



March 7, 2022

**Submitted by Electronic Submission:** [www.regulations.gov](http://www.regulations.gov)

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program [CMS-4192-P]**

Dear Administrator Brooks-LaSure:

The National Association of Specialty Pharmacy (NASP) is pleased for the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS') proposed regulation, "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program" [87 Fed. Reg. No. 8, January 12, 2022; CMS-4192-P; RIN 0938-AU30] (the Proposed Rule). NASP shares the administration's goals of lowering out-of-pocket costs for beneficiaries under Medicare Part D, improving the transparency of fees, and ensuring competitive balance under the Medicare Part D program. We thank the administration for its effort in the rule to address needed reforms to support pharmacy patients by addressing long-standing and significant pharmacy concerns with the growth of post-sale price concessions that purportedly cannot reasonably be determined at the point-of-sale. These concessions are excluded from the negotiated price of a drug and have had serious negative implications for patients, pharmacies, and the Medicare program. NASP focuses its comments on the Proposed Rule's section on pharmacy price concessions in the Negotiated Price (§ 423.100) and urges CMS to strengthen the rule so that it also ensures such reforms protect patient access to specialty pharmacies.

NASP's members are committed to the practice of specialty pharmacy with a focus on the patients served to ensure better clinical outcomes while reducing overall healthcare costs. NASP represents the entire spectrum of the specialty pharmacy industry, which includes the Nation's leading specialty pharmacies and practicing pharmacists, pharmacy benefit managers (PBMs), pharmaceutical and biotechnology manufacturers of specialty drugs, group purchasing organizations, wholesalers, distributors, integrated delivery systems, health systems, and

technology and data management companies, among others. NASP’s pharmacy members include specialty pharmacies of all types, including independent, chain, grocery store, hospital and health system, health plan owned, and home infusion. With over 150 corporate members and 2,200 individual members, NASP is the unified voice of specialty pharmacy in the United States.

### **EXECUTIVE SUMMARY**

NASP supports CMS’ efforts to improve drug prices at the point-of-sale for beneficiaries and offers analysis and legal and regulatory recommendations on how the administration must work to strengthen and implement such reform to specifically address the complex needs of specialty patients and the pharmacies that serve their needs. NASP remains committed to working with the Department of Health and Human Services (HHS)/CMS to finalize a rule that both reduces drug costs for Medicare beneficiaries and addresses important gaps that exist within the Proposed Rule. NASP believes that CMS has strong federal authority to address these gaps and, by addressing them, the final rule will protect (1) beneficiaries’ access to the specialty pharmacies of their choosing and (2) a competitive Part D pharmacy market. By implementing the reforms respectfully proposed below, CMS may use its statutory authority to ensure that the rule accomplishes what CMS intended and protects the long-term success of the Part D program by fostering transparency and fair market competition among pharmacies. **NASP strongly urges CMS to move forward to finalize the rule in Calendar Year 2022 to begin implementation in January 2023.**

The following outlines NASP’s recommendations to CMS regarding aspects of the Proposed Rule:

#### **Negotiated Price**

- NASP urges CMS to finalize the proposed changes to the “negotiated price” definition in 42 C.F.R § 423.100 that would require all pharmacy price concessions to be applied at the point-of-sale, beginning in calendar year 2023.
- NASP agrees with CMS’ proposed exclusion from the definition of negotiated price additional contingent amounts, including incentive payments to pharmacies, that would increase drug prices at the point-of-sale.
- NASP strongly urges CMS to finalize its proposal to immediately eliminate the “reasonably determined” exception that has permitted the significant escalation and abuse of post-sale pharmacy price concessions by Part D plans and PBMs (collectively, Plan or Plans).
- NASP asks that CMS permanently prohibit retroactive claw backs on pharmacies.

### **Payments to Pharmacies**

- NASP urges CMS to utilize its statutory authority to ensure that the lowest possible reimbursement at the point-of-sale and actual pharmacy reimbursement is reasonable in accordance with the Medicare statute’s Any Willing Provider and Prompt Payment requirements. NASP believes that such authority does not run afoul of Medicare’s non-interference clause.
- NASP requests CMS to ensure that a mechanism is in place to allow pharmacies to appeal a Plan’s (1) reimbursement that is below a pharmacy’s drug acquisition cost and/or (2) unreasonable “lowest possible reimbursement.”

### **Pharmacy Price Concession**

- NASP agrees with CMS that a definition for “price concession” is necessary and should be included within 42 C.F.R § 423.100. The definition must be comprehensive and inclusive of all remuneration and fees that are intended to be deducted from payments made to pharmacies for the purchase of Part D drugs. NASP therefore outlines additional fees that should be included by CMS in this definition.

### **Standardized Performance Measures**

- NASP believes CMS has the authority based on the Any Willing Provider statute to require and oversee standardized metrics for pharmacy performance. This will ensure that pharmacies are not subjected to irrelevant and unreasonable measures. CMS should proceed immediately to standardize and oversee pharmacy performance measure to ensure that: (1) any incentive payments tied to metrics do not increase costs for beneficiaries; and (2) measures are relevant to the actual performance of a pharmacy and applied in a manner that is specific to the pharmacy type, drugs dispensed, and disease states being managed.

### **Medicare Coverage Gap**

- NASP urges CMS to include all pharmacy price concessions in the negotiated price for prescriptions dispensed to beneficiaries who reach the Medicare Part D coverage gap.

### **Administrative Service Fees**

- NASP agrees with CMS’ efforts to ensure that administrative service fees are applied at the point-of-sale if such fees are utilized to reduce drug reimbursement. NASP also agrees that any administrative fees that are otherwise applied, must be included in the Plan’s bid.

- NASP recommends that CMS conduct oversight of the growth, and appropriate reporting, of “administrative service fees.” NASP respectfully requests that CMS require Plans and their PBMs to certify or attest that any administrative fees are actually utilized for administrative services and that such services are relevant and applicable to the pharmacy against which the fees are applied.
- NASP asks that all fees that are collected from pharmacies, including all administrative fees and concessions, are included in the Part D Plan’s Medical Loss Ratio calculation to reduce “incurred claims.”

### **Claims and Price Concession Transparency**

- NASP believes it is necessary that CMS require that Plans provide claims-level detail to pharmacies on the lowest possible reimbursement for each drug covered under the pharmacy’s participation agreement.
- NASP also requests that CMS require Plans to provide claims-specific detail regarding post-sale price concessions.

### **Part D Plan Bids**

- NASP believes CMS must disincentivize those Plans that underestimate prospective DIR during their bid submissions, and CMS should prohibit those Plans from retaining overpayments obtained from DIR and administrative fees that are in excess of their DIR bid estimates. CMS must maintain strict oversight of bid estimations and reporting of DIR and other fees.

## **NASP COMMENTS ON PROPOSED RULE**

### **I. Summary of Current Problem and Importance of Pharmacy DIR Reform**

NASP’s specialty pharmacy members have seen a dramatic growth in the collection of pharmacy DIR fees since 2012. Certain Plans opt for higher negotiated prices in exchange for higher pharmacy DIR, and in some cases, even prefer a higher net cost drug over a cheaper alternative. Those Plans make this decision for two reasons: (1) they may generate profit by charging total pharmacy DIR above the projected DIR in their bid and retaining overpayments as during reconciliation; and (2) they may acquire profits by inflating negotiated prices to concentrate expenditures in the catastrophic coverage phase where the Plan’s liability is

limited.<sup>1</sup>

#### **A. Impact on Specialty Pharmacy Patients**

Retroactive pharmacy DIR fees are collected through claw backs that pharmacies are charged months after the pharmacy has dispensed the drug and the beneficiary has purchased the drug at a higher price. A beneficiary does not know that they paid a higher price for their drugs than they would have paid if the pharmacy DIR fees assessed had been applied at the time the beneficiary purchased their drugs. For specialty patients facing comparatively higher drug costs to manage their conditions, they pay a considerably higher copay for their drugs than they would have otherwise. Not only are patients paying a higher-than-average upfront cost, but pharmacy DIR Fees are also pushing these specialty patients into Medicare’s catastrophic coverage phase at a much faster rate. In the Proposed Rule, CMS outlines that addressing pharmacy DIR fees will save beneficiaries over \$20 billion in reduced cost sharing.<sup>2</sup> CMS makes clear that “for more than half of Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, [pharmacy DIR] means, on average, higher overall out-of-pocket costs, even after accounting for the premium savings tied to higher DIR.”<sup>3</sup>

When drugs are unaffordable, Medicare beneficiaries often discontinue their drug regimens. For patients with specialty conditions like multiple sclerosis, cancer, epilepsy, rheumatoid arthritis, organ transplantation, and HIV, disruption in treatment results in poorer health outcomes and significant health complications, costing Medicare more through avoidable emergency department visits and hospital admissions. Reforming pharmacy DIR fees will support patients, ensuring they pay less for their drugs, especially high-cost drugs for those conditions that have few-to-no alternative treatments.

#### **B. Impact on Specialty Pharmacies**

Specialty pharmacies face significant financial uncertainty as a result of pharmacy DIR fees applied after the point-of-sale, given that their actual reimbursement rate on a drug cannot be determined until well after they have dispensed the medication. When the reimbursement is reconciled, it is often far less than the actual cost of the drug, which is further complicated by the cost of the requisite pharmacy services needed to support the patient’s journey on the specialty drug. For many specialty pharmacies, certain Plans subject them to performance measures that are irrelevant to specialty pharmacy operations. Certain Plans use those irrelevant measures to charge exorbitant post-sale price concessions, which threatens the viability of many specialty pharmacies. NASP has witnessed significant, forced consolidation in

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<sup>1</sup> Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 1842 (proposed Jan. 12, 2022) (to be codified at 42 C.F.R. pt. 422, 423).

<sup>2</sup> Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 1842, 1913 (Jan. 12, 2022).

<sup>3</sup> *Id.*

the specialty pharmacy market resulting from pressures imposed by such tactics.<sup>4</sup>

*Specialty Pharmacies Are Disparately Impacted by Post-Sale Price Concessions*

The higher prices of specialty drugs create perverse incentives for certain Plans to impose higher post-sale price concessions on specialty pharmacies. Those price concessions are typically aggregated as one massive and unpredictable charge during the Plan year, occurring after numerous specialty drugs have been dispensed and Part D beneficiaries' cost sharing has been applied. Importantly, many Plans do not provide claim-specific detail explaining concessions, which prevents the specialty pharmacy from evaluating the performance-based charges.

**Specialty pharmacies are forced to pay millions of dollars in unexpected and arbitrary post-sale price concessions each year.** For example, one specialty pharmacy reported that it has been charged a total of **\$42,134,119** in post-sale price concessions since 2016. Another organization has been charged approximately **\$78,590,000** in post-sale price concessions since 2016 across the specialty pharmacies it operates. Another organization that provides patient care through a federally qualified health center owns several pharmacies, including a specialty pharmacy. This organization was charged over \$2,700,000 in post-sale concessions between 2018 and 2021, of which \$2,300,000 was recouped specifically from its specialty pharmacy. These figures clearly demonstrate the disparate harm that ongoing post-sale price concessions cause specialty pharmacies across the Nation.

As a result of these price concessions, the business operations of specialty pharmacies have been significantly harmed. NASP is aware of several specialty pharmacies that have had to restructure their operations, including laying off numerous staff members and cutting back on higher-cost inventory. Other specialty pharmacies have been forced to stop stocking and dispensing drugs to treat certain conditions due to certain Plans' historical targeting of specific specialty drugs for costly post-sale price concessions. Moreover, these pharmacies have been forced to set aside millions, sometimes tens of millions, of dollars of their operating budgets to cover potential post-sale price concessions. Finally, NASP is directly aware of numerous specialty pharmacies that were forced to sell due in part to the impact post-sale price concessions. These concessions continue to be based primarily on performance measures that are not relevant to the drugs specialty pharmacies dispense or services they provide.

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<sup>4</sup> Adam J. Fein, *Specialty Pharmacy M&A: Our Look at 2018's Deals*, DRUG CHANNELS (Jan. 3, 2019), <https://www.drugchannels.net/2019/01/specialty-pharmacy-m-our-look-at-2018s.html>.

