October 18, 2023

Jonathan Kanter
Assistant Attorney General
Antitrust Division
U. S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530-0001

Dear Assistant Attorney General Kanter,

Thank you for the Department of Justice's ("DOJ") additional scrutiny of the proposed acquisition of Amedisys, Inc. ("Amedisys") by United Health Group's ("UHG") Optum. American Pharmacy Cooperative ("APCI") consisting of more than 1,600 community pharmacies across thirty states, is opposed to this proposed acquisition and believes it represents not only a potential threat to competition, but also a further descent into an already vertically integrated healthcare supply chain in which the largest insurers and their affiliated pharmacy benefit managers ("PBMs") are able to profit off conflicts of interest and misaligned incentives.

Accordingly, APCI requests that the proposed acquisition be scrutinized closely pursuant to DOJ and Federal Trade Commission's ("FTC") draft merger guidelines. However, in light of the fact that large insurer/pharmacy benefit manager integration into the home health care space has been active, and has largely gone unchecked, despite closer scrutiny, APCI believes that analysis of unfair methods of competition pursuant to Section 5 of the FTC Act should figure centrally in any review of large insurer/PBM acquisitions of home healthcare businesses. Such an analysis should include (1) a review of the past and present practices of the acquiring insurer/PBM by and between their vertically integrated channels to determine whether vertical integration is being leveraged in a manner that constitutes unfair methods of competition; (2) whether the proposed acquisition is likely to further existing unfair methods of competition or ripen into violations of antitrust laws; and (3) whether a series of mergers or acquisitions tend to bring about the harms that antitrust laws were designed to prevent even if, individually, an individual merger or acquisition may not be in violation of antitrust laws.

Core practices of horizontally and vertically integrated insurers and PBMs have not increased efficiencies but instead led to higher drug costs, reduced access to certain medications, and reduced access to care.

Over the years insurers/PBMs have extolled the so-called benefits of integration claiming, amongst other things, "lower costs," and "increased efficiencies.[1]" However, in pharmacy today, core vertically integrated insurer/PBM practices include the following:

---

[1] Melissa Lin, "Everything You Need to Know About the CVS-etna Merger," Toptal Finance, available online at: https://www.toptal.com/finance/mergers-and-acquisitions/cvs-aetna#:~:text=According%20to%20CVS%20CEO%20Larry%20Merlo%2C%20the%20merger,wholesaler

- Rebates: As more fully elaborated below, rebate practices of large insurers/PBMs include (1) denying patients the benefit of drug manufacturer rebates at the point of sale; (2) mandating that patients pay for more expensive brand drugs as a condition of coverage when there are lower cost generic equivalents available, including in the deductible phase; and (3) engaging in rebate driven restrictive/exclusionary formulary practices.[2]

- Drug pricing methodologies: Large insurers/PBMs use a variety of complex methodologies to set the prices patients and payers pay for prescription drugs. Insurers/PBMs are often able to play arbitrage, exploiting pricing variations between the parties as well as through the use of drug manufacturer rebates and pharmacy discounts.[3] These practices include the practice of spread pricing (charging plan sponsors more for a drug than a pharmacy is reimbursed), and DIR fees in Medicare Part D whereby patient cost shares and deductibles are based on inflated prices at the counter with the PBMs clawing pharmacy discounts back from pharmacies retroactively thereby denying patients the benefit of the discounts and increasing the prices patients pay at the counter.[4]

- Patient steering: A practice that has grown as a result of vertical integration, PBMs are engaging in tactics to steer patients to insurer/PBM affiliated pharmacies.[5] Large insurers/PBMs aggressively target patients on specialty medications to treat serious conditions such as cancer and HIV, as well as patients on medications to manage chronic conditions such as diabetes, high blood pressure and heart disease.[6]

---

s%2C%20pharmacies%2C%20insurers%2C%20and%20pharmacy%20benefit%20managers%20%28PBMs%29; see also Shelby Livingston, "Cigna and Express Scripts close on $67 billion merger, Modern Healthcare, December 2018, available online at: https://www.modernhealthcare.com/article/20181220/NEWS/181229999/cigna-and-express-scripts-close-on-67-billion-merger.

