

Nos. 21-3128, 21-3405

In the
United States Court of Appeals
for the **Seventh Circuit**

ELI LILLY AND COMPANY and LILLY USA, LLC,
Plaintiffs-Appellants-Cross-Appellees,

v.

XAVIER BECERRA, DANIEL J. BARRY, UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, DIANA ESPINOSA, AND HEALTH
RESOURCES AND SERVICES ADMINISTRATION
Defendants-Appellees-Cross-Appellants.

On Appeal from the United States District Court for the Southern District of Indiana,
Indianapolis Division Case No. 1:21-cv-00081-SEB-MJD Honorable Sarah Evans Barker

BRIEF OF THE COMMUNITY ONCOLOGY ALLIANCE, INC. AS *AMICUS CURIAE*
IN SUPPORT OF PLAINTIFFS-APPELLANTS/CROSS-APPELLEES ELI LILLY AND
COMPANY AND LILY USA, LLC

FRIER & LEVITT, LLC

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Dated: June 1, 2022

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3405

Short Caption: Eli Lilly and Company and Lilly USA, LLC v. Xavier Becerra, et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

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- ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:
N/A
- (4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:
N/A
- (5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:
N/A

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N/A

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Attorney's Printed Name: Steven L. Bennet, Esq.

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TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENTS	i
TABLE OF AUTHORITIES	iv
STATEMENT OF IDENTITY AND INTEREST OF THE <i>AMICUS</i>	1
STATEMENT OF THE ISSUE ON APPEAL	2
INTRODUCTION AND SUMMARY OF ARGUMENT.....	2
FACTUAL SUMMARY	3
A. Community Oncology Practices.....	3
B. 340B was Created to Benefit America’s Most Vulnerable Patients and the CEs that Serve Them.....	4
C. The 340B Pharmacy Benefits Landscape	5
D. The Exponential Growth of Contract Pharmacies	8
ARGUMENTS	11
I. The Lack of Regulation Regarding the Exponential Growth of CPs Has Allowed PBMs to Profit Off of 340B.....	11
A. PBM-Owned or Affiliated Pharmacies Comprise a Disproportionate Share of 340B CPs.....	11
B. PBM Owned or Affiliated CPs Siphon Substantial Amounts of the 340B Financial Benefits Away from Covered Entities and the Patients They Serve.....	13
i. PBM Owned or Affiliated CPs Are Estimated to Retain at Least \$2.58 Billion of 340B Drug Discounts in 2022.....	13
ii. PBMs and CPs Have Indicated that Reductions to Their 340B CP Footprint Would Significantly and Materially Affect Overall Profitability	14
C. PBMs Use Their Market Leverage to Optimize 340B Profits	15
i. PBMs Exclude CE-Owned CPs from Their Networks, Including Specialty Networks, While Simultaneously “Offering” to Serve as the CE’s CPs.....	15
ii. PBMs Mandate CEs Use a PBM Owned or Affiliated TPA that Retains a Percentage of 340B Discounts.....	15
iii. PBMs Use 340B-Specific Pricing to Further Capture 340B Profits.....	16

II.	The Profit Opportunities Presented by 340B and 340B CPs Have Incentivized PBMs to Drive Out Non-Affiliated Pharmacies to the Detriment of Patients	17
A.	PBMs Engage in Exclusionary Tactics Against Independent Pharmacy Providers to Drive Business to PBM Owned CPs	17
B.	PBMs Engage in Patient Slamming and Prescription Trolling on an Individual Claims Level to Obtain 340B Prescriptions	18
C.	Mandatory “White Bagging” to Pull Prescriptions Out of the Medical Benefits Channel and Into the Pharmacy Benefits Channel, Allowing PBM CPs to Optimize 340B Profits	19
III.	CONCLUSION	22
	CERTIFICATE OF COMPLIANCE	24
	CERTIFICATE OF SERVICE	25

TABLE OF AUTHORITIES

CASES

<i>RxStrategies, Inc. v. CVS Pharmacy, Inc.</i> , 390 F. Supp.3d 1341 (M.D.Fl. 2019)	16
---	----

STATUTES

42 U.S.C. § 256b.....	4, 6
-----------------------	------

REGULATIONS

75 Fed. Reg. 10272 (Mar. 5, 2010).....	5, 15
HRSA, <i>Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services</i> , 61 Fed. Reg. 43,551 (Aug. 23, 1996).....	5

RULES

Fed. R. App. P. 29(a)(2)	1
--------------------------------	---

OTHER AUTHORITIES

AIR340B, <i>The Impact and Growth in 340B Contract Pharmacy Arrangements – Six Years Later</i> , https://340breport.com/wp-content/uploads/2020/12/AIR340B-Report-on-the-Impact-of-Growth-in-340B-Contract-Pharmacy-Arrangements.pdf	8, 9, 11, 12
American Hospital Association, <i>Health Insurer Specialty Pharmacy Policies Threaten Patient Quality of Care</i> , (Mar. 2021), https://www.aha.org/system/files/media/file/2021/03/AOMarch8white-bagging-0221.pdf	21, 22
Maia Anderson, Becker’s Hospital Review, <i>Top 15 specialty pharmacies by revenue</i> , (April 28, 2020), https://www.beckershospitalreview.com/pharmacy/top-15-specialty-pharmacies-by-revenue.html	10
BRG, <i>340B Program at a Glance</i> , https://media.thinkbrg.com/wp-content/uploads/2021/12/09062840/340B_Forecast-Report-Infographic_2021.pdf	8, 14
Community Oncology Alliance, <i>The Real-Life Patient Impact of PBMs: Volume I</i> , (April 1, 2017), https://communityoncology.org/study/the-real-life-patient-impact-of-pbms-volume-i/	19
CVSHealth, <i>A New Path to Better Health</i> , https://cvshealth.com/aetna	7
CVSHealth, <i>Retail Pharmacy</i> , https://www.cvshealth.com/about/our-offerings/retail-pharmacy	7
CVSHealth, <i>Specialty Pharmacy</i> , https://cvshealth.com/about/our-offerings/cvs-specialty	7

Drug Topics, <i>Physician in-office dispensing of Rx drugs</i> (2014), https://www.drugtopics.com/hse-business-management/physician-office-dispensing-rx-drugs	3
Express Scripts, express-scripts.com	7
Express Scripts, Specialty Pharmacies: FAQs, express-scripts.com	7
Adam Fein, <i>Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs</i> , https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html	12
Adam Fein, Drug Channels, <i>Exclusive: The 340B Program Soared to \$38 Billion in 2020 – Up 27% vs 2019</i> , https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html	8
Adam Fein, Drug Channels, <i>How Hospitals and PBM Profit—and Patients Lose—From 340B Contract Pharmacies</i> , (July 23, 2022), https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html	17
Adam Fein, Drug Channels, <i>PBM-Owned Specialty Pharmacies Expand Their Role In-and Profits From-the 340B Program</i> , https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html	10, 13
Adam Fein, Drug Channels, <i>Specialty Pharmacy’s Explosive 340B Growth</i> , https://www.drugchannels.net/2021/07/specialty-pharmacys-explosive-340b.html	10, 12
Adam Fein, Drug Channels, <i>The Top 15 Specialty Pharmacies of 2018: PBMs Keep Winning</i> , (Apr. 9, 2019), https://www.drugchannels.net/2019/04/the-top-15-specialty-pharmacies-of-2018.html	17
Adam Fein, Drug Channels, <i>The Top PBMs of 2021: The Big Get Event Bigger</i> , (Apr. 5, 2022), https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html	7
Adam Fein, Drug Channels, <i>Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?</i> , https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html	8, 9
Adam Fein, Drug Channels, <i>White Bagging Update: PBMs’ Specialty Pharmacies Keep Gaining on Buy-and-Bill Oncology Channels</i> , https://www.drugchannels.net/2021/10/white-bagging-update-pbms-specialty.html	21
Adam Fein & Doug Long, <i>The Specialty Pharmacy Industry Update and Outlook</i> , May 3, 2022, https://drugch.nl/asembia22	12
Frier Levitt, <i>Emerging Trends in Payor-Mandated White Bagging</i> , (Jan. 6, 2021), https://www.frierlevitt.com/articles-publications/emerging-trends-in-payor-mandated-white-bagging/#:~:text=White%20Bagging,patient%20in%20the%20clinical%20setting	20
Frier Levitt, <i>Pharmacy Benefit Managers’ Attack on Physician Dispensing and Impact on Patient Care</i> , Community Oncology Alliance (Aug. 7, 2016), https://directscripts.com/wp-content/uploads/2016/09/COA-Frier-Levitt-PBM-Attack-Physician-Dispensing.pdf	4