### **C. Pharmacy Price Concessions Are Not Due to Pharmacy-Plan Negotiations**

NASP is deeply concerned by CMS' statements in the preamble to the Proposed Rule regarding why pharmacy price concessions have grown over 107,400 percent over the last 10 years.<sup>5</sup> CMS attributes the significant growth of these fees to "Part D sponsors and their contracted PBMs having been *increasingly successful in recent years in negotiating price concessions* from network pharmacies."<sup>6</sup> NASP respectfully submits that this is false. As almost any pharmacy will attest, contracting between pharmacies and many Plans/PBMs is one-sided and in most cases involves little to no negotiation. The draconian imposition of these price concessions, which are forcibly extracted from pharmacies, has grown from \$8.9 million collected in 2010 to \$9.5 billion in 2020.<sup>7</sup> This growth is directly correlated with and has been incentivized by CMS' 2014 Part D final rule<sup>8</sup> that allowed for the "reasonably determined" exception to the negotiated price. That rule has incentivized some Plans and PBMs to arbitrarily impose so-called performance-related measures against pharmacies after the point-of-sale strictly as a mechanism of generating Plan profit, rather than incentivizing quality care. If those certain Plans/PBMs truly were assessing pharmacy performance, it would mean, based on CMS' statistics on concession growth, that nearly every pharmacy in the U.S. is failing to provide quality pharmaceutical care. **NASP believes that CMS is not understanding that the growth in performance-related concessions after the point-of-sale has generally not been due to Plans negotiating price concessions from pharmacies. It has also not been primarily due to fair evaluation of pharmacy performance. NASP submits that the growth in post-sale price concessions has been due to certain Plans, and their PBMs, generating profits by exploiting incentives in the Medicare program. Some Plans/PBMs have used "performance-based" concessions and other arbitrary fees to recoup payments from pharmacies, at the Plan's discretion, as a pretext for profiteering.** Those Plans have not been increasingly successful at negotiating fees/discounts from pharmacies. Importantly, NASP understands that many Plans' contract terms are forced on pharmacies as "take-it-or-leave-it." There is generally no fair pharmacy performance evaluation occurring. For specialty pharmacies, there is no relevant performance evaluation occurring either. For example, some Plans use a metric such as Generic Dispense Rate (GDR) to unfairly hold a specialty pharmacy accountable for having dispensed brand-name drugs instead of generic drugs, regardless of what was prescribed by the physician and even if there is no generic equivalent to substitute or interchange for the specialty condition being treated. The reality is that certain Plans are: (1) inflating drug prices at the point-of-sale to the detriment of beneficiaries, pharmacies, and the Medicare program, as patients are forced into Medicare's catastrophic coverage phase where those Plans' liability is limited; and (2) retaining overpayments from Medicare by clawing back pharmacy DIR as

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<sup>5</sup> Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. at 1910.

<sup>6</sup> *Id.* (emphasis added).

<sup>7</sup> *Id.* at Table 3: Pharmacy Price Concessions by Year (2010-2020).

<sup>8</sup> Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29844, 29962 (May 23, 2014); 42 C.F.R. § 423.100 (2021).

profit through risk corridors and the reconciliation process, which permits Plans to retain up to seven and one-half percent of overpayments as profit.

**NASP respectfully requests that CMS seriously reexamine this issue and the associated evidence to understand what is contributing to the excessive growth of post-sale pharmacy price concessions.**<sup>9</sup> In finalizing a separate rule last year,<sup>10</sup> CMS determined that it would establish a requirement under § 423.514 for Part D sponsors to disclose to CMS the measures the Plans use to evaluate pharmacy performance. CMS stated that this disclosure process would provide information on how measures are being applied by pharmacy type and whether and how rewards or penalties are being applied to a pharmacy.<sup>11</sup> It stands to reason that CMS has acknowledged that a review of measures that have led to excessive growth in price concessions is necessary, and it is therefore concerning that CMS would attribute price concession growth to “successful plan-pharmacy negotiations” before conducting the pharmacy performance measure analysis it outlined in its 2021 final rule. It is also concerning that CMS would attribute the growth in these price concessions to “successful plan-pharmacy negotiations,” given the *years* of comments that have been submitted by pharmacy associations complaining that Plans are forcing arbitrary and unreasonable contracts on them without any meaningful opportunity to negotiate their terms.<sup>12</sup> Notably, the Federal Trade Commission has undertaken its own initial review of anticompetitive tactics by certain Plans, soliciting information on “PBMs’ use of potentially unfair, deceptive, or anticompetitive contract terms” among many other indicia of Plans refusing to meaningfully negotiate with pharmacies.<sup>13</sup>

NASP is concerned that CMS may lack requisite information about the magnitude of the abuse pharmacies have faced due to these price concessions by some Plans/PBMs; how those Plans

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<sup>9</sup> For example, it is well documented that certain Plans underestimate expected DIR fees through bids, charge pharmacies exorbitant post-sale DIR fees based on irrelevant performance measures to recoup payments, and retain overpayments from Medicare as profits through reconciliation. See Joseph Walker, et al., *The \$9 Billion Upcharge: How Insurers Kept Extra Cash From Medicare*, WALL ST. J. (Jan. 4, 2019), <https://www.wsj.com/articles/the-9-billion-upcharge-how-insurers-kept-extra-cash-from-medicare-11546617082>.

<sup>10</sup> Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 86 Fed. Reg. 5864, 5955 (Jan. 19, 2021).

<sup>11</sup> *Id.*

<sup>12</sup> See, e.g., Sheila M. Arquette, *NASP Comments on Proposed Regulation – Medicare Part D/Medicare Advantage*, NASP (Jan. 25, 2019), <https://naspnet.org/wp-content/uploads/2019/01/NASP-Comments-Part-D-Proposed-Rule.pdf>; Amended Complaint, *Nat’l Cmty. Pharmacists Ass’n v. Becerra*, No. 1:21-cv-00131-ABJ (D.D.C. Apr. 28, 2021), ECF No. 10; Inmar Intelligence, *Direct and Indirect Remuneration (DIR) Performance and the Impact on Pharmacies Serving Medicare Part D Beneficiaries*, at 2 (Revised July 2019), available at [https://www.nacds.org/pdfs/government/2019/DIR\\_Performance\\_to\\_Date\\_2019.pdf](https://www.nacds.org/pdfs/government/2019/DIR_Performance_to_Date_2019.pdf).

<sup>13</sup> F.T.C., *Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers* (Feb. 24, 2022), [https://www.ftc.gov/system/files/attachments/press-releases/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices/solicitation\\_for\\_public\\_comments\\_on\\_the\\_business\\_practices\\_of\\_pharmacy\\_benefit\\_managers.pdf](https://www.ftc.gov/system/files/attachments/press-releases/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices/solicitation_for_public_comments_on_the_business_practices_of_pharmacy_benefit_managers.pdf).



misrepresent these predatory concessions; the unreasonable conditions under which those Plans impose these concessions; the lack of any negotiations regarding these concessions; the arbitration awards issued directly stating that these concessions are unreasonable and/or based on irrelevant performance measures; and the details of the composition of these concession. Although NASP believes that the Proposed Rule takes strong steps to curb these abuses – *steps that must be finalized* – the Proposed Rule would continue to permit the abuse of post-sale pharmacy price concessions if CMS does not finalize additional reform, oversight, and protections for pharmacies. **To truly support Medicare Part D beneficiaries, it is not sufficient to only reduce beneficiary out-of-pocket drug costs at the point-of-sale. CMS must also seek to protect beneficiary access to their pharmacies. That access is at risk if CMS allows for Plan-driven post-sale price concessions without additional reform and oversight through this rule.**

**II. NASP Strongly Supports CMS Proposed Reforms to Reduce One Incentive for Post-Sale Price Concessions**

CMS has proposed changing the existing regulatory definition of “negotiated prices” at 42 C.F.R § 423.100 to “negotiated price” and further defining the term to mean “the lowest possible reimbursement such network entity will receive, in total, for a particular drug . . . including all price concessions from network pharmacies or other network providers; includes any dispensing fees; and excludes additional contingent amounts such as incentive fees, if these amounts increase prices; and is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point-of-sale.”<sup>14</sup>

**NASP appreciates CMS’ effort to make negotiated prices more transparent and supports the agency amending the definition of negotiated price to exclude the “reasonably determined exception.”** As discussed below, NASP understands that the reasonably determined exception has been exploited considerably to extract post-point-of-sale claw back fees from pharmacies and has resulted in increased drug costs for beneficiaries. We understand that revising negotiated price to ensure all possible pharmacy price concessions are included at the point-of-sale would accomplish our shared goal of lowering beneficiary out-of-pocket costs at the point-of-sale. **NASP also agrees with the exclusion from the proposed definition of negotiated price additional contingent amounts, including incentive payments to pharmacies, that would increase drug prices at the point-of-sale.**

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<sup>14</sup> Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg at 1958. NASP believes that CMS should clarify that the lowest possible reimbursement means the lowest possible reimbursement *any* pharmacy *may* receive.

**A. Amending Negotiated Price to Remove the “Reasonably Determined” Exception Must be Finalized**

**NASP calls on CMS to finalize the proposed elimination of the reasonably determined exception because NASP believes that the exception violates federal law.**<sup>15</sup> The Medicare statute mandates that “a PDP sponsor offering a prescription drug plan or a Medicare Advantage (MA) organization offering an MA prescription drug (PD) plan . . . *shall provide enrollees with access to negotiated prices* used for payment for covered Part D drugs” and that “*negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs.*”<sup>16</sup> The Medicare statute does not authorize CMS to allow any exception to an enrollee’s access to negotiated prices, particularly one that thwarts the purpose of the statute by incentivizing certain Plans to levy unfettered price concessions on pharmacies caring for Part D beneficiaries. Notwithstanding this clear statutory mandate, in 2014 CMS adopted the “reasonably determined” exception, which excludes from the definition of negotiated price those pharmacy price concessions that cannot reasonably be determined at the point-of-sale.<sup>17</sup> This regulatory change has encouraged certain Medicare Part D Plans and their PBMs to impose post-sale price concessions, because doing so lowers the Plan’s annual expenditures and correspondingly increases the Plan’s profits. Some Plans significantly inflate negotiated prices, expecting to claw back funds from pharmacies after the point-of-sale, thereby imposing significant harms on specialty pharmacies, Part D beneficiaries, and the Medicare Trust Fund.

**The “Reasonably Determined” Exception Has Directly Incentivized Rampant Post-Sale Price Concessions**

Since CMS issued regulations adopting the reasonably determined exception, post-sale price concessions have increased dramatically through the use and application of so-called pharmacy performance measures.<sup>18</sup> Specialty pharmacies generally have no bargaining power against certain Plans and are forced to agree to anti-competitive post-sale price concessions that are arbitrary and unpredictable. The performance measures applied to many specialty pharmacies to charge these price concessions are particularly egregious because they have largely had no meaningful relationship to drugs the specialty pharmacy dispenses, the services the specialty pharmacy provides, or the level of performance a specialty pharmacy has provided. The reasonably determined exception, therefore, leaves many specialty pharmacies in apprehension of future post-sale price concessions and without any way to anticipate or

<sup>15</sup> *Id.* at 1914; 42 C.F.R. § 423.100 (2021); 42 U.S.C. § 1395w-102(d)(1)(A)-(B) (2018); Amended Complaint, *Nat’l Cmty. Pharmacists Ass’n v. Becerra*, No. 1:21-cv-00131-ABJ (D.D.C. Apr. 28, 2021), ECF No. 10.

<sup>16</sup> 42 U.S.C. § 1395w-102(d)(1)(A)-(B) (2018) (emphasis added).

<sup>17</sup> 79 Fed. Reg. at 29962.

<sup>18</sup> Ctrs. for Medicare & Medicaid Services, *Fiscal Year 2022 Justification of Estimates for Appropriations Committees*, at 242 (May 28, 2021), <https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf>.

control the costly concessions, which harms their business operations, ability to provide necessary pharmaceutical services to support their patients, and, for some, their future existence.

*The “Reasonably Determined” Exception Incentivizes Certain Plans and PBMs to Shift Costs to Pharmacies, Part D Beneficiaries, and Taxpayers*

CMS’ “reasonably determined” exception directly incentivizes certain Plans to increase their profits by shifting costs to pharmacies, beneficiaries, and the Medicare Trust Fund. Specifically, the exception incentivizes Plans to inflate the negotiated prices that are initially paid to specialty pharmacies, which increases a beneficiary’s out-of-pocket costs and accelerates a beneficiary’s advancement to the catastrophic coverage phase, during which the Plan’s liability is limited and Medicare (i.e., the taxpayer) pays the lion’s share of the cost of the drug.

