shall not go into effect without implementation of small business community pharmacy protections, including but not limited to right to appeal, inquire about missing payments, and engage in dispute resolution.

- Independent community pharmacies shall be held harmless from activity of other parties in violation of the Anti-Kickback Statute ("AKS").

7. **Opportunity to Choose Business Partners**

- Independent community pharmacies shall have the opportunity to do business with any trading partner in the supply, billing, or reconciliation chain in a new system contemplated by this Proposed Rule.

In conclusion, NCPA shares the administration's goal to lower drug prices for American patients and asserts that community pharmacies are uniquely positioned to aid in accomplishing such goal. In fact, the proposal featured in this Proposed Rule to require manufacture discounts at the point of sale is closely aligned with NCPA's continuous advocacy efforts to secure a policy in which all

[18] NCPA considers a "small business" community pharmacy to have the same meaning as the Small Business Administration's small business definition in 13 C.F.R. § 121.201.

pharmacy price concessions are also included at the point of sale. Both policy changes have the potential to lower drug prices, decrease out-of-pocket costs for patients and reduce government drug spending in Federal health care programs.[19]

NCPA's Detailed Comments

I. NCPA's Minimum Requirements on the Proposed Rule Regarding New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price

1. Fix Pharmacy DIR

A system contemplated by this Proposed Rule shall not go into effect without, at a minimum, finalization of the CMS proposed rule on pharmacy price concessions, 83 Fed. Reg. 62,152 (Nov. 30, 2018).

The Proposed Rule states that the goal of applying manufacturer price reductions at the point of sale is to curb list price increases, reduce financial burdens on patients by lowering out-of-pocket costs, lower Federal expenditures, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid Managed Care Organizations ("MCOs").[20] Of these objectives, the goal to lower out-of-pocket costs is most achievable based on the perverse incentives with the current application of manufacturer rebates. This is because, as the Proposed Rule states, most rebates do not flow through to patients at the pharmacy counter as reductions in price. Thus, patients "experience out-of-pocket costs more closely related to the list price than the rebated amount during the deductible, coinsurance, and coverage gap phases of their benefits."[21]

NCPA contends, however, that rebates are not the only types of remuneration that can lead to inflated drug prices and higher out-of-pocket costs for patients. In fact, while the application of rebates is an important aspect to the drug pricing conversation in Medicare Part D, an analysis of out-of-pocket costs is incomplete without addressing all types of renumeration, including pharmacy price concessions, or pharmacy DIR, that PBMs utilize to pad their pockets. In the Medicare Part D program, PBMs usage of pharmacy price concessions has exploded over the past several years and the increased use of these pharmacy DIR fees have had an astounding impact on patients, the government, and small businesses.[22]

The retroactive nature of these price concessions means beneficiaries face higher cost-sharing for drugs and are accelerated into the coverage gap or "donut hole" phase of their benefit. What's more, beneficiaries reach the catastrophic phase faster of the benefit, for which CMS incurs

[19] 84 Fed. Reg. 2340, 2352.
[20] *Id.* at 2344.
[21] *Id.* at 2341.
[22] 83 Fed. Reg. 62,152, 62, 174.

approximately 80 percent of the cost. Finally, retroactive pharmacy DIR fees are taken back from community pharmacies months later rather than deducted from claims on a real-time basis. This reimbursement uncertainty makes it extremely difficult for community pharmacists to operate their small businesses. Fortunately, CMS has recently published a proposed rule that would change the retroactive nature of pharmacy price concessions to be assessed at the point of sale.[23] NCPA urges the administration to finalize the proposed rule on pharmacy price concessions prior to implementation of any system contemplated by this Proposed Rule for the following reasons.

First, HHS could utilize finalization of CMS' proposed rule on pharmacy price concessions to determine behavioral changes if the amount by which a patient's cost sharing is based is lowered due to the prospective application of pharmacy price concessions at the point of sale.[24] In fact, CMS has outlined a way in which pharmacy price concessions could be assessed at the point of sale, without having to operationalize a completely new system. CMS proposes Part D sponsors or PBMs load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems, which interface with contract pharmacies.[25] CMS notes that the estimated rebates at the point-of-sale field on the "Prescription Drug Event" ("PDE") record can be used to collect the amount of point-of-sale pharmacy price concessions. Further, CMS states that the fields on the "Summary and Detailed DIR Reports" can be used to collect final pharmacy price concession data at the plan and NDC levels.[26] In comments to CMS, NCPA supported this procedure to effectuate a change to include all pharmacy price concessions in the negotiated price at point of sale.[27] Thus, NCPA urges the finalization of CMS' proposed rule on pharmacy price concessions prior to the finalization of this OIG Proposed Rule.

Second, NCPA is concerned that if community pharmacists continue to be unable to detect the financial burden they will incur at the point of sale, PBMs will squeeze pharmacies with these non-transparent fees at a more alarming rate. While the OIG has studied the impact of manufacturer rebates (and despite the documented abuses stemming from the usage of pharmacy DIR in Part D) OIG has yet to conduct its own study on how pharmacy DIR leads to fraud, waste, and abuse in Medicare Part D.[28] NCPA urges the administration to not only conduct this OIG study but finalize CMS' proposed rule on pharmacy price concessions.

Third, NCPA is concerned that PBMs may use the loss of revenue from rebates to levy larger and more aggressive pharmacy price concessions against pharmacies to make up for lost revenue. As

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[23] *Id.*
[24] *Id.*
[25] *Id.* at 62,179.
[26] *Id.*
[27] NCPA Comments to *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,* CMS 4180-P (Jan. 25, 2019).
[28] *See* OIG, *Concerns with Rebates in the Medicare Part D Program* (Mar. 2011), *available at* https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf. NCPA notes that OIG has included in its work plan a study on DIR that may be released this year. *Part D Sponsors Reporting of Direct and Indirect Remunerations,* (announced Sept. 2017), *available at* https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000249.asp.

stated above, CMS has well-established data that demonstrates PBMs usage of retroactive pharmacy price concessions is growing rapidly. If the level of manufacturer rebates being paid to plans/PBMs for formulary placement and market share are reduced under the new contractual arrangements implemented under a final rule, plans/PBMs may be under pressure to provide alternative avenues to keep plan liability closer to its current levels. One way to achieve this would be to contract aggressively for increased pharmacy DIR. Increased pharmacy DIR would lead to lower pharmacy revenue, which could make it difficult for small pharmacies to continue to participate in or gain network access.[29]

Community pharmacies have seen this squeeze from PBMs before. One theory for this rise is that PBMs are utilizing aggressive pharmacy price concessions in response to the increasing number of maximum allowable cost ("MAC") transparency laws that have been enacted over the past few years.[30] NCPA is concerned that a similar trend may occur if manufacturer rebates are ostensibly applied as price reductions at the point of sale, but pharmacy price concessions are not also included in that point-of-sale price. Thus, community pharmacies need clarity in their reimbursements and pharmacy DIR continues to distort that information. The pharmacy's contracted rate should include all pharmacy DIR at the point of sale, and as expressed in CMS' Proposed Rule on pharmacy price concessions, only positive contingent amounts that are based on a pharmacy's performance should be paid retroactively.

NCPA further argues that those positive contingent amounts should be standardized. Currently, contingent amounts are based on a pharmacy's performance and there is a wide variance and complete lack of standardization across sponsors and PBMs in the quality measures utilized, terminology, timing, attribution methods, number of patients required to capture a metric, and calculation methods. In the environment community pharmacies operate in today, Part D plans and PBMs create their own "homegrown" measures with unrealistic thresholds and unattainable cut points. In NCPA's comments regarding pharmacy price concessions, NCPA urges CMS to move forward immediately and develop a standard set of metrics from which plans and pharmacies base contractual agreements.[31] This will ensure pharmacies are actually paid for the value they provide to patients. Such metrics should be directly related to patient care.

In conclusion, a system contemplated by this Proposed Rule shall not go into effect without, at a minimum, finalization of the CMS proposed rule on pharmacy price concessions, 83 Fed. Reg. 62,152 (Nov. 30, 2018).

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[29] Milliman, *Impact of Potential Changes to the Treatment of Manufacturer Rebates* (2019).
[30] NCPA, *Frequently Asked Questions About Pharmacy DIR* (2014), *available at* http://www.ncpa.co/pdf/dir-faq.pdf.
[31] NCPA Comments to *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*, CMS 4180-P (Jan. 25, 2019).

2. Timeliness of Payments

Independent community pharmacies shall, at a minimum, be paid in full for the total and final reimbursement, including any chargeback amounts, for a drug product consistent with protections provided under the Medicare Part D prompt pay rules, 42 C.F.R. § 423.520, and will earn interest on chargebacks due based on the LIBOR rate the day of the transaction.

