State of Louisiana

Pharmacy Benefit Manager (PBM) Monitoring Advisory Council

Commissioner, La. Dept. of Insurance
President, La. State Board of Medical Examiners
President, La. Board of Pharmacy
Attorney General
Director, Public Protection Division, La. Dept. of Justice
Secretary, La. Dept. of Health
President, La. Academy of Physician Assistants
President, La. State Medical Society
President, La. Association of Nurse Practitioners
President, La. Pharmacists Association
President, La. Independent Pharmacies Association
President, National Association of Chain Drug Stores
President, Pharmaceutical Research & Manufacturers of America
President, La. Academy of Medical Psychologists
President, La. Association of Health Plans
President, of *a PBM licensed by the Board of Pharmacy and selected by the Louisiana affiliate of the Pharmaceutical Care Management Association*
President, La. Association of Business & Industry
Chief Executive Officer, La. Business Group on Health
President, La. AFL-CIO
President, La. Association of Health Underwriters
The Governor
Chair, House Committee on Insurance
Chair, Senate Committee on Insurance
Chair, House Committee on Health & Welfare
Chair, Senate Committee on Health & Welfare

Meeting Minutes

October 9, 2024

A regular meeting of the council was held on **Wednesday, October 9, 2024** in the Poydras Hearing Room at the Louisiana Department of Insurance (LDI), located at 1702 North Third Street in Baton Rouge, Louisiana 70802. The meeting was conducted in a hybrid meeting format, in-person and by electronic means (Zoom).

1. Call to Order
Chairman Mills called the meeting to order at approximately 10:34 a.m.

2. Quorum Call
Chairman Mills asked Mr. Fontenot to call the roll of members to establish a quorum.

Members Present:

Mr. Frank Opelka (For the Commissioner, Louisiana Dept. of Insurance)
Mr. Marty McKay (President, Louisiana Board of Pharmacy)
Mr. D. Jeddie Smith, Jr. (For the Louisiana Attorney General)
Mr. Michael Dupree (Director of the Public Protection Division, La. DOJ)
Ms. E. Sue Fontenot (For the Secretary, Louisiana Dept. of Health) *
Mr. Scott Black (President, Louisiana Pharmacists Association) *
Mr. Don Caffery (For the President, La. Independent Pharmacies Assoc.) *
Mr. Jeff Drozda (For the President, Louisiana Association of Health Plans) *
Mr. Robert Rieger (For the President of a PBM / Prime Therapeutics / PCMA)
Ms. Cheryl Tolbert (CEO, Louisiana Business Group on Health)
Mr. Josh Sonnier (For the President, Louisiana AFL-CIO)
Ms. Kristy Copeland (For the President, La. Assoc. of Health Underwriters)
Senator Kirk Talbot (Chairman, Senate Committee on Insurance)
Rep. Chris Turner (For the Chairman, House Committee - Health & Welfare
Mr. Fred H. Mills, Jr. (For the Chairman, Senate Committee - Health & Welfare)
(* - participated by electronic means)

Members Absent:

The President of the Louisiana State Board of Medical Examiners
The President of the Louisiana Academy of Physician Assistants
The President of the Louisiana State Medical Society
The President of the Louisiana Association of Nurse Practitioners
The President of the National Association of Chain Drug Stores
The President of the Pharmaceutical Research & Manufacturers of America
The President of the Louisiana Academy of Medical Psychologists
The President of the Louisiana Association of Business & Industry
The Governor
The Chairman of the House Committee on Insurance

Mr. Fontenot certified 14 of 25 members were present, constituting a quorum for the conduct of official business. Senator Talbot arrived at approximately 10:50 a.m. which resulted in 15 members present.

Support Staff Present:

Mr. Joe Fontenot (Executive Director, Louisiana Board of Pharmacy)
Mr. Alex Deinken (IT Consultant, Louisiana Department of Insurance)

Guests Present:

Ms. Cathy McKay

3. Consideration of Minutes from Previous Meeting

Chairman Mills asked for a motion to approve the draft minutes of the previous meeting held on July 10, 2024. A motion was offered by Rep. Turner, seconded by Mr. Rieger, and then adopted after a unanimous vote of the remaining members in the affirmative declaring the minutes approved.

