

No. 26-457

IN THE
Supreme Court of the United States

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

LYNN FITCH, IN HER OFFICIAL CAPACITY AS
ATTORNEY GENERAL OF THE STATE OF MISSISSIPPI,
Respondent.

**On Petition for Writ of Certiorari to the
United States Court of Appeals
for the Fifth Circuit**

**BRIEF OF COMMUNITY ONCOLOGY
ALLIANCE, INC. AS *AMICUS CURIAE*
IN SUPPORT OF PETITIONER**

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STATEMENT OF IDENTITY AND INTEREST OF THE *AMICUS*

Pursuant to Supreme Court Rule 37, *amicus* Community Oncology Alliance, Inc. (“COA”) submits this brief in support of Petitioner.¹ COA is a non-profit organization committed to ensuring that patients with cancer have access to high-quality, affordable cancer care close to home in their own communities. For more than twenty years, COA has represented independent, physician owned and physician-run oncology practices that deliver cancer care. These practices confront firsthand the consequences of policies and business arrangements that increase patients’ costs, disrupt their treatment, and undermine access to affordable and local community cancer care.

COA supports 340B’s original patient-centered purpose: sustaining safety-net providers’ ability to care for patients in need.² However, that purpose is undermined when drug discounts intended to support vulnerable patients become revenue streams for large, vertically integrated pharmacy benefit managers (“PBMs”) and their affiliated pharmacies without

¹ No party or counsel for a party authored this brief in whole or in part. No person other than *amicus*, its members, or its counsel contributed money intended to fund the preparation or submission of this brief. COA states that it has no parent company and that no publicly held company has a 10% or greater ownership interest in COA. This disclosure is provided pursuant to Supreme Court Rule 37.6. Pursuant to Rule 37.2, this brief is filed at least 10 days before the deadline and therefore constitutes the required notice; no separate notice was required.

² Community Oncology Alliance, *Position Statement on the 340B Drug Pricing Program* (approved by the COA Board of Directors July 6, 2026) <https://mycoa.communityoncology.org/publications/position-statements/coa-340b-drug-pricing-program-position-statement> (last accessed October 13, 2026).

corresponding improvements in patient affordability or access. COA brings a distinct perspective to this case: the experience of oncology practices and patients whose interests can be obscured by a dispute framed principally around manufacturers, hospitals, and pharmacies. COA submits this brief to explain why protecting an expanding network of commercial contract-pharmacy relationships cannot be assumed to protect the patients 340B was created to serve.

A growing component of cancer treatment is utilizing the increasing availability of oral drugs—in effect, “chemotherapy in a pill”—to treat cancer patients. Community oncology practices operate in-office pharmacies or drug dispensing facilities—depending on what state pharmacy regulations allow—through which oral cancer drugs are dispensed directly to patients. Those local access points are especially important for patients who need medication promptly and who may not be well served by distant mail-order or specialty-pharmacy arrangements.

Community oncology practices must routinely interact and deal with PBMs that, among other tasks, process and adjudicate insurance claims for oral cancer drugs. The three largest PBMs—CVS/Caremark, Cigna/Express Scripts, and United-Health/OptumRx—are affiliated with large insurers and own or are affiliated with retail, specialty, and mail-order pharmacies. That vertical integration matters here because the same corporate families can administer claims, operate pharmacies, and participate in 340B contract-pharmacy arrangements.

340B is a federal drug-pricing program for designated “Covered Entities,”³ including certain safety-net

³ See 42 U.S.C. § 256b(a)(4) (defining “Covered Entity”).

clinics and hospitals. Manufacturers must offer covered outpatient drugs at discounted prices to Covered Entities as a condition of coverage of their drugs under Medicaid and Medicare Part B. Congress created 340B in 1992 to preserve access to discounted drugs for core safety-net providers, including federally funded clinics and public hospitals, serving patients in need. However, the program has grown substantially such that one cited estimate placed 2025 sales at more than \$170 billion at list prices.⁴

Because many 340B Covered Entities, such as small community health centers, do not have in-house pharmacies, they contract with external “Contract Pharmacies” that dispense 340B drugs on behalf of the Covered Entities to 340B-eligible patients. In recent years there has been a proliferation of Contract Pharmacies, driven in part by the increasing participation of PBMs in 340B by having their wholly-owned or affiliated pharmacies designated as Contract Pharmacies (“PBM-affiliated Contract Pharmacies”). An analysis by Avalere Health found that sixty-nine percent (69%) of Contract Pharmacies were associated with a PBM through vertical integration or contractual arrangement.⁵ In contrast, only sixteen percent