The Proposed Rule contemplates a system in which a manufacturer price reduction cannot be applied at the point of sale unless "the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or series of chargebacks."[32] The Proposed Rule defines a "chargeback" as "a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment the pharmacy receives for the prescription pharmaceutical product is **at least** equal to the price agreed upon in writing between the Part D sponsor, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product."[33]

Thus, the function of a chargeback system contemplated under this Proposed Rule appears to be a secondary payment from a manufacturer to a pharmacy and draws on a process by which manufactures and wholesalers account for product in place today in the supply chain. NCPA's internal analysis finds that roughly $5.04 billion in total money from independent community pharmacies could be tied up in a secondary payment (also known as a chargeback or a series of chargebacks). The sheer amount of money at stake in a system contemplated by this Proposed Rule lends itself to an extensive operational evaluation, including the timing of such payments.[34]

Slow payments, like retroactive fees, have been a source of concern for community pharmacies' cash flow since the implementation of the Part D program. In fact, following the passage of Medicare Part D, NCPA members began to experience severe lags in payment from Part D plans/PBMs.[35] During NCPA's prompt pay advocacy efforts in 2006, the first year of Medicare Part D, the number of independently owned community pharmacies decreased by over 1,000 (the largest drop in over 20 years) due to a lack of timely payments.[36] This drop in the number of pharmacies led to an estimated loss of 15,000 jobs at these pharmacies, often in communities who could least afford to lose jobs.[37] An analysis conducted at that time found that community pharmacies had a slower median time to payment following adjudication of claims by Part D plans

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[32] 84 Fed. Reg. 2340, 2349.
[33] *Id.* (emphasis added).
[34] Altarum, *The Impact of Prescription Drug Rebates on Health Plans and Consumer* (Apr. 2018).
[35] NCPA, *Improve Medicare Part D: Support Prompt Pay*, (Mar. 2, 2006), *available at* https://www.ncpanet.org/pdf/leg/prompt_pay_co-branding_1_pager.pdf.
[36] *2008 NCPA Digest Sponsored by Cardinal Health* (2008).
[37] *Id.*

compared with chain pharmacies in 2006 (31 days vs. 29 days).[38] Further, delays in payment had increased the cash flow issues faced by independent pharmacies, forcing them to borrow more from their lines of credit. Interest payments on these credit lines erode the pharmacy's operating margin, leaving less money available for paying salaries, marketing, and capital investments. While Part D created cash flow issues for all pharmacies, chain pharmacies had access to cash on hand and a variety of financing mechanisms to help them manage their accounts receivable while most independent pharmacies did not have before prompt pay rules (and do not have today due to the grave consequences of Medicare Part D DIR fees).[39]

Under today's Medicare Part D prompt pay rules, a Part D plan sponsor must issue payment for all clean claims within 14 days after the date on which the claim is received (also known as "adjudication") if the claim is electronic.[40] Clean claims are defined as a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under this section.[41]

Under any system contemplated under this Proposed Rule, community pharmacies must be paid in full for the total and final chargeback amounts, if any, on a timetable no later than 14 days after adjudication of the original claim as contemplated under the Part D prompt pay rules. This is critical to a pharmacy's cash flow, which impacts the ability for a small business community pharmacy to pay its staff, lease, and inventory. While current prompt pay rules only govern claims submitted in Medicare Part D, NCPA proffers that this timeline is the bare minimum to ensure appropriate and efficient pay to community pharmacies. Without this bare minimum, community pharmacies will be forced to float unaccounted for dollars while already operating on razor thin margins. Forcing them to in essence hold a figurative "I.O.U." until the chargeback is paid puts them in a very difficult financial position. Chargebacks should at least be equal to the price agreed in writing. Whatever entity is holding the chargeback will receive interest "float" for up to 14 days under prompt pay rules. To incent the holder of the chargeback to remit the pharmacy's chargeback as quickly as possible, the pharmacy should be paid interest on the chargebacks being held based on LIBOR rate on the date of the PDE. As the supply chain charges forward into the future, NCPA would expect systems to facilitate any chargebacks in real-time and that level of accountability from the supply chain will ensure compliance with any timeliness of payments requirement.

NCPA also expects the supply chain to need to validate the chargebacks within the minimum timeline contemplated under the prompt pay rules, which may dictate the time component of any chargeback system. Validation of chargebacks plays an important role in ensuring there is no

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[38] Journal of Managed Care Pharmacy, *A Bleak Future for Independent Community Pharmacy Under Medicare Part D* (Dec. 2008), *available at* http://my.amcp.org/data/jmcp/878-881.pdf.
[39] *Id.*
[40] The Part D plan sponsor must issue payment for all clean claims within 30 days after adjudication of a claim if the claim is submitted in any other way than electronic. 42 C.F.R. § 423.520.
[41] *Id.*

impropriety in the supply chain. However, NCPA expects a system contemplated under this Proposed Rule would not allow trading partners to require different purchase requirements in relation to chargebacks. Every pharmacy should be treated equally in regard to validation and timeliness of payments.

Without proper guardrails around timeliness of chargebacks, especially those related to validation of chargebacks, NCPA is concerned that a chargeback system contemplated under this Proposed Rule would provide incentives for manufacturers to only work with a narrow set of pharmacies who agree to the manufacturer's validation and time processes. For example, manufacturers, given the criminal nature of the AKS, may only deal with a subset of pharmacies who agree to a set of contract terms that a manufacturer sets for compliance requirements under the AKS, even if such terms exceed what is expected for compliance under the AKS. This type of behavior could be detrimental to community pharmacies who are at a stark disadvantage to larger chain pharmacies to negotiate contracts.

NCPA reminds the OIG that the "any willing pharmacy" provision found in section 1860D 4(b)(1)(A) of the Social Security Act is a linchpin of the Medicare Part D program and helps to ensure that beneficiaries have adequate access to pharmacy care services and prescription medications.[42] Any limitation of the any willing pharmacy provisions in Medicare Part D create a conflict between two bodies of law (that is, the Medicare Part D program and the AKS), which creates an impossible choice for compliance for players in the supply chain. Thus, any unintended consequences of this Proposed Rule may undermine the important protections found in the any willing pharmacy law in Medicare Part D and the AKS.

In conclusion, independent community pharmacies shall, at a minimum, be paid in full for the total and final reimbursement, including any chargeback amounts, for a drug product consistent with protections provided under the Medicare Part D prompt pay rules, 42 C.F.R. § 423.520, and will earn interest on chargebacks due based on the LIBOR rate the day of the transaction.

3. Transparency

a. Independent community pharmacies shall have at the point of sale full visibility, in the approved claim, to the total and final reimbursement due the pharmacy.

The Proposed Rule's chargeback system presents a series of challenges regarding what a community pharmacy will know at the point of sale. Regardless of the presence of the net price at the point of sale for which a patient's cost-sharing will be based, a community pharmacy must have the total and final reimbursement due to the pharmacy be based on the pharmacy's contracted rate negotiated with the plan/PBM (before applying the discount amount). The negotiated rate via contract between a plan/PBM and pharmacy would be broken into three parts: 1) plan payment amount; 2) beneficiary cost-sharing amount; and 3) point-of-sale price reduction. In Medicare Part

[42] Codified at 42 U.S.C. § 1395w-104(b)(1).

D, NCPA expects the sum of the three parts to equal the statutorily defined "negotiated price" that is the contracted rate between plan/PBM and pharmacy.

Full visibility is important to community pharmacies as they, among other activities, plan to pay staff, any leases, or stock inventory. Currently, pharmacy claims are adjudicated electronically via standard transactions developed by the industry at the National Council for Prescription Drug Programs ("NCPDP") pursuant to and compliant with the Health Information Portability and Accountability Act of 1996 and the regulations thereunder (collectively, "HIPAA"). Through those standard transactions, pharmacies receive a paid claim message from a patient's health plan informing the dispensing pharmacy that a claim is approved as well as itemizing the amount the plan will pay and the beneficiary out-of-pocket amount to collect. To implement the Proposed Rule, the NCPDP standard claim response message would also need to separately itemize the applicable point-of-sale price reductions so that community pharmacies could track the chargeback amounts.

As stated earlier, accessing the pharmacy's total and final reimbursement would not be a monumental lift. CMS' recent proposed rule regarding pharmacy price concessions states that Part D sponsors or PBMs would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems, which interface with contract pharmacies. CMS notes that the estimated rebates at the point-of-sale field on the PDE record can be used to collect the amount of point-of-sale pharmacy price concessions. Further, CMS states that the fields on the Summary and Detailed DIR Reports can be used to collect final pharmacy price concession data at the plan and NDC levels. We agree with this procedure to effectuate a change to include all pharmacy price concessions in the negotiated price at point of sale.

Thus, independent community pharmacies shall have at the point of sale full visibility, in the approved claim, to the total and final reimbursement due the pharmacy and as described below, to the chargeback amount.

b. Independent community pharmacies shall have at the point of sale full visibility to the existence and total and final amount of any chargeback amounts due.

The Proposed Rule defines a "chargeback" as "a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment the pharmacy receives for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Part D sponsor, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product."[43]

Community pharmacies must have full visibility, at the point of sale, of any chargeback so that they can plan their future cash flow. Further, while other actors in the supply chain may argue that these chargeback amounts are propriety, NCPA counters that these chargebacks are vital to a pharmacy's ability to operationalize its business. Transparency into the claim amount is not transparency into

[43] 84 Fed. Reg. 2340, 2349.

the discount contract itself. What is not known is if the product is one of two on the formulary, or one of four. Is the product discount indication based? Is there a performance aspect to the contract? Does the discount only apply after a prior authorization? Transparency of discounts is likely to lower list prices and reduce misaligned incentives. Transparency for the patient will also be useful. Patients who know the plan's discount amount for a product can be in a better position to pick the right plan.