4. Opportunity for Public Comment

Chairman Mills solicited public comment and acknowledged that there were three submissions by email which will be entered into the meeting minutes.

Attachment A: October 8, 2024 email from Kyle Stevens, Bellingrath Pharmacy
Attachment B: October 9, 2024 email from Ella Vasquez, DBS Pharmacy
Attachment C: October 9, 2024 email from Christina Brown, Picou's Drug Store

Chairman Mills further stated that he has briefly discussed the communications with Mr. Rieger. Mr. Rieger expressed his willingness to address any issues regarding his members in a scheduled meeting. Contact information to schedule such meetings was provided. There was no further public comment.

5. Federal Trade Commission (FTC) Interim Staff Report (July 2024)

Chairman Mills noted that the executive summary of this report has been provided by Mr. Joe Fontenot and is available as a link on the agenda for this meeting and can be found on the PBM Monitoring Advisory Council webpage of the Board of Pharmacy website. He then asked for comments or statements regarding that report. None were offered.

6. FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices

The document titled *"Statement of FTC Bureau of Competition Deputy Director Rahul Rao on Lawsuit Against PBMs and the Role of Drug Manufacturers in Distorting Competition in the U.S Drug Distribution System"* was distributed to members in person and made available electronically to all in attendance. There were no member questions or comments.

7. Review of Industry Trends and Emerging Issues

Chairman Mills solicited comments from the members, calling on Mr. Opelka, who advised that his agency continues the rulemaking process for the bills reviewed at the last Pharmacy Benefit Manager (PBM) Monitoring Advisory Council meeting.

Chairman Mills asked for information regarding complaints received by individual agencies with each agency reporting little activity in this area.

8. Review of Rulemaking Activity
The members had no rulemaking activity to report in addition to what was previously discussed.

9. Calendar Notes
Chairman Mills requested that Mr. Fontenot provide calendar notes. Mr. Fontenot advised that the tentative meeting dates for calendar year 2025 are January 8, April 9, July 9, and October 8 at 10:30 a.m.

10. Adjourn
Having completed the tasks itemized on the posted agenda, with no further business pending before the council and without objection, Chairman Mills adjourned the meeting at approximately 11:06 a.m.

Minutes approved during subsequent meeting of the Council on January 8, 2025.

Attachment A

From: kyle stevens
To: Joe Fontenot
Subject: Public comments__ PBM advisory commitee public comment
Date: Tuesday, October 8, 2024 9:27:25 PM

Good morning Mr. Fontenot / Committee,

My name is Kyle Stevens.
I own Bellingrath Pharmacy in Greenwell Springs near Baton Rouge.

In the last 14 days I learned of 3 independent pharmacy closures within 20 miles of my location, the capital city of Baton Rouge.
I know each owner personally.

These pharmacies place PBMs as the major factor for closure.

Last month Express Scripts required me to pay $150 to re-credential.
The re-credentialing consisted of me telling them that nothing has changed since last year.

This week Optum requested $1,500 (one thousand, five hundred dollars) for a re-credential fee. I notified Optum that nothing has change since last year and the fee was still required.

PBMs do not provide a service to patients of Louisiana.
PBMs process prescriptions that Louisiana pharmacies dispense to patients of Louisiana. PBMs require pharmacies to pay exorbitant fees to provide these services.

PBMs are putting Louisiana pharmacies out of business with below cost reimbursement contracts and a number of other bad practices.

It is important that all members of this committee know that PBMs are responsible for underpaying pharmacies for prescriptions.

It is important that all members understand that underpaying pharmacies reduces access to medications.

It is important that all members know if any chair of this committee works for or has an affiliation with a PBM.

KYLE STEVENS

Attachment B

From: Ella Echavia
To: Joe Fontenot
Subject: PBM Public comment
Date: Wednesday, October 9, 2024 1:20:59 AM

Mr Joe,

I won't be able to attend the PBM meeting tomorrow but would like to submit examples of PBM experiences…

Example #1

I called the PSAO about some below cost reimbursements (more or less $100 below acq cost for brand names per Rx) from OPTUM and ESI. PSAO got a reply from ESI and confirmed that those particular claims were reimbursed "Effective rate". I replied to the PSAO and pointed out these Louisiana laws prohibits effective rates.

