May 25, 2022

Chair Lina Khan
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Pharmacies and Consumers; FTC-2022-0015-0001

Dear Chair Khan:

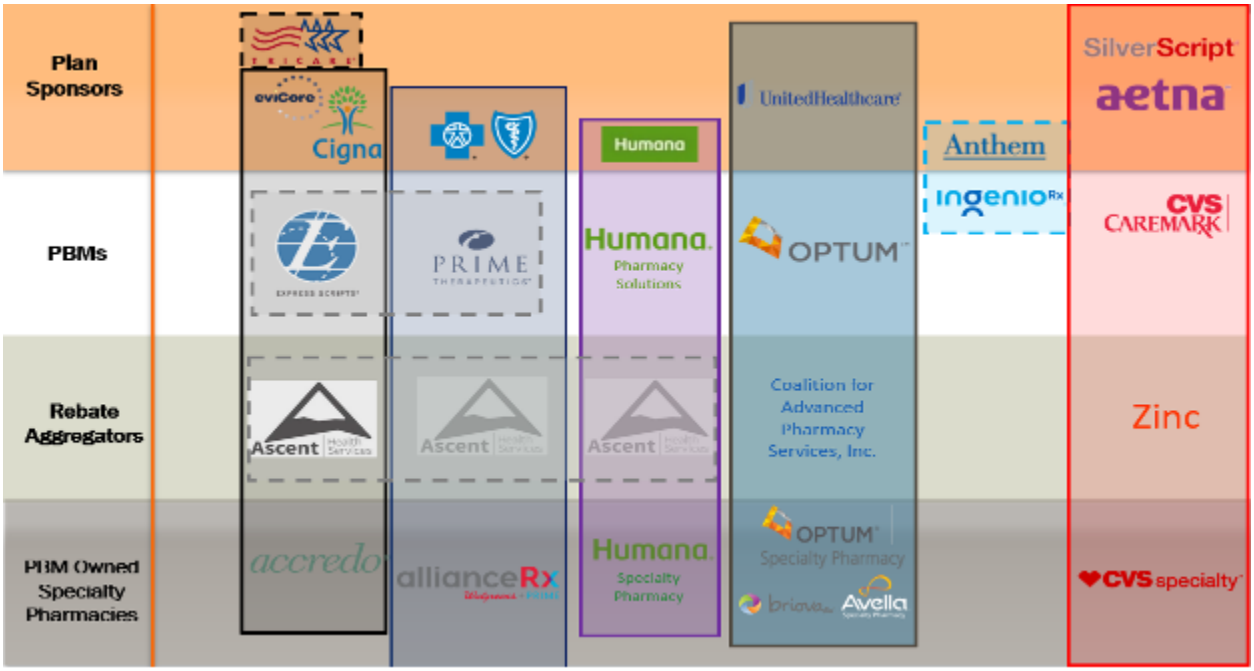
On behalf of the food industry and the thousands of supermarket pharmacies operated by our member companies, we at FMI – the Food Industry Association thank the Federal Trade Commission (FTC) for once again requesting public comment about the practices of Pharmacy Benefit Managers (PBMs) and their impact on patients, physicians, employers, independent and chain pharmacies, and other businesses across the pharmaceutical distribution system. Our comments, which reflect not only FMI's insight, but also the expertise of FMI's Pharmacy Operations Task Force, focus on the anticompetitive effects of the contract terms imposed by PBMs and how PBMs leverage their concentrated market power to the detriment of supermarket pharmacies and consumers, among others. We are particularly concerned about the way PBMs' anticompetitive practices threaten patient access and the way PBMs are leveraging such practices to erode competition among pharmacies. FMI therefore calls on the Commission to move forward with a 6(b) study of the PBM industry, including the relationship between large PBMs, pharmacies and health insurers as well as the impact of PBM anticompetitive practices on both drug prices and pharmacies, and to use all the tools at the agency's disposal to protect patient access and competition.