Finally, NCPA has participated in NCPCP's drafting of comments to this Proposed Rule. As part of our participation we understand that the current version of the NCPDP standard approved by HHS is Telecommunication Standard version D.0 and in order to operate in any new system contemplated in this Proposed Rule, certain types of modifications may be made in the near-term to the Telecommunication Standard that do not require a new version, just expedited code values. Therefore, it is possible for point-of-sale transactions to comply with the conditions of this proposed safe harbor and for community pharmacies to receive an itemized chargeback amount for each prescription drug claim processed. NCPA must have this transparent level of detail to support this Proposed Rule.

Moreover, as a general concern, transparency of these chargeback amounts should be important to the supply chain as there is a current perverse incentive to use hidden amounts to game certain government programs. In Medicare Part D, there is a disconnect between estimated DIR in Part D bids and DIR reported annually by plan sponsors at the end of the year. The DIR projected in bids is an estimate made in early June of the preceding year and so is subject to errors in estimation. However, CMS does not have a formal process for checking on the reasonableness of DIR projected in the bids as compared with subsequent actual results. We contend that due to lack of oversight plans are using DIR, and more narrowly pharmacy price concessions, to "game the bids." A *Wall Street Journal* investigation conducted this year also reported evidence of plans gaming bids. Their investigation reported that health insurers kept $9.1 billion in excess payments from Medicare in the years 2005-2016 by inaccurately estimating the prescription drug benefits they proposed to offer to beneficiaries in their Medicare Part D bids. The Wall Street Journal concluded that the lack of transparency in U.S. healthcare is driving up spending.[44]

Thus, in the name of transparency, independent community pharmacies shall have at the point of sale full visibility to the existence and total and final amount of any chargeback amounts due.

c. Independent community pharmacies shall receive claim-level detail in electronic remittance advices that substantiate the total and final reimbursement of payor amounts and chargeback amounts.

The Proposed Rule's only parameters related to a pharmacy's payment in a system contemplated under this Proposed Rule include: 1) the reduction in price could not involve a rebate unless the full

[44] Joseph Walker & Christopher Weaver, *The $9 Billion Upcharge: How Insurers Kept Extra Cash From Medicare*, WALL ST. J. (Jan. 4, 2019), *available at* https://www.wsj.com/articles/the-9-billion-upcharge-how-insurers-kept-extra-cash-from-medicare-11546617082.

value of the reduction in price is provided to the dispensing pharmacy through a chargeback or series of chargebacks; and 2) the reduction in price must be completely reflected in the price the pharmacy charges to the beneficiary at the point of sale. Nothing contemplates how a pharmacy will substantiate its payment.

NCPA contends that the point-of-sale amounts must be equal to the exact amount provided to the pharmacy after all chargebacks are received. Further, NCPA argues that these amounts must be provided to the pharmacy on a per claim level. In our comments to CMS regarding the proposed rule on pharmacy price concessions, NCPA urged CMS to require plan sponsors and PBMs to include suitable claim-level detail on the electronic remittance advices that accompany payments. NCPA supports that claim-level data should include all fields needed to properly identify the claim, including the Claim Authorization Number, payment amounts, and the appropriate qualifier codes for each payment adjustment.[45]

We argue the same for chargebacks. To enable full tracking by the pharmacy, the final rule must require that the chargeback administrator furnish, along with the chargeback payments, electronic remittance advices in the NCPDP approved X12 835 format with all chargeback amounts detailed at the claim level. Similar transactions are being done today (coupons) however the volume of transactions with secondary payments would expand and may require new business arrangements to support this specific methodology.

Therefore, independent community pharmacies shall receive claim-level detail in electronic remittance advices that substantiate the total and final reimbursement of payor amounts and chargeback amounts.

4. Financial Viability

a. Independent community pharmacies shall assume no monetary liability for implementation of a system contemplated by the Proposed Rule. For example, should fees transpire from the operation of such system, such fees shall not be paid by pharmacies.

The new safe harbor for certain price reductions on prescription pharmaceuticals only contemplates the exchange of funds between certain players in the supply chain, namely the manufacturer, PBM, and pharmacy. As NCPA discusses throughout these comments, the Proposed Rule states that chargeback systems will include "a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment the pharmacy receives for the prescription pharmaceutical product is at least equal to the price agreed upon in writing between the Part D sponsor, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product."[46] NCPA is concerned that the facilitation of a chargeback

[45] In relation to pharmacy price concessions, NCPA contends that appropriate qualifiers include any fees or incentive payments.
[46] 84 Fed. Reg. 2340, 2349.

system may negatively impact small business community pharmacies in a variety of ways that are not contemplated under this Proposed Rule.

First, this chargeback definition does not contemplate additional fees that may arise among trading partners for the operation of a chargeback. Additionally, this chargeback definition does not address which party must bear the cost of any fees that come out of such a system. NCPA contends such fees are an inevitable business practice any time funds are being exchanged between business partners. This Proposed Rule must contemplate how those fees should be operationalized under a chargeback definition. NCPA argues that any fees that arise from the operation of a chargeback or multiple chargebacks to the pharmacy must not be paid by pharmacy as additional costs outside of the chargeback amount.

Today's transaction and related fees are handled in different ways by a variety of actors engaging with pharmacies. Some partners bundle fees while others charge a fee on a per claim basis. A recent example from a NCPA member pharmacist demonstrated four different transaction fees related to claim adjudication for just one drug that passed through both private, Medicare, and Medicaid payors hands. Transaction fees like these are a source of frustration for community pharmacies. Still, small business community pharmacies manage these fees because they have no alternative options in the drug channel. The point-of-sale price reduction, however, is rightfully designed to solely benefit the patient. Community pharmacies are pleased to be part of enabling this transaction for our patients, but we should be held harmless under such a system. The proposed chargeback system is not part of a pharmacy's cost of doing business and NCPA contends that the Proposed Rule should not mandate pharmacies facilitate such a process without adequate compensation from the government or business partners for being part of such a system. Thus, in order for independent community pharmacies to assume no monetary liability for implementation of a system contemplated by the Proposed Rule, NCPA contends that any transaction fees created through the facilitation of a chargeback system should be borne by manufacturers, wholesalers, plans or other parties to the discount contract or administrators of such a chargeback system.

Second, NCPA is concerned the Proposed Rule's Regulatory Flexibility Act ("RFA") analysis does not fully contemplate the impact on small business community pharmacies. An agency is required to conduct an RFA analysis or certify that a proposed rule will have a significant impact on a substantial number of small entities.[47] Pursuant to section 603 of the RFA any agency seeking to certify that the rule will not have a significant impact must provide a factual basis for the certification.[48] That means that the agency must provide a description of the number of affected entities and the size of the economic impact on those small businesses (i.e., the impact measured by the business' revenue or some other metric).[49] HHS generally uses the measure of three to five percent of a small business' revenue as their measure of significant impact.[50]

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[47] 5 U.S.C. § 601-612.
[48] *Id.*
[49] *Id.*
[50] 70 Fed. Reg. 4194, 4497 (Jan. 28, 2005) ("HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.").

In this Proposed Rule's RFA section, HHS certifies that the Proposed Rule will not have a significant impact on a substantial number of small entities. NCPA contends that HHS' certification does not meet the factual basis standard outlined above. Specifically, HHS' RFA certification only relies on analysis under the Regulatory Impact Analysis ("RIA") that assumes that the only costs on affected entities will be associated with reviewing the Proposed Rule and reviewing policies to come into compliance with the rule's requirements.

The Proposed Rule's RIA does contain some relevant data and assumptions. For example, NCPA agrees with OIG's finding that there are approximately 21,909 small business community pharmacies operating in the United States. NCPA does not agree, however, with the assumptions under section D of the RIA related to the cost for these small business community pharmacies to comply with the changes contemplated under this Proposed Rule. NCPA disagrees that it would only take a community pharmacy two to ten hours to review and implement the changes if the Proposed Rule were finalized. Within our own association, we have spent countless hours evaluating systems that may or may not comply with the definition of a chargeback as contemplated under this Proposed Rule. We expect small business community pharmacies will have to read the final rule and find business partners (including IT system vendors) in the supply chain that will appropriately facilitate a chargeback. This will require a substantial amount of time to vet and negotiate with business partners to finalize a new contract. Likewise, small business community pharmacies will need to train staff to comply and understand the operations of a chargeback system. Given the criminal nature of the AKS, small business community pharmacies will take this training component seriously and could require multiple hours of continuous education. Thus, NCPA contends the time and costs estimated in the RIA is grossly underestimated and OIG should prepare a true analysis on the costs of this proposal on small business community pharmacies.

NCPA disagrees with the Proposed Rule's contention that some small business community pharmacies would save money should there be a reduction in patients abandoning drugs at the pharmacy counter (cost savings allegedly are related to storing and tracking of abandoned prescriptions).[51] This potential behavioral change is not a notable cost saver for small business. NCPA urges OIG to abandon this argument as the cost of dealing with product at the pharmacy is already contemplated in our members' business models.