The following law outlaws effective rate pricing in Louisiana. This is found in R.S. 22:1860.2.

§1860.2. Certain pharmacy claims fees prohibited

A. A health insurance issuer or a pharmacy benefit manager shall not directly or indirectly charge or hold a pharmacist or pharmacy responsible for any fee related to a claim that is any of the following:

(1) Not apparent at the time of claim processing.

(2) Not reported on the remittance advice of an adjudicated claim.

(3) After the initial claim is adjudicated.

La. R.S. 22:1863

§1863. Definitions

As used in this Subpart, the following definitions apply:

(2) "Maximum Allowable Cost List" means a listing of the National Drug Code used by a pharmacy benefit manager setting the maximum allowable cost on which reimbursement

to a pharmacy or pharmacist may be based. "Maximum Allowable Cost List" shall include any term that a pharmacy benefit manager or a healthcare insurer may use to establish reimbursement rates for generic and multi-source brand drugs to a pharmacist or pharmacy for pharmacist services. The term "Maximum Allowable Cost List" shall not include any rate mutually agreed to and set forth in writing in the contract between the pharmacy benefit manager and the pharmacy or its agent and shall not include the National Average Drug Acquisition Cost. ***A pharmacy benefit manager may use effective rate pricing for a pharmacist or pharmacy that is not a local pharmacy or local pharmacist as defined in R.S. 46:460.36(A).***

ESI's replies:

1)

ESI has confirmed that the pharmacy did receive this effective rate and this was paid correctly. ESI has pointed out that the legislation provided specifically points out "fees" and not rates, thus does not apply in this situation.

2) *The claim processed correctly in accordance with LA law.*

PSAO told me that that's ESI's interpretation of the law and there's nothing else they can do about that effective rate reimbursement and to ask for help from the state association.

We have laws but not being followed by PBMs and the independents are the ones bleeding out money everytime we dispense brand names

Example #2
I have a patient who don't want to deal with CVS pharmacy because of horrible service. So she transferred her meds to our store, after 3 months that she got her maintenance meds from us, I got a rejection…. "Must fill at cvs store or mail order". I told her that patient steering is prohibited in Louisiana, so she contacted cvs (there's nothing they can do, she needs to get it from cvs or mail order) so she then filed a complaint with LDI, but she was told by LDI that since her plan is from company XYZ, which is a national account, they can't really do anything about it.

I have other patients that complained about being steered back to cvs after transferring to us

Example #3
dispensing pain medicine is very time consuming because you need to check pmp, check doctor if legit, and etc. you probably spend 3-4x the amount of time filling a controlled drug versus non controlled but yet most of the times we get reimbursed 50% of our cost. It's horrible! Nobody wants to work for free so much more giving the medicine below cost and also have corresponding responsibility and liability dispensing controlled drugs.

Thank you very much

Ella Vasquez
DBS Pharmacy

Attachment C

From: Picou"s Drug Store
To: Joe Fontenot
Cc: Picou's Drug Store
Subject: LABOP PBM council public comment
Date: Wednesday, October 9, 2024 7:05:32 AM

Good Morning,

PBMs continue to impact our small community in Eunice. Despite laws and regulations, PBM continue to steer patients to the pharmacy they want them to use, whether it be mail order, one that they own, or another.

I had a claim this week come through stating that the patient had to pay non contract full price at our pharmacy because quote "non Walmart, non Costco" pharmacy. We have a contract with this PBM so why would our patient be told to use another pharmacy to get the full effect of the insurance that they pay a lot of money for monthly?

Another example is the Acadian medical Center hospital in Eunice. Their prescription insurance steers them to only one local pharmacy and tells them that any maintenance medications must be filled at a mail order pharmacy in Baton Rouge. I have had my own friends that I grew up with that were filling at our drug store have to transfer because refills were not covered at my drug store. This same PBM also denies all other non-refill claims and we have to stop workflow to call their helpdesk for the girl only to tell us "It is a known glitch in the system" and override the claim so we can fill their antibiotic at our pharmacy that they need to start taking immediately. This is absurd that they are using tactics that other pharmacies may not know that they could use the patient's insurance if they would take 5 minutes (that we don't have) to call and ask them to allow us to process the claim.