*Post-Sale, Performance-Based Price Concessions Have Been Arbitrarily Applied to Specialty Pharmacies*

Once CMS’ reasonably determined exception became effective, certain Plans increasingly used post-sale price concessions as a mechanism of applying their own arbitrary measures to *revoke* pharmacy reimbursement, with little-to-zero bonus or incentive opportunity for specialty pharmacies. Pharmacy price concessions have taken the form of many various charges to pharmacies, such as preferred network access fees or administrative fees. However, many Plans have increasingly imposed post-sale pharmacy price concessions on specialty pharmacies through so-called performance-based price concessions.

**Many Plans use performance-based measures that are irrelevant to specialty pharmacies to justify the price concessions they unilaterally impose.<sup>19</sup> These Plans typically apply measures based on the specialty pharmacy’s performance relating to medications used to treat primary care conditions.<sup>20</sup> These medications are used to treat common conditions that are considered chronic or long-term, such as high blood pressure, heart disease, depression, and diabetes.<sup>21</sup> These conditions, however, are not specialty conditions nor are they typically related to the drugs a specialty pharmacy is dispensing.** As a result, many specialty pharmacies are unable to improve performance scores related to these types of irrelevant measures.

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<sup>19</sup> Frier Levitt, “Performance” Based DIR Fees: A Rigged System with Disparate Effect on Specialty Pharmacies, Medicare Part D Beneficiaries and the U.S. Healthcare System (Mar. 2017), at 19, available at <https://naspnet.org/dir-white-paper> [hereinafter “Frier Levitt 1”].

<sup>20</sup> Frier Levitt, *PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues*, at 4, <https://communityoncology.org/pbm-dir-fees-costing-medicare-and-beneficiaries-investigate-white-paper-on-background-cost-impact-and-legal-issues/> [hereinafter “Frier Levitt 2”].

<sup>21</sup> See, e.g., CVS Caremark, *CVS Caremark Maintenance Drug List* (Dec. 15, 2021), [https://www.caremark.com/portal/asset/CVS\\_Caremark\\_Maint\\_DrugList.pdf](https://www.caremark.com/portal/asset/CVS_Caremark_Maint_DrugList.pdf).

**Some Plans attempt to justify their application of irrelevant performance-based measures to specialty pharmacies under the guise of improving the Plan’s score under CMS’s Five Star Rating System.**<sup>22</sup> Medicare uses a Star Rating System to measure how well Medicare Part D prescription Plans perform. For Plans, there are four rating categories: (1) drug Plan customer service; (2) member complaints and changes in the drug Plan’s performance; (3) member experience with the drug Plan; and (4) drug safety and accuracy of drug pricing.<sup>23</sup> Within each category are several sub-categories of “measures.” The fourth category, “drug safety and accuracy of drug pricing,” contains the common measures that are improperly applied to specialty pharmacies by Plans. These measures include: (1) medication adherence for diabetes medications; (2) medication adherence for hypertension; (3) medication adherence for cholesterol; and (4) medication therapy management program completion rate for comprehensive medication reviews; and (5) statin use in patients with diabetes.<sup>24</sup> These measures relate to medications used to treat primary health conditions and are generally irrelevant to specialty pharmacy operations. Nevertheless, many Plans improperly apply their own iteration of these irrelevant measures to specialty pharmacies as false justification for assessing costly post-sale price concessions; exploiting Medicare’s profit incentives through the “reasonably determined” exception; and exploiting Medicare’s bid-reconciliation process to retain overpayments.

Plans impose two general categories of performance-based post-sale pharmacy price concessions: flat rate fees and percentage fees.<sup>25</sup> Plans may apply one or both types of fees under their pharmacy contracts. Flat rate fees typically range from \$2.00 to \$7.00 per prescription claim.<sup>26</sup> The more common percentage-based fees generally range from three percent to nine percent of the gross drug reimbursement per prescription claim.<sup>27</sup> For countless specialty pharmacies, which primarily dispense high-cost medications for rare and complex medical conditions, Plans arbitrarily impose percentage-based performance concessions, resulting in millions to tens of millions of dollars in unforeseeable concessions per specialty pharmacy each year. This is because the total percentage-based concession increases with the price of the specialty drugs, which are often very costly. These concessions significantly threaten specialty pharmaceutical access because they significantly diminish, if not eliminate, the pharmacy’s gross revenue margins.

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<sup>22</sup> See, e.g., Frier Levitt 2, *supra* note 21, at 15–17.

<sup>23</sup> Ctrs. for Medicare & Medicaid Services, *Medicare 2021 Part C & D Star Ratings Technical Notes*, at 62–72 (Oct. 1, 2020), <https://www.cms.gov/files/document/2021technotes20201001.pdf-0>.

<sup>24</sup> *Id.* at 72–82.

<sup>25</sup> *Id.*

<sup>26</sup> Adam J. Fein, *Behind Diplomat Pharmacy’s Plunge: A Primer on DIR Fees in Medicare Part D*, DRUG CHANNELS (Nov. 8, 2016), <https://www.drugchannels.net/2016/11/behind-diplomat-pharmacys-plunge-primer.html>; Frier Levitt 2, *supra* note 21, at 4.

<sup>27</sup> Pharmacy Times, *White Paper: DIR Fees Simply Explained* (Oct. 25, 2017), *available at* <https://www.pharmacytimes.com/view/white-paper-dir-fees-simply-explained>; Frier Levitt 2, *supra* note 21, at 4.

*Certain Plans Have a Profit Incentive to Charge Post-Sale Price Concessions*

Part D of the Medicare statute requires beneficiaries to contribute out-of-pocket “cost-sharing” amounts on a basis that is generally proportional to the negotiated price of the drug.<sup>28</sup> More specifically, a beneficiary’s cost-sharing is mostly based on a percentage of the drug’s “actual cost,” which is defined as “the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy.”<sup>29</sup>

A beneficiary’s cost sharing responsibility is also determined by the phase of Medicare Part D coverage that the beneficiary is in. There are four coverage phases of standard Part D Plans: the (1) initial deductible phase; (2) initial coverage phase; (3) coverage gap phase; and (4) catastrophic coverage phase.<sup>30</sup> During the initial deductible phase of a standard Plan, the beneficiary is responsible for 100 percent of the negotiated price of the drug, up to a cap (\$445 in 2021).<sup>31</sup> In the initial coverage phase, beneficiaries pay twenty-five percent of the negotiated price of the drug at network pharmacies, and the Plan pays seventy-five percent, up to a cap.<sup>32</sup> For 2021, the total drug expenditure cannot exceed \$4,130 during the initial coverage phase, leaving the beneficiary to pay \$1,366.25 in cost-sharing.<sup>33</sup>

During the next phase, the coverage gap phase (previously referred to as the “doughnut hole”), the beneficiary is responsible for twenty-five percent of the negotiated price of brand and generic drugs, plus twenty-five percent of the pharmacy’s dispensing fee (approximately \$1-\$3).<sup>34</sup> In the coverage gap phase, a Plan pays seventy-five percent of the cost of generic drugs and five percent for brand drugs.<sup>35</sup> The remaining seventy percent for brand drugs is paid by manufacturers as a discount.<sup>36</sup> Once the beneficiary has paid \$5,183.75 in this coverage gap phase (\$6,550 total across the first three phases in 2021 and set to increase to \$7,050 in 2022),

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<sup>28</sup> Beneficiary cost-sharing percentages are a function of “actual cost” defined as the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a). 42 U.S.C. § 1395w-102(b)(1)–(4) (2018); 42 U.S.C. §1395 (1965).

<sup>29</sup> 42 C.F.R. § 423.100 (2021).

<sup>30</sup> *Id.*; see 42 C.F.R. § 423.104(d) (2021).

<sup>31</sup> Ctrs. for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies*, at 75 (Jan. 15, 2021), <https://www.cms.gov/files/document/2022-announcement.pdf>. [hereinafter “CMS 2022 Coverage Announcement”].

<sup>32</sup> 42 U.S.C. §§ 1395w-102(b)(1)–(4) (2018).

<sup>33</sup> CMS 2022 Coverage Announcement, *supra* note 32, at 75.

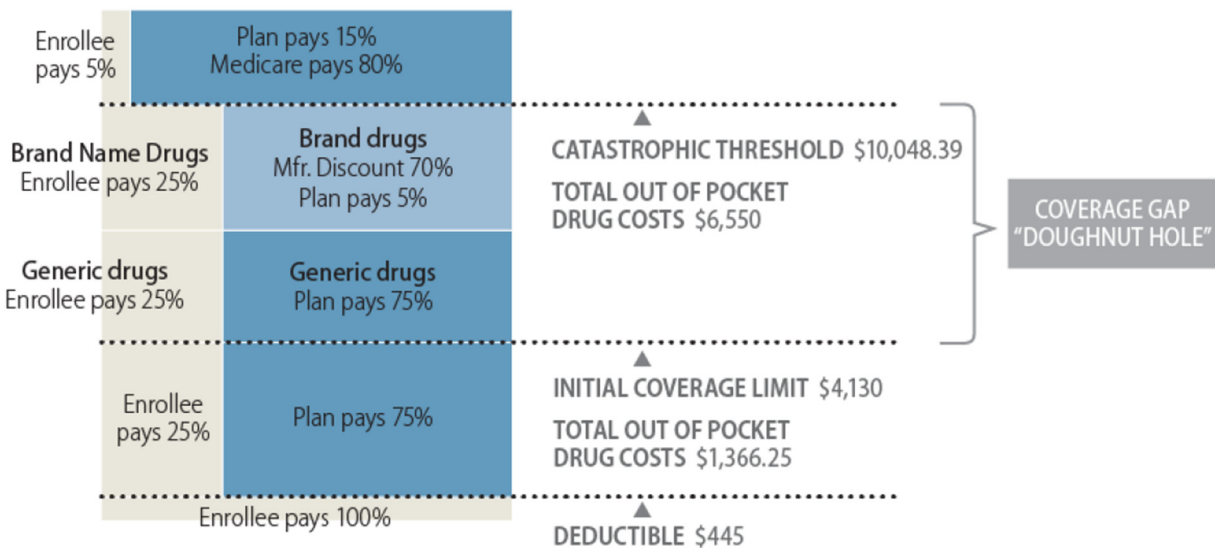
<sup>34</sup> 42 C.F.R. § 423.104(d)(3)–(4) (2021).

<sup>35</sup> *Id.*

<sup>36</sup> Under the Medicare Coverage Gap Discount Program manufacturers agree to pay the Plan seventy percent of the negotiated price of brand-named drugs in the coverage gap phase. 42 C.F.R. § 423.2305 (2021).

the beneficiary’s coverage moves to the catastrophic phase.<sup>37</sup> Part D beneficiaries may also progress to the catastrophic phase when their total annual out-of-pocket spending, including what they pay directly and the value of manufacturer discounts on brand-named drugs, exceeds the catastrophic threshold of \$10,048.39.

During the catastrophic phase, the beneficiary’s liability is for five percent of negotiated prices, *without any liability cap*. Therefore, a beneficiary receiving costly specialty drugs could pay hundreds of dollars for one drug dispensed. Meanwhile, the Plan is responsible for only fifteen percent of costs for generic and brand drugs *while Medicare subsidizes eighty percent of costs*.<sup>38</sup> The Part D coverage phases are illustrated in the graphic below, reproduced from the Congressional Research Service.<sup>39</sup>



During each of these Medicare phases, CMS’ “reasonably determined” exception allows the cost sharing amounts that a beneficiary pays to be overstated, because those amounts are largely calculated as a percentage of the negotiated price and the negotiated price does not account for any post-sale concessions that cannot be reasonably determined at the point-of-sale. Stated differently, under Medicare regulations, the negotiated price may be inflated in comparison to the true price net of all post-sale price concessions. The amount that the Plan purportedly pays may be understated because it does not account for the recoupments that the Plan receives as the result of pharmacy price concessions that are not determined at the

<sup>37</sup> CMS 2022 Coverage Announcement, *supra* note 32, at 75.

