

July 16, 2018

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

**Re: CMS-2018-0075-0001 - HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs**

Dear Secretary Azar:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to comment on the Department of Health and Human Services' request for information, "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" (RFI or Blueprint). NCPA represents America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an \$80 billion health care marketplace and employ more than 250,000 individuals on a full- or part-time basis. Independent community pharmacies are typically located in underserved rural and urban communities and provide critical access to residents of these communities. Importantly, community pharmacists are health care providers on the front lines who regularly talk to patients about their concerns with prescription drug costs and work diligently to address these concerns in the Medicare Part D program.

NCPA members stand ready to help you and the administration accomplish your goals of lowering drug prices. However, our members need help to hold onto the patient relationships they have and the small businesses they have built. Independent community pharmacies need to compete in an unbiased environment that best serves the interests of our patients. As evidenced by the nearly 2,000 public comments to the Blueprint that have been posted as of July 15, 2018, mostly from independent pharmacists, now is the time to bring more transparency to our health care system and a reprieve to small business community pharmacies.

In addition to dispensing critical medications to patients, NCPA members are a part 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 43 networks in 40 states across the United States.<sup>1</sup>

CPESN pharmacy providers see their complex patients 35 times a year, while physicians only see their patients 3.5 times a year. NCPA member pharmacies in this network work directly with payers to add enhanced services into contracts and lower drug costs.<sup>2</sup> However, Pharmacy Benefit Managers (PBMs) make it difficult to pursue these patient-focused goals by not allowing patients to visit their pharmacy of choice and charging retroactive fees that increase seniors' costs at the pharmacy counter. These practices are specifically prevalent in the Medicare Part D program, leading patients to demand much-needed policy changes to drug prices and drug spend.

For example, *Morning Consult* recently polled voters on their views regarding the Part D benefit in Medicare.<sup>3</sup> Seventy percent of seniors think the Medicare Part D program is effective and they want Congress to protect the program. To protect the program, pharmacy-related reforms are viewed favorably by voters, including reforms to ensure seniors are able to obtain prescriptions at the pharmacy of their choice. Additionally, voters favor Part D proposals to increase stability and lower costs for seniors, including allowing seniors to share in any savings negotiated by plan sponsors. One such reform would be to ensure "middlemen can't retroactively charge fees that artificially increase senior's drug costs at the pharmacy counter." Specifically, voters are concerned with PBMs' incentive to benefit from higher drug prices.<sup>4</sup>

Given the clear messaging from the results of this poll, the administration should implement policies that would prevent PBMs from exploiting their largely unregulated position in the supply chain to extract profits at the expense of American seniors and taxpayers. NCPA addresses a number of these policies below in the hope that community pharmacists can add meaningful solutions for patients, especially those seniors in the Medicare Part D program.

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<sup>1</sup> CPESN, available at <https://www.cpesn.com/>.

<sup>2</sup> *Id.*

<sup>3</sup> NCPA, *Morning Consult 2018 Survey* (July 2018), available at <http://www.ncpanet.org/newsroom/morning-consult-2018-survey>.

<sup>4</sup> *Id.*

## **Better Negotiation**

### ***Value-based arrangements and price reporting***

In the RFI, there are several proposals in which HHS is seeking stakeholder input on which benefits would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs discounts, rebates, or price guarantees included in value-based arrangements. HHS also proposes to explore the effects of excluding payments received from, and rebates or discounts provided to, PBMs from the determination of Average Manufacturer Price (AMP) and the potential elimination of provisions that exclude manufacturer discount programs from the calculation of AMP. NCPA is concerned with any proposed changes to AMP, which is currently tied to Federal Upper Limits (FULs) in the Medicaid program. Specifically, if manufacturers are allowed to exclude discounts, rebates, or price guarantees included in value-based arrangements from AMP, there may be serious downstream effects on pharmacy reimbursement.

AMP was originally designed as a benchmark to determine manufacturer rebates in the Medicaid program. However, since the enactment of the Deficit Reduction Act of 2005<sup>5</sup> and later with the enactment of the Affordable Care Act (ACA), AMP is now being used as a basis to calculate pharmacy reimbursement for generic medications dispensed to Medicaid beneficiaries.