There are several other PBM that also patient steer and make our community members use CVS, which is located in Opelousas, not even in our town. Those patients have to either pay our discounted cash price or drive to Opelousas to pickup their prescriptions.

Another big issue we have been having is mail order pharmacies like SelectRX have been contacting our elderly patients and tricking/persuading them into changing to their mail order pharmacy. My question is how do they know our patients and their phone numbers? Who is providing them with this information, and who owns these mail order pharmacies that continue to confuse and ultimately lead to sub optimal care from the mail order pharmacy they push them to? We have had two elderly patients leave but come back to us within a few months, but the mail order pharmacy refused to transfer back the prescriptions. We had to contact all of our patients physicians to get new scripts and now its a fight to fill on the patients insurance because the mail order pharmacy tries to fill it and ship it to the patient that told them they don't want mail order before we can process it on their insurance to fill it for our patient.

We are a locally owned drug store that is the oldest business in Eunice. We have been open since 1903. If PBM abuse continues (I didn't even address below water claims or extreme fees that we cannot financially sustain) we do not know the fate of our future. Our community looks to us for quick answers when their physician is unavailable, they come in and show me rashes and bites, I counsel their complicated discharge med list from a hospital stay, I open up after hours and on weekends to fill emergency prescriptions, and so much more. They want to be our patients, but their insurance/PBM refuses to let them choose. We are a crucial part of the health care of our community. And, unfortunately, the large chain pharmacies in Eunice are so busy and understaffed they cannot provide the customer service that we provide to Eunice. Unlike big chains we strive.

God bless you all and thank you for your time,
Christina Brown, Owner, Pharmacist in Charge
Picou's Drug Store

“TO MEET OUR PATIENTS’ NEEDS WITH COMPREHENSIVE CARE AND COMPASSION”

FEDERAL TRADE COMMISSION

Pharmacy Benefit Managers:
The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies

Interim Staff Report
July 2024

U.S. Federal Trade Commission
Office of Policy Planning

Table of Contents

I. EXECUTIVE SUMMARY

This Interim Report is part of an ongoing study by the Federal Trade Commission ("FTC" or the "Commission") of pharmacy benefit managers ("PBMs") and their impact on access to and affordability of medicines. It describes how, amidst increasing vertical integration and concentration, these powerful middlemen may be profiting by inflating drug costs and squeezing Main Street pharmacies.

PBMs are at the center of the complex pharmaceutical distribution chain that delivers a wide variety of medicines from manufacturers to patients. PBMs serve as middlemen, negotiating the terms and conditions for access to prescription drugs for hundreds of millions of Americans. Due to decades of mergers and acquisitions, the three largest PBMs now manage nearly 80 percent of all prescriptions filled in the United States. They are also vertically integrated, serving as health plans and pharmacists, and playing other roles in the drug supply chain as well. As a result, they wield enormous power and influence over patients' access to drugs and the prices they pay. This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.[1]

PBMs also exert substantial influence over independent pharmacies, who struggle to navigate contractual terms imposed by PBMs that they find confusing, unfair, arbitrary, and harmful to their businesses. Between 2013 and 2022, about ten percent of independent retail pharmacies in rural America closed. Closures of local pharmacies affect not only small business owners and their employees, but also their patients. In some rural and medically underserved areas, local community pharmacies are the main healthcare option for Americans, who depend on them to get a flu shot, an EpiPen, or other lifesaving medicines.[2]

PBMs oversee critical decisions about access to and affordability of medications without transparency or accountability to the public. Indeed, PBM business practices and their effects remain extraordinarily opaque. Accordingly, in 2022, the FTC issued special orders pursuant to

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[1] Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices; *see also* Laryssa Mykyta & Robin A. Cohen, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, NAT'L CTR. FOR HEALTH STAT. DATA BRIEF, June 2023, at 5 (finding by Centers for Disease Control and Prevention that 9.2 million adults in U.S. not taking prescription drugs as prescribed due to high medication costs).