As the food industry association, FMI works with and on behalf of the entire industry – from retailers who sell to consumers, including supermarket pharmacies, to producers who supply the food and other products sold in grocery venues – to advance safer and more efficient consumer supply chains for both food and pharmaceuticals. In total, FMI member companies, which range from independent operators to the largest national and international players, operate roughly 33,000 grocery stores and 12,000 pharmacies, ultimately touching the lives of more than 100 million U.S. households on a weekly basis and representing an $800 billion industry with nearly 6 million employees. Throughout the ongoing COVID-19 health emergency, our members have

been and continue to be a critical component of ensuring the availability of food, pharmacy and health care services in communities across this nation. Moreover, supermarket pharmacies have played an outsized role in the COVID-19 vaccination effort while also serving as a bridge between our communities and other providers, offering patients immediate care that is close and convenient to home. www.fmi.org

Background

PBMs were originally formed in the late 1960s, initially to assist with processing claims. Insurance plans were offering prescription drug benefits and PBMs filled out the paperwork, ensuring that reimbursements were passed along to pharmacies. Over time, PBMs portrayed themselves as cost-reducers that could form large patient networks, negotiate discounts from drug companies and pharmacies, and pass savings through to health plans and consumers. They claimed to be simple intermediaries between the health care entities. However, today's reality is very different as the PBM industry has grown and consolidated rapidly in recent decades. For perspective, in 1989, roughly 60 million prescription drug customers had their coverage administered by PBMs. However, PBMs now control nearly 80 percent of the market share for prescription drug access and around 180 million prescription drug customers. Additionally, these PBMs are also vertically integrated with health insurance companies, rebate aggregators and acquired pharmacies (retail, specialty and mail-order), giving them unprecedented power.



This situation, coupled with a lack of transparency, lends itself to a wide range of anti-competitive activities. For example, these vertically integrated payor entities

(Plans/PBMs/pharmacies) result in "no bid" contracts between Plans and PBM affiliates.[1] These entities also distort incentives for PBM-owned pharmacies, allowing them to accept lower reimbursement, because the additional profits will inure to the affiliated PBM or Plan, which then essentially subsidize their pharmacies. These predatory pricing arrangements eviscerate the pharmacy marketplace by forcing supermarket pharmacies to compete, not merely against PBM-owned pharmacies, but against the PBMs and Plans with these subsidized arrangements. This arrangement also permits PBM-owned pharmacies to increase their market share. Thus, CVS Specialty now holds approximately 27% of the specialty drug market, permitting it to purchase drugs below the acquisition costs of other pharmacies and further eroding equity in the market.

This landscape also enables PBMs to enjoy multiple hidden revenue streams from other stakeholders throughout the health care system. The hidden revenue streams include, but are not limited to, the difference between the amount a pharmacy is reimbursed and the amount the PBM bills to the health plan (spread pricing), post-adjudication fees that are charged to pharmacies and often referred to as Direct or Indirect Remuneration (DIR) fees, and manufacturer rebates that pharmaceutical companies pay to have their drugs placed on preferred formularies. The retroactive DIR fees are described by the PBMs as "performance-based pharmacy incentive" fees designed to incentivize pharmacies to perform better, yet there is no transparency to the process and pharmacies are not told what metrics are being used to evaluate their performance.

Importantly, this market concentration empowers the PBMs to offer supermarket pharmacies of all sizes take-it-or-leave-it contracts. The pharmacy must either accept a PBM's mandated contract terms (including, among other things, allowing the PBM to unilaterally set prices for certain drugs and then later impose retroactive DIR fees based on an opaque methodology), or give up the ability to serve the many customers whose health plans contract with the PBM; importantly, this would include existing customers who have longstanding relationships with their pharmacists. Furthermore, given PBMs also operate their own pharmacies, FMI pharmacy members are effectively forced to accept contractual terms from their direct competitors – a clear conflict of interest.

In short, PBMs are one of the least regulated sectors of the healthcare system and drug supply chain. There is almost no federal antitrust enforcement, oversight, or regulation, which has created an environment in which PBMs are free to engage in anticompetitive, deceptive, and fraudulent behavior that harms patients, employers, and pharmacies/providers while significantly increasing drug costs and eroding access. Additionally, given their market power

[1] E.g., Cigna, the Plan that owns Express Scripts, Inc. ("ESI") utilizes ESI as its PBM; similarly, SilverScript, Inc. and Aetna—both Plans owned by CVS Health, use Caremark as their PBM, and UnitedHealthcare, which owns the PBM OptumRx, Inc. (Optum), also contracts with Optum as its PBM.

and vertical integration, these middlemen increasingly stifle competition from the country's most accessible and trusted health care professionals – pharmacies. As mentioned above and discussed in greater detail below, PBMs create endless schemes to reduce reimbursement, claw back funds, restrict networks, and effectively force pharmacies to provide drugs below cost. Supermarket pharmacies are especially important access points for consumers in underserved, low-income and rural neighborhoods, but these unfair and coercive tactics by PBMs result in inferior health care, less choice and higher costs.