By OIG's own admission, "[t]he actuarial analyses [OIG] commissioned were not designed to evaluate the effects on the pharmacy supply chain by moving from a system where reimbursement rates were divorced from actual negotiated prices after accounting for rebates."[52] If the impact to pharmacies was not actually contemplated, how can HHS certify that there is no significant impact on a number of small business community pharmacies? NCPA recognizes that OIG seeks information on how to structure an analysis to evaluate the effects on the pharmacy supply chain. First, OIG should have solicited this information prior to certifying there is no significant impact to a substantial number of small entities. Second, given the sizeable amount of dollars that may be tied

[51] *Id.*
[52] *Id.* at 2361.

up in a chargeback system, NCPA postures that, at a minimum, this analysis should be structured around the timing implications of a chargeback to a small business community pharmacy.[53] NCPA stands ready to work with OIG to facilitate such an analysis.

OIG also admits that this analysis does not consider "the range of strategic behavior changes stakeholders may make in response to this rule, including the extent to which . . . PBMs change benefit designs or obtain additional price concessions."[54] As stated above, NCPA is concerned that the elimination of retroactive rebates could lead to PBMs utilizing other forms of remuneration, namely pharmacy DIR, to make up for loss of revenue on the rebates. NCPA incorporates by reference our arguments made in section I.1. of these comments related to the dire impact pharmacy DIR has had on community pharmacy and the bleak outlook for our members should CMS not take additional regulatory action.

Finally, the Proposed Rule asks whether this proposal could lead to further consolidation in the healthcare market. NCPA contends yes, this is a stark possibility and continued consolidation of the market has had a notable impact on community pharmacies' bottom-line. PBMs already have extraordinary market power; the top three PBMs control approximately 85-89% of the market: 238 million lives[55] out of 266 million lives.[56] This dominance has allowed PBMs to leverage their market power to the detriment of plan sponsors (government and commercial payors), providers, and consumers. Additionally, PBMs claim that they help plan sponsors generate savings by negotiating rebates, however, recent reports have shown the opposite. A report from 2017 found that PBMs have been utilizing their market power to try to increase their profits and encourage higher list prices for prescription drugs, which increases out of pocket payments for patients.[57] To address PBM market dominance, NCPA has long argued for additional scrutiny of PBMs, including their inherent conflicts of interest, lack of transparency, and one-sided take-it-or-leave-it contract negotiations with independent pharmacies. NCPA urges OIG to consider the impact this Proposed Rule will have on the market that will ultimately impact small business community pharmacies.

Therefore, we urge OIG to perform a more thorough analysis of this rule's impacts on small pharmacies as is required under the RFA. Also, we encourage OIG to work with the relevant antitrust agencies to take a closer look at PBM consolidation under this Proposed Rule for potential effects on patient access, costs, and competition.

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[53] As noted earlier in these comments, internal NCPA number show the possibility of around $5.04 billion in potential money being floated amongst all community pharmacies under a system contemplated by this Proposed Rule.
[54] 84 Fed. Reg. 2340, 2353.
[55] Mathematical calculation based on number of covered lives CMS/Caremark, UnitedHealth, and ESI self-reported.
[56] White House Council of Economic Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad* (Feb. 2018), *available at* https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf; *see also* Mark Merritt, PCMA CEO, Testimony before the U.S. House of Representatives Energy & Commerce Committee Subcommittee on Health (Dec. 13, 2017).
[57] Steve Pociask, *Pharmacy Benefit Managers: Market Power and Lack of Transparency* (2017), *available at* http://www.theamericanconsumer.org/wp-content/uploads/2017/03/ACI-PBM-CG-Final.pdf.

b. Independent community pharmacies' total and final reimbursement shall not be affected by the price reduction agreed upon between the plan/PBM and manufacturer under a system contemplated by the Proposed Rule. Instead, pharmacies shall be made whole under such system based on the pharmacy's contracted rate negotiated with the plan/PBM.

The Proposed Rule states that "the reduction in price could not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through a chargeback or series of chargebacks.[58] A chargeback is a payment made directly or indirectly by a manufacturer to a dispensing pharmacy so that the total payment the pharmacy receives for the prescription pharmaceutical product **is at least equal** to the price agreed upon in writing between the Part D sponsor, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product."[59] This definition seemingly avails a pharmacy's reimbursement to negotiations between a plan/PBM and a manufacturer, a relationship the pharmacies are not currently privy to or engage in between those parties. The Proposed Rule also specifically states the intent of this proposed rulemaking is to reduce the negotiated prices paid by plans to pharmacies by incorporating up front discounts into them.[60]

NCPA questions whether OIG intended to revise the statutory definition of "negotiated price" utilized in the Medicare Part D program as it was further interpreted in 42 C.F.R. § 423.100.[61] NCPA has made the assumption that OIG did not intend to make this revision, but rather OIG utilized the same term in making reference to point-of-sale price reductions negotiated between plans/PBMs and manufacturers. NCPA seeks clarification from OIG that our assumption is correct. Shifting from back-end rebates to point-of-sale price reductions should not alter the financial arrangement between Medicare Part D plans and their PBMs and community pharmacies participating in such Medicare Part D plans' pharmacy network. Pharmacies have had to acquire the inventory based on list price, insure the inventory at that value and carry the inventory for 30 days or longer. Therefore, community pharmacies should continue to be reimbursed for drugs dispensed to Medicare Part D enrollees at the rates such pharmacies have negotiated with the Medicare Part D plans and/or their PBMs and will receive those negotiated, contracted amounts in three parts: 1) plan payment; 2) beneficiary cost-share amount; and 3) chargeback amount reflecting the price reduction applied at the point of sale. NCPA urges OIG to clarify this issue in the final rule.

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[58] 84 Fed. Reg. 2340, 2348.

[59] *Id.* at 2363 (emphasis added).

[60] *Id.* at 2361.

[61] Negotiated prices means prices for covered Part D drugs that meet all of the following: 1) the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; 2) are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and 3) include any dispensing fees; but 4) excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale; 5) must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part. 42 C.F.R. § 423.100.

The Proposed Rule states that the first criteria for a price reduction to satisfy the new safe harbor for certain price reductions would need to be set in advance between plan/PBM and manufacturer. Set in advance, the Proposed Rule continues, means fixed and disclosed in writing to the plan by the time of the initial purchase of a product.[62] NCPA argues that the criterion should also include a requirement that the formulary discount must be available to all Part D providers. To do otherwise would violate the spirit of the any willing provider protections under Medicare Part D and leave open a new unchecked opportunity for misaligned incentives such as favoring pharmacies owned by the PBM. At no point should a PBM/manufacturer price reduction rate be applied differently for different types, or different pharmacies. Under other business practices today, PBMs negotiate different pay rates for chain pharmacies, community pharmacies, and specialty pharmacies, and their owned pharmacies to name a few. PBMs should be prohibited from executing similar business practices for price reductions and their accompanying chargeback amounts. NCPA urges OIG to make this clarification in its final rule.

Therefore, independent community pharmacies' total and final reimbursement shall not be affected by the negotiated point-of-sale price reduction between the plan/PBM and manufacturer under a system contemplated by the proposed rule. Instead, pharmacies shall be made whole under such system based on the pharmacy's contracted rate negotiated with the plan/PBM.

5. Agency Oversight

A system contemplated by this Proposed Rule shall not go into effect without relevant regulatory action from relevant agencies to ensure appropriate oversight and alignment of such system in applicable government programs.

While the OIG has the authority to promulgate safe harbors to and enforce the AKS, the agency does not have operational oversight of the Medicare or Medicaid programs. Rather, CMS administers the Medicare program and works in partnership with state governments to administer Medicaid.

NCPA consistently engages with CMS regarding regulatory oversight of these programs. Since the creation of both programs, CMS' guidance and rules have shaped community pharmacies' role within these programs. Thus, while the changes contemplated under this Proposed Rule fit squarely within OIG's authority, the Proposed Rule alone does not give industry enough framework to facilitate a system contemplated by the Proposed Rule without future regulatory input from CMS and potential state Medicaid agencies with oversight for such programs. Given the monumental future implications on the Medicare and Medicaid programs, the OIG must operate in consultation with CMS and potential state Medicaid agencies in order to preserve the integrity and viability of both programs' prescription drug benefit.

[62] 84 Fed. Reg. 2340, 2349.

For instance, CMS may want to revise the PDEs to reflect that its net of point-of-sale price reductions passed through to enrollees that pharmacies will later receive in chargeback payments. Also, CMS may amend the prompt pay regulations to reflect that chargebacks for point-of-sale price reductions must be processed and paid within the 14-day period. Additional Medicare Part D regulations and guidance as to what happens to the negotiated point-of-sale price reductions when a Part D plan utilizes flat-dollar co-payments in an actuarial equivalent plan design would also be welcome.

Further, NCPA is aware that the role of regulatory actors over a system contemplated by this Proposed Rule is dependent on the model by which industry (or agency) adopt to accomplish the goals of this proposed Rule. NCPA supports CMS' regulatory oversight should the system be operationalized via systems utilizing HIPAA standards under the purview of CMS today.

If this system ultimately is governed by private industry, however, NCPA is concerned that there may not be proper regulation and oversight in the federal Medicare and Medicaid programs. This is concerning to NCPA because small business community pharmacies would have no regulatory entity to oversee any potential abuses against pharmacies and the patients they serve. For example, what would happen if a community pharmacy did not receive a chargeback from a trading partner, or if a pharmacy did not recognize that the total discount was not passed along to a patient? In those scenarios, the pharmacy would have no forum (other than through legal avenues given the criminal nature of the AKS) to address those issues. Further, community pharmacies would need guidance from CMS on whether their pharmacies are still in compliance with HIPAA if a chargeback system utilizes the existing named standard or subsequent standards with new qualifiers identified by NCPDP. NCPA broadly contends that there are potential legal ramifications if the federal government does not regulate this system.