[2] *See* Nat'l Rural Health Ass'n, FTC-2022-0015-0846-A1, at 3 (May 17, 2022), https://www.regulations.gov/comment/FTC-2022-0015-0846 ("Given the unique size of rural pharmacies, they're often the only outfit in town."); JOANNE CONSTANTIN ET AL., RUPRI CTR. FOR RURAL HEALTH POL'Y ANALYSIS, RURAL AND URBAN PHARMACY PRESENCE – PHARMACY DESERTS 4 (2022), https://rupri.public-health.uiowa.edu/publications/policybriefs/2022/Pharmacy%20Deserts.pdf ("[M]ail-order services fail to replace the other fundamental functions provided by pharmacists beyond filling prescriptions, such as health screenings, patient education and counseling, and vaccinations."); *see also* Remarks of Chair Lina M. Khan Regarding the 6(b) Study on Pharmacy Benefit Managers, FTC File No. P221200, at 1 (Feb. 17, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/p221200khanstatementrepbms.pdf ("[S]mall, local, and family-owned pharmacies—the backbone of so many communities across the nation . . . [are the] types of community institutions [that] have at times proven themselves to be superior at delivering for their patients and customers."); Statement of Comm'r Alvaro M. Bedoya Regarding the 6(b) Orders to Study Contracting Practices of Pharmacy Benefit Managers (June 7, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Bedoya_Statement_re_PBM_Study_%28FINAL%29_6-7-2022.pdf ("People say independent pharmacies are a 'critical part' of the healthcare infrastructure. In many parts of rural and urban America, independent pharmacies are the healthcare infrastructure, full stop.").

Section 6(b) of the Federal Trade Commission Act (the "6(b) Orders" or "Orders") to the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc. (the "PBM respondents" or "respondents").[3] The Orders requested data and documents regarding these six large PBMs' businesses and business practices. In May and June 2023, the FTC issued supplemental Orders to produce data and documents to three additional PBM-affiliated entities.[4]

The FTC's ongoing review of materials produced by the PBMs to date, and publicly available data, focuses on the impact of increased consolidation and vertical integration involving the six largest PBMs on the accessibility and affordability of prescription drugs.

Although the FTC issued its Orders to the PBMs over two years ago, some of the PBM respondents have not yet fully complied; they have not yet completed their required submissions. The failure of certain respondents to timely produce data and documents has hindered the ability of the Commission to perform its statutory mission. FTC staff has demanded that the companies finalize their productions required by the Orders promptly and eagerly awaits promised productions. If, however, any of the companies fail to fully comply with the Orders or engage in further delay tactics, the FTC can take them to court to compel compliance.

Even as FTC staff continues to press the PBM respondents to turn over the required information, the Commission is committed to ensuring that delay tactics by some companies do not prevent it from sharing preliminary findings with the public and policymakers as quickly as possible. This Interim Report accordingly provides the following key insights supported by the documents and data obtained to date, as well as by publicly available information:

- ***The market for pharmacy benefit management services has become highly concentrated, and the largest PBMs are now also vertically integrated with the nation's largest health insurers and specialty and retail pharmacies.*** Over the past two decades, the PBM industry has undergone substantial change as a result of horizontal consolidation and vertical integration. The top three PBMs processed nearly 80 percent of the approximately 6.6 billion prescriptions dispensed by U.S. pharmacies in 2023, while the top six PBMs processed more than 90 percent.[5] All of the top six PBMs are vertically integrated downstream, operating their own mail order and specialty pharmacies, while one PBM owns and operates the largest chain of retail pharmacies in the nation. Pharmacies affiliated with the three largest PBMs now account for nearly 70 percent of all specialty drug revenue. In addition, five of the top six

[3] *See* Press Release, Fed. Trade Comm'n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 6, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry. These entities will be referred to herein, respectively, as "CVS Caremark," "Express Scripts" or "ESI," "OptumRx," "Humana Pharmacy Solutions" or "HPS," "Prime," and "MedImpact."

