



NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY

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Lina Khan
Chairperson
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Submitted by Electronic Submission: www.regulations.gov

RE: RFI on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

Dear Chairperson Khan:

The National Association of Specialty Pharmacy (NASP) is pleased to have the opportunity to provide comments in response to the Federal Trade Commission's Request for Information (RFI), *Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers*. NASP urges the FTC to carefully evaluate the comments it receives and to proceed with a study on certain contractual provisions, reimbursement adjustments, and other practices that disadvantage specialty pharmacies that are not otherwise owned by or affiliated with PBMs and health plans, and negatively impact market competition and patient access to the specialty pharmacy of their choice.

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, wholesale distributors, integrated delivery systems, health insurers, 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 2,500 individual members, NASP is the unified voice of specialty pharmacy in the United States.

What is Specialty Pharmacy

Specialty pharmacies support patients who have complex health conditions like cancer, rheumatoid arthritis, multiple sclerosis, cystic fibrosis, hemophilia, organ transplantation and rare diseases. There are many different operating models for specialty pharmacies separate and apart from plan- and PBM-owned or affiliated specialty pharmacies. These include independent pharmacies, academic medical center, and hospital-health system based pharmacies, regional and national chain pharmacies, grocery store owned specialty pharmacies and home infusion pharmacies. The medications a specialty pharmacy dispenses are typically expensive. Historically, there are limited generic or biosimilar alternatives to brand specialty drugs. Specialty prescription medications are not routinely dispensed at a typical retail pharmacy because the medications are focused on a limited number of patients and require significant patient education and monitoring on utilization and adherence. While all pharmacies provide patient care, the unique knowledge, patient support, and prescription handling that specialty pharmacies provide, and the time involved on a per-patient basis is acutely different than how any other pharmacy type operates. Typical retail pharmacies are not designed to provide the intense and time-consuming patient care services that specialty medications require. Though many specialty medications are taken orally, still many need to be injected or infused. The services a specialty pharmacy provides includes patient training on how to administer the medications; comprehensive treatment assessment; ongoing patient monitoring; side effect management and mitigation; and frequent communication and care coordination with caregivers, physicians, and other healthcare providers. A specialty pharmacy's expert services drive patient adherence, proper management of medication dosing and side effects, and ensure costly and complex drug therapies and treatment regimens are used correctly and not wasted. Managing life-or-death medications also requires specialty pharmacies to address complex side effects that impact therapy success and management, frequently employing nurses and other clinical experts to support this work. For example, an oral oncology drug like Tarceva, which is a specialty drug, can have a complex side effect profile. Many oral oncology drugs have complex dosing and administration schedules dependent on patient diagnosis, response, and tolerability. Tarceva frequently causes significant rashes, which is both a side effect and an indication of the treatment's success. It is imperative the specialty pharmacist has in-depth training and knowledge of the drug itself, the drug schedule, and of the side effects/indications of the treatment's performance to ensure a patient does not deviate from treatment and remains compliant and adherent to the full treatment regimen in order to achieve a maximum therapeutic outcome.

The following is a summary list of explained differences between the retail and specialty pharmacy models:

- Drug manufacturers sometimes set up limited distribution networks for specialty drugs, selecting specialty pharmacies with the needed expertise to dispense these drugs, which are not otherwise accessible by other pharmacies.

- Specialty pharmacies have disease-state expertise and clinical management expertise on specific specialty-identified diseases and are frequently staffed with nurses and other health care providers in addition to specialty pharmacists.
- Specialty pharmacies have operations equipped to staff and allow the time for close and frequent communication with patients, including extensive call center operations.
- Specialty pharmacies frequently provide robust data to manufacturers and health plans/PBMs regarding drug performance and concerns.

Concerns with Market Dominance and Impact on Specialty Pharmacy

While the number of specialty medications only comprises 2.2 percent of the total number of prescriptions dispensed in the United States, it represents approximately 50 percent of overall drug spend in the U.S., which by the end of 2021 was estimated to be about \$600 billion.¹ Distribution for most specialty medications is limited, with payers working to keep them even smaller. The market for specialty medications is heavily dominated by the largest PBMs and the health insurers that own those PBMs.