The ACA Congress made it clear that AMP is defined and to be calculated to reflect the prices paid to manufacturers by retail community pharmacies and by wholesalers for medications distributed to retail community pharmacies.<sup>6</sup> In addition to defining AMP, Congress also determined that sales to entities other than retail community pharmacies are not to be included in AMP calculations.

Consistent with the requirements of the ACA, and as finalized by CMS' Covered Outpatient Drugs Final Rule,<sup>7</sup> transactions with PBMs, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long-term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy should not be included in AMP calculations. Furthermore, discounts or benefits from vouchers, or manufacturer-sponsored programs, or manufacturer-sponsored discounts are also to be excluded from AMP.

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<sup>5</sup> Pub. L. No. 109-171, § 6001 (2006) (codified at 42 U.S.C. § 1396r-8).

<sup>6</sup> Pub. L. No. 109-171, § 6001 (2006) (codified at 42 U.S.C. § 1396r-8).

<sup>7</sup> 81 Fed. Reg. 5349, 5216 (Feb. 1, 2016) (codified at 42 C.F.R. § 447.504).

It is clear that manufacturers must exclude specific discounts and fees from AMP calculations and as such, discounts and fees do not reduce the cost of a pharmacy purchasing a medication. Initiatives that would modify the standing definition of AMP, the criteria used to calculate AMP, or include price concessions from PBMs or manufacturer discount cards would lower AMP and further decrease pharmacy reimbursement to levels that are well below the cost of acquiring and dispensing prescription medications in the Medicaid program.

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, 16 percent of all prescription revenues are from Medicaid.<sup>8</sup> 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 stop participating in the Medicaid program, creating medication access issues for those who rely on the program. Therefore, while we fully understand that the goal of HHS' proposals is to decrease drug prices, NCPA is opposed to modifications to the definition of AMP.

#### ***Part B to D***

NCPA is receptive to adjusting policies to provide more access to drugs in Medicare. It should be noted that most drugs that community pharmacies dispense are covered under Part D. Currently, however, certain drugs dispensed under Part B contribute to a cumbersome system because drugs dispensed under Part B are outside the typical dispensing methods. Obtaining payment for these drugs is administratively burdensome, and payments are delayed.

The Part D payment and processing system is preferred by community pharmacists due to electronic claims processing and real-time eligibility checks. Drugs that our members dispense most commonly that are currently covered under Medicare Part B and that are patient administered include inhalation drugs and immunosuppressants. NCPA recommends that patient administered drugs be considered first when discussing moving Part B drugs to Part D coverage.

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<sup>8</sup> NCPA, *NCPA 2017 Digest* (July 2017), available at <http://www.ncpa.co/pdf/digest/2017/2017-digest-lr.pdf>.

## Creating Incentives to Lower List Prices

### *Fiduciary duty for Pharmacy Benefit Managers*

NCPA continues to urge the administration to require PBMs to have a fiduciary duty with respect to plan assets that they manage for other entities. The HHS' RFI posed the question, "[s]hould PBMs be obligated to act solely in the interest of the entity for whom they are managing pharmaceutical benefits?" The RFI goes on to ask if there are any unintended consequences for beneficiaries' out-of-pocket spending from imposing a fiduciary duty.

NCPA urges the administration to require PBMs have a fiduciary duty to the entity for which they manage pharmaceutical benefits, a move that would shed light on opaque PBMs' practices, including the PBM's incentive to charge the plan more than the pharmacy is reimbursed and keep the difference as profit, which ultimately raises senior and taxpayer costs. PBMs have been very clear that they do not believe they have an obligation to manage costs. As reported earlier this 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."<sup>9</sup> A fiduciary duty would force PBMs to put plans' financial interests before their own.

A recent Council of Economic Advisers report titled *Reforming Biopharmaceutical Pricing at Home and Abroad* found that just three PBMs serve as the "middleman" for 85 percent of the market.<sup>10</sup> All PBMs are able to leverage the number of beneficiaries in a particular plan in order to negotiate lucrative rebates from pharmaceutical manufacturers. Unless a plan has negotiated a transparent "pass through" contract with its PBM (and typically only the largest and most sophisticated plans are able to do so), the PBM will keep for themselves a significant percentage of the rebate dollars that they have obtained for plan beneficiaries.