[4] *See* Press Release, Fed. Trade Comm'n, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen (issuing 6(b) Orders to two PBM-affiliated GPOs, Zinc Health Services, LLC ("Zinc") and Ascent Health Services, LLC ("Ascent")); Press Release, Fed. Trade Comm'n, FTC Further Expands Inquiry Into Prescription Drug Middlemen Industry Practices (June 8, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices (issuing 6(b) Order to Emisar Pharma Services LLC ("Emisar")).

[5] *See* ADAM J. FEIN, DRUG CHANNELS INST., THE 2024 ECONOMIC REPORT ON U.S. PHARMACIES AND PHARMACY BENEFIT MANAGERS 51, 163 (2024) [hereinafter "DCI 2024 Report"] (estimating 2023 prescriptions and PBM shares).

PBMs are now part of corporate healthcare conglomerates that also own and operate some of the nation's largest health insurance companies, including three of the five largest health insurers in the country.[6] Four of the PBMs are owned by publicly traded parent companies that own affiliates that operate health care clinics. Three have recently expanded into the drug private labeling business, partnering with drug manufacturers to distribute drug products under different trade names.[7] Four healthcare conglomerates now account for an extraordinary 22 percent of all national health expenditures, as compared to 14 percent eight years ago.[8]

- ***As a result of this high degree of consolidation and vertical integration, the leading PBMs can now exercise significant power over Americans' access to drugs and the prices they pay.*** Decades ago, PBMs began as administrative service providers working to validate and process pharmacy benefits provided by separate insurance plans. They then expanded into negotiating with pharmaceutical manufacturers on behalf of those plan clients, developing reimbursement terms and conditions for pharmacies, and developing formularies (i.e., lists of drugs a health plan will cover and reimburse for). But now, after years of acquisitions, the leading PBMs are each part of massive healthcare conglomerates that are often comprised of a health insurer, pharmacies, and the PBM negotiator between health insurers and pharmacies—all rolled into one. The result is that the dominant PBMs can often exercise significant control over which drugs are available, at what price, and which pharmacies patients can use to access their prescribed medications.

- ***Vertically integrated PBMs may have the ability and incentive to prefer their own affiliated businesses, which in turn can disadvantage unaffiliated pharmacies and increase prescription drug costs.*** Vertical integration in PBM business structures, particularly with respect to integrated health insurers and specialty and mail order pharmacies, likely creates the ability and incentive for PBMs to increase utilization of certain drug products at affiliated pharmacies to generate the greatest revenue and profits for their respective conglomerates. As a result of vertical integration, PBM-affiliated pharmacies now compete with the unaffiliated pharmacies to distribute medications to patients. Our initial analyses in Section III suggest that certain PBMs may be steering patients to their affiliated pharmacies and away from unaffiliated pharmacies. Our analyses also highlight examples of affiliated pharmacies receiving significantly higher reimbursement rates than those paid to unaffiliated pharmacies for two case study drugs. These practices have allowed pharmacies affiliated with the three largest PBMs to retain levels of dispensing revenue well above estimated drug acquisition costs, resulting in nearly $1.6 billion of additional revenue on just two cancer drugs in under three years.[9]

- ***Evidence suggests that increased concentration may give the leading PBMs the leverage to enter into complex and opaque contractual relationships that may disadvantage smaller, unaffiliated pharmacies and the patients they serve.*** Independent pharmacies generally lack the leverage to negotiate terms and rates when enrolling in PBMs' pharmacy networks, and subsequently may face effectively unilateral changes in contract terms without meaningful choice and alternatives. The proliferation of complex and opaque contract terms and

[6] *See infra* § II.D.1.

[7] *See infra* § II.D.3.

[8] *See infra* § II.A.

[9] *See infra* § III.B.2.

adjustments has increased uncertainty in pharmacy reimbursements, which can make it difficult for smaller pharmacies to manage basic business operations. For instance, the rates in PBM contracts with independent pharmacies often do not clearly reflect the amount the pharmacy will ultimately be paid.