<sup>38</sup> See 42 C.F.R. §§ 423.100, 423.104(d)(3)-(5) (2021) (emphasis added); see also CMS 2022 Coverage Announcement, *supra* note 32, at 75.

<sup>39</sup> Patricia A. Davis, et. al., Cong. Research Serv., R40425, Medicare Primer 25 (May 21, 2020), available at <https://crsreports.congress.gov/product/pdf/R/R40425/55>.

point-of-sale. Not only does this distortion of the negotiated price cause Part D beneficiaries to pay higher cost sharing amounts at every Medicare coverage phase, but it also causes a beneficiary to reach the \$6,550 catastrophic threshold more quickly, a stage in which the Plan’s liability is reduced to only fifteen percent and Medicare pays eighty percent, resulting in a decrease in annual expenditures for the Plan and an increase for Medicare.<sup>40</sup> It is important to note that some Plans prefer high-cost brand drugs due to coverage gap discounts, and the majority of drugs that specialty pharmacies dispense are brand drugs because there are limited generic equivalents or biosimilars for many specialty medical conditions.<sup>41</sup>

CMS explained in a 2017 Proposed Rule that the growing imposition of post-sale price concessions has contributed to an important shift in how Part D spending is distributed across the Part D coverage phases, particularly for high-cost drugs.<sup>42</sup> CMS has stated that inflated negotiated prices from pharmacy price concessions “shifts more of the total drug spend into the catastrophic phase, where Medicare liability is highest (eighty percent, paid as reinsurance) and Plan liability, after the closing of the coverage gap, is lowest (fifteen percent)”.<sup>43</sup> This strategy by certain Plans has resulted, in part, in an increase of \$58 billion in total Part D spending during the catastrophic phase from 2006 to 2019 or a 233 percent increase.<sup>44</sup>

*The Explosion in Post-Sale Price Concessions Has Occurred After the “Reasonably Determined” Exception Was Promulgated*

**Plans have exploited CMS’ “reasonably determined” exception, resulting in an explosion in pharmacy price concessions, net of all pharmacy incentive payments, of 107,400 percent between 2010 and 2020.**<sup>45</sup> The following graph from *The Drug Channels Institute* illustrates the significant increase in Part D pharmacy price concessions since establishment of the “reasonably determined” exception up to 2019, which has since grown further, according to CMS’ data.

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<sup>40</sup> Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 82 Fed. Reg. 56,336, 56,420 (Nov. 28, 2017).

<sup>41</sup> See, e.g., CVS Specialty, *CVS Specialty® Pharmacy Distribution Drug* (Jan. 2022), <https://www.cvsspecialty.com/content/dam/enterprise/specialty/pdfs/SpecialtyDrugs.pdf> (only 83 of the 560 specialty drugs listed have generic alternatives).

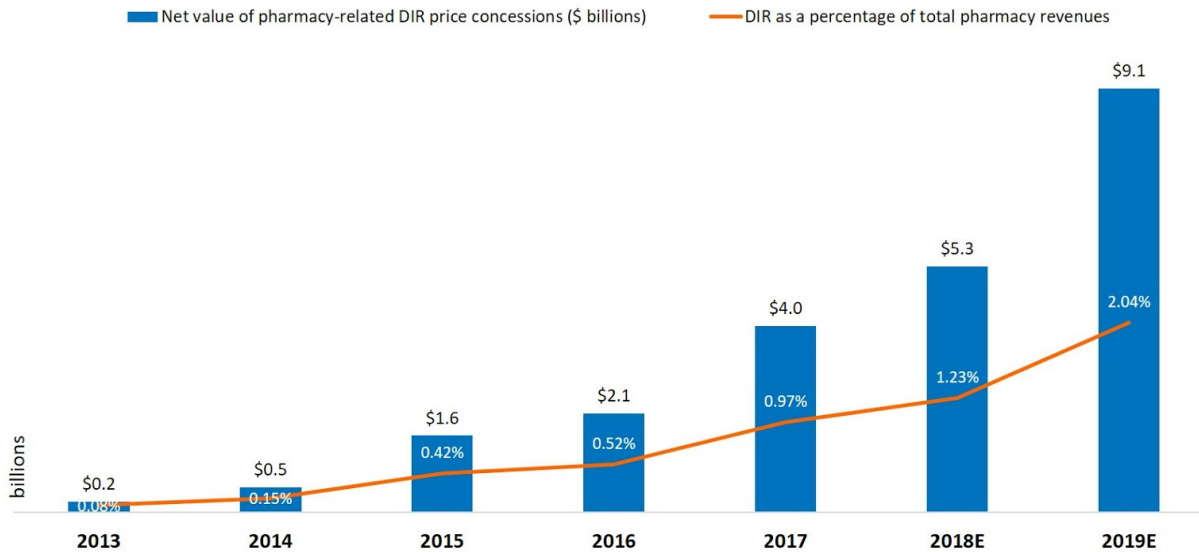
<sup>42</sup> Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 82 Fed. Reg. at 56,420.

<sup>43</sup> *Id.*

<sup>44</sup> See *An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 13, 2021), <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/>.

<sup>45</sup> Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. at 1910.

## Net Value of Pharmacy DIR Fees in Medicare Part D, 2013 to 2019



DIR = Direct and Indirect Remuneration

Source: Drug Channels Institute analysis of data reported by the Centers for Medicare & Medicaid Services and U.S. Government Accountability Office (2013 to 2017); Drug Channels Institute estimates based on Inmar Intelligence data on DIR as percentage of pharmacy revenues (2018 to 2019). Figures in billions.

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Importantly, the cause-and-effect of the CMS regulation is intensified for specialty pharmacies simply because the drugs that they dispense to treat complex specialty medical conditions are expensive and frequently lack a generic medication substitute. The Medicare program defines the specialty tier as drugs with negotiated prices equal to or exceeding \$670 per month.<sup>46</sup> CMS has noted that the combination of high drug prices and high price concessions, which it referred to as the “the high price-high DIR trend,” results in lower spending by Part D Plans.<sup>47</sup> Specifically, CMS has stated that, “as a result of the increasing preference for high price-high DIR arrangements, that proportion [of Plan spending] is shrinking each year.”<sup>48</sup> For that reason, patients of a specialty pharmacy have higher out-of-pocket costs and are more likely to reach the catastrophic phase of coverage than are individuals who do not require specialty medications.<sup>49</sup> Accordingly, CMS’ incentive for post-sale price concessions uniquely impacts

<sup>46</sup> Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services, 86 Fed. Reg. 5864, 5949–50 (Jan. 19, 2021).

<sup>47</sup> Ctrs. for Medicare & Medicaid Servs., *Medicare Part D – Direct and Indirect Remuneration (DIR)* (Jan. 19, 2017), <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>.

<sup>48</sup> *Id.*

<sup>49</sup> See *The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019*, KFF (Feb. 1, 2019) <https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/> (noting that Part D beneficiaries pay thousands of dollars out-of-pocket for specialty tier drugs, with the majority of costs for many drugs above the catastrophic threshold).



specialty pharmacies because they dispense primarily high-cost brand-named medications to their patients and pay higher concessions, which yield relatively greater profits for Plans.

*Removal of the “Reasonably Determined” Exception Will Reduce One Incentive for Plans to Charge Predatory Post-Sale Price Concessions*

**The “lowest possible reimbursement” definition of “negotiated price” as set forth in the Proposed Rule will positively affect beneficiaries by reducing their cost sharing amounts. By making this change, the Rule would remove one key incentive for Plans to inflate negotiated prices at the point-of-sale and recoup exorbitant post-sale price concessions from pharmacies at the Plan’s discretion.** This is because Plans will no longer be incentivized by CMS’ “reasonably determined” exception to inflate negotiated prices to increase beneficiary cost sharing amounts and concentrate expenditures in the catastrophic coverage phase where the Plan’s liability is reduced. Plans would no longer be able to concentrate expenditures in the catastrophic phase because beneficiaries’ cost sharing amounts will be strictly based on the lowest possible reimbursement according to the Plan’s contract, inclusive of the highest possible price concession. Finally, Plans will be less inclined to underestimate catastrophic phase spending during bid submissions.

**III. NASP Urges CMS to Provide Additional and Necessary Regulatory Protections**

**Along with the proposed removal of the “reasonably determined” exception, CMS must also ensure that there are regulatory safeguards in place to address inappropriate means, or loopholes, to which some Plans will turn to make up for lost profit due to CMS’ proposed reform. CMS must incorporate additional safeguards into the Proposed Rule to prevent Plans from exploiting certain Medicare incentives that allow them to hinder pharmacy competition. NASP fully expects that Plans/PBMs will impose unreasonable cuts in reimbursement that threaten Part D network participation for unaffiliated pharmacies (pharmacies that are not owned or under common ownership with the Plan/PBM), and consequently threaten patient access to pharmacies.** Specifically, NASP is deeply concerned that without incorporating the below-mentioned safeguards into CMS’ proposed reforms, some Plans will remain incentivized, for example, to:

- Charge pharmacies unreasonable fees, including post-sale price concessions that are based on irrelevant pharmacy performance measures;
- Charge pharmacies higher amounts of certain fees and other DIR that are not expressly included in the regulatory definition of pharmacy price concessions;
- Pay unreasonably low reimbursement to pharmacies upfront as the “negotiated” price (Plans will be incentivized to more frequently and arbitrarily reimburse at the lowest possible reimbursement and/or reimburse below the pharmacy’s acquisition cost for the drug);

- Charge pharmacies higher amounts of administrative fees, which are excluded from pharmacy price concessions within the negotiated price and do not appear to apply to “incurred claims” in the Plan’s medical loss ratio calculation; and
- Overbid by underestimating prospective pharmacy DIR to retain federal overpayments (obtained through charging post-sale price concessions) as profit during the Plan’s reconciliation process.

If these practices are not addressed through inclusion of appropriate guardrail protections in the Proposed Rule, as outlined below, there will be significantly reduced pharmacy access for patients due to further rampant pharmacy market consolidation and pharmacy closures.<sup>50</sup>

**A. CMS is Authorized to Amend the Proposed Rule to Protect Against Unreasonable and Irrelevant Plan Contracts with Pharmacies**

First, it is important to note that **existing federal law provides a statutory basis for CMS to incorporate baselines and guardrails into the Proposed Rule to protect against the predatory practices discussed in these comments.** For example, CMS maintains statutory authority to regulate Plans to ensure that pharmacies are promptly paid for clean claims.<sup>51</sup> This statutory provision provides no basis for Plans to adjust pharmacy reimbursement outside of the mandated prompt payment timeframes. Moreover, federal law requires Plans to pay pharmacies reimbursement that is reasonable, meaning that Plans may not pay pharmacy providers an unreasonably low reimbursement rate.<sup>52</sup> CMS has issued guidance in the Medicare Prescription Drug Benefit Manual (Part D Manual) stating that “standard contracting terms and conditions must be reasonable and relevant” and that “Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 C.F.R. § 423.505(b)(18).”<sup>53</sup> Importantly, this federal requirement is applicable to contract terms for

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<sup>50</sup> See, e.g., F.T.C., *FTC Requests Public Comments on the Impact of Pharmacy Benefit Managers’ Practices* (Feb. 24, 2022), <https://www.ftc.gov/news-events/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers>; see also Letter from Laura Boudreau, Chief of Operations/Risk Mgmt. and Quality Improvement, AIDS Healthcare Found., to Makan Delrahim, Assistant Att’y. Gen., U.S. Dep’t of Justice, Antitrust Div. (Feb. 26, 2020), [https://www.ftc.gov/system/files/attachments/798-draft-vertical-merger-guidelines/ftc\\_doj\\_vergical\\_merger\\_guidelines\\_comments\\_ahf\\_2-26-20.pdf](https://www.ftc.gov/system/files/attachments/798-draft-vertical-merger-guidelines/ftc_doj_vergical_merger_guidelines_comments_ahf_2-26-20.pdf) (imploing the FTC to address the wide-ranging anti-competitive concerns associated with vertical integration in the healthcare industry and stating that vertical mergers among Plans and PBMs inflict foreclosure harms on providers and their patients).

<sup>51</sup> 42 U.S.C. § 1395w-112 (2018); 42 C.F.R. § 423.520 (2021).