PBMs Leverage Concentrated Market Power to Force Pharmacies to Accept Below-Cost Pricing and Other Financially Oppressive Practices

PBMs' profit model is dependent upon their ability to dictate prices and impose upon pharmacies arbitrary and often below-cost reimbursement terms for generic drugs through maximum allowable cost ("MAC") price lists. Unlike with on-patent drugs, where PBM reimbursements typically are based on the actual prices paid by drug wholesalers to manufacturers, PBM reimbursements to pharmacies for generic drugs are based on PBMs' "proprietary" MAC lists, which bear no necessary relation to pharmacies' acquisition costs. Additionally, one of the many ways PBMs profit is by maximizing the difference between what they pay pharmacies for a drug and the inflated amount they charge a health care plan for that same transaction. To take just one reported example, an Iowa county was billed by its PBM $198.22 for a drug that the PBM reimbursed the dispensing pharmacy just $5.73 – a markup of more than 3,400 percent.[2]

PBMs frequently assert that below-cost reimbursement is a problem only for poorly run pharmacies and that low PBM reimbursement rates create an incentive for such poorly run pharmacies to improve their purchasing practices. However, the PBM industry has resisted attempts to force price transparency that would reveal the basis for these claims. Furthermore, pharmacies of all sizes – not just "poorly run" ones – are suffering as a result of PBMs' below-cost MAC pricing. Even FMI's largest members – Fortune 500 companies with efficiencies, expertise in supply chain logistics, and economies of scale – struggle to operate financially viable pharmacies.

Importantly, PBM contracts often require competing pharmacies to relinquish ownership to all data and information sent from them to the PBM. The data and information transmitted represents essentially the entire record of the dispensing event and claim(s) for coverage and reimbursement. This not only gives PBMs access to a pharmacy's competitively sensitive information, but it also enables the PBMs to utilize the information to manipulate reimbursements and fees while steering patients to PBM-affiliated pharmacies.

[2] Robert Langreth et al., *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, Bloomberg, Sept. 11, 2018.

In addition, PBMs typically include broad confidentiality language in their contracts to prohibit pharmacists from discussing their own drug costs, services, business practices, or the undefined term "other information" contained in the contract or provider manuals with third parties.

Pharmacy DIR Fees

Below-cost pricing is just one way that PBMs systematically leverage their market power. As previously noted, PBMs also impose on pharmacies unfair and exorbitant retroactive DIR fees. PBMs charge these fees to pharmacies without warning or market justification weeks or months after the pharmacy dispenses a drug to a beneficiary. The Centers for Medicare & Medicaid Services ("CMS") tracks DIR fees and recently reported an increase in such post-sale fees charged to pharmacies by PBMs of more than 107,400 percent from 2010 to 2020.[3] There is no competitive market justification for such an exponential growth in these fees.

As with MAC pricing, PBMs tout these post-sale fees as disincentives to "poor performance" by pharmacies. In reality, however, they are just another example of PBMs leveraging their market power to maximize their profits. Charges for "poor performance" far exceed incentive payments to pharmacies intended to reward "high performance." As a result, beneficiaries pay higher costs and drug prices become even less transparent. Additionally, FMI members cite these fees as a key reason for their pharmacies' financial struggles, forcing some to close their pharmacies altogether and others to scrap expansion plans. It is particularly egregious that with pharmacy DIR fee reform proposals being considered and advanced by policymakers, including CMS' recent final rule, PBMs have started including contingencies in their pharmacy contracts that would allow them to impose upon pharmacies even more aggressive rates and less favorable reimbursement terms if/when retroactive DIR fees become prohibited. Case in point, the following clause was recently included by a PBM in a take-it-or-leave-it contract that was presented to an FMI member. Although it cleverly does not reference "DIR fees," that is clearly the focus:

> *Change in Law. In the event [guidance is released] that prohibits or materially alters the economics of a Participating Sponsor's Program (the "Change in Law"), the parties agree to promptly renegotiate the effected provisions of this Schedule, to the extent feasible, in order to preserve the relative economics of the Members, the Participating Sponsor, and Provider to that which existed immediately prior to such Change in Law.*

[3] Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed. Reg. 27704 (May 9, 2022).