[2] Xcenda, "Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access," September 16, 2020, available online at https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf; see also 46Brooklyn, "Wreck-fidera: How Medicare Part D has hidden the benefits of generic competition for a blockbuster Multiple Sclerosis treatment," December 1, 2021, available online at: https://www.46brooklyn.com/research/2021/12/1/tecfidera.

[3] Frier Levitt - commissioned by the Community Oncology Alliance, "Pharmacy Benefit Manager Expose: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers," February 2022, available online at: https://mycoa.s3.amazonaws.com/1678994901525_COA_FL_PBM_Expose_2-2022.pdf.

[4] Id.

[5] Id.; see also Marty Schladen, Catherine Candisky, "Mail-order pharmacy system delays care for some patients," The Columbus Dispatch, June 3, 2018, available online at https://www.dispatch.com/story/lifestyle/health-fitness/2018/06/03/mail-order-pharmacy-system-delays/12069189007/.

[6] Frier Levitt - commissioned by the Community Oncology Alliance, "Pharmacy Benefit Manager Expose: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers," February 2022, available online at: https://mycoa.s3.amazonaws.com/1678994901525_COA_FL_PBM_Expose_2-2022.pdf; see also Marty Schladen, "Pharmacist: CVS dominates cancer-drug business," The Columbus Dispatch, June 3, 2018, available online at https://www.dispatch.com/story/lifestyle/health-fitness/2018/06/03/pharmacist-cvs-dominates-cancer-drug/12069174007/.

While community pharmacists have long warned of the harms of integration in the insurer/PBM space, recently several studies have been released from various federal agencies that bear out their warnings.

In June of 2022, the Office of Inspector General ("OIG") released a report on the impact of Medicare Part D prescription drug plan ("PDP") brand requirements in connection with Hepatitis C drugs.[7] The report found that many plans failed to include lower cost authorized generics of certain Hepatitis C drugs and rather, required more expensive brand name drugs.[8] The report also found increased costs to the Medicare program as a result of brand preferences and, more importantly, found that "because beneficiary cost-sharing is based on pre-rebate prices, the use of higher-cost hepatitis C drugs in Part D led to thousands of dollars in additional costs for some Medicare beneficiaries."[9]

In July of 2023, a landmark study was released by the Medicare Payment Advisory Commission ("MedPAC") focusing on Medicare Part D in the year 2021.[10] The report found, amongst other things:

- Vertical integration resulted in higher costs to seniors;
- PBMs often paid their vertically integrated pharmacies more than non-affiliated pharmacies;
- Vertical integration created conflicts of interest and that a vertically integrated entity can benefit from higher payments to their vertically integrated pharmacies;
- PBMs denied beneficiaries $50 billion in drug manufacturer rebates at the counter in 2021 alone;
- 8% of the time, PBMs paid less for a drug than the patient paid out of pocket; and
- One PBM charged patients an average cost share for an asthma drug that was 156% more than the PBM was itself paying for the drug.[11]

Most recently, in September of 2023, the U.S. Government Accountability Office ("GAO") released a report analyzing CMS data and found, amongst other things, that for the seventy-nine highest rebated drugs in 2021, beneficiary payments were $21 billion and plan sponsor expenditures after rebates were only $5.3 billion, a direct result of PBMs and prescription drug plans not passing rebates back to patients at the pharmacy counter.[12]

[7] U.S. Department of Health and Human Services Office of Inspector General, "Part D Plan Preference for Higher Cost Hepatitis C Drugs Led to Higher Medicare Beneficiary Spending," August 2022, available online at https://oig.hhs.gov/oei/reports/OEI-BL-21-00200.pdf.
[8] Id.
[9] Id.
[10] Medicare Payment Advisory Commission, "Medicare and the Health Care Delivery System," Chapter 2, June 2022, available online at: https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v4_SEC.pdf.
[11] Id.
[12] The United States Government Accountability Office, "Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending," September 2023, available online at https://www.gao.gov/assets/gao-23-105270.pdf.

The foregoing reports offer a crucial peak behind the veil into how insurers/PBMs are able to leverage integration to shift the financial burden of prescription drugs to patients and, in government plans, to taxpayers as opposed to leveraging integration to lower drug costs.

Large insurer and PBM rebate practices under the Section 5 FTC Act microscope.