<sup>52</sup> See, e.g., Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918, 1970 (Jan. 10, 2014) (to be codified at 42 C.F.R. pt. 409, 417, 422, 423, 424) (CMS recognizing that any willing provider requirements permit CMS to regulate reasonable reimbursement provisions, but not permitting CMS to set exact equations for reimbursement).

<sup>53</sup> Ctrs. for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual*, Chapter 5, Section 50.8.1., at 51 (Sept. 20, 2011), [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5\\_093011.pdf](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf).

both point-of-sale reimbursement and the pharmacy's actual reimbursement after predatory post-sale price concessions have been clawed back.<sup>54</sup>

These provisions emanate directly from the Medicare statute. Courts read statutes as a whole, with consideration of the structure, purpose, and application of various provisions.<sup>55</sup> Courts also must give regard to all words used by Congress, and as far as possible give effect to them.<sup>56</sup> Accordingly, Medicare statutes that are designed to protect a competitive market, including federal prompt payment and any willing provider law, must be given full effect so that they are not rendered ineffective. **CMS is therefore authorized to promulgate regulations in accordance with the Medicare statute's any willing provider and prompt payment requirements, and such regulations would not run afoul of Medicare's non-interference clause. Moreover, CMS retains authority to promulgate such regulations in the interest of protecting market competition, which is consistent with the plain meaning of the text of the non-interference clause.**

The non-interference clause states that, "[i]n order to *promote competition* under this part and in carrying out this part," the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors" and "may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."<sup>57</sup> CMS has stated that "since the [Medicare] statute establishes numerous requirements that CMS must regulate concerning access to network pharmacies and negotiated prices, we believe that a CMS role in negotiations between Plan sponsors and pharmacies *is not prohibited* under the non-interference clause of the statute."<sup>58</sup> CMS has interpreted the language "in order to promote competition under this part" as requiring it to "seek to encourage certain features of the market that promote more perfect competition" including "such goals as decreasing the transaction cost of acquiring information on products offered in the market, increasing the transparency of prices, ensuring a large number of buyers and sellers, and minimizing barriers to entry to the extent possible while still ensuring quality."<sup>59</sup> CMS has noted that it has pursued these types of goals since the start of Part D program.

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<sup>54</sup> 42 U.S.C. § 1395w-104(b)(1)(A) (2018); 42 C.F.R. § 423.505(b)(18) (2021).

<sup>55</sup> See, e.g., *FCC v. AT&T Inc.*, 562 U.S. 397, 407–08 (2011) (considering meaning of "personal privacy" in light of its use in a distinct but similar exemption within the same statute); *Holder v. Hall*, 512 U.S. 874, 883 (1994) (comparing the functioning of two sections within the Voting Rights Act of 1965 that "differ in structure, purpose, and application").

<sup>56</sup> See *Louisville & Nashville R.R. Co. v. Mottley*, 219 U.S. 467, 475 (1911) ("We must have regard to all the words used by Congress, and as far as possible give effect to them").

<sup>57</sup> 42 U.S.C. § 1395w-111(i) (2018).

<sup>58</sup> Medicare Program; Contract Year 2015 Policy and Technical Changes to Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. at 1970.

<sup>59</sup> *Id.* at 1969.

**B. NASP Supports Protecting Pharmacy Network Access: Protections Against Unreasonable and Irrelevant Fees**

**Definition of Negotiated Price Should Be Revised to Eliminate Retroactive Pharmacy DIR Claw Backs**

While NASP supports CMS' proposed changes to the definition of negotiated price, we are extremely concerned that the rule "does not affect what sponsors may arrange in their contracts with network pharmacies regarding payment adjustments after the point-of-sale."<sup>60</sup> CMS emphasizes that "the requirement that pharmacy price concessions be passed through to the point-of-sale price only directly impacts the price that is used to determine beneficiary cost sharing and the information that is populated on the PDE record, but it does not dictate the amount that is ultimately paid to the pharmacy or the timing of payments and adjustments."<sup>61</sup> What CMS is setting up in this proposed approach is an allowance for Plans/PBMs to continue to retroactively claw back pharmacy DIR fees. The only difference in this proposal is that the negotiated price is to reflect all newly defined price concessions, which in essence, will be used to: 1) set a beneficiary's out-of-pocket costs, and 2) set a floor for the pharmacy's reimbursement. However, Plans/PBMs would remain incentivized to claw back funds, particularly by using performance-based price concessions that lack transparency or any oversight by CMS in this Proposed Rule or otherwise. These claw backs will remain extremely difficult to challenge by pharmacies and will further generate overpayment revenue that Plans may retain through Medicare's reconciliation process. **Eliminating retroactive claw backs on pharmacies is essential to ensuring the viability of network pharmacy providers and beneficiaries' access to the pharmacy of their choosing. Including all pharmacy price concessions in the negotiated price at the point-of-sale and prohibiting retroactive claw backs on pharmacies would allow pharmacies to understand upfront their actual reimbursement and allow them to Plan their business services.** This understanding and certainty will afford pharmacies with much needed transparency, which is required for them to effectively challenge unreasonably low reimbursement.<sup>62</sup>

**Recommendation: CMS should amend the Proposed Rule to eliminate retroactive claw backs. CMS should also require standardized and relevant (by pharmacy type) performance measures.** CMS should require that Plans only utilize reasonable and relevant performance measures. The Proposed Rule does not fully disincentivize or protect against the ongoing application of irrelevant performance measures to pharmacies. CMS may incorporate protections against irrelevant performance measures to strengthen the Proposed Rule to

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<sup>60</sup> Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg at 1915.

<sup>61</sup> *Id.*

<sup>62</sup> CMS may even become better apprised of *systematic and unreasonable actual reimbursement* that many pharmacies currently face across the Nation.

ensure that the lowest possible reimbursement reported by Plans is based on reasonable and relevant measures.

**At the least, CMS must incorporate, or cross-reference, federal reasonable and relevant requirements into the definition of the negotiated price by clarifying that the lowest possible reimbursement must be based on contract provisions that are relevant to the drugs dispensed and services provided by the pharmacy. Plans should be subject to penalty for false certification, claims, or unfair trade practices when they apply irrelevant performance measures to pharmacy price concessions and report lowest possible reimbursement based on concessions derived from these illegal measures.**

**CMS must memorialize in the Proposed Rule a baseline for what constitutes relevant performance measures.** CMS is authorized to require that Plans only apply measures that are relevant to the pharmacies' actual business, patients, and services. Specialty pharmacies, for example, are often subject to irrelevant performance measures. NASP members repeatedly report that many Plans apply performance measures that pertain to medications used to treat chronic primary health conditions and which are irrelevant to specialty pharmacies. For example, some Plans rely on CMS' Star Rating System, which is limited to diabetes, congestive heart failure, hypertension, respiratory, coronary artery disease, depression, and cholesterol. However, these measures are often irrelevant to specialty conditions and many specialty pharmacies' operations.

Finally, it is important to note that CMS is responsible for ensuring that its regulatory incentives do not violate the Administrative Procedure Act. Specifically, **CMS must ensure that the Proposed Rule and Medicare's incentives are not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance federal any willing provider law, prompt payment law, or the non-interference clause's mandate for promotion of a competitive Part D market.**<sup>63</sup> CMS must develop standardized performance measures to ensure that the above-mentioned predatory practices do not further exclude specialty pharmacies from the Part D market and drive further anti-competitive market consolidation in violation of federal law.

*CMS May Suspend Performance-Based DIR Claw Backs Until CMS Has Analyzed the Reasonableness and Relevance of Performance-Based Measures*

In the CY 2023 Part D Proposed Rule, CMS explains that to address concerns pharmacies have raised about the lack of transparency in the use of performance measures to evaluate

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<sup>63</sup> 5 U.S.C. § 706(2)(A) (1966) (stating that courts must hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law). It is also questionable whether certain incentives with the Medicare program constitute an illegal pricing scheme and/or whether the incentivization of bid overestimations resulting in unreasonable pharmacy price concessions constitute a "taking" under the Fifth Amendment of the U.S. Constitution.

pharmacy performance, the agency issued a final rule in January 2021<sup>64</sup> to establish, through an amendment to 42 CFR § 423.514(a), a requirement for Part D sponsors, beginning January 1, 2022, to disclose to CMS the pharmacy performance measures they utilize to evaluate pharmacy performance in their network agreements with pharmacies. CMS' intention is to eventually publish a list of pharmacy performance measures to support necessary transparency.

NASP is frustrated that CMS has not finalized its assessment of pharmacy performance measures currently utilized by Plans. NASP had hoped that CMS would work to finalize its assessment of Plan measures and examine whether such measures are reasonable and relevant. NASP had also hoped that CMS would work to standardize performance measures to prohibit Plans from manipulating the use of performance measures going forward. The experience of NASP members with dispute resolution against large Plans/PBMs instructs that CMS must curtail these practices immediately until CMS has made publicly available the measures it understands are being utilized by Plans/PBMs as reported. CMS' collection of Plan/PBM measures in accordance with its 2021 final rule was supposed to begin in January 2022; however, CMS has yet to issue any requirements associated with this mandatory reporting effort. It is not clear where the agency's measures-collection efforts stand or what information it has collected or assessed at this time.

**Recommendation:** CMS should not permit Plans to utilize performance-based concessions until CMS has (1) issued requirements for Plans to meet the terms of its 2021 final rule, including outlining the data to be provided to the agency by the Plans; (2) received the data submissions from Plans/PBMs; (3) analyzed the reasonableness and relevance of the measures data collected from Plans/PBMs to the pharmacies with which they have been applied; and (4) made such information publicly accessible and transparent. Transparency will ensure that pharmacy stakeholders may verify and further inform CMS of Plans' anti-competitive practices of using irrelevant and unreasonable performance measures to impose price concessions in the Part D market.

*Define Pharmacy Price Concession to Include All Adjustments That Reduce Reimbursement for a Part D Drug*

**NASP agrees with CMS that a definition for “price concession” is necessary and should be included within 42 C.F.R § 423.100. NASP strongly believes that in order to protect pharmacies against retroactive claw back fees and to ensure that patients receive the benefit of all discounts at the point-of-sale, the definition of price concession must be comprehensive and inclusive of all remuneration and fees that are intended to be deducted from payments made to pharmacies for the purchase of Part D drugs. The definition should be broad enough**

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<sup>64</sup> Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 86 Fed. Reg at 5684.

to not only account for all pharmacy price concessions used within the Part D program, but also for anticipated concessions that Plans may apply against pharmacies. **It is important that CMS protect against any loopholes the definition could present if Plans were to reclassify certain pharmacy price concessions with a term that falls outside of any definition.**

NASP recommends to CMS that this definition should be revisited with pharmacy stakeholders within a defined period of time to understand whether the definition remains relevant or needs to be periodically updated after it is put in place. NASP recommends that CMS revisit this issue within one year of finalization of the Proposed Rule.

**Recommendations:** NASP offers the following recommended edits (strikethrough and additions in red font) to CMS' proposed definition for price concession to ensure the definition is comprehensive as explained above:

**Price concession means any form of discount, direct or indirect subsidy, ~~or~~ rebate, fee paid by a pharmacy or deducted from payments to a pharmacy, or any other remuneration received directly or indirectly by the Part D sponsor or its intermediary contracting organization from any source, that serves to decrease the costs incurred under the Part D Plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, transaction fees, credentialing fees, adjustments, network participation fees and other administrative fees collected, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.**

NASP requests that CMS amend the Proposed Rule to apply pharmacy price concessions to the negotiated price of applicable drugs in the Medicare Part D coverage gap phase, as discussed later in these comments.

**CMS must require Plans to include all pharmacy-related fees in the negotiated price as it eliminates the “reasonable determined” exception. Any direct or indirect payments collected by Plans from pharmacies serve to reduce drug costs, and under the revised definition of negotiated price, as proposed, must be accounted for in the negotiated price.**

NASP also recommends that CMS oversee the operation of the changes to the negotiated price definition by requiring Plans to provide an attestation from the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Operating Officer (COO) or other delegated individual as to the accuracy and completeness of the pharmacy price concessions included in negotiated price at the point of sale. There is precedent in regulation for such a requirement to ensure accurate reporting.<sup>65</sup> Such a requirement will provide CMS with documentation of impropriety if such price concessions are not included in the negotiated price.