Although PBMs claim the purpose of DIR fees is to encourage better health outcomes by incentivizing pharmacies to perform better, this clause clearly demonstrates DIR fees are being used as a profit stream.

The impact of pharmacy DIR has been devastating to supermarket pharmacies and the patients who depend on them. These experiences include commentary from an FMI member company that boasts a growing pharmacy solution servicing more than 300 sites in almost two dozen states with an estimated retail volume of more than $1 billion:

> *DIR Fees have had an increasingly negative impact on pharmacy operations, growing from 1.75% of revenue in 2018 to 2.65% of revenue in 2021 in our corporate stores. Extrapolating this across our participants, we estimate that our group paid $27.7 million in fees in 2021 alone. DIR fees are taking resources from our operators that should be invested in their pharmacies and teams for the benefit of the patients and communities we serve. In many cases profitability and cash-flow are being compressed to the point where several operators are contemplating exiting the profession. The difficulty that this poses to our patients is that many of our sites are in under-served rural communities that will struggle to find another pharmacy to replace it.*

Another member reports:

> *We have seen increased numbers of independent pharmacies seeking to sell to us, especially over the past 6 months. This is occurring in an environment where one would expect a lift in pharmacy revenues through COVID immunizations, etc.*

The information above is of particular concern to FMI members, as pharmacy closures result in fewer choices for patients and less competition among pharmacies, which may result in increased costs for consumers. A related problem is the decision not to expand to underserved areas. FMI members point to rising DIR as the greatest contributing factor to both closures and decisions not to expand. For example, another FMI member points out that the average net profit its pharmacy realizes after DIR in one particular Plan is -$0.21, a loss on every prescription filled in that network. Another regional supermarket chain reports, since the introduction of DIR, it went from a profit of more than $60 thousand per pharmacy per year to a deficit of $60 thousand per pharmacy per year, forcing closures in the past four years of seven pharmacies. Another large chain paid $136 million in DIR in the last three years. If this trend continues, chains like this are likely to exit the pharmacy business altogether, again reducing competition. Indeed, a large chain reported $30 million in DIR in 2021, resulting in a decision not to open new

stores containing pharmacies, while suffering 17 pharmacy closures in its markets. These closures represent the dominant trend in the industry and threaten patient access to prescription drugs and other pharmacy services.

The manner in which DIR Programs are implemented is also opaque and inscrutable, often resulting in pharmacies being unable to predict or improve their own scores. With respect to FMI members operating specialty pharmacies, these pharmacies' adherence is unfairly measured in a manner that fails to account for the difficulties inherent in maintaining adherence, like drug vacations and holds for adverse reactions. These programs force pharmacies to expend significant additional resources, not to improve patient adherence but merely to obtain data about how a PBM is tracking adherence. Moreover, PBMs use arbitrary metrics like formulary compliance and generic dispense rate, which penalize pharmacies for dispensing drugs as prescribed by a physician and as approved by the Plan itself.

Furthermore, due to the unpredictability of pharmacy DIR, FMI members are often unable to account and accrue for any losses they may incur when PBMs recoup DIR fees months after the point of sale. Pharmacies that are solvent when they dispense a drug may find months later (and as demonstrated in members' statements above) that their pharmacy DIR netted an unforeseen loss for the pharmacy. This unpredictability limits our members' ability to open new pharmacies, especially in rural and underserved areas, as they cannot predict whether they can sustain expansion, as attested to by member chains who have ceased building new stores with pharmacies. Indeed, one large member chain recently built new sites in urban locations and had to forego including pharmacies in those new stores, as they could not build large enough stores to mitigate the losses from pharmacy. The same chain has had to reduce pharmacy hours and staffing, and it has even had to reduce or eliminate patient cost-savings and rewards programs. As these experiences attest, negative profits driven by pharmacy DIR have the foreseeable results of ultimately closing supermarket pharmacies entirely, thus further limiting patient access. Absent substantial enforcement and/or reform, this trend will likely continue.