⁴ Chuan Sun et al., IQVIA, *The Cost of 340B to State Employee Health Plans*, Feb. 2026, <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2026/the-cost-of-340b-to-state-employee-health-plans.pdf> (last accessed October 13, 2026); *see also* Congressional Budget Office, *Medicare Baseline Projections*, <https://www.cbo.gov/system/files/2026-02/51302-2026-02-medicare.pdf> (last accessed October 13, 2026) (actual Medicare Part D expenditure of \$163 billion in fiscal year 2025).

⁵ Avalere, *PBM, Mail-Order, and Specialty Pharmacy Involvement in 340B*, <https://web.archive.org/web/20250801152646/https://advisory.avalerehealth.com/insights/pbm-mail->

(16%) of non-340B pharmacies were vertically integrated or affiliated with a PBM.⁶ The rise of PBM-affiliated Contract Pharmacies within 340B has allowed some of the largest for-profit corporations to siphon billions of dollars from the 340B program that should be going to the benefit of indigent and underserved patients.

The expansion of 340B also raises concerns for independent community oncology practices and their patients. Hospital acquisition and PBM restrictions on pharmacy participation can reduce patients' ability to receive coordinated care through their oncology practices. When a prescription is routed away from the treating practice, the care team may face additional steps to coordinate treatment initiation, dose changes, refills, and monitoring. The relevant question is whether protecting additional Contract Pharmacy relationships improves affordable access to cancer treatment, rather than merely increasing revenue for the entities participating in those arrangements.

A major contributor to these concerns is the lack of transparency in 340B transactions. Under a replenishment arrangement, a prescription may be identified as 340B-eligible after it has been dispensed, and discounted inventory is then purchased to replenish the pharmacy's stock. Manufacturers may lack the claims-level information needed to verify eligibility and identify overlapping discounts. The statutory prohibition on duplicate Medicaid discounts should be distinguished from the treatment of commercial

order-and-specialty-pharmacy-involvement-in-340b (last accessed October 14, 2026).

⁶ *Id.*

rebates, which depends on the applicable contractual arrangements.

Covered Entities remain responsible for compliance when they use Contract Pharmacies and Third Party Administrators (“TPAs”). Yet these arrangements can divide the financial benefit among multiple participants without making clear how much reaches the Covered Entity or supports patients. Financial incentives and limited visibility into transactions make effective oversight especially important. Growth in the number of arrangements, standing alone, does not demonstrate that the program is achieving its safety-net purpose.

In light of the ongoing exploitation of 340B and its impact on patient care especially in the state of Mississippi, COA submits this brief to explain why the commercial incentives underlying Contract Pharmacy expansion warrant scrutiny when evaluating the national importance of this case. The program’s safety-net purpose does not establish that every expansion of commercial Contract Pharmacy arrangements advances patient access. Substantial financial benefits now flow to some of the country’s largest corporations through these arrangements, instead of the safety-net providers for clinical care.

Presently, PBMs and their Contract Pharmacies are taking advantage of the lack of transparency surrounding which claims and patients are 340B-eligible and where the 340B dollars are flowing. The Mississippi law compounds this problem by limiting drug manufacturers from taking steps to detect and prevent 340B abuse.

COA submits this brief not to duplicate the parties’ legal arguments, but to provide factual context about

the capture of 340B by PBMs and affiliated Contract Pharmacies and 340B administrators, and the real-world consequences of that vertical integration for patients and providers. Mississippi's mandate protects these 340B abuse arrangements without conditioning protection on lower patient costs or demonstrated improvements in access. As similar mandates proliferate, their effects extend beyond the parties to this dispute. COA respectfully submits that these consequences for patients and community cancer care reinforce the national importance of the question presented and support granting the petition.

SUMMARY OF ARGUMENT

Congress established the 340B program in 1992 with the goal of making health care affordable and accessible at certain designated safety-net providers serving uninsured, low-income, or otherwise vulnerable patients. Congress created 340B because voluntary discounts provided to safety-net providers were reduced or withdrawn when, in 1990, Congress required that manufacturers provide their "best price" for drugs to Medicaid as a mandatory part of participation in Medicaid.