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<sup>65</sup> Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, 81 Fed. Reg. 41036, 41099 (June 23, 2016); 42 C.F.R. § 414.504 (2021).

*Administrative Service Fees Should Be Included in a Part D Plan's Bid or in the Definition of Price Concession*

In the Proposed Rule, CMS addresses certain fees that are currently being charged to network pharmacies (network access fees, administrative fees, technical fees and service fees). CMS says that when pharmacy administrative service fees are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are *price concessions* and must be treated as such in Part D cost reporting.<sup>66</sup> CMS says that when administrative service fees are used to offset the sponsor's or its intermediary's operating costs under Part D, they must be included in the Plan sponsor's bid.<sup>67</sup> **NASP agrees with CMS' proposal for addressing Plan administrative service fees and ensuring such fees are transparent and appropriately categorized and reported as concessions when they will reduce payment to the pharmacy for the cost of the drug. NASP agrees with CMS' proposal that when such administrative service fees are not used to reduce payment to the pharmacy, that such fees are to otherwise be included in the Plan's bid.**

**Recommendations: NASP recommends that just as CMS has tracked changes in the growth of pharmacy DIR fees over multiple years, CMS should also consider conducting oversight in the growth and appropriate reporting of "administrative service fees" as the agency moves to define negotiated price.** Plans have had no incentive to report administrative service fees, and as a result, under-report the administrative cost of providing the benefit. Understanding the type and volume of fees that fall outside of price concessions and could potentially impact the price beneficiaries pay at the point-of-sale will help to improve program efficiencies over time as CMS seeks to lower drug prices. Likewise, given that administrative service fees to date have had minimal-to-no value to pharmacies, it is important that CMS understands whether and how such fees are adjusted over time and the impact such fees have on pharmacy network participation. As discussed below, it's CMS' responsibility and in its interest to ensure that a competitive pharmacy market exists to serve Part D beneficiaries, and that fees are not used to negatively impact pharmacy network participation.

**NASP also recommends that CMS oversee the operations of Plans' reported administrative service fees by requiring Plans to provide an attestation from the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Operating Officer (COO) or other delegated individual that administrative overhead fees that reduce the price of the drug to pharmacies are being reported as pharmacy price concessions at the point-of-sale and that all other administrative service fees are being submitted during the Plan bidding process.**

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<sup>66</sup> Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. at 1918.

<sup>67</sup> *Id.*



All Price Concessions, Including Administrative Service Fees Reported as Price Concessions, Must Be Included in Medical Loss Ratio (MLR) Calculations

The Medical Loss Ratio (MLR) was created to “encourage health Plans to provide value to enrollees,” to promote “greater transparency and accountability around the expenditures made by health insurers and to help bring down the cost of health care.”<sup>68</sup> The MLR is a financial measurement used to calculate how health Plans spend premium dollars. It compares premium dollars spent on expenses like salaries, administrative costs, marketing, and profits, with premium dollars spent on medical benefits like servicing claims, quality improvement, and prescription drugs.<sup>69</sup> For example, when a health Plan spends eighty-five cents of every premium dollar on medical claims and quality improvements, it has an MLR of eighty-five percent. This means the remaining fifteen percent goes to salaries, marketing, and profits. Under Medicare Part D, most stand-alone prescription drug Plans and Medicare Advantage Plans including a Part D drug benefit must meet an MLR of eighty-five percent.<sup>70</sup> If a Plan’s MLR falls below eighty-five percent, it must pay the difference as a penalty or rebate to CMS, which is returned to beneficiaries. In general, the formula for calculating the MLR is as follows:

$$\text{The MLR} = \frac{\text{Incurred Claims} + \text{Quality Improvement Expenditures}}{\text{Earned Premiums} - \text{Taxes, Licensing and Regulatory Fees}}$$

Importantly, administrative services and administrative fees *are excluded* from the numerator. The MLR excludes administrative services and administrative fees from constituting either incurred claims or quality improvement expenditures.<sup>71</sup> Administrative services and administrative fees are excluded in two manners. First, “incurred claims” contains an exclusion for “non-claim costs.”<sup>72</sup> Non-claim costs are defined as “*expenses for administrative services that are not*” incurred claims, expenditures for quality improvement, licensing and regulatory

<sup>68</sup> Ctrs. for Medicare & Medicaid Servs., *Medical Loss Ratio (MLR)*, HEALTHCARE.GOV (last visited Feb. 25, 2022), <https://www.healthcare.gov/glossary/medical-loss-ratio-mlr/#:~:text=A%20basic%20financial%20measurement%20used,to%20provide%20value%20to%20enrollees;> Suzanne M. Kirchhoff, Cong. Research Serv., R42735, *Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act (ACA): Issues for Congress, Summary* (Jan. 29, 2015), <https://crsreports.congress.gov/product/pdf/R/R42735#:~:text=The%20ACA%20requires%20an%20annual,the%20cost%20of%20health%20care.%E2%80%9D.>

<sup>69</sup> Ctrs. for Medicare & Medicaid Servs., *Medical Loss Ratio* (last visited Feb. 25, 2022), <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Medical-Loss-Ratio.>

<sup>70</sup> Kirchhoff *supra* note 77, at 14.

<sup>71</sup> MLR requirements for MA organizations and Part D sponsors are codified in the regulations at 42 C.F.R. Part 422, Subpart X, and 42 C.F.R. Part 423, Subpart X. Calculation specifics are located at 42 C.F.R. § 422.2420 (MA) and 42 C.F.R. § 423.2420 (Voluntary Prescription Drug Benefit). The particular exclusions are stated at 42 C.F.R. §§ 422.2420, 423.2420.

<sup>72</sup> 42 C.F.R. § 422.2420(b)(4)(i) (2021); 42 C.F.R. § 423.2420(b)(4)(i) (2021).

fees, and state and federal taxes and assessments.<sup>73</sup> Second, incurred claims exclude “amounts *paid*, including amounts paid to a pharmacy, for professional or *administrative services* that do not represent compensation or reimbursement for covered services provided to an enrollee, such as attorney fees, subrogation vendor fees, bona fide services fees, and compensation for certain personnel.”<sup>74</sup> Further, “incurred claims” excludes “[a]mounts *paid* to third party vendors for . . . [a]dministrative fees.”<sup>75</sup> Lastly, neither administrative services nor administrative fees constitute expenditures under the definition of “improving health care quality.”<sup>76</sup> NASP is concerned that the terms of the MLR may permit Plans to inflate their actual expenditures, or “incurred claims,” by classifying their arbitrary charges to pharmacies as “administrative fees” or “administrative service fees.” By doing so, Plans can retain those recoupments while simultaneously reducing the Plan’s probability of paying penalties under the MLR due to self-inflated incurred claims.

By contrast, post-sale price concessions are used to calculate “incurred claims” in the numerator of the MLR.<sup>77</sup> Under this section, incurred claims must include “[d]irect drug costs that are actually paid (as defined in § 423.308).”<sup>78</sup> “Actually paid” is defined as a cost “actually *incurred* by the Part D sponsor and must be net of any direct or indirect remuneration (including . . . *price concessions*) . . . from any source . . . that would serve to decrease the costs incurred under the Part D plan.”<sup>79</sup> Further, “[d]irect and indirect remuneration includes . . . *price concessions*.”<sup>80</sup> Therefore, reporting charges against pharmacies as post-sale price concessions increases the Plan’s probability of Plan paying a rebate penalty under the MLR.

**Recommendation: NASP urges CMS to consider whether penalties can be avoided under the Part D medical loss ratio rule (MLR) by misclassifying any pharmacy price concessions as administrative fees, and if so, work to immediately remove this regulatory incentive by linking this Rule, when finalized, to the MLR rule. NASP also asks that when finalizing this Proposed Rule’s treatment of administrative service fees that are used by Plans to reduce Part D drug expenditures to pharmacies, CMS clarify that these specific administrative service fees must be reported as price concessions for the purpose of reporting MLR.**

**C. NASP Supports Protecting Pharmacy Network Access: Protections Against Unreasonable Reimbursement**

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<sup>73</sup> 42 C.F.R. § 422.2401 (2021); 42 C.F.R. § 423.2401 (2021).

<sup>74</sup> 42 C.F.R. § 422.2420(b)(4)(i)(C) (2021); 42 C.F.R. § 423.2420(b)(4)(i)(C) (2021).

<sup>75</sup> 42 C.F.R. § 422.2420(b)(4)(B)(2) (2021); 42 C.F.R. § 423.2420(b)(4)(B)(2) (2021).

<sup>76</sup> 42 C.F.R. § 422.2420 (b)(1)(iii) (2021); 42 C.F.R. § 423.2420 (b)(1)(iii) (2021) (citing the definition of “activities that improve health care quality” at 422.2430).

<sup>77</sup> 42 C.F.R. § 423.2420 (2021).

<sup>78</sup> *Id.*

<sup>79</sup> 42 C.F.R. § 423.308 (2021).

<sup>80</sup> *Id.*

**CMS must require that both the lowest possible reimbursement and actual pharmacy reimbursement are reasonable.** CMS has a statutory responsibility under the non-interference clause to promote a competitive market. The Medicare statute also mandates that CMS must ensure that Plans use only reasonable and relevant terms in their pharmacy contracts to promote network participation by any willing pharmacy provider. To satisfy these statutory mandates, CMS should ensure that the lowest possible pharmacy reimbursement is reasonable to protect pharmacies from anti-competitive efforts that force market consolidation.

**Recommendation: CMS should modify the Proposed Rule to require that Plan reimbursement be reasonable, inclusive of all post-sale price concessions.**

*NASP is Concerned that, Without Regulatory Protections, Pharmacy Reimbursement at Lowest Price Will Not Cover Pharmacy Costs*

**NASP is extremely concerned that the Proposed Rule does not contain any baseline regulatory protections to ensure reasonable pharmacy reimbursement when addressing the lowest possible reimbursement within the negotiated price. NASP believes most Plans will significantly reduce pharmacy reimbursement at the point-of-sale, reducing payments to below the pharmacy’s cost to obtain the drug, dispense the drug, and provide the necessary specialty patient management services to support use of the drug.** Being paid below cost is not sustainable to maintaining a highly regulated pharmacy business and threatens the pharmacy’s participation in Plan networks. If network participation is threatened due to unreasonable reimbursement, beneficiary access to their pharmacies is also threatened. Unreasonably low reimbursement is particularly egregious for specialty pharmacies because (1) they require significant cashflow to acquire very costly specialty drugs; and (2) they manage comparatively higher overhead expenditures required for complex specialty services, such as complex drug storage, maintaining specialty accreditation, drug and disease data collection and reporting, and establishing patient monitoring and support service infrastructure, for example.<sup>81</sup> Unreasonably low reimbursement directly threatens the business sustainability of specialty pharmacies and will cause further market consolidation which undermines Congress’ intent behind the Medicare statute and non-interference clause. Under the present construct of the Proposed Rule, NASP is concerned that certain Plans will be incentivized to pay less to the pharmacy at the point-of-sale to make up for the significant reinsurance profits that some Plans will lose once the “reasonably determined” exception is eliminated.

Specialty pharmacies have already seen evidence that some Plans will reduce their point-of-sale reimbursement. As referenced earlier, **specialty pharmacies have indicated that in 2022 and**

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<sup>81</sup> The revenue margins on specialty medications are generally only two to five percent of the cost of the specialty medications, whereas gross margin over all independent pharmacies was approximately 21.2 percent in 2020. Frier Levitt 1, *supra* note 20, at 17; see Adam J. Fein, *Five Things to Know About the State of Independent Pharmacy Economics*, DRUG CHANNELS (Feb. 15, 2022), <https://www.drugchannels.net/2022/02/five-things-to-know-about-state-of.html#:~:text=For%202020%2C%20gross%20margins%20on,per%20prescription%20figure%20for%202019.>

**in recent years since CMS addressed prospective DIR reform in the CY 2019 Medicare Part D Proposed Rule, some Plans have begun including a lower point-of-sale reimbursement alternative in their pharmacy contracts. This alternative reimbursement is *significantly* and *unreasonably lower*<sup>82</sup> than current rates and many times far below the cost of the drug.** Contract terms state that these low reimbursement terms will be triggered when CMS initiates reform of pharmacy DIR fees. Unfortunately, the Proposed Rule’s reliance on the lowest possible reimbursement does not by itself provide any guardrails to protect against unreasonably low reimbursement.