Frier Levitt, <i>Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers</i> , (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf	17, 18, 19, 22
GAO, GAO-18-840, <i>Drug Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement</i> , (June 2018), https://bit.ly/3vKXcxg	11
GAO, GAO-20-108, <i>340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements</i> (Dec. 2019), https://bit.ly/3tCct4	10
H.R. 4390, Protect 340B Act.....	15
H.R. Rep. No. 102-384, pt. 2 (Sept, 22, 1992).....	4
https://www.linkedin.com/jobs/search/?currentJobId=3062077478&keywords=optumrx%20director%20business%20development	14
Bruce Japsen, <i>Cigna-Express Scripts Merger's A Done Deal</i> , Forbes, Dec. 19, 2018, https://www.forbes.com/sites/brucejapsen/2018/12/19/cigna-express-scripts-merger-a-done-deal-by-thursday/#261d98a55688).....	7
Deborah Abrams Kalan, Managed Healthcare Executive, <i>How 'White Bagging' Affects Patients, Physicians and 340B Funding</i> , Vol. 1, Issue 2, (Feb. 18, 2021)	21, 22
Rhiannon Klein, cv340b, <i>Express Scripts Issues 340B Claims Identification Requirements</i> , (Mar. 11, 2021, https://www.cv340b.org/express-scripts-issues-340b-claims-identification-requirements/	16
Legacy Health Endowment, <i>PBMs and the 340B Program</i> , https://340breport.com/wp-content/uploads/2021/06/PBMs-and-340B-White-Paper-June-29-2021.pdf	17
Bruce Levinson, <i>Measuring the Effectiveness of the 340B Program</i> , https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3284078	9
Jeffrey Lewis et al, <i>PBMs and the 340B Program</i> , https://340breport.com/wp-content/uploads/2021/06/PBMs-and-340B-White-Paper-June-29-2021.pdf	15, 18
Rory Martin, IQVIA, <i>340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect</i>	8
Marwood Group, <i>Pharmacy White Bagging: Growth And Countermeasures</i> , (Nov. 24, 2021), https://www.marwoodgroup.com/wp-content/uploads/2021/11/White-Bagging-Whitepaper-11_24_2021.pdf	20, 21
Neal Masia, PhD, AIR340B, <i>340B Drug Pricing Program: Analysis Reveals \$40 Billion in Profits in 2019</i> , https://340breform.org/wp-content/uploads/2021/05/AIR340B-Neal-Masia-Report.pdf	10

Karen Mulligan, PhD, University of Southern California, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments* (Oct. 14, 2021), https://healthpolicy.usc.edu/wp-content/uploads/2021/10/The_340B_Drug_Pricing_Program.pdf..... 11, 12

Nephron, *Decade-Long 34B Tailwind Gives Way to Significant Pharmacy Headwind in 1Q 2022*..... 9, 12, 13, 14, 16

Sayeh Nikpay et al., *Association of 340B Contract Pharmacy Growth With County-Level Characteristics*, American Journal of Managed Care, <https://www.ajmc.com/view/association-of-340b-contract-pharmacy-growth-with-county-level-characteristics>..... 9

PhRMA, PR Newswire, *New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients*, <https://www.prnewswire.com/news-releases/new-analysis-shows-contract-pharmacies-financially-gain-from-340b-program-with-no-clear-benefit-to-patients-301148590.html> 13

OIG Report, *Contract Pharmacy Arrangements in the 340B Program*, (Feb. 4, 2014), <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>..... 7

Optum, Specialty Pharmacy, <https://specialty.optumrx.com/> 7

Ed Silverman, STAT, *Two dozen states side with HHS in its raucous dispute with pharma over a drug discount program*, (May 16, 2022), https://www.statnews.com/pharmalot/2022/05/16/hhs-340b-hospitals-prescription-drugs/?utm_campaign=pharmalittle&utm_medium=email&hsmi=21%E2%80%A6 9

SilverScript, About SilverScript Insurance Company, <https://www.silverscript.com/about-us>..... 7

Brandy Snyder et al, HOPA News, *An Overview of White Bagging: The Effect on Systems and Potential Strategies*, Hematology/Oncology Pharmacy Association, Vol. 18, Issue 3, <https://www.hoparx.org/hopa-news/volume-18-issue-3-2021/all-pages>..... 21

UnitedHealth Group, Optum Products & Services, <https://www.unitedhealthgroup.com/businesses/optum.html>..... 7

US GAO, *DRUG DISCOUNT PROGRAM: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, June 2018..... 11

Aaron Vandervelde et al, BRG, *For-Profit Pharmacy Participation in 340B Program* (Oct. 2020), <https://bit.ly/36X0eUG> 8, 9, 11, 13

Walgreens, *Walgreens and Prime Therapeutics Complete Formation of AllianceRx Walgreens Prime*, <https://news.walgreens.com/press-center/news/walgreens-and-prime-therapeutics-complete-formation-of-alliancerx-walgreens-prime-a-combined-central-specialty-pharmacy-and-mail-services-company.htm> 7

STATEMENT OF IDENTITY AND INTEREST OF THE *AMICUS*¹

Pursuant to Federal Rule of Appellate Procedure 29(a)(2) and Seventh Circuit Rule 29, *amicus* Community Oncology Alliance, Inc. (“COA”) submits this brief in support of Plaintiffs-Appellants/ Cross-Appellees Eli Lilly Company and Lilly USA, LLC. COA is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. For close to twenty years, COA has built a national grassroots network of community oncology practices to enhance the effectiveness and efficiency of cancer care. COA has a compelling interest in ensuring that all patients with cancer have access to local, affordable health care.

COA absolutely supports the 340B Drug Pricing Program (“340B”), especially in ensuring that Americans in need receive financial help with their cancer drugs and other critical therapies. However, COA is extremely concerned that the out-of-control growth of 340B contract pharmacies (“CPs”), particularly mail order and specialty pharmacies owned or affiliated with pharmacy benefit managers (“PBMs”), has increasingly diverted 340B discounts into the coffers of Fortune 500 companies as opposed to helping patients in need. Congress vested non-profit safety-net providers with 340B drug discounts; they never contemplated that 340B would become a profit center for mega for-profit corporations or even large “nonprofit” health systems. As such, COA is compelled to submit this *amicus* brief to inform the Court how 340B has mutated from a well-intentioned community benefit to a virtual ATM cash machine due to the exponential growth in CPs, especially those owned by PBMs or affiliated under the same corporation.

¹ Pursuant to Fed. R. App. P. 29(a)(2), all parties have consented to the filing of this *amicus curiae* brief. Under Fed. R. App. P. 29(a)(E)(4), COA states that no party or its counsel authored this brief in whole or in part, or contributed money intended to fund the filing of this brief.