PBM Practices Are Driving Food Retailers Out of the Pharmacy Business

Unlike independent pharmacies, FMI members that operate supermarket pharmacies are not dependent solely on their pharmacy operations for survival. Therefore, PBM abuses may not threaten to force integrated food retailers to close their doors. Instead, PBM practices make it likely that food retailers will be forced to continue leaving the pharmacy business – either by outsourcing their pharmacy operations to the biggest, PBM-affiliated players in the market, or worse, by abandoning pharmacy operations altogether.

Neither of these scenarios is merely hypothetical as several FMI members have already sold their pharmacy operations to PBM-operated chains. The number of pharmacies in supermarkets

decreased by more than seven percent between 2007 and 2017[4], while food and mass-market retailers accounted for more than 45 percent of the pharmacy closures during the year from July 2018 to July 2019.[5] Supermarket pharmacy closures, and abandoned expansions, thus contribute to the overall trend of decreased access to pharmacies and "pharmacy deserts." The effect of such closures is particularly acute in some rural communities, where closures are more prevalent and more detrimental to a community's access to health care. The closure of pharmacies in recent years has created "pharmacy deserts" in some underserved urban communities as well.

PBMs' Concentrated Market Power Harms Health Care Plans and Beneficiaries

As employers that sponsor plans to provide health care coverage to their employees, FMI members also see how PBM practices exploit inherent conflicts of interest to the detriment of health care plans and beneficiaries. For example, PBMs are often responsible for developing health care plan formularies, or lists of drugs that a plan will cover, and drug companies compete to have their drugs listed on those formularies by offering compensation to PBMs in the form of rebates. PBMs may be incentivized to obtain more expensive drugs, to the extent their rebates correlate with the cost of the drugs they include on formularies. FMI members' health plans typically have little visibility into these rebates, making it difficult for them to monitor whether their contracted PBMs are choosing drugs to reduce plan costs or to increase the PBMs' own financial model.

Additionally, since PBMs own and have financial interests in pharmacies, they frequently steer patients to those outlets as the sole source for pharmaceuticals. By steering patients to their own pharmacies, PBMs reduce competition and have additional incentives to provide patients with more expensive drugs. As CMS has recognized, "[m]arket competition is best achieved when a wide variety of pharmacies are able to compete in the market for selective contracting with plan sponsors and PBMs," not when PBMs can simply direct patients to themselves.[6]

Conclusion

PBMs have been allowed to operate without oversight, shrouded in secrecy. Increased antitrust enforcement, regulation and transparency are necessary to help curb existing and prevent future abusive practices, while controlling consumers' drug costs and preserving their access to supermarket pharmacies. Moreover, the Supreme Court's unanimous decision in the case of

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[4] Sharon Terlep & Jaewon Kang, *The Pharmacist Is Out: Supermarkets Close Pharmacy Counters*, Wall St. J., Jan. 27, 2020.

[5] Xil Consulting, *Payers and PBMs Profit from Obscure Pharmacy Fees, While Seniors See No Relief in Prescription Costs* (Feb. 11, 2020)

[6] 83 Fed. Reg. 62,176 (Nov. 30, 2018)

Rutledge v. Pharmaceutical Care Management Association – which reaffirmed the states' rights to regulate PBMs – provides a strong vote of confidence to achieve greater oversight of PBMs.[7]

In conclusion, we respectfully urge the Commission to move forward with the proposed 6(b) study of the PBM industry. Again, FMI thanks the FTC for the opportunity to provide input on this critically important topic. If you have questions about these comments or would like additional information, please feel free to contact me at pmatz@fmi.org or (202) 452-8444.

Sincerely,

Peter Matz
Director, Food and Health Policy

[7]Brief for FMI as Amicus Curiae, p. 9-17, Leslie Rutledge v. Pharmaceutical Care Management Association, available at https://www.supremecourt.gov/DocketPDF/18/18-540/134582/20200302123959805_18-540%20tsac%20FMI.pdf