The FTC utilizes two criteria in evaluating whether a method of competition is unfair and goes beyond competition.[13] The two criteria are (1) whether the conduct is coercive, exploitive, collusive, abusive, deceptive, predatory, restrictive, or exclusionary, and (2) whether the conduct negatively affects competition (impair opportunities of market participants, limits choice, lower quality, raise prices, otherwise harm consumers).[14]

While several core practices of large insurers/PBMs deserve scrutiny under Section 5 of the FTC Act, this letter will focus on their rebate practices. Importantly, the FTC issued a policy statement on rebates and fees in exchange for excluding lower cost drug products from formularies.[15] In its policy statement on rebates, the FTC cited several authorities that may apply to exclusionary rebate practices including Section 5 of the FTC Act.[16]

Rebate practices of large insurers/PBMs should be scrutinized to determine whether they are restrictive, exclusionary, exploitive, deceptive, or predatory.

The core rebate practices of large insurers/PBMs in administering prescription drug benefits include leveraging their size and market share to extract rebates and discounts paid by drug manufacturers to PBMs via a variety of tools including step therapy requirements, prior authorizations, tiered formularies with higher cost shares for higher tiered drugs, and formulary exclusions.[17] With regard to formulary exclusions, the three largest PBMs, which manage approximately 80 percent of the prescriptions in the United States, continue to be more and more aggressive in utilizing formulary exclusions to extract rebate dollars from drug manufacturers, increasing the number of drugs excluded from standard formularies by 961% in less than ten years, and excluding over eleven hundred unique medications from the standard formularies of at least one PBM in 2022.[18]

---

[13] Federal Trade Commission, "Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act, November 2022, available online at https://www.ftc.gov/system/files/ftc_gov/pdf/p221202sec5enforcementpolicystatement_002.pdf.
[14] Id.
[15] Federal Trade Commission, "Policy Statement of the Federal trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, June 2022, available online at https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf.
[16] Id.
[17] Xcenda, "Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access," September 16, 2020, available online at https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[18] Id.

While large PBMs have proven adept at implementing exclusionary standard formulas, prior authorization requirements, and step therapy requirements as a means of extracting rebates from drug manufacturers, those rebates are not typically reflected in patient drug prices at the counter.[19] Rather, patient cost shares and deductibles are typically calculated based on a drug's manufacturer list prior to the calculation of any drug manufacturer rebates and discounts.[20]

This is born out in the recent MedPAC study, which found that PBMs denied beneficiaries $50 billion in drug manufacturer rebates at the counter in 2021 alone.[21] It also led to absurd results including PBMs paying less for a drug than the Part D beneficiary patient paid out of pocket 8% of the time in 2021. In addition, one PBM charged patients an average cost share for an asthma drug that was 156% more than the PBM was itself paying for the drug.[22]

Adding another layer to large PBM rebate practices, is the practice of mandating brand name drugs when there is a cheaper generic available. An OIG report found that in Medicare Part D, many plans failed to include lower cost authorized generics of certain Hepatitis C drugs and rather required more expensive brands.[23] This practice is not reserved for Hepatitis C drugs.

Indeed, patients whose benefits are administered by large PBMs often are mandated to receive higher cost brand name insulin drugs.[24] By way of example, in 2020 two of the largest PBMs excluded two insulin authorized generics and favored higher list price brand name drugs despite list prices for the authorized generics being as much as half the price of its brand equivalent.[25]

Similarly, a December 2021 report from 46 Brooklyn found PBM brand over generic mandate practices in connection with a Multiple Sclerosis ("MS") drug in Medicare Part D.[26] More specifically, the report highlighted MS patients being required to obtain brand name Tecfidera ($8,276 list price for 1 month supply) despite the fact that there were generic equivalents available at as much as a 96% discount.[27]

---

[19] Frier Levitt - commissioned by the Community Oncology Alliance, "Pharmacy Benefit Manager Expose: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers," February 2022, available online at: https://mycoa.s3.amazonaws.com/1678994901525_COA_FL_PBM_Expose_2-2022.pdf.
[20] Id.
[21] Medicare Payment Advisory Commission, "Medicare and the Health Care Delivery System," Chapter 2, June 2022, available online at: https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v4_SEC.pdf.
[22] Id.
[23] U.S. Department of Health and Human Services Office of Inspector General, "Part D Plan Preference for Higher Cost Hepatitis C Drugs Led to Higher Medicare Beneficiary Spending," August 2022, available online at https://oig.hhs.gov/oei/reports/OEI-BL-21-00200.pdf.
[24] Xcenda, "Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access," September 16, 2020, available online at https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[25] Id.
[26] 46 Brooklyn (2021).Wreck-fidera: How Medicare Part D has hidden the benefits of generic competition for a blockbuster Multiple Sclerosis treatment. Available online at https://www.46brooklyn.com/research/2021/12/1/Tecfidera.
[27] Id.