STATEMENT OF THE ISSUE ON APPEAL

The issue before the Court is whether Section 340B requires pharmaceutical manufacturers to deliver discounted drugs to contract pharmacies without limitation. *Amicus* COA supports the position of Plaintiffs-Appellants/Cross-Appellees Eli Lilly Company and Lilly USA, LLC in that the unconstrained and unregulated use of contract pharmacies by covered entities, particularly contract pharmacies affiliated with pharmacy benefit managers, has warped the 340B Drug Pricing Program into a profit center for large for-profit enterprises. Eli Lilly's Contract Pharmacy Initiative promotes the original intention of Congress, a drug pricing program that benefits America's most vulnerable patients.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress established 340B in 1992 with the goal of making health care affordable and accessible at specified safety-net providers that serve certain uninsured, low-income, or otherwise vulnerable patients. The mutation of 340B, especially CP arrangements with 340B covered entities, is such that the largest PBMs have found an extremely profitable source of drug discounts. Instead of promoting accessible and affordable health care for the nation's most vulnerable patients, 340B has been distorted into benefitting some of America's largest public companies.

The number of vertically integrated CPs participating in 340B, and the number of arrangements these for-profit pharmacies have with 340B covered entities ("CEs"), has grown exponentially since the 2010 guidance issued by the Health Resources and Services Administration ("HRSA"), which permitted CEs to enter into virtually unlimited and unconstrained arrangements with CPs.

Over the last two decades, extreme consolidation and vertically integrated business models—combined with flawed government guidance and lax oversight—have allowed the largest insurers and PBMs, through their owned or affiliated CPs, to increasingly dominate (and reap substantial profits

from) 340B. The profits PBMs generate through 340B are retained; these savings are not passed on to patients. Making matters worse, the enormous profits these for-profit entities retain through 340B incentivizes them to monopolize the broader pharmacy market, driving independent pharmacies out of business.

Today's 340B has diverged significantly from the one Congress designed, with the growth of for-profit CPs a primary driver. The expansive use of 340B CPs has occurred without sufficient oversight or regulation and, more importantly, has actually detracted from the 340B safety-net mission. Put simply, 340B has become a profit center for large for-profit corporations, to the detriment of patients in need.

FACTUAL SUMMARY

A. Community Oncology Practices

Oncology deals with the prevention, diagnosis, and treatment of cancer. Modern-day cancer care requires that oncologists have the ability not only to administer intravenous chemotherapy (a medical benefit), but also to dispense oral cancer medications (a pharmacy benefit) directly to patients at the site-of-care in a coordinated and integrated manner as part of a cancer patient's overall treatment plan. Oncologists, specifically those in independent oncology practices (as opposed to hospitals), dispense oral cancer drugs to patients under one of two practice models based on state board of pharmacy regulations and restrictions. One type of physician practice is known as a "dispensing physician practice," which is a physician practice that dispenses medication pursuant to the physician's plenary medical license as permitted by state and federal law.² These types of practices do not hold a pharmacy license. The other type is a practice known as "physician-owned pharmacy," which include practices that dispense all types of drugs, including oral cancer drugs, through a licensed retail

² Drug Topics, *Physician in-office dispensing of Rx drugs*, (2014), <https://www.drugtopics.com/hse-business-management/physician-office-dispensing-rx-drugs>.

pharmacy in the practice.³ In this instance, the licensed retail pharmacy may be the same entity as the medical practice. This model is similar to a dispensing physician practice with the exception that the physician-owned pharmacy is independently licensed as a pharmacy by the applicable state board of pharmacy and follows all requirements necessary to operate as a licensed pharmacy.

As used throughout this Brief, the term “community oncology practices” refers broadly to both dispensing physician practices and to physician-owned pharmacies. Community oncology practices provide a majority of cancer treatment in the United States, with the largest practice consisting of over 500 oncologists. Due to the increased availability and use of oral cancer drugs, most practices now dispense these drugs under one of the models described herein.

B. 340B was Created to Benefit America’s Most Vulnerable Patients and the CEs that Serve Them

Congress designed 340B to assist certain healthcare facilities serving poor, uninsured or otherwise vulnerable populations. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602 (codified as amended at 42 U.S.C. § 256b). Under 340B, drug manufacturers—in exchange for Medicaid and Medicare Part B drug coverage—are required to charge CEs no more than a significantly discounted “ceiling price” on certain outpatient prescription drugs purchased by the CEs for their patients. 42 U.S.C. § 256b(a)(1),(4). 340B’s purpose is “to enable covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384, pt. 2 at 12 (1992). It is fundamental to 340B that CEs are credited for their ability to “provide direct clinical care to large numbers of uninsured Americans” regardless of the patient’s ability to pay. *See* H.R. Rep. No. 102-384, pt. 2, at 12 (Sept. 22, 1992). Indeed, HRSA, the agency charged with administering 340B, has opined that 340B is designed so that CEs would

³ Frier Levitt, *Pharmacy Benefit Managers’ Attack on Physician Dispensing and Impact on Patient Care*, Community Oncology Alliance, 17 (Aug. 7, 2016), <https://directscripts.com/wp-content/uploads/2016/09/COA-Frier-Levitt-PBM-Attack-Physician-Dispensing.pdf>.

“pass all or significant part of the discount to their patients.” HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,551 (Aug. 23, 1996). Thus, the clear purpose of 340B is that uninsured, poor, and otherwise vulnerable patients would benefit by receiving discounted drugs or charity care.

Under 340B, CEs can acquire drugs from manufacturers at extreme discounts from what is normally available. In turn, CEs are (in theory) able to “pass on” those savings to their patients through lower costs for medications, or, as contemplated by 340B itself, the CEs can seek reimbursement for 340B drugs in the normal course and use those greater profit margins to subsidize other unfunded areas of their operations. Because certain CEs, such as small community health centers, may not have in-house pharmacies, HRSA issued sub-regulatory guidance in 1996 permitting CEs to “contract” with outside pharmacies (i.e., CPs). *See* 61 F.R. at 43,549.

Initially, HRSA restricted CEs to contracting with only a single CP. *Id.* at 43,551. In 2010, however, HRSA dramatically shifted the course of 340B’s use of CPs by permitting CEs to maintain an unlimited number of CP relationships. *See* 75 F.R. 10,272-01 (Mar. 5, 2010). In the wake of this HRSA guidance, for-profit pharmacies, especially those owned or affiliated with PBMs, have seized on the opportunity to capitalize on substantial 340B drug discounts. In effect, the 2010 guidance provided an open door for sophisticated for-profit pharmacies (and their parent and affiliated companies) to realize substantial drug discounts through a federal drug pricing program designed to aid non-profit CEs caring for vulnerable patients.

C. The 340B Pharmacy Benefits Landscape

Any examination of 340B’s use of CPs must be grounded in a sound understanding of the relationships between the relevant stakeholders. On the front line of care for 340B patients are the providers: CEs and CPs. CEs include a select number of hospitals, clinics, and health centers that serve a disproportionate share of poor patients in urban and rural areas. 340B specifically limits the

entities eligible to participate as CEs. *See* 42 U.S.C. § 256b(a)(4). Conversely, 340B provides little guidance on the use and eligibility of CPs. 340B CPs include retail, specialty, and mail-order pharmacies.

There are differences between retail, mail order, specialty and community oncology pharmacies. Patients typically use a physical retail pharmacy for short-term illness and more stable long-term conditions, such as hypertension. Mail order pharmacies typically mail longer day supplies of medications, such as a 90-day supply, directly to patients. Specialty pharmacies (both with physical retail and mail order locations) and community oncology practices dispense and administer drugs typically requiring special handling and storage requirements.