Additionally, NCPA argues that pursuant to contractual mechanisms, neither plans nor manufacturers can require pharmacies to participate without a negotiation with pharmacies regarding how and by whom a pharmacy will be paid. In order to require a pharmacy to facilitate this transaction at the point of sale and accept a payment from anyone other than the plan (i.e., the manufacturer pays the pharmacy a chargeback), the plan sponsor would have to include these additional obligations in their network pharmacy or some other contract. Presumably, plans/PBMs would include these new "terms and conditions" in the network pharmacy agreement and the plan would offer this amendment to the pharmacy agreement as a "take it or leave it" proposition. NCPA argues this situation would implicate the "any willing pharmacy" provisions in section 1860-D4(b)(1)(A) of the Social Security Act[63] and NCPA questions whether plans in Part D can require pharmacies to take on this new payment process that will now come from a third party (manufacturer), based upon the agreement between the plan sponsor and that third party. NCPA postures that this payment requirement can only be taken on if changes to network agreements via negotiations between pharmacy and plan occur. As stated above, only CMS can provide clarification

[63] Codified at 42 U.S.C. § 1395w-104(b)(1).

on this situation and is yet another example of the inter-agency guidance needed to appropriately implement a system contemplated under the Proposed Rule.

Therefore, a system contemplated by this Proposed Rule shall not go into effect without relevant regulatory action from relevant agencies to ensure appropriate oversight and alignment of such system in applicable government programs.

6. Small Business Protections

a. A system contemplated by this Proposed Rule shall not go into effect without implementation of small business community pharmacy protections, including but not limited to right to appeal, inquire about missing payments, and engage in dispute resolution.

Likewise, the Proposed Rule does not provide any additional assurances that small businesses need to operate in a supply chain that is saturated with larger and consolidated actors. NCPA has made pushes for small business protections in a litany of other government programs. For example, NCPA has long advocated for and successfully secured the current MAC regulations operating in today's Part D program. By way of background, generic drug pricing (also known as "maximum allowable cost" or "MAC") lists refer to the upper limit or maximum amount that a PBM will reimburse a community pharmacy for generic drugs. It also refers to the separate source of prices used by PBM corporations to bill plan sponsors. Currently, each PBM corporation has free reign to pick and choose products for its MAC lists and to determine their associated pricing for both the pharmacy and the plan sponsor.

NCPA advocacy efforts with MAC legislation has revolved around the fact that MAC lists fluctuate constantly and PBMs do not update and disclose their pricing lists to reflect current market conditions for the benefit of providers and plans. This was especially troublesome between 2014 and 2016 when hundreds of generic drugs suddenly and without warning skyrocketed in price. Not only were consumers impacted but community pharmacies lost thousands of dollars because the PBM MACs did not adjust to the new, higher, cost of the drug for weeks or sometimes months.[64] When a PBM fails to update pricing lists in a timely manner, pharmacies are forced to dispense at a notable loss and such losses can be significant and equate to hundreds of dollars per prescription. Under current Part D regulations related to MAC pricing, PBMs are required to update their MAC lists every seven days and pharmacies have the right to appeal should they believe the pharmacy was not appropriately reimbursed under a MAC pricing scheme.[65]

NCPA contends that similar protections for community pharmacies are necessary to protect the interest of small businesses against larger entities. Chiefly, NCPA argues that there must be a robust system that allows pharmacies to inquire to trading partners about missing chargeback payments

[64] AARP, *Price Spike for Some Generic Drugs* (Aug. 2015), *available at* https://www.aarp.org/health/drugs-supplements/info-2015/prices-spike-for-generic-drugs.html.
[65] 42 C.F.R. § 423.505(b)(21).

given the large sums of money that may be tied up in a secondary payment to the pharmacy. NCPA supports robust documentation of these inquiries by trading partners, including if a trading partner denies payment to a pharmacy for any chargeback amount. An appeals process should also go into effect for small businesses to appeal any denied payment. NCPA argues that appeals processes should not be within the sole purview of trading partners and that at some point, pharmacies shall have the right to appeal a denial of payment through public judicial venues. NCPA understands that many of the processes outlined above will require a detailed framework to operate correctly. NCPA supports the relevant regulating agency to issue guidance after consideration of industry input to effectuate such framework for these small business protections.

Regarding audit protections, NCPA submits there should be no need for audit protections because there should be no retroactive adjustments for chargeback amounts because this dispute is between the parties contracting for the price reductions, which are the manufacturers and plans/PBMs.[66] NCPA supports that any disputes between business partners that did not incur to the benefit of the pharmacy be handled outside of the purview of the pharmacy, through dispute resolution language that could take the following form:

> **Dispute Resolution**
>
> As they do today, manufacturers must continue to audit and validate discount contract compliance by the PBM or health plan. In the case that a discount was improperly applied at the point-of-sale, the plan pay amount on the claim would be understated by the discount amount. In other words, the plan benefitted from the mistake. In this case, the manufacturer should dispute the claim and the PBM would pass the amount due on to the health plan. No action should be required on the part of the pharmacy to reverse and rebill the original paid claim which could result in the beneficiary's out-of-pocket amount being increased. The dispute could come to light months after the dispense and should be handled solely between the PBM and the manufacturers, the two parties to the discount contract.

Finally, NCPA seeks finalization of OIG's statement that the changes in the Proposed Rule are not meant to alter the current usage of discounts on prescription pharmaceutical products offered to other entities, including wholesalers and pharmacies.[67]

Thus, a system contemplated by this rule shall not go into effect without implementation of small business community pharmacy protections.

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[66] NCPA has advocated at the state level that certain audit protections should be in place to prevent PBM abuses against community pharmacies. NCPA, *PBM Reform, available at* https://www.ncpanet.org/advocacy/state-advocacy/pbm-reform.
[67] 84 Fed. Reg. 2340, 2348.

b. Independent community pharmacies shall be held harmless from activity of other parties in violation of the Anti-Kickback Statute.

As stated earlier in these comments, OIG is the agency with authority to promulgate AKS safe harbors, interpret the AKS, and prosecute AKS violations through administrative proceedings. Given the criminal nature of the AKS, NCPA is concerned any mistakes or operational problems that may arise from the facilitation of such a system may implicate community pharmacies. Specifically, NCPA is concerned that if other actors in the supply chain do not adhere to the criteria set forth in the new safe harbor for certain price reductions on prescription pharmaceutical products and an illegal rebate is given, community pharmacies may have no way of knowing that such impropriety has occurred. A pharmacy could specifically be implicated if the pharmacy accepted a chargeback for a drug product from a third party.

Another example that NCPA members have expressed is the concern that a manufacturer may not pass 100 percent of a discount to a patient at the point of sale, which would violate the safe harbor criteria. This is why NCPA's minimum requirement argues for claim level information including the chargeback amounts so that to some extent, pharmacies have the ability to police transactions that may implicate their business at the pharmacy counter. Above all, however, this policing should not be the sole responsibility of pharmacies. In fact, pharmacies should be held harmless should upstream trading partners engage in activity that violates the safe harbor and the AKS and OIG should clarify such in the final rulemaking.

7. Opportunity to Choose Business Partners

Independent community pharmacies shall have the opportunity to do business with any trading partner in the supply, billing, or reconciliation chain in a new system contemplated by this Proposed Rule.

NCPA understands there are multiple entities who could administer the chargeback transactions, including plans/PBMs, wholesalers, and independent third-party entities for example. As addressed in our comments above, new contractual relationships between community pharmacies and both plans/PBMs and chargeback administrators will need to be created. We question if new terms and conditions for these administrative services are included in a written arrangement acceptable to CMS, is there the possibility that additional third-party contractors (chargeback administrator and manufacturer) would be regulated by CMS as downstream entities for the purposes of 42 C.F.R. § 423. NCPA requests that clarifications are needed as to which agency has the requisite authority to regulate market conduct, especially when a third-party chargeback administrator administers the chargeback.

NCPA has evaluated two business models that could emerge as a system under this Proposed Rule: 1) Plan/PBM Administered Model; and 2) Non-PBM Administered Model. After our analysis and given the significant problems that community pharmacies have endured under current relationships with PBMS, NCPA advocates for a Non-PBM Administered Model as a way to remedy

the non-transparent and biased environment that has misaligned incentives that hinder patient care in today's healthcare system. Further, as stated earlier, NCPA has participated in the NCPCP drafting of comments to this Proposed Rule and understands that in order to operate in any new system, certain types of modifications may be made in the near-term to the Telecommunication Standard that do not require a new version, just expedited code values. Therefore, it is possible for point-of-sale transactions to comply with the conditions of this proposed safe harbor and for community pharmacies to receive an itemized chargeback amount for each prescription drug claim processed.

In the Non-PBM Administered Model, pharmacies have full visibility to the existence and chargeback amounts at the point of sale, including claim-level detail in electronic remittance advices that substantiate the chargeback. Opportunities exist under this model since new pharmacy pricing models could potentially be designed and implemented. Under this model, pharmacies are more likely to have the flexibility to contract with trading partners of their choice in the supply, billing, or reconciliation chain under the new system.