Second, the amount that the PBM pays the pharmacy for dispensing the is rarely the same amount that the PBM "charges" the plan for the same drug. Typically, the PBM "marks up" the cost of the drug, charging the plan more than the pharmacy is reimbursed, keeping the difference as profit for the PBM. It is precisely these hidden spread amounts that need to be disclosed in some way to plan sponsors and made transparent to consumers. The vast sums of money that PBMs are

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<sup>9</sup> 60 Minutes, *The Problem with Prescription Drug Prices* (May 6, 2018), available at <https://www.cbsnews.com/news/the-problem-with-prescription-drug-prices/>.

<sup>10</sup> 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>.

making by virtue of the drug spend of a particular plan are not in fact “proprietary” on the part of the PBM, but rather belong to the plan. If plan sponsors have a clearer picture about the amount of money that is being made by their vendor for handling the plan’s business, this may provide them with a greater ability to negotiate more competitive contracts. It is important to note that PBMs often expressly disclaim any fiduciary duty in contracts with plan sponsors. Ultimately, without any fiduciary obligation, there is no transparency or accountability for PBM conduct.

The concept that PBMs have a fiduciary duty to plans is not a new idea. In recent years, the U.S. Department of Labor addressed this idea by questioning whether PBMs have a fiduciary duty under Employee Retirement Income Security Act (ERISA) plans. Numerous witnesses testified in support of such a fiduciary responsibility, including many large plan sponsors.<sup>11</sup> Nevertheless, PBMs continue to assert that they should not be held to a fiduciary standard. Shockingly, in a recent filing in the Second Circuit, both Express Scripts (the PBM) and Anthem (the plan sponsor) each argued that neither had a fiduciary duty with respect to the plan’s drug benefit. Then just who is responsible for safeguarding plan assets used for prescription drugs? It is nonsensical that such a critical component of health care should be left unaccounted for. Therefore, NCPA urges the administration to require PBMs to have a fiduciary duty to plan sponsors to eradicate PBMs’ opaque and self-serving behavior.

### ***Reducing the impact of rebates***

NCPA recognizes that the administration has largely focused on manufacturer rebates in the RFI. NCPA would clarify, however, that rebates are not the only concession that can lead to inflated drug prices and higher out-of-pocket costs. In fact, while the application of rebates is an important aspect to the drug pricing conversation, an analysis of out-of-pocket costs is incomplete without addressing all direct and indirect remuneration (DIR), including pharmacy price concessions in the Part D program that PBMs utilize to pad their pockets at the expense of patients, the government, and small businesses.

DIR fees imposed on pharmacies participating in Medicare Part D networks by plan sponsors and their PBMs have exploded in recent years.<sup>12</sup> The treatment of these pharmacy price concessions

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<sup>11</sup>Advisory Council of Employee Welfare and Pension Benefit Plans, *Report to the Honorable Thomas E. Perez, United States Secretary of Labor, PBM Compensation and Fees Disclosure* (Nov. 2014), available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf>.

<sup>12</sup> The HHS Office of Inspector General has noted that these catastrophic costs that are driven by retroactive pharmacy DIR fees have tripled in recent years from \$10 billion in 2010 to \$33 billion in 2015. See Office of Inspector General, *High-Price*

as DIR rather than as reductions in the “negotiated price” of a drug has had a negative impact on patients, the government, and a crippling effect on community pharmacies. The retroactive nature of these fees 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 approximately eighty 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.

As the administration has discussed the possibility of prohibiting rebates between manufacturers and plan sponsors in Part D contracts, NCPA argues that the same policy should be applied to pharmacy price concessions. That is, if manufacturer rebates were to be prohibited, the existence of DIR in the Part D program and its subsequent reporting would become unnecessary. Therefore, NCPA requests that if the administration prohibits the use of rebates in contracts between Part D plan sponsors and drug manufacturers, then the administration should also eliminate pharmacy DIR in the Medicare Part D program.

Alternatively, if Part D plans/PBMs are not prohibited from negotiating rebates with drug manufacturers or pharmacy price concessions, CMS could mandate that Medicare Part D plan sponsors and their PBMs include any retrospective rebate be included in the negotiated price. Such a move would not implicate the non-interference clause because CMS is not inserting itself into negotiations between plan sponsors and/or their PBMs and pharmacies and pharmaceutical manufacturers. Rather, CMS is placing parameters around the Part D benefit similar to when it mandated payment of clean claims within ten days for electronic claims and fifteen days for other claims or when it required sponsors or their PBMs to update the pricing metrics on January 1st of each year and every seven days thereafter. Sponsors and/or their PBMs and pharmacies are still free to negotiate any reimbursement, concessions, or pay structure they like just as pharmaceutical manufacturers and Sponsors, and/or their agents are free to negotiate any rebate amounts, terms, and conditions they choose.