**NASP also urges CMS to ensure that a mechanism is in place to allow pharmacies to appeal any Plan sponsor decisions that offer reimbursement to pharmacies that is below a pharmacy’s drug acquisition cost.** Negotiated price should be determined on a contractual basis, but appropriate safeguards must be in place to ensure reimbursement of Part D drugs is appropriate when all pharmacy price concessions are applied at the point-of-sale. **Part D Plans must be required to outline in their submitted Plan year bids a process to facilitate appeals from pharmacies, particularly appeals in relation to the Plan’s reimbursement falling below a pharmacy’s drug acquisition costs. CMS should also ensure that the Complaints Tracking Module (CTM)<sup>83</sup> in place today for Part D Plans is utilized to provide timely response to pharmacy complaints, including complaints regarding reimbursement being below a pharmacy’s costs.** The CTM currently allows for the receipt of provider and pharmacy complaints and outlines a process for timely response. NASP asks that CMS clarify in revised guidance on the CTM that Plans are to be responsive to complaints addressing reimbursement concerns in relation to lowest price under negotiated price as defined.

*NASP Is Concerned That Plans Can Continue to Circumvent Prompt Payment Laws*

As stated above, post-sale price concessions create significant financial uncertainty among pharmacies. The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 added requirements with regard to prompt payment by Part D Sponsors for all clean claims submitted by network pharmacies within specified timeframes for electronic and all other (non-electronically submitted) claims.<sup>84</sup> **Part D Sponsors must make payment for clean claims within 14 calendar days of the date on which an electronic claim is received and within 30 calendar days of the date on which non-electronically submitted claims are received.** CMS may incorporate these timing requirements to further its goal of creating financial certainty and transparency among a competitive pharmacy market, instead of permitting Plans to continue to

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<sup>82</sup> Pharmacies have seen terms where the contract rate reductions to the pharmacy upon CMS’ changes to the application of DIR are by as much as a thirty percent reduction in reimbursement.

<sup>83</sup> Ctrs. for Medicare & Medicaid Servs., *Updated Guidance on Standard Operating Procedures (SOP) for the Complaints Tracking Module* (June 8, 2012), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/UpdatedGuidanceStandardOperatingProcedures.pdf>.

<sup>84</sup> 42 U.S.C. § 1395w-112(b)(4)(A) (2018); 42 C.F.R. § 423.520(a)(1)(i)-(ii) (2021).

game the marketplace by waiting months before adjusting pharmacy reimbursement through post-sale price concessions.

**Recommendation: Pharmacy actual reimbursement should be reflected in the negotiated price by incorporating requirements of federal prompt payment law. CMS should require that all pharmacy payments, inclusive of post-sale price concessions, be remitted to the pharmacy consistent with federal prompt payment law.**

**D. NASP Supports CMS Using Its Authority to Intervene in Pharmacy Contract Disputes Involving Systematic and Illegal Contract Terms**

CMS must refrain from avoiding its statutory duties to promote a competitive Part D market and require reasonable and relevant contract terms with pharmacies. **CMS must use its statutory authority to intervene in contract disputes whenever credible allegations of illegal contracting terms have been asserted. CMS should also generate guidelines for arbitrators with respect to reasonable and relevant contract terms to ensure that ongoing and systematic anti-competitive terms and practices are not carried forth by Plans as a broad mechanism of consolidating the Part D pharmacy market.** By doing so, CMS can ensure the integrity and legitimacy of the Proposed Rule for beneficiaries and pharmacies.

According to specialty pharmacies, large Plans have been subject to arbitration regarding millions of dollars of post-sale pharmacy price concessions emanating from Plans' illegal and anti-competitive contract terms. These awards have resulted in tens of millions of dollars being adjudged against Plans. The disputes often involve whether the aforementioned pharmacy performance measures are reasonable or relevant to the Plan's contract; whether the contract terms are so unreasonable that they are unconscionable; whether Plans used their significantly unequal bargaining leverage to subject pharmacies to contracts of adhesion; and various other contractual matters. Importantly, specialty pharmacies have noted that these predatory contract terms have been systematic, demonstrating broadscale unfair trade practices by PBMs and refusal to negotiate. Specialty pharmacies find themselves often arbitrating with Plans the same anti-competitive contract issues. Due to confidentiality provisions in many PBM contracts, specialty pharmacies are usually forced to expend significant resources to arbitrate issues that have already been settled by other arbitrators.

For smaller pharmacies, they are unable to afford the cost required to contest and then recontest the same or very similar contractual issues that have already been established as anti-competitive in other arbitrations. Large Plans that have their own specialty pharmacies have a serious competitive advantage over smaller non-affiliated pharmacies, as they can expend time and money to contest illegal contract terms. Because the terms of the contracts are confidential and the arbitration awards are largely redacted, Plans may impress on an entire pharmacy market illegal terms with little-to-no real penalty. These Plans have likely calculated

that the cost of losing a few arbitrations is lower than the revenue they generate from illegal contract terms applied to pharmacies and beneficiaries throughout the country.

CMS has failed to require reasonable and relevant contract terms and a competitive Part D marketplace by contending that the non-interference clause precludes its intervention in “private negotiations.” However, as explained earlier, *Part D pharmacy contracts are not negotiated*. They are offered as take-it-or-leave-it agreements, leaving specialty pharmacies with virtually no choice but to accept illegal contract terms. For example, the Part D Manual states:

*With rare exceptions, CMS does not generally involve itself in determining whether standard contracting terms and conditions are “reasonable and relevant,” since these are fact-specific questions that are best left between negotiating parties.*<sup>85</sup>

Rather, Plans are using their significant market leverage to systematically force upon specialty pharmacies illegal contract terms. **The dramatic explosion in predatory post-sale price concessions and severe market consolidation demonstrates that meaningful negotiations between Plans and pharmacies are not occurring within Part D. By relying on the non-interference clause as the basis for avoiding its responsibility to require Plans to offer reasonable and relevant standard terms and conditions, CMS is not promoting a competitive pharmacy marketplace. The Proposed Rule is CMS’ critical opportunity to address these establish meaningful guardrails to protect against anti-competitive market practices.**

#### **E. NASP Supports Detailed Prescription Claims Transparency for Pharmacies**

##### **Pharmacies Must Be Apprised of Claim-Level Detail Regarding the Lowest Possible Reimbursement**

CMS notes that one of the purposes of the Proposed Rule is to foster price transparency and consistency among pharmacies with respect to their reimbursement.<sup>86</sup> CMS also notes that under the Proposed Rule, Part D PBMs “would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies.”<sup>87</sup> To comply with this requirement, the Plan may show the amount that is to be charged to a patient. However, the Proposed Rule does not explicitly state that the negotiated price must define for the pharmacy the maximum price concessions that are being applied for each claim in the appropriate field in the claim response (e.g., whether the lowest possible reimbursement will be disclosed to pharmacies). Such information is of critical

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<sup>85</sup> Part D Manual, Chapter 5, Sections 50.5.3, at 44. (emphasis added).

<sup>86</sup> Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. at 1914.

<sup>87</sup> *Id.* at 1935.

importance if CMS' goal of ensuring transparency with respect to pharmacy reimbursement is to be recognized. This data will be critical to business planning for specialty pharmacies, eliminating the lack of transparency they face today without understanding how or to what extent their reimbursement can be altered. Without understanding the lowest price, pharmacies will also be unable to ensure that any post-sale price concessions that are assessed result in actual reimbursement that is no lesser than the lowest possible reimbursement reported by Plans on the PDE.

**Recommendations: CMS must include in this Proposed Rule, and potentially through additional and timely guidance, a requirement that Plans provide to pharmacies the lowest possible reimbursement for each drug covered under the pharmacy's participation agreement in the appropriate field on the claim response for every claim at the point of sale.**

CMS should also take additional steps to support transparency to the pharmacy by requiring Plans to provide consistent claim-level detail, including the lowest possible reimbursement, in the electronic ASC X12 835 electronic remittance file that details reimbursement payments to pharmacies. The claim-level detail should include constant and preset fields required to appropriately identify the claim and the lowest possible reimbursement for the drug.

**Recommendations: CMS could require Part D Plans to provide to the pharmacy the lowest possible reimbursement for each claim at the point of sale in the claim response via 42 CFR 423.505, which outlines terms and conditions of the contract between CMS and Part D Plans. CMS could also require Plans to provide consistent claims-level detail in the electronic remittance advice that accompanies reimbursement payments to pharmacies.**

Such reporting requirements will provide transparency to CMS regarding Plan practices and certainty to pharmacies regarding the minimum reimbursement they may receive. It is important to note that CMS has recognized that Medicare's "non-interference clause" requires HHS to promote a competitive market through certain efforts, including "decreasing the transaction cost of acquiring information on products offered in the market," "increasing the transparency of prices," and "minimizing barriers to entry to the extent possible."<sup>88</sup> **CMS should modify the Proposed Rule to require lowest price reporting to pharmacies in line with this long-standing interpretation of the Medicare statute to promote a transparent and competitive market.**

#### **F. The Negotiated Price Definition Should Apply to the Medicare Coverage Gap**

In the Proposed Rule, CMS excludes the negotiated price definition from the Medicare Part D coverage gap. NASP strongly disagrees with this decision, and **NASP urges CMS to include all pharmacy price concessions in the negotiated price for prescriptions dispensed to**

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<sup>88</sup> Medicare Program; Contract Year 2015 Policy and Technical Changes to Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. at 1970.

**beneficiaries who reach the Medicare Part D coverage gap.** To not do so would allow Plans to inflate beneficiary drug costs during the coverage gap, increasing cost sharing for our sickest beneficiaries, including specialty pharmacy patients. The lowest possible reimbursement definition should therefore apply to the coverage gap to provide beneficiaries with necessary drug pricing transparency.

Allowing Plans to exclude a portion of pharmacy price concessions during this Medicare phase would also create immense contracting and operational challenges for pharmacies and Plans. It would also create much confusion among beneficiaries who are about to enter or exit the coverage gap who would be turning to their pharmacies for answers. If there are different rules and price concessions at the point-of-sale for these individuals, it would be immensely challenging for pharmacies and Plans to clearly navigate how to adjudicate claims.

**In the Proposed Rule, CMS states that it believes it has the authority to require Plans to include all pharmacy price concessions in negotiated prices during the coverage gap, and NASP certainly agrees.** The regulatory definition of “negotiated price” at 42 C.F.R § 423.230 is comparable to the definition of negotiated price outside of the coverage gap at 42 C.F.R. § 423.100. The coverage gap reference to negotiated price references the price a pharmacy will receive “in total” for a particular drug. The definition itself indicates that to get to the total price, the total must include all price concessions.

**G. NASP Supports CMS Encouraging Rather than Discouraging Pharmacy Incentive Payments (Additional Contingent Amounts)**

Under Medicare’s reconciliation process, pharmacy incentive payments count as actual expenditures for the Plan, decreasing the overpayment amount the Plan would otherwise retain.<sup>89</sup> Since the reasonably determined exception was put into place in 2014, Plans have increasingly used post-sale price concessions as a mechanism of applying their own arbitrary pharmacy performance measures to *revoke* pharmacy reimbursement, with little-to-no bonus or incentive opportunity for pharmacies.

Even for pharmacies that perform well under the unchecked and arbitrary metrics imposed by Plans, to the extent that Plans receive from CMS incentive payments under the Star Rating System, CMS unfortunately does not require them to pass any portion of the payment to pharmacies. Instead, some **Plans use CMS’ Star Rating System as a justification for imposing irrelevant performance measures and charging post-sale price concessions rather than paying performance incentives to high-performing pharmacies.**

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<sup>89</sup> Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 82 Fed. Reg. at 56,419.