Conversely, in the Plan/PBM Administered Model the plan/PBM will continue to handle transactions that have been acknowledged by HHS and OIG to have led to the misaligned incentives in the market today. Some would argue that if the PBMs had been trustworthy partners to the plan sponsors, beneficiaries, and community pharmacies this proposed rule would not be necessary. Unfortunately, it clearly is necessary and casts a long shadow of doubt regarding the PBMs acting as the chargeback administrator.

For these reasons, NCPA advocates for the Non-PBM Administered Model. Above all, however, any model that may ultimately grow from this Proposed Rule shall give independent community pharmacies the opportunity to do business with any trading partner in the supply, billing, or reconciliation chain.

II. Other Considerations

1. Average Manufacturer Price ("AMP")

The Proposed Rule states that discounts at point of sale would not alter obligations under the statutory provisions for Medicaid prescription drug rebates under Section 1927 of the Social Security Act, including without limitation the provisions related to best price, the additional rebate amounts for certain drugs if the rate of increase in AMP and the increase in the consumer price index for all urban consumers ("CPI–U"), or provisions regarding supplemental rebates negotiated between states and manufacturers. Nor would the Proposed Rule alter the regulations and guidance to implement Section 1927 provisions, although the Department may issue separate guidance if this proposal is finalized to clarify the treatment of pharmacy chargebacks in calculation of AMP and Best Price.

The Proposed Rule recognizes that rebates paid by manufacturers to Medicaid MCOs should be treated differently than supplemental rebates paid by manufacturers to states because of the

differing risk posed under the Federal anti-kickback statute.[68] We urge OIG to coordinate with CMS as to the issuance of guidance addressing the treatment of point-of-sale price reductions in AMP and best price. Specifically, NCPA believes that point-of-sale price reductions would be excluded from AMP as such amounts are not concessions to retail pharmacies and qualify for exclusion from AMP and best price as coupons or discounts to consumers, the full value of which are passed on to consumers (Medicare Part D enrollees and Medicaid managed care beneficiaries).[69]

It is critical that the change from back-end rebates to point of sale price reductions do not impact AMP because since the enactment of the Deficit Reduction Act of 2005[70] (and later with the enactment of the Affordable Care Act), AMP is used in reimbursement—specifically the Federal Upper Limit on Medicaid reimbursement for multiple source drugs dispensed to Medicaid beneficiaries is based on AMPs for covered outpatient drugs.

Community pharmacies are often located in underserved rural and urban communities and serve a large number of Medicaid patients. In fact, for the average independent community pharmacy, 17 percent of all prescription revenues are from Medicaid.[71] It is imperative that pharmacies be fairly compensated for the medications they dispense under Medicaid and that such reimbursements consider both the actual ingredient cost as well as the cost to dispense the prescription. Otherwise, some pharmacies may stop participating in the Medicaid program, creating medication access issues for those who rely on the program. Therefore, it is imperative OIG coordinate with CMS to clarify that the proposed rule will not negatively impact the AMP-based Federal Upper Limit on Medicaid reimbursement.

2. New Safe Harbor for Certain PBM Service Fees

OIG chooses not to define "PBM" or "pharmacy benefit management services" and instead considers PBM services such as "contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs".

NCPA seeks to highlight and emphasize that PBMs do not conduct many of the services outlined above on behalf of manufacturers. In fact, some of the activities attributed to PBMs involve the practice of pharmacy which is overseen by state boards of pharmacy. The "services" set forth in the Proposed Rule are services PBMs provide to plans, not manufacturers. Specifically, NCPA is concerned that the OIG states that PBMs negotiate pharmacy networks on behalf of manufacturers, an activity that is typically done by PBMs on behalf of plans and for which community pharmacies pay a type of pharmacy DIR fee to participate in such a network (known as a pay-to-play fee). In the

[68] 84 Fed. Reg. 2340, 2344.
[69] *See* 42 C.F.R. § 447.504(e)(13); *see also* 42. C.F.R. § 447.504(e)(8) (outlining the exclusion related to any prices negotiated by or on behalf of Medicare Part D plans).
[70] Pub. L. No. 109-171, § 6001 (2006) (codified at 42 U.S.C. § 1396r-8).
[71] *NCPA 2017 Digest* by Cardinal Health (July 2017).

PBM-manufacturer relationship, PBMs typically receive administration fees from manufacturers for acting as a purchasing agent for the underlying plans to which PBMs provide services (and also for the provision of data). Thus, NCPA urges OIG to revise its description of "pharmacy benefit management services" and narrow any further description of PBM services to the actual services PBMs provide to manufacturers so that PBMs do not create a *de facto* rebate composed of new classes of fees charged to manufacturers.

If a PBM performs services on behalf of the plan (like negotiations of pharmacy networks), these fees should be included in a plan's bid. NCPA recently made the same argument in CMS' proposed rule on pharmacy price concessions. In that proposed rule, CMS restates that the agency has long held that so-called pharmacy administrative service fees that are deducted by plans sponsors and their PBMs from reimbursement due to pharmacies participating in their Part D networks represent valid administrative costs and should be accounted for as such in their Part D bids.[72] CMS correctly highlighted that fees charged to pharmacies such as "network access fees," "administrative fees," "technical fees," or "service fees" only serve the ability of pharmacies to participate in the Part D plan's pharmacy network and bring no additional value. These fees must be accounted for as administrative costs in the bid. Otherwise, a plan sponsor could misrepresent the costs that are necessary to provide a benefit resulting in an artificially low bid and subsequent premiums.

Further, PBMs should be required as an additional condition of safe harbor compliance to disclose the fee arrangements to the health plans and fee arrangements to the Secretary upon request.[73] NCPA supports this reporting requirement as NCPA has long advocated for reporting obligations for PBMs. In today's Medicare Part D program, plans are required to account for any DIR in either a Part D plan's bid or in an after-the-fact annual report to CMS.[74] In CMS' proposed rule on pharmacy price concessions, CMS stated that the proposal would require a standardized reporting to CMS of drug prices at the point of sale.[75] NCPA contends that these reporting requirements should also be required for any PBM fee arrangements with manufacturers.

Additionally, NCPA has long advocated that PBMs have a fiduciary duty to the entity for which they manage pharmaceutical benefits, including reporting fee arrangements between manufacturer and PBM. NCPA supports this move as it would shed light on opaque PBMs' practices. PBMs have been very clear that they do not believe they have an obligation to manage costs. As reported last year by the television newsmagazine "60 Minutes" in court documents filed by Express Scripts to dismiss a lawsuit filed against them by the city of Rockford, Illinois, Express Scripts stated that it is not "contractually obligated to contain costs."[76] A fiduciary duty would force PBMs to put plans' financial interests before their own. This reporting requirements in the Proposed Rule is a step in the right direction to hold PBMs accountable for their opaque practices.

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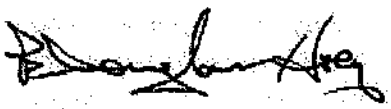
[72] 83 Fed. Reg. 62,152, 62,179.
[73] 84 Fed. Reg. 2340, 2350.
[74] *Id.*
[75] *Id.*
[76] 60 Minutes, *The Problem with Prescription Drug Prices* (May 6, 2018), *available at* https://www.cbsnews.com/news/the-problem-with-prescription-drug-prices/.

III. Conclusion

We appreciate the opportunity to share with you our comments and suggestions on *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, OIG-0936-P.* Should you have any questions, please contact us.

Sincerely,



B. Douglas Hoey, Pharmacist, MBA
Chief Executive Officer

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National Community Pharmacists Association

Re: *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, OIG-0936-F (the "Rebate Rule")

July 8, 2019

2

The strength of our numbers

NCPA represents America's community pharmacists, including 22,000 independent community pharmacies. Together, our members represent a $76 billion healthcare marketplace and employ 250,000 individuals.