While the specialty market has grown, so has market consolidation, resulting in significant vertical integration (with retail and specialty pharmacies) in the market as well as relationships that tie several of them horizontally. The three largest PBMs—CVS Caremark (subsidiary of CVS Health, Inc.; 2019 revenue: \$141.5 billion), Express Scripts (subsidiary of Cigna, Corp.; 2019 revenue: \$96.4 billion), and OptumRx (subsidiary of UnitedHealth Group; 2019 revenue: \$74.3 billion)—account for more than 80% of the PBM market.²³ The largest PBMs also dominate the specialty pharmacy market by owning or having an affiliation with three of the four largest specialty pharmacies in the United States: CVS Specialty (owned by CVS Health, Inc.), Accredo / Freedom Fertility (owned by Express Scripts), and Optum Specialty Pharmacy (owned by OptumRx).⁴ Revenue growth at the largest PBM owned/affiliated pharmacies is driven by the dispensing of specialty medications, which accounted for more than 38% of the pharmacy industry's prescription revenues in 2021.⁵

In 2020, nearly *nine out of ten* Part D enrollees (eighty-eight percent) were projected to be enrolled with plans operated by five firms: UnitedHealth, Humana, WellCare, CVS Health, and

¹ Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis, Working Paper 2019-02 (Congressional Budget Office, March 2019), www.cbo.gov/publication/55011.

² <https://www.acpjournals.org/doi/abs/10.7326/M17-2506?journalCode=aim>.

³ <https://docs.house.gov/meetings/JU/JU05/20151117/104193/HHRG-114-JU05-Wstate-BaltoD-20151117.pdf>.

⁴ Drug Channels, *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation* (Apr. 6, 2021), <https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html>.

⁵ Drug Channels, *The Top 15 U.S. Pharmacies of 2021: Market Shares and Revenues at the Biggest Companies* (Mar. 8, 2022), <https://www.drugchannels.net/2022/03/the-top-15-us-pharmacies-of-2021-market.html>.

Cigna (based on Part D enrollment as of September 2019).⁶ All five firms offered plans in all 34 plan regions.⁷ In 2022, eight major companies with national stand-alone Part D plans account for 685 (eighty-nine percent) of the total 766 Medicare Part D plans.

Vertical integration has also resulted in PBMs joining forces with large specialty pharmacies, mail order pharmacies, health plans, distributors, and even physician clinics to control each step in the care continuum. PBMs often direct patients to their owned or affiliated assets, particularly in the pharmacy space, which reduces patient choice and possibly increases cost due to a limited and non-competitive marketplace. There are also significant conflicts of interest with this consolidation -- a health plan's goal is to manage cost; a PBM's goal is to manage cost by maximizing rebates and fees; and a specialty pharmacy's goal is to earn revenue via dispensing. If a higher cost alternative drug is available that would create the most revenue for the pharmacy and the highest fees for the PBM, why would an integrated PBM pursue the lowest cost option as requested by the health plan or employer?

Consolidation in the market in many cases has resulted in some non-PBM/plan-owned and non-PBM/plan-affiliated specialty pharmacies being subjected to anti-competitive terms, including unreasonable reimbursement and price concessions, this effectively forces specialty market consolidation by making it impossible for non-PBM and plan owned/affiliated specialty pharmacies to compete. Without intervention and oversight, NASP is concerned that exorbitant fees by vertically-integrated plans/PBMs will continue to distress those specialty pharmacies who have historically been targeted due to the high cost of the drugs they dispense. Without oversight the application of reimbursement cuts, unreasonable contract terms, and other tactics intended to diminish network participation will continue, making it near impossible for independent – or non-affiliated – specialty pharmacies to compete against plan/PBM subsidiaries and affiliates.