PBMs are fiscal intermediaries that administer and manage drug benefits on behalf of health insurance plans. But, as discussed below, the distinction between PBMs and health plans have become increasingly blurred. PBMs are primarily responsible for processing and paying prescription drug claims submitted by participating providers on behalf of covered beneficiaries. The largest PBMs unilaterally dictate the pharmacy provider's reimbursement for dispensing or administering the drug and the health plan will, in turn, reimburse the PBM for the amount paid to the provider. PBMs also provide a host of related services associated with the administration of pharmacy benefits including formulary design, formulary management, negotiation of rebates, and controlling network access of providers.

The largest PBMs are owned or affiliated with the nation's largest health insurance companies. These PBMs own retail, mail-order and/or specialty pharmacies or are affiliated with them. As a result, a small number of huge, vertically integrated, companies wield near limitless power and influence in the prescription drug market and the adjudication of 340B eligible claims. Today, three PBMs control nearly 80 percent of the prescription drug market: CVS Caremark ("Caremark"), Express Scripts, Inc.

(“ESI”) and OptumRx.⁴ Each of these PBMs also share common ownership with a major insurer and specialty pharmacy: Caremark is owned by CVS Health, which also owns the Aetna⁵ and SilverScript⁶ health insurers, and CVS retail, mail order and specialty pharmacies.⁷ Health insurer Cigna owns ESI⁸, which operates its own mail-order pharmacy⁹ and Accredo Health, Inc. which operates Accredo Specialty Pharmacy.¹⁰ Insurance company UnitedHealth Group owns OptumRx,¹¹ which owns OptumRx Specialty Pharmacy.¹² Further, Walgreens Boots Alliance (“Walgreens”) is vertically integrated with the PBM Prime Therapeutics, which in turn operates the specialty and mail order pharmacy AllianceRx Walgreens Prime.¹³

The process of determining whether a particular claim is 340B eligible is complex, and responsibility for compliance lies with the CE. Generally, CEs hire third-party administrators (“TPAs”) to retroactively determine 340B eligibility.¹⁴ TPAs provide claims processing and management services and retroactively determine which claims are 340B eligible. CEs rely on TPAs

⁴ Adam Fein, Drug Channels, *The Top PBMs of 2021: The Big Get Event Bigger*, (Apr. 5, 2022, <https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html>)

⁵ CVSHealth, A New Path to Better Health, <https://cvshealth.com/aetna>, (last visited May 25, 2022).

⁶ SilverScript, About SilverScript Insurance Company, <https://www.silverscript.com/about-us>, (last visited May 25, 2022).

⁷ CVSHealth, Retail Pharmacy, <https://www.cvshealth.com/about/our-offerings/retail-pharmacy>, CVSHealth, Specialty Pharmacy, <https://cvshealth.com/about/our-offerings/cvs-specialty> (last visited May 25, 2022).

⁸ Bruce Japsen, *Cigna-Express Scripts Merger's A Done Deal*, Forbes, Dec. 19, 2018, <https://www.forbes.com/sites/brucejapsen/2018/12/19/cigna-express-scripts-merger-a-done-deal-by-thursday/#261d98a55688>).

⁹ Express Scripts, [express-scripts.com](https://www.express-scripts.com) (“We manage your pharmacy plan, and we’re a pharmacy.”).

¹⁰ Express Scripts, Specialty Pharmacies: FAQs, [express-scripts.com](https://www.express-scripts.com).

¹¹ UnitedHealth Group, Optum Products & Services, <https://www.unitedhealthgroup.com/businesses/optum.html>.

¹² Optum, Specialty Pharmacy, <https://specialty.optumrx.com/>, (last visited May 25, 2022).

¹³ Walgreens, Walgreens and Prime Therapeutics Complete Formation of AllianceRx Walgreens Prime, <https://news.walgreens.com/press-center/news/walgreens-and-prime-therapeutics-complete-formation-of-alliancerx-walgreens-prime-a-combined-central-specialty-pharmacy-and-mail-services-company.htm>, (last visited May 25, 2022).

¹⁴ OIG Report, *Contract Pharmacy Arrangements in the 340B Program*, (Feb. 4, 2014), at 5, <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>

for 340B compliance and to maximize their received benefits. The largest TPAs are also vertically integrated with the largest PBMs: CVS Health owns the TPA Wellpartner.¹⁵ Cigna owns the TPA Verity Solutions.¹⁶ Walgreens owns the TPAs 340B Complete and Shields Health Solutions.¹⁷

D. The Exponential Growth of Contract Pharmacies

Approximately 14% of all pharmaceutical sales in the United States, or \$93.6 billion, are accounted for under 340B.¹⁸ 340B has grown five times faster than the overall drug market,¹⁹ with 340B expenditures quadrupling since 2014.²⁰ In terms of magnitude, it is the second largest federal drug program, behind only Medicare Part D. By 2026, 340B is expected to exceed the size of both Medicaid and Medicare.²¹ The primary component driving 340B's tremendous expansion is not a rise in the number of 340B eligible patients or increased need for charity care, but rather the expansive use of CPs, particularly CPs owned or affiliated with PBMs.

As a result of HRSA's 2010 guidance, both the number of CPs participating in 340B and the number of arrangements these CPs maintain with CEs grew exponentially. In January 2010, less than 1,300 unique locations participated as CPs.²² As of July 2020, there are approximately 30,000 unique CPs participating in 340B—half of the entire U.S. pharmacy industry—with more than 112,000

¹⁵ Aaron Vandervelde et al (“Vandervelde”), BRG, *For-Profit Pharmacy Participation in 340B Program*, at 4 (Oct. 2020), <https://bit.ly/36X0eUG>; see also AIR340B (“AIR340B”), *The Impact and Growth in 340B Contract Pharmacy Arrangements – Six Years Later*, at 8, <https://340breport.com/wp-content/uploads/2020/12/AIR340B-Report-on-the-Impact-of-Growth-in-340B-Contract-Pharmacy-Arrangements.pdf>

¹⁶ Vandervelde, at 4; see also AIR340B, at 8.

¹⁷ *Id.*

¹⁸ Rory Martin, IQVIA, *340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect*, at 2.

¹⁹ *Id.*

²⁰ Adam Fein, Drug Channels, *Exclusive: The 340B Program Soared to \$38 Billion in 2020 – Up 27% vs 2019*, <https://www.drugchannels.net/2021/06/exclusive-340b-program-soared-to-38.html>

²¹ BRG, *340B Program at a Glance*, https://media.thinkbrg.com/wp-content/uploads/2021/12/09062840/340B_Forecast-Report-Infographic_2021.pdf.

²² Adam Fein, Drug Channels, *Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?*, <https://www.drugchannels.net/2020/07/walgreens-and-cvs-top-28000-pharmacies.html>

contractual relationships with CEs.²³ The number of CP arrangements with CEs grew by 4,228%,²⁴ with each hospital CE utilizing 22 different CPs on average, and federal grantees utilizing 11 different CPs.²⁵ Further, the distance between hospital CEs and their CPs has increased dramatically, from an average of 34 miles in 2010 to 334 miles in 2020.²⁶ In some instances, the CP can be thousands of miles away from the CE.²⁷ Today, 28% of 340B revenue is generated by the use of CPs.²⁸ These 30,000+ CPs share in the 340B discounts from manufacturers; however, the current regulatory landscape imposes no requirement that they use those discounts to help patients.