As for payers, there can be severe cost implications to brand mandates as well. By way of example, according to the OIG Report on hepatitis C drug rebates:

> Medicare paid $155 million more in catastrophic coverage reinsurance payments for higher-cost hepatitis C drugs—spending that could have been reduced if more beneficiaries had used lower-cost options.[28]

To summarize, large insurers/PBMs are using their market power and restrictive formulary practices to drive drug manufacturer rebate revenue, deprive beneficiaries of the benefit of drug manufacturer rebates/discounts at the pharmacy counter, drive beneficiaries to purchase more expensive brand name drugs, and in many cases charging beneficiaries cost shares that exceed the net price of the drugs after rebates. It is APCI's belief that these practices go beyond competition on the merits and warrant scrutiny in that regard to determine whether they are, amongst other things, restrictive, exclusionary, exploitive, deceptive, or predatory.

Rebate practices of large insurers/PBMs should be scrutinized to identify their negative effects on competitive conditions.

Large insurer/PBM rebate practices can result in reduced choice of and access to certain drugs as well as higher drug prices when beneficiaries do not receive the benefit of drug manufacturer discounts at the pharmacy counter or when beneficiaries are forced to use brand name drugs when there are cheaper generics available.

With regard to higher prescription prices, beyond the obvious impact on the pocketbook of beneficiaries, the implications are far reaching and severe. At its most basic level, higher cost prescription medications can result in a beneficiary foregoing medication treatment that she or he simply cannot afford.[29] So that when a beneficiary's drug is excluded from a plan's formulary and therefore not covered or when a prescription drug price for a beneficiary with a cost share or deductible is high because it is based on a drug's list price rather than the net price after drug manufacturer rebates and/or pharmacy discounts, a beneficiary may simply do without the drug.[30]

In the FTC's policy statement regarding rebates, it acknowledged that "the increased cost of insulin has caused many patients to ration it, causing suffering, severe illness, and death.[31]"

---

[28] U.S. Department of Health and Human Services Office of Inspector General, "Part D Plan Preference for Higher Cost Hepatitis C Drugs Led to Higher Medicare Beneficiary Spending," August 2022, available online at https://oig.hhs.gov/oei/reports/OEI-BL-21-00200.pdf.
[29] Matt Phillion, "The Impact of Cost on Medication Adherence," Patient Safety & Quality Healthcare, May 2022, available online at https://www.psqh.com/analysis/the-impact-of-cost-on-medication-adherence/#:~:text=According%20to%20a%202020%20report%20by%20the%20IQVIA,60%25%20when%20the%20cost%20is%20more%20than%20%24500.
[30] Id; see also Xcenda, "Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access," September 16, 2020, available online at https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[31] U.S. Federal Trade commission, "Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, June 2022, available online at: https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%2

Short of such severe consequences, exclusionary formularies and higher drug prices can result in lower adherence, non-adherence, as well as delays in treatment, and poorer outcomes.[32]

It is well documented that increasing patient cost shares for medication leads to decline in medication adherence and poorer patient health outcomes.[33]

Additionally, these brand mandates and other formulary practices can also delay care, and tax pharmacists and prescribers who often have to go through arduous prior authorization processes.[34] It can also raise costs for pharmacists and other dispensers who may be forced to purchase more expensive brand name drugs for which they are sometimes negatively reimbursed.

Raising prices for beneficiaries at the pharmacy counter, limiting choice and restricting access to medication, lowering patient adherence, and harming patient outcomes are all negative effects of large insurer/PBM rebate practices and they warrant scrutiny by the DOJ and the FTC under Section 5 of FTC Act in connection with any proposed acquisitions.

Optum's acquisition of Amedisys.