As a result of immensely inequitable bargaining power, plan contracts are typically proffered to specialty pharmacies as “take it or leave it” which often does discriminate against non-affiliated specialty pharmacies, and are unilaterally modifiable by the PBM or plan. Thus, non-affiliated specialty pharmacies are frequently left with an anticompetitive “Hobson’s choice” – they either accept PBM contract terms, including irrelevant “performance” measures and related price concessions, or lose access to the large PBM’s patient base.

The FTC and other federal departments, including the Department of Health and Human Services should exercise their authority to protect non-owned and non-affiliated pharmacies against anti-competitive market practices.

⁶ KFF, *Medicare Part D: A First Look at Prescription Drug Plans in 2020* (Nov. 14, 2019), [https://www.kff.org/report-section/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2020-issue-brief/#:~:text=Most%20\(15\)%20of%20the%20national,the%20same%20amount%20since%202017.](https://www.kff.org/report-section/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2020-issue-brief/#:~:text=Most%20(15)%20of%20the%20national,the%20same%20amount%20since%202017.)

⁷ *Id.*

Pharmacy Networks

Consistent with federal law, pharmacy providers must be able to participate in plan pharmacy networks.⁸ In many instances, specialty pharmacies have witnessed increased efforts by the largest PBMs to limit the participation of non-owned/non-affiliated specialty pharmacies in a given pharmacy network. Tactics such as demanding impossible terms for participation and non-negotiable reimbursement rates that do not cover the acquisition cost of the drug alone – let alone the patient management and product support services needed to go with a specialty drug - are all too common. Impossible terms can include: requiring a specialty pharmacy to stock non-specialty drugs that are outside the needs of its patient base; and mandating that a pharmacy set up additional physical locations despite the PBM knowing that most specialty pharmacies have a hub and spoke model where they successfully ship medications to patients from a central location and provide remote ongoing patient services. Specialty pharmacies must repeatedly work through state and federal laws and fight to get into provider networks. Examples of anti-competitive actions vertically integrated PBMs take to limit pharmacy network participation include the following:

- **Complex, duplicative, and excessive credentialing and staffing requirements**—Many PBM networks require in-network specialty pharmacies to be accredited by at least two of the independent accrediting bodies such as ACHC, NCQA, URAC or the Joint Commission. NASP supports independent national third-party accreditation as a tool to drive quality based on uniformly applied measures, standards, and processes. However, many PBMs that also own a specialty pharmacy frequently require accreditation by their own PBM as a condition for network participation, despite a pharmacy being accredited by a third-party independent organization. In addition to charging a fee for this accreditation, the PBM-owned accreditation process includes a detailed audit of business processes which captures photos and reviews other proprietary and strategic documents all under the auspices of “network credentialing.” Most of this entire process is not relevant whatsoever for specialty pharmacies’ ability to dispense drugs and take care of patients. Rather, it may be an attempt to gather sensitive competitive business intelligence that will be used in an anti-competitive manner. There is very little confidence in the fire wall that is supposed to exist between a PBM and its own accreditation process.
- **Providing contract terms that under-reimburse drugs**—PBM’s offer drug reimbursement rates below, and sometimes significantly below, the purchase price for specialty pharmacies. For example, many of the current Pharmacy Services Administration Organization (PSAO) contracts contain a take it or leave it reimbursement rate that is well below a pharmacy’s acquisition cost. This ability is driven by the PBM in its effort to favor its own specialty pharmacy that is provided either a better reimbursement rate or can sustain the loss where other pharmacies

⁸ 42 CFR § 423.505(b)(18); 42 U.S.C. § 1395w-104(b)(1)(A).

cannot because of the owned/affiliated pharmacy's size and dominance in the marketplace.

- **Contracting specialty pharmacies as retail pharmacies**—PBMs typically contract specialty pharmacies as retail pharmacies rather than recognizing specialty pharmacies for placement in a specialty pharmacy network. A specialty pharmacy is often not a retail pharmacy, and as discussed above many specialty pharmacies provide for and manage distinctly different drugs and services than a typical retail pharmacy. Specialty pharmacy often dispenses medications by mail, but because vertically integrated PBMs own their own mail order pharmacy, they will not offer a specialty pharmacy a contract that allows for that specialty pharmacy to deliver medications to patients via the mail. By contracting in this manner, a PBM can accuse a specialty pharmacy of not meeting retail requirements, and when this occurs, a specialty pharmacy can be penalized by being removed from the network. This same threat does not exist for a PBM-owned specialty pharmacy that equally dispenses the same amount of drug through the mail. Many of NASP's members have received notice or have been thrown out of a network over the years for violating the "mail order" clause of their retail contracts.