Moreover, CMS, as the agency delegated responsibility from Congress to oversee the Medicare Part D program, is charged with ensuring that all entities delivering the Part D benefit do so in accordance with the statutorily designed program requirements.<sup>13</sup> A possible CMS’ action to include DIR at point of sale serves such purposes by ensuring consistent recognition of such price

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*Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage* (Jan. 2017), available at <https://oig.hhs.gov/oei/reports/oei-02-16-00270.asp>.

<sup>13</sup> See generally 42 U.S.C. § 1395w-112; 42 C.F.R. § 423.752.

concessions by sponsors such that there is a more uniform reflection of the net cost of a drug out-the-door from a pharmacy for Medicare Part D beneficiaries and CMS alike.

Thus, as a contingency if all DIR, including pharmacy price concessions, is not eliminated, the administration should prohibit all retroactive pharmacy DIR fees leveraged against pharmacies, as it has considered this policy move several times over the past few years. Just this spring, CMS collected information on what it would mean if DIR, including pharmacy price concessions, were included in the negotiated price at point of sale. CMS has yet to do anything with this information, but the recent beneficiary survey makes clear voters want something to change.

More specifically, voters want to ensure the longevity and success of the Part D program, including supporting proposals that will increase stability in the Medicare Part D program and lower costs for seniors.<sup>14</sup> Specifically, voters want to ensure drug middlemen do not retroactively charge fees that artificially increase seniors drug costs at the pharmacy counter. Voters also want to give seniors access to more of the savings on their medicines that their Part D plans negotiate with drug companies. Ensuring that rebates and pharmacy price concessions are shared with patients is a voter top-priority because it will meaningfully address rising drug costs.

Passing DIR on to patients at the point of sale does not just impact out-of-pocket spending. Such a policy change can also improve adherence for patients. For example, a recent study conducted by IHS Markit found over the next 10 years, passing rebates to the point of sale for diabetes medications “could reduce total medical spending by approximately \$20 billion.”<sup>15</sup> This is in large part due to improved access to recommended medications that improve health outcomes. Rebates included at point of sale are an attractive approach to ultimately lower patients’ out of pocket spending as many prescriptions for brand medicines are subject to patient cost-sharing. Even patients with flat copays would benefit because rebates at point of sale would stave off their quick progression through the coverage phases of the Part D benefit. Thus, sharing rebates and pharmacy price concessions at point of sale would be a successful approach to not only lower patients’ costs, but to improve adherence.

Finally, the administration should seek to limit and control the way in which PBMs and plan sponsors impose arbitrary and inconsistent quality and/or performance-based standards on community pharmacies. While not all pharmacy DIR is performance-based, the proliferation of

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<sup>14</sup> NCPA, *Morning Consult 2018 Survey* (July 2018), available at <http://www.ncpanet.org/newsroom/morning-consult-2018-survey>.

<sup>15</sup> IHS Markit, *Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare* (May 14, 2018), available at <https://cdn.ihs.com/www/pdf/IHSM-RebateSharingReport-10May2018.pdf>.

pharmacy DIR is now intricately tied to quality/performance-based standards. PBMs and plan sponsors have argued they should have the ability to create quality-based programs that are accounted for as DIR to reward pharmacies for achieving contractual, performance-based metrics.

However, many of these retroactive fees are based on a payment methodology that does not reward higher performing pharmacies rather all pharmacies are punished, and higher performing pharmacies are just punished less. Some plans withhold a certain dollar amount from Part D claims with the opportunity for a small fraction of pharmacies to “earn back” what has been withheld but the incentive plan may be structured so that 80 percent of pharmacies are returned only pennies on each withheld dollar. Other plans structure their pharmacy performance plans by subtracting retroactive fees based on achieving certain arbitrary quality measures. Therefore, NCPA requests that the administration define pharmacy quality within the Medicare Part D program and hold plans accountable for determining performance-based payments. Performance-based payments should be based on standardized, achievable, and proven criteria that measure pharmacy performance, as opposed to criteria that focus on measuring plan performance or criteria that pharmacies have little or no opportunity to influence.