UHG is one the largest insurers in the nation, is one of the two largest plan sponsors in Part D, owns one of the largest PBMs in the nation via Optum, and is also one of the largest employers of physicians in the nation.[35]

UHG/Optum is aggressively seeking to grow in the home health care space, acquiring LHC Group which operates in-home health and hospice care from over 960 locations in 37 states for

---

0Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf.

[32] Xcenda, "Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access," September 16, 2020, available online at https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf; see also Matt Phillion, The Impact of Cost on Medication Adherence, Patient Safety & Quality Healthcare, May 2022, available online at: https://www.psqh.com/analysis/the-impact-of-cost-on-medication-adherence/#:~:text=According%20to%20a%202020%20report%20by%20the%20IQVIA,60%25%20when%20the%20cost%20is%20more%20than%20%24500; Medicare Payment Advisory Commission, "Medicare and the Health Care Delivery System," Chapter 2, June 2022, available online at: https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v4_SEC.pdf.

[33] Id; see also Eaddy et al. How Patient Cost-Sharing trends Affect Adherence and Outcomes: A literature review PT. 2012 Jan; 37(1):45-55. Available online at https://pubmed.ncbi.nlm.nih.gov/22346336/.

[34] Xcenda, "Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access," September 16, 2020, available online at https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.

[35] Jakob Emerson, "150 things to know about the 'Big 6' health insurers," Becker's Healthcare, September 2023, available online at https://www.beckerspayer.com/payer/150-things-to-know-about-the-big-6-health-insurers.html; Jakob Emerson, "Meet America's largest employer of physicians: United Health Group," Becker's Healthcare, February 2023, available online at: https://www.beckerspayer.com/payer/meet-americas-largest-employer-of-physicians-unitedhealth-group.html;

$5.4 billion.[36] Optum now seeks to acquire Amedisys, one of the largest providers of home health and hospice care in the nation with 522 care centers in 37 states for $3.3 billion.[37]

While APCI believes analysis under the DOJ and FTC's draft merger guidelines is appropriate, it also believes analysis under Section 5 of the FTC Act for unfair methods of competition is appropriate and necessary. This analysis should include whether Optum's integration into the home health care space is likely to further existing unfair methods of competition or ripen in violations of antitrust laws; and whether its acquisition of Amedisys, combined with its acquisition of LHC Group as well as other acquisitions over the years will tend to bring about the harms that antitrust laws were designed to prevent.

Finally, APCI believes that scrutiny of whether UHG/Optum's practices with regard to rebates, drug pricing, and patient steering run afoul of Section 5 of the FTC Act constituting unfair methods of competition and, if so, whether its acquisition of Amedisys with enable UHG/Optum to further leverage those practices to the detriment of patients.

APCI believes attempts by large insurers/PBMs to vertically integrate with prescriber entities are particularly insidious as they represent an opportunity for insurers/PBMs to control not only drug prices, rebates, formularies, insurance premiums, and networks, but also potentially what drugs are prescribed by physicians and other prescribers. Large insurers/PBMs have already shown a willingness to leverage vertical integration in manner that raises costs for seniors, a group that will be very much affected by consolidation in the home healthcare space.

Conclusion

In light of these concerns, APCI stands in opposition to UHG/Optum's proposed acquisition of Amedisys. Additionally, prior to any approval by the DOJ, APCI respectfully requests further scrutiny of current UHG and Optum practices and the prospective acquisition under Section 5 of the FTC Act for unfair methods of competition.

Should you have any questions, or if you would like to discuss the above issues in more detail, please do not hesitate to contact us. Thank you for the opportunity to comment and for your diligent work thus far on this important matter.

Sincerely,

S/ Greg Reybold

Greg Reybold
Director of Healthcare Policy & General Counsel
gregr@apcinet.com
5601 Shirley Park Drive
Bessemer, Alabama 35022

---

[36] Patsy Newitt, "Optum's $8B+ year of deals: 6 acquisitions to know, Beckers Healthcare, December 2022, available online at: https://www.beckersasc.com/asc-transactions-and-valuation-issues/optums-8b-year-of-deals-6-acquisitions-to-know.html.

[37] Amedisys, Inc. Schedule 14A , August 2023, available online at https://d18rn0p25nwr6d.cloudfront.net/CIK-0000896262/92594108-ba75-4d82-894f-2a414eedc843.html.