Patient Steering

Far too often, even when pharmacies get into a network, vertically integrated PBMs will work to capture a prescription away from a network pharmacy – a practice referred to as patient steering. Vertically integrated PBMs can see a patient's insurance information and will use the information to call or send a letter to a patient or prescriber, instructing them to transfer their prescription to the PBM-owned specialty pharmacy, or otherwise risk losing drug coverage. Extremely sick and vulnerable patients are then threatened to lose their coverage for a drug they otherwise may not be able to afford or access if they do not comply with the PBM's demands. Generally, PBMs enforce this requirement either by excluding alternative pharmacies from the network or imposing significant cost sharing penalties on patients that choose a different pharmacy. The result is the patient has less choice, including inability to use a pharmacy that may specialize in his or her condition while also increasing revenue and profitability to the PBM. In other instances, such a PBM will require a prior authorization from an in-network pharmacy but will waive the prior authorization if a patient uses a PBM-owned specialty pharmacy. While the prescription is "under review," the PBM-owned specialty pharmacy will sometimes fill and dispense the specialty drug, thereby essentially stealing the prescription from the non-owned/non-affiliated specialty pharmacy.

PBMs also steer patients through accumulator and maximizer programs. These programs prevent patient cost share funding assistance from impacting the patient's progression to deductible and out-of-pocket spending maximums. The result is additional cost to the patient, potentially affecting their medication compliance and adherence when they cannot afford their specialty medications. In a most egregious example, Express Scripts, a PBM, uses an offering

called SaveOnSP⁹ which manipulates the patient health care benefits so that their plan excludes drugs based on their cost and volume, rather than clinical considerations. Patients are required to enroll in SaveOnSP where their patient cost sharing is changed to a 30% coinsurance. SaveOnSP then uses manufacturer assistance programs to pay for the coinsurance, while keeping a quarter of the savings themselves as a fee. While the patient's upfront cost for the drug is zero, in many cases, the lack of progression for a patient's deductible means the patient experiences more cost in the end. In addition, the PBM, via its intermediary, is deriving financial benefit by taking money that was originally intended to help the patient afford their medication. The PBM further benefits in that these patients, as a requirement of the SaveOnSP program, are often steered toward the PBM's specialty pharmacy. Also of significant concern is that the exclusion of certain drugs from a patient's benefit plan based only on utilization and cost could be viewed as discrimination toward patients with conditions that just happen to be treated by higher-cost drugs.¹⁰

Without federal oversight through such entities as the Federal Trade Commission or the HHS Office of Civil Rights, or the establishment of enforcement protections, network pharmacies continue to fall victim to these anti-competitive practices, and patient access to the pharmacy of their choice is eliminated.

Pharmacy DIR Fees

An anti-competitive market practice that for years has contributed to high consumer drug costs under Medicare Part D is the use and application of pharmacy direct and indirect remuneration fees by plans and their PBMs – fees known as pharmacy DIR fees. Pharmacy DIR fees are monies received by PBMs and Medicare Part D health plans that today include concessions pharmacies are forced by PBMs to pay six-months or longer after the pharmacy dispenses medications to a Medicare beneficiary. Since Medicare Part D was established, these fees have not been used by PBMs or plans to reduce the cost of the drugs for seniors. Pharmacy DIR fees have resulted in immense profit for PBMs/payers, forcing pharmacies to fill Medicare prescriptions below cost, and primarily contributing to pharmacy acquisitions and closures. Indeed, in 2022, CMS reported that pharmacy DIR fees grew more than 107,400 percent between 2010 and 2020.¹¹

Post-sale price concessions are typically referred to as “performance-based” fees and are charged as a percentage of total drug reimbursement. Because of this dynamic these fees disparately harm specialty pharmacies, given the higher prices of specialty drugs. Plans provide very little transparency when charging these concessions. Plans that apply these concessions will aggregate pharmacy concessions in one massive and unpredictable charge

⁹ [Cost-Effective Solutions | Express Scripts \(express-scripts.com\)](#) (See SaveOnSP)

¹⁰ Drug Channels, *Why Do CVS and Express Scripts Rely on Secretive Private Companies to Run Their Copay Maximizer Programs* (May 21, 2020), <https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html>.