In conclusion, CMS’ request for information in its Proposed Part D Rule for Contract Year 2019, which highlighted the possibility of placing retroactive pharmacy DIR fees at point of sale, was a step in the right direction to battle the skyrocketing costs of prescription drugs. If the administration does not eliminate DIR, CMS should swiftly review all input received from stakeholders and expeditiously finalize, through rulemaking procedures, a rule to place all retroactive pharmacy DIR fees at point of sale. A rule of this stature would demonstrate the administration’s dedication to meaningfully address rising prescription drug costs for beneficiaries. At a minimum, CMS should hold plans accountable and standardize performance-based programs that are arbitrarily and inconsistently imposed on community pharmacies and give the pharmacy profession meaningful control over these metrics to best serve the patient.

### ***The 340B drug discount program***

NCPA recommends that with any changes to the 340B program, the administration ensure that the contract pharmacy networks specifically include access to community pharmacies, the small businesses that provide convenient access, unique services, and trusted relationships with their patients in the community.

For example, in many instances community pharmacies are often located in medically underserved areas, including both urban and rural areas and provide much needed services to populations that tend to be older, sicker, and poorer. In this way, community pharmacies are uniquely positioned

to provide the needed services to the types of populations contemplated under the 340B Program, including enhanced clinical services and education programs to un- and underinsured patients. In fact, a recent GAO report on contract pharmacy stated that roughly 20 percent of contract pharmacies in the 340B program are independent pharmacies.

The report goes on to state that critical access hospitals have a higher proportion of independent contract pharmacies compared with other covered entity types and that this relationship is likely due to critical access hospitals and independent contract pharmacies being located and serving rural communities. Given this relationship with critical access hospitals, independent contract pharmacies, and rural communities, protecting the patients' access to these providers and the services these providers offer to rural communities is paramount.

### **Reducing Patient Out-of-Pocket Spending**

#### ***Part D end-of-year statement on drug price changes and rebates collected***

Regulations require that a Part D sponsor directly submit a written explanation of benefits to enrollees on a monthly basis.<sup>16</sup> Because Part D plans already are required to provide their members with an explanation of benefits, NCPA supports including additional information in the explanation of benefits such as rebates and any pharmacy price concessions that the plan or PBM negotiated. This information would be best distributed by the Part D plan sponsor/PBM to prevent confusion for the enrollee. By placing this duty on the pharmacist, the administration would run the risk of imposing an increased burden on pharmacists to become familiar with each patient's plan information, which would simply not be efficient in the workplace.

#### ***Federal preemption of contracted pharmacy gag clause laws***

NCPA supports this administration's efforts to abolish so-called "gag clauses" or provisions that impede a pharmacies ability to ensure that patients pay the lower cost for drugs. The President's Blueprint calls for immediate action to prohibit "gag clauses" in Part D contracts. NCPA has long warned that under some contracts, pharmacists have been unable to inform patients of lower-cost alternatives due to overbroad confidentiality clauses and the pharmacist's inability to disclose the negotiated price to patients. NCPA supports the administration's efforts to abolish all pharmacy gag clauses to the extent such clauses were present in Medicare Part D contracts, including CMS' recent letters sent to plan sponsors that state gag clauses in contracts are unacceptable.

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<sup>16</sup> See 42 C.F.R. § 423.128.

However, NCPA remains concerned about the number and scope of other provisions in one-sided PBM contracts that pharmacists are forced to sign, including multiple provisions that in one way or the other prohibit the free flow of information. Those include overly broad confidentiality provisions, non-disparagement clauses, and requirements that the pharmacy charge insured patients what the PBM tells them to charge.

Moreover, PBMs sometimes use veiled threats and intimidation to discourage pharmacies from expressing concerns to patients and plan sponsors about their prescription drug benefit. NCPA urges this administration to examine all contract provisions that prevent the pharmacist from discussing drug costs with patients.

### **Conclusion**

NCPA appreciates the opportunity to share with you NCPA's comments and suggestions and we look forward to working with you to lower drug prices and reduce out-of-pocket costs.

Sincerely,

A handwritten signature in blue ink, appearing to read "Karry K. LaViolette", followed by a horizontal line extending to the right.

Karry K. LaViolette  
Senior Vice President  
Government Affairs and Director of Advocacy Center