The exponential growth of CPs and CP arrangements, on its own, would not be an issue if it resulted in increased access and affordability of care to patients of CEs without an in-house pharmacy. But financial help for patients in need is “*negatively correlated*” with growth of 340B CPs.²⁹ The “growth of contracts with 340B hospitals [is] uncorrelated with uninsured rates, poverty rates, or areas of medical underservice.”³⁰ Rather, the vast majority of the CP growth has occurred in for-profit pharmacies that have capitalized on 340B’s enormous drug profits. In 2015, for-profit chain pharmacies alone represented 15% of total participating CPs.³¹ Five years later for-profit chain pharmacies account for over 66% of the total participating CPs.³²

²³ *Id.*

²⁴ Vandervelde, at 4; *see also* AIR340B, at 1.

²⁵ Vandervelde, at 7; *see also* Nephron (“Nephron”), *Decade-Long 34B Tailwind Gives Way to Significant Pharmacy Headwind in 1Q 2022*.

²⁶ Vandervelde, at 4.

²⁷ *Id.*

²⁸ Ed Silverman, STAT, *Two dozen states side with HHS in its raucous dispute with pharma over a drug discount program*, (May 16, 2022), https://www.statnews.com/pharmalot/2022/05/16/hhs-340b-hospitals-prescription-drugs/?utm_campaign=pharmalittle&utm_medium=email&_hsmi=21%E2%80%A6

²⁹ *Id.* (emphasis added); *see also* Bruce Levinson, *Measuring the Effectiveness of the 340B Program*, at 4, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3284078

³⁰ Sayeh Nikpay et al., *Association of 340B Contract Pharmacy Growth With County-Level Characteristics*, *American Journal of Managed Care*, <https://www.ajmc.com/view/association-of-340b-contract-pharmacy-growth-with-county-level-characteristics>

³¹ Vandervelde at 5.

³² *Id.*

In recent years, 340B CP growth has skyrocketed with specialty and mail order pharmacies. Since 2017, 340B purchases flowing through specialty and mail order pharmacies have grown by 56% per year; six times faster than non-340B specialty and mail order pharmacy purchases.³³ Compared to the average annual growth of non-340B mail order purchases (i.e., 9%),³⁴ the recent growth of 340B mail order is over six times greater. The growth in specialty and mail order has been quickest in oncology.³⁵ Oncology’s share of 340B sales has increased from 37.5% in 2015 to 52.4% in 2019, and oncology-generated 340B profits increased from 19.1% to 32.6% of total 340B provider profits over the same period.³⁶ As discussed in more detail below, these dramatic increases are due in large part because of increased participation in 340B by the four largest (and vertically integrated) specialty and mail order pharmacies owned by or affiliated with the top PBMs: Caremark/CVS Specialty, ESI/Accredo, OptumRx/Optum Specialty Pharmacy, and AllianceRx Walgreens Prime/Walgreens.³⁷

The significant growth of 340B CP arrangements, especially PBM specialty and mail order CPs, is simply due to the profit potential of 340B and virtually no CP oversight by HRSA. Typically, CPs are paid a flat fee by the CE for each eligible drug claim per prescription, *plus* many “covered entities also agree[] to pay [contract] pharmacies a percentage of the revenue generated by each [340B] prescription.”³⁸ As a result of these favorable reimbursements, the average profit margin for CPs on

³³ Adam Fein, Drug Channels, *Specialty Pharmacy’s Explosive 340B Growth*, <https://www.drugchannels.net/2021/07/specialty-pharmacys-explosive-340b.html>

³⁴ *Id.*

³⁵ Neal Masia, PhD, AIR340B, *340B Drug Pricing Program: Analysis Reveals \$40 Billion in Profits in 2019*, at 1, <https://340breform.org/wp-content/uploads/2021/05/AIR340B-Neal-Masia-Report.pdf> (noting that “oncology drugs dominate [340B] , accounting for a large and growing share of total program profits”).

³⁶ *Id.*

³⁷ Maia Anderson, Becker’s Hospital Review, *Top 15 specialty pharmacies by revenue*, (April 28, 2020), <https://www.beckershospitalreview.com/pharmacy/top-15-specialty-pharmacies-by-revenue.html>; see also Adam Fein, Drug Channels, *PBM-Owned Specialty Pharmacies Expand Their Role In-and Profits From-the 340B Program*, <https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html>

³⁸ GAO, GAO-20-108, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, at 1 (Dec. 2019), <https://bit.ly/3tCctH4> (finding that percentage-

340B claims for brand name drugs is an astounding 72%, compared with just 22% for non-340B brand name drug claims.³⁹ Put another way, a CP's profit margin is approximately three times greater for 340B brand name claims than for non-340B. This profit sharing between CEs and CPs indicates that CPs owned or associated with PBMs are a primary stakeholder in 340B.

ARGUMENTS

I. The Lack of Regulation Regarding the Exponential Growth of CPs Has Allowed PBMs to Profit Off of 340B

“The enormous growth in 340B contract pharmacy arrangements seems to boil down to a *single factor: outsized profit margins.*”⁴⁰ And HRSA's lack of virtually any oversight on use of CPs by CEs has allowed PBMs to exploit 340B and retain a disproportionate share of these “outsized profit margins.” Ironically, the exponential growth of CPs owned or affiliated with PBMs has shifted the recipients of 340B's substantial drug discounts from patients and CEs to some of the largest and most profitable healthcare companies.

A. PBM-Owned or Affiliated Pharmacies Comprise a Disproportionate Share of 340B CPs

The CPs participating in 340B are primarily not independent pharmacies. Rather, the vast majority of CP arrangements are between CEs and large for-profit pharmacies that are owned by or affiliated with the largest PBMs.⁴¹ 340B has mutated to such an extent that multi-billion-dollar, for-profit, publicly traded corporations dominate the 340B CP market.

based fees can reach up to 20% of revenue generated and that flat fees for brand drugs can be as high as \$1,750 per claim); *see also* US GAO, *DRUG DISCOUNT PROGRAM: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480, June 2018, p. 21.

³⁹ Vandervelde, at 4.

⁴⁰ *Id.* (emphasis added).

⁴¹ Karen Mulligan, PhD, University of Southern California, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, (Oct. 14, 2021) at 4, https://healthpolicy.usc.edu/wp-content/uploads/2021/10/The_340B_Drug_Pricing_Program.pdf (noting that “[l]arge retail pharmacy chains—Walgreens, CVS, Walmart, and Rite Aid are disproportionately represented among contract pharmacies”); *see also* GAO, GAO-18-840, *Drug Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, (June 2018), <https://bit.ly/3vKXcxg>; *see also* AIR340B, *The Impact*

The top five corporations controlling 340B CP relationships—CVS Health, Walgreens, Cigna, UnitedHealth Group and Walmart—now control 73% of all CP relationships.⁴² Each of these entities also operate or are affiliated with a PBM. The three largest PBMs (Caremark, ESI and OptumRx), controlling 80% of the total prescription drug market account for 39% of all CP relationships through their owned or affiliated CPs.⁴³ In 2021, Walgreens and CVS held the greatest 340B CP market share with Walgreens controlling 31% of all retail CPs (up from 28% in 2020) and CVS controlling 19% of all retail CPs (up from 20% in 2020).⁴⁴ More than 80% of Walgreens retail pharmacy locations and two-thirds of CVS locations are CPs.⁴⁵

Also noteworthy, the three largest PBMs—Caremark, ESI and OptumRx—collectively have 142 mail order and specialty pharmacies participating as CPs.⁴⁶ Demonstrating the control CPs owned by PBMs have over the overall 340B CP market, these 142 CPs have a combined 25,000 arrangements with CEs.⁴⁷ Consequently, mail order and specialty pharmacies owned by or affiliated with the three largest PBMs’ account for only 0.5% of all 340B CP locations but 18% of the total 340B CP relationships with CEs.⁴⁸ And their control over these channels continues to rapidly increase. As of 2020, there were 16,293 CP arrangements between CEs and vertically integrated specialty pharmacies,

and Growth in 340B Contract Pharmacy Arrangements – Six Years Later, at 3, <https://340breport.com/wp-> (75% of contract pharmacy arrangements are held by “large for-profit retail chains”).