3

What differentiates our members

As **community-based healthcare professionals** and entrepreneurs, independent pharmacists are **uniquely positioned** to **customize solutions** to healthcare challenges affecting **local communities and employers.**

4

Discussion Topics

- NCPA's Comments/Minimum Requirements for Small Business Community Pharmacists
- Pharmacy DIR
  - The administration must address pharmacy before or along with manufacturer rebates
- Regulatory Impact Analysis
  - At a minimum, the administration must conduct a proper Regulatory Impact Analysis re small business community pharmacies before finalizing the Rebate Rule

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NCPA's Minimum Requirements to Support the Rebate Rule

1. Fix Pharmacy DIR
2. Timeliness of payments
3. Transparency
4. Financial viability
5. Agency oversight
6. Small business protections
7. Opportunity to choose business partners

6

Pharmacy DIR

- Manufacturer rebates are not the only types of remuneration that can lead to inflated drug prices and higher out-of-pocket costs for patients
- Pharmacy DIR is the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates
- From 2010 to 2017, pharmacy DIR has increased 45,000% in Medicare Part D
- From 2013 to 2017, pharmacy DIR has increased from $229 million in 2013 to $4 billion in 2017
- CMS has projected that the average growth of pharmacy price concessions will be approximately 10% per year going forward

CMS'

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Pharmacy DIR: Present Impact

- Impact of pharmacy DIR on small business community pharmacies
  - Arbitrary, inconsistent application of fees
  - Reimbursement uncertainty
  - Rise of meaningless performance-based fees
- Today, pharmacy DIR impacts about 1.5-3.5% of total revenue of a community pharmacy (~$88,500/per pharmacy)
- Increased pharmacy DIR would lead to lower pharmacy revenue, which could make it difficult for small pharmacies to continue to participate in or gain network access

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Pharmacy DIR: Future Impact

- NCPA is concerned that if manufacturer rebates are only addressed and regulations around pharmacy DIR remain the status quo, PBMs may use the loss of revenue from rebates to levy larger and more aggressive pharmacy price concessions against pharmacies
- Milliman in the Rebate Rule: "PBMs and plans will more aggressively contract for pharmacy rebates in the absence of manufacturer rebates. Pharmacy rebates would still have strong value through their treatment as DIR and there may be opportunities to offset the increases to member premium by negotiating for increased pharmacy rebates"
- Therefore, the administration must address pharmacy before or along with manufacturer rebates

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Regulatory Impact Analysis

- NCPA is concerned the Proposed Rule's Regulatory Flexibility Act ("RFA") analysis does not fully contemplate the impact on small business community pharmacies
- RFA Standard: HHS generally uses the measure of three to five percent of a small business' revenue as their measure of significant impact
- In this Proposed Rule's RFA section, HHS certifies that the Proposed Rule will not have a significant impact on a substantial number of small entities
- NCPA contends that HHS' certification does not meet the factual basis standard outlined above

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Regulatory Impact Analysis: OIG's Admissions

- By OIG's own admission, "[t]he actuarial analyses [OIG] commissioned were not designed to evaluate the effects on the pharmacy supply chain by moving from a system where reimbursement rates were divorced from actual negotiated prices after accounting for rebates"
- OIG also admits that this analysis does not consider "the range of strategic behavior changes stakeholders may make in response to this rule, including the extent to which . . . PBMs change benefit designs or obtain additional price concessions"
- OIG should have solicited this information prior to certifying there is no significant impact to a substantial number of small entities

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Regulatory Impact Analysis: Considerations

- HHS' RFA certification only relies on analysis under the Regulatory Impact Analysis ("RIA") that assumes that the only costs on affected entities will be associated with reviewing the Proposed Rule and reviewing policies to come into compliance with the rule's requirements
- OIG must consider:
  - Lack of clear chargeback administrator
  - Unclear contractual relationship with supply chain partners moving forward
  - Consequences of no clear path for regulatory oversight on small businesses
  - Impending legal risks for small business community pharmacies
  - Other

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Regulatory Impact Analysis: Timing

- At a minimum, this analysis should be structured around the timing implications of a chargeback to a small business community pharmacy
  - NCPA's internal analysis finds that roughly $5.04 billion in total money from independent community pharmacies could be tied up in a secondary payment (also known as a chargeback or a series of chargebacks)
  - Lessons from prompt pay fight at the beginning of Part D program

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Bottom Line

- The administration must address pharmacy before or along with manufacturer rebates
- At a minimum, the administration must conduct a proper Regulatory Impact Analysis re small business community pharmacies before finalizing the Rebate Rule

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Thank You

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By electronic submission

April 8, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Room 600E
Washington, DC 20201

The Honorable Daniel R. Levinson
Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue SW
Room 5527
Washington, DC 20201

Re: *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, OIG-0936-P

Dear Secretary Azar and Inspector General Levinson,

The National Community Pharmacists Association ("NCPA") appreciates the opportunity to comment on The Department of Health and Human Services-Office of Inspector General's ("HHS-OIG") proposed rule titled, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, OIG-0936-P (the "Proposed Rule").[1] 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 ensuring patients have immediate access to medications in both community and long-term care settings.[2] Together, our members represent a $76 billion healthcare marketplace, employ 250,000 individuals, and provide pharmacy services to millions of patients every day. Our members are small business owners who

[1] 84 Fed. Reg. 2340 (Feb. 6, 2019).
[2] *NCPA 2018 Digest by Cardinal Health* (2018).

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are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and long-term care independent pharmacies.

NCPA shares the administration's goal to lower drug prices for American patients and asserts that community pharmacies are uniquely positioned to aid the administration in accomplishing such goal. In fact, the proposal to require manufacturer price reductions at the point of sale featured in this Proposed Rule is closely aligned with NCPA's continuous advocacy efforts to secure a policy to assess all pharmacy price concessions at the point of sale. Both policy changes have the potential to lower drug prices, decrease out-of-pocket costs for patients, and reduce government drug spending in federal health care programs.[3]

However, while NCPA supports the spirit of this Proposed Rule and emphasizes that community pharmacies will play a key role in effectuating such a change, NCPA must secure minimum requirements from the administration before giving our support, given the significant questions surrounding how to operationalize a system contemplated under this Proposed Rule. NCPA offers the following comments to outline these necessary minimum requirements to ensure community pharmacies are securely positioned to aid the administration in accomplishing our shared goal to lower drug prices.[4]

Executive Summary

Over the past year, NCPA has stood with the administration in its efforts to lower drug prices for American patients. Last summer, NCPA offered support for many of the administration's policy considerations outlined in HHS' *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*.[5] NCPA supported the administration's proposal to prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, which is the very proposal reflected in this Proposed Rule. Importantly, NCPA supported the administration's efforts to abolish so-called "gag clauses" or provisions that impede a pharmacists ability to ensure that patients pay the lower cost for drugs.[6] Just this fall pharmacists from NCPA's leadership stood behind the President as he signed two pieces of legislation into law that prohibited pharmacist gag clauses in Medicare and private health plans.[7] The force of these laws has provided for the freer flow of information between pharmacists and their patients. NCPA celebrates this success along with the administration while acknowledging that there is still more work to be done.

Thus, NCPA continues to stand with the administration in its efforts to lower drug prices. Earlier this year NCPA, industry stakeholders, and patients provided resounding support for a proposal from

[3] 84 Fed. Reg. 2340, 2352.
[4] *NCPA 2018 Digest by Cardinal Health* (2018).
[5] 83 Fed. Reg. 22692 (May 16, 2018).
[6] NCPA Comments to *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, CMS-2018-0149 (July 16, 2018), *available at* http://www.ncpa.co/pdf/ncpa-comments-to-blueprint.pdf.
[7] *NCPA Leaders Attend White House Signing of "Gag Clause" Ban* (Oct. 10, 2018), *available at* https://www.ncpanet.org/newsroom/news-releases/2018/10/10/ncpa-leaders-attend-white-house-signing-of-gag-clause-ban.

the administration to change the current assessment of pharmacy price concessions (also known as pharmacy direct and indirect remuneration or pharmacy DIR) in Medicare Part D.[8] This Proposed Rule states that patients win when manufacturer price reductions are applied at the point of sale, but patients also win when all pharmacy price concessions are assessed at the point of sale. In fact, CMS recently estimated that beneficiaries would save $7.1 to $9.2 billion over 10 years resulting from reduced patient cost-sharing if pharmacy price concessions are assessed at the point of sale.[9] Community pharmacists continue to support CMS' proposed rule to eliminate retroactive pharmacy DIR and standardize pharmacy quality measures and urge the administration to finalize the proposal to go into effect for contract year 2020. NCPA also continues to support the total elimination of pharmacy DIR in the Medicare Part D program in the same spirit this Proposed Rule seeks to eliminate the pharmacy benefit manager ("PBM") kickbacks that exist today.

NCPA seeks future opportunities to work with the administration in its efforts to lower drug prices, including support on the Proposed Rule that is the subject of these comments. However, as NCPA continues to express to the administration, our members need support to eliminate the barriers that inhibit their patient relationships. To do this, community pharmacies need to compete in an environment that is transparent, unbiased, and has aligned incentives that best serve the interests of our patients, which is continually threatened by the tactics of PBMs. Community pharmacies also need to compete in transparent government programs that do not disproportionately punish small businesses for operating in these programs.[10] Approximately 36 and 17 percent of prescriptions in independent community pharmacies are covered by Medicare Part D and Medicaid, respectively,[11] and these government programs continue to account for more than half of all prescriptions sold in community pharmacies. Still, misaligned incentives punish small business community pharmacies for serving patients in these programs.

Specifically in the Medicare Part D program, pharmacy price concessions, net of all pharmacy incentive payments, grew an extraordinary 45,000 percent between 2010 and 2017.[12] What's more, what are meant to be performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased on average nearly 225 percent per year between 2012 and 2017 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates. The extraordinary growth of these price concessions is not an anomaly: PBMs have developed business models that utilize pharmacy DIR fees to siphon money from

[8] 83 Fed. Reg. 62,152 (Nov. 30, 2018).
[9] *Id.*
[10] Under the current system, there is a disconnect between estimated DIR in Part D bids and DIR reported annually by plan sponsors at the end of the year. The DIR projected in bids is an estimate made in early June of the preceding year and so is subject to errors in estimation. However, CMS does not have a formal process for checking on the reasonableness of DIR projected in the bids as compared with subsequent actual results. We contend that due to lack of oversight plans are using DIR, and more narrowly pharmacy price concessions, to "game the bids."
[11] NCPA focuses largely on how the Proposed Rule could impact the operation of Medicare Part D. NCPA will discuss the Proposed Rule's impact on Medicaid Managed Care in section II. of these comments.
[12] *Id.* at 62,174.

pharmacy businesses while simultaneously "gaming" the Medicare Part D bid process.[13] In fact, a recent *Wall Street Journal* article found that health insurers kept $9.1 billion in excess payments from Medicare in the years 2005-2016 by inaccurately estimating the prescription drug benefits they proposed to offer to beneficiaries in their Medicare Part D bids and that the lack of transparency in U.S. healthcare allowing such games is driving up spending.[14] Without intervention, the extraordinary extraction of pharmacy DIR fees from small business community pharmacies will not stop and could make it economically unfeasible for community pharmacies to continue to provide services to these vulnerable patient populations. .