¹¹ 87 Fed. Reg. 1842.

during the plan year, occurring after numerous specialty drugs have been dispensed and Part D beneficiaries' cost sharing has been applied. Moreover, plans typically refuse to provide claim-specific detail to justify the concessions, which prevents a specialty pharmacy from evaluating the bases of alleged performance-based charges. Specialty pharmacies pay millions of dollars in pharmacy DIR fees per year with no transparency to the pharmacy as to what the fees represent. When the reimbursement to the pharmacy is reconciled, it is often far less than the pharmacy's 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. This situation threatens the ability for specialty pharmacies that are not owned by or affiliated with a plan/PBM because they do not have the ability to offset lost revenues or costs to remain network providers, seriously compromising pharmacy access for beneficiaries. Notably, plan/PBM-affiliated specialty pharmacies benefit from being vertically integrated with the Plan/PBM, which is the payer.¹² Even if the Plan/PBM-affiliated pharmacy receives similar unreasonable reimbursement, such as reimbursement below the pharmacy's purchase price for the drug, the vertically integrated plan receives the discount on the low reimbursement, and the plan may therefore sustain the affiliated-specialty pharmacy's overhead expenditures. By contrast, the unaffiliated specialty pharmacy is forced to consolidate due to the unreasonably low reimbursement. In addition, as a result of multiple provider network structures within PBMs/plans, affiliated specialty pharmacies can benefit from preferred status in value-based care arrangements and cost efficiencies gained from volume. NASP has witnessed significant, forced consolidation in the specialty pharmacy market resulting from pressures imposed by vertically integrated plans that are affiliated with specialty pharmacies.¹³ For those specialty pharmacies that do not initially sell, many have had to restructure their operations, including laying off numerous staff members and cutting back on higher-cost inventory; others have been forced to stop stocking and dispensing drugs to treat certain conditions due to plans' historical targeting of specific specialty drugs for costly post-sale price concessions. Moreover, these specialty 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.

Plan sponsors continue to 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. Plans make this decision for two reasons: (1) the total pharmacy DIR charged by a plan that is above the projected DIR in the plan's bid contribute to the plan's profit during reconciliation; and (2) plans are acquiring windfall profits by inflating negotiated prices to concentrate expenditures in the catastrophic coverage phase where the plan's liability is limited.¹⁴

¹² 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 9, available at <https://naspnet.org/dir-white-paper>.

¹³ <https://www.drugchannels.net/2019/01/specialty-pharmacy-m-our-look-at-2018s.html>.

¹⁴ 82 Fed. Reg. 56420.

Medicare Part D prescription drug plan sponsors report pharmacy DIR to CMS within six months after the close of the plan year.¹⁵ Based on publicly available data, CMS found that in recent years, plan sponsors have consistently received higher DIR than they initially estimated during the bidding process for contracting with the Medicare Part D program.¹⁶ In other words, PBMs and plan sponsors have been underestimating DIR. This finding is important because it indicates that any DIR received by PBMs and plan sponsors above the projected amount factored into a plan's bid contributes primarily to plan profits, not lower premiums for Medicare beneficiaries.

Certain Pharmacy DIR Reforms Initiated – But Additional Reforms and FTC Oversight Needed

In April 2022, CMS released a final rule for *Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs*¹⁷ that will initiate certain pharmacy DIR fee-related reforms in Medicare Part D, but those reforms do not go into effect until January 1, 2024.