For example, there are specialty pharmacies who have been subjected to millions in post-sale price concessions despite attempting on several occasions to negotiate with Plans to exclude irrelevant performance measures from a contract. Due to persistent refusal to exclude these measures, the inequitable bargaining leverage that many large Plans maintain, and a severe lack of transparency regarding the prescription claims that purportedly resulted in the concessions, these pharmacies had no practical means of affecting their scores under the irrelevant measures. This has resulted in arbitration with vertically integrated Part D PBMs to fight millions of dollars in predatory post-sale price concessions. Through this process, it was discovered that (1) the performance measures that the Plan/PBM applied were largely irrelevant to specialty pharmacy operations; (2) the Plan/PBM did not provide transparency regarding its performance-based concession program to CMS; and (3) the Plan/PBM improperly charged millions in concessions. It was also discovered that under CMS's Star Rating System, if a pharmacy does not have experience for a particular performance measure, the measure simply is excluded and not evaluated for the pharmacy. However, Plan's alleged performance assessment system *did not exclude measures that were irrelevant to specialty pharmacies*.

**In its current form, the Proposed Rule will continue to permit reduced pharmacy reimbursement through post-sale price concessions (claw backs) and Plan retention of overpayments through reconciliation. Plans have no real reason to pay pharmacy incentives, especially given that they are not required to pass incentive payments they receive from CMS for meeting their Star Ratings to the pharmacy.**

**Recommendation: To appropriately address reasonable and relevant pharmacy performance concessions (as outlined above) for the purpose of allowing incentive payments to pharmacies, it is critically important that CMS work to standardize and oversee performance measures for use by Plans with pharmacies.**

#### **H. NASP Supports CMS Discouraging Plans from Underestimating Prospective DIR in Their Bids**

Plans are incentivized to generate significant profits across large beneficiary cohorts by underestimating DIR fees, inflating their bids, and charging unreasonable and excessive post-sale price concessions and administrative fees to retain up to seven and one-half percent of Medicare overpayments as profit.<sup>90</sup> Current regulations concerning the bid and reconciliation processes do not meaningfully protect unaffiliated specialty pharmacies from post-sale price concessions or unreasonably low reimbursement. Plans that use these tactics generate overpayments from Medicare.

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<sup>90</sup> Neither the Bid Pricing Instructions nor Part D bid regulations *strictly* prohibit Plans from under-projecting expected DIR fees.

Plans submit a bid to CMS estimating their anticipated cost for providing covered benefits for each beneficiary during each phase of coverage.<sup>91</sup> A bid reflects the estimated cost of providing the “basic benefit” to an average beneficiary plus, if applicable, the estimated cost of supplemental or enhanced benefits. Medicare, and therefore taxpayers, are responsible for paying two elements of the Part D expenditure based on the bid during the Plan year. These payments are the direct subsidy of the premium, which is based on bid expectations, and the reinsurance subsidy of excess costs in the catastrophic phase, which is set at eighty percent of total catastrophic phase expenditures and is paid directly to the Plan. Importantly, Plans must *estimate* and submit to CMS the DIR fees they expect to obtain during the Plan year.<sup>92</sup> This estimation serves to reduce the total bid amount, the direct subsidy payment the Plan will receive from Medicare, and the premiums that beneficiaries pay.<sup>93</sup>

At the end of each year, Medicare reconciles overpayments and underpayments that were directly made to Plans throughout the year. If a Plan’s costs for providing the basic benefit are below or above their bid estimations, the direct subsidy payments are reconciled with the Plan’s actual costs at the end of the year.<sup>94</sup> This reconciliation process is based on risk corridors, or preset percentages of profits and losses, that the Plan retains or pays back to CMS. Importantly, *the Plan may keep as profit all subsidy overpayments up to five percent above its bid*. Plans may also keep half of subsidy overpayments above five percent but below ten percent of the bid amount. NASP is concerned that this incentive will continue with the terms of the Proposed Rule in the absence of any guardrails against unreasonable and irrelevant post-sale price concessions.<sup>95</sup>

NASP believes that Plans may also avoid reporting post-sale price concessions today by classifying the fees they charge pharmacies as administrative service fees instead of DIR fees. While CMS is supposed to recover a fraction of the overpayments issued to Plans during the year, it is NASP’s understanding that Plans avoid reducing their actual expenditures incurred by classifying post-sale pharmacy price concessions as administrative fees.

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<sup>91</sup> 42 C.F.R. § 423.265 (2021).

<sup>92</sup> 42 C.F.R. § 423.265(d)(2) (2021); Ctrs. for Medicare & Medicaid Servs., *Instructions for Completing the Prescription Drug Plan Bid Pricing tool for Contract Year 2022*, at 13 (Apr. 9, 2021), <https://www.cms.gov/medicarehealth-plansmedicareadvtspeccratestatsbid-forms-instructions/2022>.

<sup>93</sup> 42 C.F.R. § 423.279(a) (2021) (CMS uses approved bids to calculate a national average monthly bid which determines CMS’s subsidy to the Plan and a national base beneficiary premium); 42 C.F.R. § 423.286 (2021) (The base premium is then used to determine the actual beneficiary premium for each Plan. For example, if a Plan’s bid exceeds the national average bid, its beneficiaries are responsible for the excess through a higher monthly premium.).

<sup>94</sup> This actual cost includes post-sale price concession reporting but does not include administrative fees charged to pharmacies, which furthers predatory gamesmanship by Plans.

<sup>95</sup> See Joseph Walker, et al., *The \$9 Billion Upcharge: How Insurers Kept Extra Cash From Medicare*, WALL ST. J. (Jan. 4, 2019), <https://www.wsj.com/articles/the-9-billion-upcharge-how-insurers-kept-extra-cash-from-medicare-11546617082>.

The overbidding (and underestimation of DIR fee) directly harms beneficiaries by inflating the premiums they pay. This is because CMS calculates premiums based on the Plan’s bid amount. CMS uses approved Plan bids to calculate a national average monthly bid which determines CMS’s subsidy payments to Plans and a national base beneficiary premium.<sup>96</sup> The base premium is then used to determine the actual beneficiary premium for each Plan.<sup>97</sup> For example, if a Plan’s bid exceeds the national average bid, its beneficiaries are responsible for the excess through a higher monthly premium which the beneficiary must pay. The bid-reconciliation profit incentive harms: beneficiaries through inflated premiums, pharmacies through unreasonable post-sale price concessions that are used to generate overpayments, and taxpayers through retained Medicare overpayments through reconciliation.

Under the Proposed Rule’s terms, NASP remains concerned that the Medicare program will continue to incentivize some Plans to generate profit by inflating their bids through low DIR estimations, charge pharmacies unreasonable and irrelevant post-sale price concessions resulting in overpayments from Medicare, and retain those overpayments as profit during reconciliation after the plan year. Without instituting “reasonable and relevant” protections, the Proposed Rule will permit ongoing incentives for Plans to use post-sale price concessions and administrative fees to exploit the bid-manipulation-reconciliation process. Without protections, Plans could utilize this reconciliation process to recover profits they otherwise would have retained through reinsurance during the catastrophic coverage phase through use of the “reasonably determined” exception to inflate negotiated prices – a form of gamesmanship this Proposed Rule seeks to now eliminate. Without reasonable and relevant protections, CMS needs to understand that Plans remain incentivized to exploit pharmacy providers and taxpayers to cover their profit margins.

CMS needs to understand that other incentives for post-sale price concessions remain in place, notwithstanding removal of the “reasonably determined” exception from the definition of negotiated price. *This is partly because it will be more difficult for pharmacies to challenge post-sale price concessions than it will be for them to challenge unreasonably low point-of-sale reimbursement.* Post-sale price concessions are already charged in a nontransparent manner based on irrelevant performance measures, which create significant impediments for pharmacies to ascertain the basis of the fees and adequately challenge them under existing law.<sup>98</sup> Therefore, unreasonable post-sale price concessions must completely be eliminated.<sup>99</sup>

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<sup>96</sup> 42 C.F.R. § 423.279(a) (2021).

<sup>97</sup> 42 C.F.R. § 423.286 (2021).

<sup>98</sup> T. Joseph Mattingly II, *Reforming Pharmacy direct and Indirect Remuneration in the Medicare Part D Program*, HEALTH AFFAIRS (July 19, 2021), <https://www.healthaffairs.org/doi/10.1377/forefront.20210714.70749/full/>.

<sup>99</sup> Importantly, CMS is authorized to prohibiting Plans from retaining overpayments obtained from DIR fees and administrative fees above the Plan’s bid estimates. In addition to including reasonable and relevant guiderails in the proposed rule, CMS should undertake further regulatory reform by eliminating a Plan’s ability to retain overpayments generated from post-sale price concessions. CMS may accomplish this by modifying is reconciliation and risk corridor regulations.

**Recommendation: CMS should disincentivize Plans from underestimating prospective DIR during their bid submissions as a mechanism of generating overpayments. CMS may accomplish this during the reconciliation process. CMS may prohibit Plans from retaining overpayments obtained from DIR and administrative fees that are in excess of their bid estimates.**

Without incorporating “reasonable and relevant” guardrails into the Proposed Rule as outlined earlier in these comments, NASP is concerned that the bid-reconciliation process under Medicare Part D will continue to incentivize Plans to charge our Nation’s pharmacy providers *unreasonable* post-sale price concessions, forcing many specialty and other pharmacies out of the Part D market.<sup>100</sup>

### **I. NASP Supports Implementation of the Rule for Contract Year 2023**

NASP supports CMS’ proposed timeline for implementation of the revised definition of negotiated price and the associated requirements with an implementation date of January 1, 2023. It is most critical that patients, pharmacies, and the Medicare program begin to see the benefits of these adjustments without further delay, given the astronomical growth of post-sale DIR fees, their destructive effects, and ongoing anti-competitive consolidation occurring in the Part D pharmacy market.<sup>101</sup>

Indeed, as referenced earlier in these comments, specialty pharmacies have seen Plans prepare for changes in the treatment of post- point-of-sale price concessions since CMS began to address reform concepts through regulations in 2018. Since that time, pharmacies have witnessed Plans provide two different contract rates (“negotiated” rates) in their proposed agreements. One contract rate representing what the drug payment would be for the upcoming year, and another representing what the drug payment rate should CMS move forward and adjust pharmacy price concessions impacting direct and indirect remuneration. Such contract terms demonstrate that Plans are highly capable and willing to make adjustments to a pharmacy contract in a given contract year. NASP would expect the same ability to prepare for CMS’ proposed reform at least six months before the start of the new contract year.

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<sup>100</sup> Plan’s may retain all moneys overpaid up to five percent of the original bid estimate, and a portion of overpayments above five percent. 42 U.S.C. § 1395w-115(e)(3)(c) (2018); 42 C.F.R. § 423.336(a)(2)(ii) (2021); see Joseph Walker, et al., *The \$9 Billion Upcharge: How Insurers Kept Extra Cash From Medicare*, WALL ST. J. (Jan. 4, 2019), <https://www.wsj.com/articles/the-9-billion-upcharge-how-insurers-kept-extra-cash-from-medicare-11546617082>.

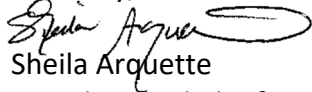
<sup>101</sup> F.T.C., *Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers* (Feb. 24, 2022), [https://www.ftc.gov/system/files/attachments/press-releases/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices/solicitation\\_for\\_public\\_comments\\_on\\_the\\_business\\_practices\\_of\\_pharmacy\\_benefit\\_managers.pdf](https://www.ftc.gov/system/files/attachments/press-releases/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices/solicitation_for_public_comments_on_the_business_practices_of_pharmacy_benefit_managers.pdf).

**Recommendation: CMS should ensure that all Part D payers update their systems in time to meet the January 1, 2023, implementation date.**

### **CONCLUSION**

NASP thanks CMS for its work in formulating the Proposed Rule and believes that **the Proposed Rule’s elimination of the “reasonably determined” exception and revised definitions of negotiated price and price concession should be finalized and that the rule should go into effect in January 2023, as proposed.** However, NASP urges that CMS must put in place regulatory protections as outlined to ensure other incentives within the Medicare program are not exploited by Plans once the Rule is finalized. Ensuring CMS applies reasonable and relevant regulations to the Rule’s requirements to: 1) protect pharmacies against unreasonably low reimbursement at the point-of-sale, and 2) protect pharmacies from unreasonable performance measures as the basis for post-sale price concessions, is critically important to preserving patient access to pharmacies and protecting a competitive pharmacy market under Medicare Part D. For questions and discussion, please contact me at 703-842-0122 or [sarquette@naspnet.org](mailto:sarquette@naspnet.org).

Sincerely,



Sheila Arquette

President and Chief Executive Officer  
National Association of Specialty Pharmacy