⁴² Adam Fein & Doug Long, *The Specialty Pharmacy Industry Update and Outlook*, May 3, 2022, <https://drugch.nl/asebia22>

⁴³ *Id.*

⁴⁴ Nephron (“Nephron”), *Decade-Long 34B Tailwind Gives Way to Significant Pharmacy Headwind in 1Q 2022*, at 9-10; *see also* Mulligan, at 4.

⁴⁵ Adam Fein, *Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs*, <https://www.drugchannels.net/2021/06/exclusive-340b-continues-its-unbridled.html>

⁴⁶ Adam Fein, Drug Channels, *Specialty Pharmacy’s Explosive 340B Growth*, <https://www.drugchannels.net/2021/07/specialty-pharmacys-explosive-340b.html>; *see also*,

⁴⁷ *Id.*

⁴⁸ *Id.*

representing a 1,006% growth from 2016.⁴⁹ CVS controls the largest share of specialty CPs, with 30.1% of the market.⁵⁰

B. PBM Owned or Affiliated CPs Siphon Substantial Amounts of the 340B Financial Benefits Away from Covered Entities and the Patients They Serve

A lack of regulation over the growth and use of PBM owned and affiliated CPs has allowed for-profit corporations to exploit 340B and divert the financial benefits intended for patients in need and the CEs that serve them.⁵¹ In other words, the exponential growth of CPs has not translated into increased financial assistance for patients in need, but instead has served to create a new and very lucrative source of profits for large corporations.

i. PBM Owned or Affiliated CPs Are Estimated to Retain at Least \$2.58 Billion of 340B Drug Discounts in 2022

In 2021, Walgreens CPs retained \$994 million of 340B drug discounts, ESI CPs retained \$561 million and OptumRx CPs retained \$281 million.⁵² Collectively, in 2022, Walgreens, Caremark, ESI and OptumRx are conservatively estimated to retain upwards of \$2.58 billion in 340B discounts.⁵³ This is no small matter. If these corporations retain these discounts as profit, which is likely considering the CE supplies 340B drugs to the CP at essentially no cost to the CP, it would equate to between 6.4% to 17.4% of their adjusted operating profit.⁵⁴ However, the lack of transparency surrounding the financial relationships between CEs and CPs adds a degree of uncertainty to these

⁴⁹ Vandervelde, at 4 (Oct. 2020), <https://bit.ly/36X0eUG>; Adam Fein, Drug Channels, *PBM-Owned Specialty Pharmacies Expand Their Role In-and Profits From-the 340B Program*, <https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html>

⁵⁰ Nephron, at 10.

⁵¹ PhRMA, PR Newswire, *New Analysis Shows Contract Pharmacies Financially Gain From 340B Program With No Clear Benefit to Patients*, <https://www.prnewswire.com/news-releases/new-analysis-shows-contract-pharmacies-financially-gain-from-340b-program-with-no-clear-benefit-to-patients-301148590.html> (“It is clear that contract pharmacies have levered market power to drive unprecedented program growth and siphon money out of the program and away from vulnerable patients”).

⁵² Nephron, at 8-12.

⁵³ *Id.*

⁵⁴ *Id.*

retention estimates.⁵⁵ In effect, the largest CPs (PBM owned or affiliated) are using 340B to fund their own for-profit operations, rather than to benefit underserved communities and the CEs that serve them.

ii. PBMs and CPs Have Indicated that Reductions to Their 340B CP Footprint Would Significantly and Materially Affect Overall Profitability

340B has become a significant profit center for for-profit corporations owning PBMs and CPs. The annual reports of CVS Health and Walgreens Boots Alliance confirm that 340B profits are material to their business operations and warn that restrictive CP policies enacted by drug manufacturers, such as Eli Lilly, will negatively impact their bottom lines. *See e.g.*, CVS Health Corporation, Form 10-K FY 2021, p. 22-23 (“[a] reduction in ‘Covered Entities’ participation in contract pharmacy arrangements, as a result of the pending enforcement actions or otherwise, a reduction in the use of [CVS/Caremark’s] administrative services by Covered Entities, or a reduction in drug manufacturers’ participation in the program could materially and adversely affect [CVS/Caremark]”; WBA, Form 10-K FY 2021, p. 22 (“[c]hanges in pharmaceutical manufacturers’ pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B drug pricing program, could also significantly reduce [WBA’s] profitability.”)⁵⁶ Furthermore, OptumRx, which has lagged others in exploiting 340B, is advertising for a Director of 340B Business Opportunities.⁵⁷ Clearly, with the huge increase in CPs, 340B has mutated away from the original intention of Congress, to serve communities and patients in need, to increasing profits for large corporations.

⁵⁵ *See* BRG, *340B Program at a Glance* (estimating that “\$10B in 340B profits [will be] captured by for-profit contract pharmacies in 2022.”), https://media.thinkbrg.com/wp-content/uploads/2021/12/09062840/340B_Forecast-Report-Infographic_2021.pdf.

⁵⁶ Nephron, at 9 (“Walgreens is by far the most exposed to 340B, given long dominance in contract pharmacy, TPA, and tech services to covered entities”).

⁵⁷ <https://www.linkedin.com/jobs/search/?currentJobId=3062077478&keywords=optumrx%20director%20business%20development>

C. PBMs Use Their Market Leverage to Optimize 340B Profits

The top PBMs use their huge market leverage to optimize the enormous profit potential of 340B.

i. PBMs Exclude CE-Owned CPs from Their Networks, Including Specialty Networks, While Simultaneously “Offering” to Serve as the CE’s CPs

Many CEs have now opened their own in-house pharmacies. Naturally, these CEs seek to send their patients to their own in-house pharmacy, rather than a CP that could be hundreds or even thousands of miles away in the case of a mail order pharmacy.

Seeking to retain the 340B discounts it otherwise would have realized through use of their own CPs, PBMs have excluded CE-owned CPs from their networks.⁵⁸ Rather than permit the CE to dispense drugs to 340B eligible patients, PBMs restrict patients to only “in-network” pharmacies, ostensibly that they own or are affiliated with.⁵⁹ Using their enormous market leverage, the top PBMs also make aggressive offers to become CPs for the excluded CE and seek to coerce CEs to send their patients to a PBM owned or affiliated CP, in order to ensure that the PBM CP captures the 340B profits. This scenario could not be more contradictory to the intent and purpose of 340B.

ii. PBMs Mandate CEs Use a PBM Owned or Affiliated TPA that Retains a Percentage of 340B Discounts

Although the use of CPs increases the potential distribution of discounted drugs, it also greatly increases the complexity of identifying which claims are 340B eligible. In order to accurately determine which prescriptions are 340B eligible, such eligibility determinations for many CEs are performed by TPAs that CEs rely on to retroactively reconcile which of their claims are 340B-qualified.⁶⁰

⁵⁸ Jeffrey Lewis et al, *PBMs and the 340B Program*, <https://340breport.com/wp-content/uploads/2021/06/PBMs-and-340B-White-Paper-June-29-2021.pdf>.

⁵⁹ In fact, the House of Representatives has proposed a bill to prohibit PBMs from excluding certain contract pharmacies from their networks or engaging in discriminatory practices. *See* H.R. 4390, Protect 340B Act.