While NCPA urges CMS to fix pharmacy DIR immediately, NCPA continues to support alternative methods to change the pharmacy payment model that would allow community pharmacies to compete in a transparent and unbiased environment that has aligned incentives to serve today's Medicare Part D patients. As Secretary Azar was able to personally witness during his visits to community pharmacies in Pittsburgh and New Orleans this past October and February, respectively, our pharmacies do more than dispense. They know their patients and provide valuable products and services that stave patients from hospital and emergency room readmissions. It is for these reasons that NCPA members are increasingly joining together to demonstrate that value by becoming members of the Community Pharmacy Enhanced Services Network ("CPESN®"), a clinically integrated network of community pharmacies that coordinates patient care with physicians, care managers, and other patient care teams to provide medication optimization activities and enhanced services for high-risk patients. CPESN now has 47 networks in 44 states across the United States.[15] CPESN is setting the tone for a future that combats today's misaligned incentives as community pharmacies in this network work directly with payers to add enhanced services into contracts that lower medical and drug costs for patients.[16] CPESN will play a critical role in changing the pharmacy payment model, and NCPA encourages policymakers to consider this initiative as the administration looks for alternative methods to lower drug prices and overall healthcare costs for patients.

This Proposed Rule, however, seeks to combat high drug prices in government programs by effectuating a system by which manufacturer price reductions are applied at the point of sale. Once

[13] In fact, the Medicare Payment Advisory Commission ("MedPAC") identified that plan sponsors generally have an incentive to receive price concessions in the form of DIR rather than higher point-of-sale discounts, all else being equal. This is due to the timing of when these price concessions are made or reflected in the costs, and which parties share in the costs at different stages. MedPAC stated that "it is reasonable to ask if there is a financial advantage to a plan's bidding approach," or in other words, using various factors to "game" the bidding process. MedPAC, *Sharing Risk in Medicare Part D* (Mar. 5, 2015), *available at* http://www.medpac.gov/docs/default-source/meeting-materials/march-2015-meeting-presentation-sharing-risk-in-medicare-part-d-.pdf?sfvrsn=0. OIG has identified similar games are being played when Part D plan sponsors underestimate rebates in their bids. *See* OIG, Concerns with Rebates in the Medicare Part D Program (Mar. 2011), *available at* https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf.

[14] Joseph Walker & Christopher Weaver, *The $9 Billion Upcharge: How Insurers Kept Extra Cash From Medicare*, WALL ST. J. (Jan. 4, 2019), *available at* https://www.wsj.com/articles/the-9-billion-upcharge-how-insurers-kept-extra-cash-from-medicare-11546617082.

[15] CPESN, *available at* https://www.cpesn.com/.

[16] *Id.*

applied, these point-of-sale reductions would effectively base a patient's out-of-pocket cost on the "net price" of a drug and prevent backend kickbacks from manufacturers to PBMs.[17] This proposal is a step in the right direction to change the pharmacy payment model as it relates to a patient's drug spend. It is NCPA's understanding, however, that in order to facilitate a system contemplated by the Proposed Rule, a pharmacy's reimbursement would be subject to certain chargebacks from the manufacturer to the pharmacy, either directly or indirectly, to make the pharmacy whole.

To this end, NCPA has evaluated two business models that could emerge as a system under this Proposed Rule: 1) Plan/PBM Administered Model; and 2) Non-PBM Administered Model. After our analysis and given the significant problems that community pharmacies have endured under current relationships with PBMs, NCPA advocates for a Non-PBM Administered Model to remedy the non-transparent and biased environment that has misaligned incentives that hinder patient care in today's healthcare system. In supporting such a model, NCPA must secure the following necessary minimum requirements for independent community pharmacies:

1. **Fix Pharmacy DIR**

   - A system contemplated by this Proposed Rule shall not go into effect without, at a minimum, finalization of the CMS proposed rule on pharmacy price concessions, 83 Fed. Reg. 62,152 (Nov. 30, 2018).

2. **Timeliness of Payments**

   - Independent community pharmacies shall, at a minimum, be paid in full for the total and final reimbursement, including any chargeback amounts, for a drug product consistent with protections provided under the Medicare Part D prompt pay rules, 42 C.F.R. § 423.520, and will earn interest on chargebacks due based on the LIBOR rate the day of the transaction.

3. **Transparency**

   - Independent community pharmacies shall have at the point of sale full visibility, in the approved claim, to the total and final reimbursement due the pharmacy.

   - Independent community pharmacies shall have at the point of sale full visibility to the existence and total and final amount of any chargeback amounts due.

   - Independent community pharmacies shall receive claim-level detail in electronic remittance advices that substantiate the total and final reimbursement of payor amounts and chargeback amounts.

[17] 84 Fed. Reg. 2340, 2352.

4. **Financial Viability**

- Independent community pharmacies shall assume no monetary liability for implementation of a system contemplated by the Proposed Rule. For example, should fees transpire from the operation of such system, such fees shall not be paid by pharmacies.

- Independent community pharmacies' total and final reimbursement shall not be affected by the price reduction agreed upon between the plan/PBM and manufacturer under a system contemplated by the Proposed Rule. Instead, pharmacies shall be made whole under such system based on the pharmacy's contracted rate negotiated with the plan/PBM.

5. **Agency Oversight**

- A system contemplated by this Proposed Rule shall not go into effect without relevant regulatory action from relevant agencies to ensure appropriate oversight and alignment of such system in applicable government programs.

6. **Small Business Protections**[18]

- A system contemplated by this Proposed Rule shall not go into effect without implementation of small business community pharmacy protections, including but not limited to right to appeal, inquire about missing payments, and engage in dispute resolution.

- Independent community pharmacies shall be held harmless from activity of other parties in violation of the Anti-Kickback Statute ("AKS").

7. **Opportunity to Choose Business Partners**

- Independent community pharmacies shall have the opportunity to do business with any trading partner in the supply, billing, or reconciliation chain in a new system contemplated by this Proposed Rule.

In conclusion, NCPA shares the administration's goal to lower drug prices for American patients and asserts that community pharmacies are uniquely positioned to aid in accomplishing such goal. In fact, the proposal featured in this Proposed Rule to require manufacture discounts at the point of sale is closely aligned with NCPA's continuous advocacy efforts to secure a policy in which all

[18] NCPA considers a "small business" community pharmacy to have the same meaning as the Small Business Administration's small business definition in 13 C.F.R. § 121.201.

pharmacy price concessions are also included at the point of sale. Both policy changes have the potential to lower drug prices, decrease out-of-pocket costs for patients and reduce government drug spending in Federal health care programs.[19]

NCPA's Detailed Comments

I. NCPA's Minimum Requirements on the Proposed Rule Regarding New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price

1. Fix Pharmacy DIR

A system contemplated by this Proposed Rule shall not go into effect without, at a minimum, finalization of the CMS proposed rule on pharmacy price concessions, 83 Fed. Reg. 62,152 (Nov. 30, 2018).

The Proposed Rule states that the goal of applying manufacturer price reductions at the point of sale is to curb list price increases, reduce financial burdens on patients by lowering out-of-pocket costs, lower Federal expenditures, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid Managed Care Organizations ("MCOs").[20] Of these objectives, the goal to lower out-of-pocket costs is most achievable based on the perverse incentives with the current application of manufacturer rebates. This is because, as the Proposed Rule states, most rebates do not flow through to patients at the pharmacy counter as reductions in price. Thus, patients "experience out-of-pocket costs more closely related to the list price than the rebated amount during the deductible, coinsurance, and coverage gap phases of their benefits."[21]

NCPA contends, however, that rebates are not the only types of remuneration that can lead to inflated drug prices and higher out-of-pocket costs for patients. In fact, while the application of rebates is an important aspect to the drug pricing conversation in Medicare Part D, an analysis of out-of-pocket costs is incomplete without addressing all types of renumeration, including pharmacy price concessions, or pharmacy DIR, that PBMs utilize to pad their pockets. In the Medicare Part D program, PBMs usage of pharmacy price concessions has exploded over the past several years and the increased use of these pharmacy DIR fees have had an astounding impact on patients, the government, and small businesses.[22]

The retroactive nature of these price concessions means beneficiaries face higher cost-sharing for drugs and are accelerated into the coverage gap or "donut hole" phase of their benefit. What's more, beneficiaries reach the catastrophic phase faster of the benefit, for which CMS incurs

[19] 84 Fed. Reg. 2340, 2352.
[20] *Id.* at 2344.
[21] *Id.* at 2341.
[22] 83 Fed. Reg. 62,152, 62, 174.