- ***PBMs and brand drug manufacturers sometimes negotiate prescription drug rebates that are expressly conditioned on limiting access to potentially lower cost generic alternatives.*** While this Interim Report principally focuses on the relationship between PBMs and pharmacies, we share evidence that PBMs and brand pharmaceutical manufacturers sometimes enter agreements to exclude generic drugs and biosimilars from certain formularies in exchange for higher rebates from the manufacturer.[10] These exclusionary rebates may cut off patient access to lower-cost medicines and warrant further scrutiny by the Commission, policymakers, and industry stakeholders.

To date, FTC staff has reviewed more than 1,200 public comments to identify predominant areas of concern,[11] as well as initial submissions of internal documents and data from PBM respondents and their affiliates. Staff has also interviewed various industry experts and participants and reviewed other public data and information. The insights gained thus far underscore the importance and urgency of scrutinizing the role and influence of PBMs in the nation's health care system. This is especially important since federal and state governments are the largest purchasers of healthcare.[12] We remain committed to providing timely updates as we receive and review additional information.

[10] *See infra* § IV.

[11] Regulations.gov, Solicitation for Public Comments on the Impact of Prescription Benefit Managers' Business Practices, FTC-2022-0015 (Feb. 24, 2022), https://www.regulations.gov/docket/FTC-2022-0015. Specifically, the FTC received 1,238 unique comments.

[12] *See* CTRS. FOR MEDICARE & MEDICAID SERVS., CMS ROADMAPS FOR THE TRADITIONAL FEE-FOR-SERVICE (FFS) PROGRAM: OVERVIEW 1 (2020) ("The Centers for Medicare & Medicaid Services (CMS) is the single largest payer for health care in the United States. Nearly 90 million Americans rely on health care benefits through Medicare, Medicaid, and the State Children's Health Insurance Program"); Submission of Documents from 6(b) Order Respondents [hereinafter "Respondent(s) Document Submission(s)"] [redacted]

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Rahul Rao
Deputy Director
Bureau of Competition

Statement of FTC Bureau of Competition Deputy Director Rahul Rao on Lawsuit Against PBMs and the Role of Drug Manufacturers in Distorting Competition in the U.S Drug Distribution System

September 20, 2024

Today's lawsuit against the nation's three largest pharmacy benefits managers (PBMs)—Optum Rx, Caremark, and Express Scripts—and their respective group purchasing organizations (GPOs), is the result of a wide-ranging investigation into distortions in the pharmaceutical distribution chain and their effects on patient access to insulin, a life-saving drug relied on by over 8 million Americans. As the complaint explains, the PBMs have created and manage a system in which drug manufacturers compete for formulary placement by raising (not lowering) drug list prices so they can feed the higher rebates that PBMs demand. This perverse system results in billions of dollars in rebates and fees for the PBMs and their health plan sponsor clients—but does so at the expense of certain vulnerable diabetic patients who must pay significantly more out-of-pocket for their critical medications.

The PBMs, however, are not the only actors who have contributed to this broken system that has driven up the price of insulin and other drugs. While the Commission has exercised its discretion to move forward with suing only the PBMs and GPOs now, FTC staff's investigation has also shed light on the concerning and active role that the insulin manufacturers—Eli Lilly, Sanofi, and Novo Nordisk—play in the challenged conduct. As detailed in the complaint, over the years, the insulin manufacturers have sharply inflated the list price of their insulin products in response to the PBMs' demand for higher rebates. For example, the list price of Lilly's Humalog soared from $21 in 1999 to $274 in 2017—a staggering increase of more than 1200%. The skyrocketing list price of insulin has had devastating consequences for far too many diabetic patients who have struggled to afford their medication and have been forced to ration these life-saving drugs.

With today's suit, the Commission is focusing this vital enforcement action against the PBMs, who sit at the center of the drug reimbursement system, and their affiliated GPOs. The Bureau of Competition, however, remains deeply troubled by the role drug manufacturers play in driving up prices of life-saving medications like insulin. We expect that development of a full factual record in this lawsuit, as well as suits brought by state Attorneys General, will help shape the appropriate parameters of permissible conduct in this area.

Although not named in this case, all drug manufacturers should be on notice that their participation in the type of conduct challenged here can raise serious concerns, with a potential for significant consumer harm, and that the Bureau of Competition reserves the right to recommend naming drug manufacturers as defendants in any future enforcement actions over similar conduct.