⁶⁰ 75 Fed. Reg. 10272, 10274-10278 (Mar. 5, 2010).

As discussed above, many of the largest 340B CPs are part of vertically integrated companies, which also own or are affiliated with TPAs. Consistent with their virtual stranglehold on the CP market and motive to divert every 340B discount to themselves, TPAs vertically integrated with PBMs require CEs to contract with and use their CPs. For example, beginning in 2018, CVS Health required CEs that wanted to use CVS for 340B CP services to also use its wholly owned TPA, Wellpartner, for 340B claim reconciliation.⁶¹ CEs were presented with a choice: either use the PBM TPA or not contract with CVS' vast network of CPs. CVS's Wellpartner now serves as the *exclusive* TPA for any CVS CP arrangement—accounting for 19% of all retail CPs and 30.1% of all specialty CPs.⁶² Compounding this situation, Wellpartner charges the CE a percentage of each claim they reconcile. CVS has leveraged its market power and vertically integrated business model to monopolize significant portions of the 340B TPA market and to siphon a significant portion of 340B revenue for CVS' own benefit.

iii. PBMs Use 340B-Specific Pricing to Further Capture 340B Profits

When adjudicating pharmacy claims at the point-of-sale, PBMs require pharmacies, including CPs, to submit claims using electronic standards developed by the National Council for Prescription Drug Programs (“NCPDP”). Under current NCPDP protocols, a CP may identify a particular claim as a 340B eligible prescription with a particular data entry in field 420-DK, called a “Submission Clarification Code.” A Submission Clarification Code of “20” identifies to the payor or their PBM that the claim being submitted is a 340B claim. In the past several years, several PBMs have sought to make the identification of 340B claims mandatory by 340B providers. ESI, for example, issued notice in February 2021 that CPs in ESI's networks must retrospectively identify 340B claims.⁶³ Thereafter,

⁶¹ See *RxStrategies, Inc. v. CVS Pharmacy, Inc.*, 390 F. Supp.3d 1341, 1347 (M.D.Fl. 2019) (“CVS now requires any covered entity that wants to fill 340B Program prescriptions at a CVS pharmacy to use Wellpartner as its program administrator. If the covered entity does not want to use Wellpartner as its 340B program administrator, it cannot utilize CVS as a contract pharmacy for the 340B program.”).

⁶² Nephron, at 10.

⁶³ Rhiannon Klein, cv340b, *Express Scripts Issues 340B Claims Identification Requirements*, (Mar. 11, 2021, <https://www.cv340b.org/express-scripts-issues-340b-claims-identification-requirements/>)

PBMs (like ESI) began to impose significantly lower reimbursement rates for 340B claims, essentially usurping the savings that should have flowed to CEs, even when a PBM owned or affiliated pharmacy may not have been the CP.⁶⁴ In effect, PBMs are singling out 340B drugs for reduced reimbursement, “which essentially transfers the benefit of the program from safety net providers to for-profit payers.”⁶⁵ PBMs have thus ensured that they profit from 340B in as many ways as possible.

II. The Profit Opportunities Presented by 340B and 340B CPs Have Incentivized PBMs to Drive Out Non-Affiliated Pharmacies to the Detriment of Patients

The substantial profit opportunities in 340B for CPs have further spurred PBM attempts to divert patient volume to their own affiliated CPs and drive unaffiliated CPs out of the market. PBMs have engaged in exclusionary tactics against unaffiliated independent providers participating in 340B, and for those unaffiliated providers able to obtain admission to these restrictive networks, PBMs actively seek to divert as much patient volume to their owned or affiliated pharmacies at every opportunity.

A. PBMs Engage in Exclusionary Tactics Against Independent Pharmacy Providers to Drive Business to PBM Owned CPs

PBMs engage in exclusionary tactics against independent pharmacy providers, including community oncology practices, by employing restrictive networks and overly burdensome admission requirements. In the specialty and mail order markets, PBMs have created both exclusive and near-exclusive networks whereby all PBM affiliated pharmacies are able to participate, but virtually no other pharmacy is permitted access.⁶⁶ Indeed, there are PBM networks that are effectively closed to any

⁶⁴ Adam Fein, Drug Channels, *How Hospitals and PBM Profit—and Patients Lose—From 340B Contract Pharmacies*, (July 23, 2022), <https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html>

⁶⁵ Legacy Health Endowment, *PBMs and the 340B Program*, at 1, <https://340breport.com/wp-content/uploads/2021/06/PBMs-and-340B-White-Paper-June-29-2021.pdf>

⁶⁶ Adam Fein, Drug Channels, *The Top 15 Specialty Pharmacies of 2018: PBMs Keep Winning*, (Apr. 9, 2019), <https://www.drugchannels.net/2019/04/the-top-15-specialty-pharmacies-of-2018.html>; see also Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers*, (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf

pharmacy unaffiliated with PBMs.⁶⁷ This is driven in large part by PBMs' quest to optimize 340B profits in as many ways as possible.

As noted above, specialty and mail order prescriptions account for a significant portion of 340B eligible claims revenue. PBMs have made their specialty network application and approval process extremely onerous, and block admission to pharmacies failing to meet the PBMs' self-created and unachievable admission criteria.⁶⁸ When PBMs deny independent pharmacy applications, they often require them to wait a year or more before they can reapply. For example, PBMs require applying pharmacies to demonstrate a broad level of expertise in dispensing a wide range of specialty medications in numerous therapeutic classes.⁶⁹ Yet, without being admitted to PBM specialty networks, pharmacies have virtually no patients to dispense these specialty medications. The PBMs have created a sham application and admission process that, in all practicality, only allows their affiliated pharmacies to participate.⁷⁰

Again, this is all by strategic design. By creating narrow networks where they are the only provider, PBM CPs ensure that they capture the vast majority of lucrative 340B prescriptions.

B. PBMs Engage in Patient Slamming and Prescription Trolling on an Individual Claims Level to Obtain 340B Prescriptions

Even when an independent pharmacy provider gains access to a PBM's network, PBMs continue to leverage their market power to drive patients away from unaffiliated pharmacies, including community oncology practices, and towards their own CPs. Relying on their market leverage, the largest PBMs have effectively utilized patient information and data received during claim submission

⁶⁷ *Id.*

⁶⁸ Jeffrey Lewis et al, *PBMs and the 340B Program*, <https://340breport.com/wp-content/uploads/2021/06/PBMs-and-340B-White-Paper-June-29-2021.pdf>; Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers*, (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf

⁶⁹ *Id.*

⁷⁰ *Id.*

and sought to divert prescriptions towards their own CPs. When a PBM receives a patient's information from an unaffiliated pharmacy provider through the claim submission and/or prior authorization process, the PBM will transmit this information to its own affiliated pharmacy to divert the patient/prescription.⁷¹ This is done without the explicit knowledge or consent of the patient. These PBM tactics are colloquially referred to as “prescription trolling,” “patient slamming,” and “claim hijacking”⁷² and are especially pronounced in dealing with expensive specialty medications or lucrative mail order services.

C. Mandatory “White Bagging” to Pull Prescriptions Out of the Medical Benefits Channel and Into the Pharmacy Benefits Channel, Allowing PBM CPs to Optimize 340B Profits

Another manipulative PBM practice to realize additional 340B profits is mandating “white bagging,” which is the distribution of infusible drugs, such as chemotherapy, direct to the provider for administration to the patient. Typically, these physician-administered drugs are purchased and stored at the site-of-care for administration under physician supervision. By the PBM mandating that it purchases the drug and ships to the physician from its specialty CP, the PBM is able to realize additional 340B profits beyond oral medications. A key distinction in “white bagging” is that prescriptions for these infusible drugs are not only now filled by a PBM CP (as opposed to purchased by the physician's office) but are also billed to the PBM through the pharmacy benefit.