Through the rule, CMS eliminated the “reasonably determined exception” that has permitted plans/PBMs to apply price concessions after the point of sale. The use of the reasonably determined exception has primarily focused on concessions tied to assessing pharmacy “performance.” This regulatory exception has been identified as a predominant reason for the excessive growth of pharmacy DIR fees, and pharmacies have long argued that performance assessments are arbitrary and onerous, serving as an excuse for the collection of millions in annual fees from individual pharmacies. Removal of this exception within regulation is expected to reduce one incentive for plans to inflate negotiated prices at the point-of-sale and recoup exorbitant post-sale price concessions from pharmacies at a plan's discretion. However, removal of this exception does nothing to address the fairness or application of plan-driven pharmacy performance measures.

For specialty pharmacy, most if not all measures used by plans/PBMs to evaluate pharmacy performance have nothing to do with the drugs a specialty pharmacy dispenses or the services a specialty pharmacy provides to patients. For specialty pharmacies, there is no relevant performance evaluation occurring either. For example, plans will 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 for the specialty condition being treated. Plans often 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.¹⁸ 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

¹⁵ <https://fas.org/sgp/crs/misc/R40611.pdf>.

¹⁶ <https://www.govinfo.gov/content/pkg/FR-2017-11-28/pdf/2017-25068.pdf>.

¹⁷ 87 Fed. Reg. 27704 (May 9, 2022).

¹⁸ See, e.g., Frier Levitt 2, at 15-17.

experience with the drug plan; and (4) drug safety and accuracy of drug pricing.¹⁹ 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.²⁰ These measures relate to maintenance medications and are irrelevant to most specialty pharmacy operations. Nevertheless, plans improperly apply their own iteration of these irrelevant measures to specialty pharmacies as false justification for assessing costly post-sale pharmacy 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.²¹ 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.²² The more common percentage-based fees generally range from three percent to nine percent of the gross drug reimbursement per prescription claim.²³ 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.

CMS is also planning to reduce out-of-pocket costs for Medicare beneficiaries in the rule by requiring all pharmacy price concessions to be applied at the point-of-sale, providing beneficiaries the lowest price for a drug in which their out-of-pocket cost sharing will be assessed. The lowest price will provide transparency and significant savings to the patient by reducing their cost sharing amounts; however, the rule does not provide full transparency to, or protections for the pharmacy. The plan/PBM is permitted under the rule to continue to assess post-point-of-sale price concessions if it chooses to do so. There is also nothing in the final rule that ensures that reimbursement to the pharmacy will be overseen to determine whether it is reasonable and not below a pharmacy’s cost, resulting in unfair market competition.

¹⁹ CMS, *Medicare 2021 Part C & D Star Ratings Technical Notes* (Oct. 1, 2020), at 62-72, <https://www.cms.gov/files/document/2021technotes20201001.pdf-0>.

²⁰ CMS, *Medicare 2021 Part C & D Star Ratings Technical Notes* (Oct. 1, 2020), at 72-82, <https://www.cms.gov/files/document/2021technotes20201001.pdf-0>.

²¹ *Id.*

²² Adam Fein, *Behind Diplomat Pharmacy’s Plunge: A Primer on DIR Fees in Medicare Part D* (Nov. 8, 2016), <https://www.drugchannels.net/2016/11/behind-diplomat-pharmacies-plunge-primer.html>; Frier Levitt 2, at 4.

²³ Pharmacy Times White Paper; Frier Levitt 2, at 4.

Additional and Necessary Oversight and Regulatory Protections Needed to Address Pharmacy DIR

Along with the proposed removal of the “reasonably determined” exception, there must also be regulatory safeguards put into place to address inappropriate means, or loopholes, which plans will use to make up for lost profit due to CMS’ limited pharmacy DIR reform and exploit certain Medicare incentives that allow certain plans/PBMs to hinder pharmacy competition. NASP is extremely concerned that certain plans/PBMs will impose unreasonable cuts in reimbursement that threaten Part D network participation for unaffiliated specialty pharmacies and consequently threaten market competition and patient access to pharmacies. NASP is concerned that when the final rule goes into effect, plans will remain incentivized to:

- Charge pharmacies unreasonable fees, including post-sale price concession (retroactive claw backs) that are based on irrelevant plan-established and plan-overseen pharmacy performance measures that lack transparency or any oversight by the government today;
- Charge pharmacies higher amounts of certain fees and other DIR fees 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 price 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.