From a clinical perspective, “white bagging” typically results in treatment delays because the drug(s) have to be shipped on an individualized patient basis, mistakes when incorrect drugs are

⁷¹ Community Oncology Alliance, *The Real-Life Patient Impact of PBMs: Volume I*, (April 1, 2017), <https://communityoncology.org/study/the-real-life-patient-impact-of-pbms-volume-i/> (documenting instances where PBMs blatantly lied to patients and pharmacy staff, alleging the prescribing physician had authorized a transfer of the prescription, when in fact, they had not).

⁷² See Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers*, (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (describing in detail the various forms of patient steering and its impact on patients, payers and providers).

shipped, waste when dosages and or therapies need to be adjusted or switched based on patient response, and administrative nightmares for practices.⁷³ However, PBMs are not monitored or regulated based on patients' clinical outcomes; they are motivated and rewarded by maximizing output from their 340B CPs. Contributing to the explosive growth of CPs, PBMs have found every opportunity to profit from oral drugs, and now infusible drugs as they attempt to mandate “white bagging” from their owned or affiliated specialty CPs.

The Court needs to understand that PBMs' quest to maximize profits through use of 340B CPs have a myriad of negative impacts from adversely affecting patient treatment and care to fueling drug prices and costs for Americans. PBM mandates to use their mail order and specialty pharmacies for both oral and infusible drugs wreak havoc with patient care by creating unnecessary treatment delays, denials, and costly waste. Not only do patients in need not get access to 340B discounts due to PBMs diverting them, but the growth of 340B is fueling pharmaceutical list prices. If drug manufacturers are forced to give out increasing discounts to middlemen, they will, and have, account for these discounts in the list prices of their drugs.

While the practice of “white bagging” is not necessarily new, the trend of payor-mandated “white bagging” has dramatically increased along with the consolidation of the pharmacy benefit landscape, the rise of expensive specialty drugs, and the explosion of PBM-owned CPs. PBMs have increasingly required that certain specialty medications be filled by PBM-owned or associated specialty pharmacies and then “white bagged” to the provider.⁷⁴ Indeed, a 2019 survey of infused therapies revealed that in physician-affiliated clinics, “11% of oncology and 43% of nononcology treatments

⁷³ Frier Levitt, *Emerging Trends in Payor-Mandated White Bagging*, (Jan. 6, 2021), <https://www.frierlevitt.com/articles-publications/emerging-trends-in-payor-mandated-white-bagging/#:~:text=White%20Bagging,patient%20in%20the%20clinical%20setting>.

⁷⁴ Marwood Group, *Pharmacy White Bagging: Growth And Countermeasures*, (Nov. 24, 2021), https://www.marwoodgroup.com/wp-content/uploads/2021/11/White-Bagging-Whitepaper-11_24_2021.pdf

were obtained via white bagging” and in hospital outpatient departments, “28% of oncology and 31% nononcology infusions were from white bagging.”⁷⁵ Recently, several PBMs (who have integrated specialty pharmacies) have made “white bagging” mandatory for certain specialty medications.⁷⁶

The lure of 340B profits has accelerated this phenomenon. Whereas before, PBMs were largely unable to tap into office-administered medications that were purchased and stored at the site-of-care by providers, mandatory “white bagging” forces these products into the pharmacy channel, and ostensibly, directs them to PBM-owned CPs. In the case of a 340B claim, “white bagging” allows the PBM to control the distribution of 340B eligible drugs, which “undermine[s] the intent of 340B to allow hospitals to use savings from discounted drugs to improve access to care for the vulnerable communities they serve.”⁷⁷ PBMs are especially motivated to mandate “white bagging” of oncology and other expensive infusible drugs given the substantial discounts afforded by 340B. Self-referrals to PBM-owned or affiliated specialty pharmacies “allows the insurance industry to retain the associated revenue, take advantage of rebates from pharmaceutical [manufacturers], and negotiate to obtain part of the 340B savings for eligible entities.”⁷⁸

⁷⁵ Deborah Abrams Kalan, Managed Healthcare Executive, *How ‘White Bagging’ Affects Patients, Physicians and 340B Funding*, Vol. 1, Issue 2, (Feb. 18, 2021).

⁷⁶ Adam Fein, Drug Channels, *White Bagging Update: PBMs’ Specialty Pharmacies Keep Gaining on Buy-and-Bill Oncology Channels*, <https://www.drugchannels.net/2021/10/white-bagging-update-pbms-specialty.html>; see also Marwood Group, *Pharmacy White Bagging: Growth And Countermeasures*, (Nov. 24, 2021), https://www.marwoodgroup.com/wp-content/uploads/2021/11/White-Bagging-Whitepaper-11_24_2021.pdf (detailing the white bagging policies of the nation’s largest health insurers).

⁷⁷ American Hospital Association, *Health Insurer Specialty Pharmacy Policies Threaten Patient Quality of Care*, (Mar. 2021), at 2, <https://www.aha.org/system/files/media/file/2021/03/AOMarch8white-bagging-0221.pdf>

⁷⁸ Brandy Snyder et al, HOPA News, *An Overview of White Bagging: The Effect on Systems and Potential Strategies*, Hematology/Oncology Pharmacy Association, Vol. 18, Issue 3, at 8, <https://www.hoparx.org/hopa-news/volume-18-issue-3-2021/all-pages>

This practice, which has had documented instances of increased waste to plan sponsors⁷⁹ and harm to patients,⁸⁰ is fueled by PBMs' desire to divert more drugs through their own CPs, thus optimizing their profits from 340B.

III. CONCLUSION

Given the unregulated and unchecked growth of for-profit CPs participating in 340B that are owned by or affiliated with vertically integrated PBMs, and the mounting evidence that these entities are siphoning substantial portions of 340B drug discounts, warping the original congressional-intended purpose of 340B, *amicus* Community Oncology Alliance, Inc. supports Plaintiffs-Appellants/Cross-Appellees Eli Lilly and Company and Lilly USA, LLC and the District Court's ruling granting in part their motion for summary judgement. *Amicus* Community Oncology Alliance Inc. further respectfully urges this Court to reverse and remand the District Court's ruling regarding whether HHS's May 2021 Enforcement Letter is contrary to 340B regulations and guidance as the purpose of the Program is not served through covered entities' use of multiple vertically integrated, for-profit CP arrangements. Patients do not benefit from such an arrangement, but in fact are harmed.

⁷⁹ Deborah Abrams Kaplan, Managed Healthcare Executive, *How 'White-Bagging' Affects Patients, Physicians and 340B Funding*, Vol. 31, Issue 2, (Feb. 18, 2021); Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers*, (Feb. 2022), https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf

⁸⁰ AHA, *Health Insurer Specialty pharmacy Policies Threaten Patient Care*, <https://www.aha.org/white-papers/2021-03-08-health-insurer-specialty-pharmacy-policies-threaten-patient-quality-care>; Frier Levitt, *Pharmacy Benefit Manager Exposé: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers and Taxpayers*, (Feb. 2022), at 51, https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

1. This *amicus curiae* brief complies with the type-volume limitation of Seventh Circuit Rule 29 because, according to the “word count” function of Microsoft Word, it contains 6,951 words, excluding the parts of the brief exempted from the word count by Federal Rule of Appellate Procedure 32(f).
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CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2022, I electronically filed the foregoing Brief with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the appellate *CM/ECF* system. I certify that all of the listed participants in the case are registered *CM/ECF* users and that service will be accomplished by the appellate *CM/ECF* system.

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