NASP is significantly concerned that without oversight and protections against irrelevant pharmacy performance measures, the lowest possible reimbursement reported by plans under the new regulation will be invalid and illegal because it will be based on measures that violate existing regulatory requirements for reasonable and relevant contract terms. Plans should be subject to penalty for false certification, claims, or unfair trade practices when they apply irrelevant performance measures to pharmacies to derive price concessions and when they report lowest possible reimbursement based on concessions derived from these illegal measures. If any of the practices outlined above are not addressed through regulation and/or FTC oversight, NASP is very concerned there will be significantly reduced pharmacy access for patients due to further rampant pharmacy market consolidation and pharmacy closures.

There are likewise no protections in the final rule issued by CMS to ensure that plans and PBMs that own their own - or are affiliated with - a specialty pharmacy business are restricted from providing more advantageous pricing to their own entities in an effort to limit a pharmacy network, limit specialty pharmacy competition, and gain greater specialty pharmacy market

share. This protection is all the more important when addressing pricing for specialty drugs, many of which have limited-to-no drug alternatives for patients, such as those with rare and other specialized conditions. Specialty pharmacies provide medication and services that are tailored to managing these unique patient populations, and network adequacy is essential to ensuring access to these medications for patients.

The CMS Part D rule does not address protections for ensuring that payment to pharmacies is reasonable. Being paid below cost is not sustainable to maintaining a highly regulated pharmacy business and threatens specialty pharmacy 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, transportation, and patient monitoring. Unreasonably low reimbursement directly threatens the business sustainability of specialty pharmacies and will cause further market consolidation.

NASP is concerned that with the lack of guardrails in the final Part D rule, coupled with the delay in implementation of the minor pharmacy DIR reforms included, we may begin to see several changes occur in the marketplace that could further hamper fair market competition for pharmacies. Plans and PBMs will want to ensure they can make up for any financial losses the rule's provisions will cause. Contract terms have already started to shift, and drastic upfront cuts are already being seen. There may also be an effort to avoid the inclusion of pharmacy fees in the price at the point-of-sale. NASP cannot emphasize enough the importance of oversight, which is role where the FTC can assist. There must be oversight over the growth and appropriate reporting by plans/PBMs of fees they charge that are outside of the price at the point-of-sale, and effort to restrict these fees. Recommendations should be made on how Congress and HHS can prohibit practices that hamper pharmacy network participation, especially participation by unaffiliated specialty pharmacies that are contracted with a plan/PBM that owns or is affiliated with a specialty pharmacy.

Conclusion

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 judgements against plans, following determinations that contract terms are unreasonable. Due to confidentiality provisions in many PBM contracts, specialty pharmacies are usually forced to expend significant resources to arbitrate issues that have likely 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 may 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. More must be done to protect pharmacies, and the FTC can help to address protections and advocate for reforms outside of the legal and costly process pharmacies must turn to today.

NASP appreciates the opportunity to provide comments in response to the FTC RFI and encourages the FTC to consider these comments and to reconsider pursuing its planned “Study on PBMs’ Relationship with Affiliated and Independent Pharmacies.” There must be oversight over anti-market practices that are gravely limiting patient access to specialty pharmacies today. Policymakers and federal agencies also need recommendations and guidance from the FTC on areas for legislative and regulatory intervention that may be outside of the FTC’s authority but that must be addressed to ensure market competitiveness and fairness. The impact on pharmacy access for patients and cost to the overall health care system as vertical integration persists is dire. If we can provide additional information as you consider market impact on specialty pharmacy, please contact me at Sheila.arquette@naspnet.org or (703) 842-0122.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Sheila Arquette", with a large, stylized flourish at the end.

Sheila M. Arquette, R.Ph.
President and Chief Executive Officer