Consolidation and vertical integration have enabled large insurers and PBMs, through their owned or affiliated Contract Pharmacies, to obtain substantial financial benefits from 340B arrangements. Those benefits are not automatically passed on to patients or retained by Covered Entities to support care. The Court should examine the challenged mandate with an understanding that a protected Contract Pharmacy may be part of the same corporate organization that administers prescription benefits and influences pharmacy network participation.

The federal government has identified the same concerns. In an October 2026 policy brief, HHS’s Office of the Assistant Secretary for Planning and Evaluation (“ASPE”) described incentives to prioritize the margin between discounted acquisition prices and reimbursement over patient needs, concerns about revenue-driven Contract Pharmacy expansion, and the consequences of consolidation for affordability.⁷

Mississippi illustrates the transformation. The State has 446 contract pharmacies intended to serve needy Mississippi patients, but 100—22%—are located outside Mississippi, including some in Hawaii and California.⁸ The leading contract pharmacy by contracts is Optum Pharmacy 705, LLC, associated with Optum and UnitedHealth, followed by Walgreens locations.⁹ Fifty-one percent of Mississippi contract pharmacies are located in high-income districts, even though 18.0% of the State’s population lives in poverty.¹⁰

The question presented has practical significance beyond the terms on which manufacturers sell discounted drugs. Mississippi’s law protects Contract Pharmacy arrangements, including those involving

⁷ Aiden Lee et al., *Mission vs. Margin: Misaligned Incentives in the 340B Drug Pricing Program*, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, at 4–7 (Oct. 8, 2026) (hereinafter “ASPE Brief”) <https://aspe.hhs.gov/sites/default/files/documents/6ec5c02373a85f8bdfd21eae48b72417/2026-10-06-%20ASPE%20340B%20Brief.pdf> (last accessed October 20, 2026).

⁸ Pioneer Institute, *340B Program Requires Federal Reform: 340B in Mississippi*, <https://pioneerinstitute.org/wp-content/uploads/Mississippi-2025.pdf> (last accessed October 13, 2026).

⁹ *Id.*

¹⁰ *Id.*

vertically integrated PBM businesses, without requiring proof that the protected arrangements reduce patients' costs or improve access. COA supports reasonable safeguards that improve transparency and program integrity while preserving legitimate safety-net access. Its support for review rests on the consequences for patients and providers, rather than a blanket endorsement of every manufacturer restriction.

FACTUAL SUMMARY

A. The 340B Program was Created to Benefit America's Most Vulnerable Patients and the 340B Providers 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—as a requirement to participate in Medicaid—are required to charge hospitals and other 340B providers no more than a significantly discounted “ceiling price” on certain outpatient prescription drugs purchased by these entities 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). A fundamental aim of 340B is supporting the 340B providers' ability to “provide direct clinical care to large numbers of uninsured Americans” regardless of their ability to pay. *See id.* Indeed, HRSA, the agency charged with administering 340B, has opined that 340B is designed so that 340B providers would “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 and/or charity care. This patient-centered purpose should inform the assessment of commercial arrangements that allow intermediaries to retain a portion of the program’s financial benefits.

A recent legislative-history study in *The Milbank Quarterly*, based on 175 primary-source documents and interviews with 18 participants in the program’s creation, identified two original objectives: restoring access to discounts disrupted by Medicaid’s best price rules, and establishing minimum drug discounts for core safety-net providers.¹¹ The study concluded that the program’s current scope exceeds its original intent.¹² This history supplies the proper context for examining whether mandatory expansion of commercial Contract Pharmacy networks advances affordable care for vulnerable patients.

Under 340B, eligible 340B providers can acquire drugs from manufacturers at extreme discounts from the usual price. In turn, *and in theory*, 340B providers can “pass on” those savings to their patients through lower costs for medications, or, as contemplated by 340B itself, 340B providers can seek reimbursement

¹¹ Sayeh Nikpay, Mikayla Reinke & Nicole Quinones, *Stretching Scarce Authorizing Legislation as Far as Possible: A Legislative History of the 340B Drug Pricing Program*, *Milbank Quarterly* (May 20, 2026), <https://doi.org/10.1111/1468-0009.70090>.

¹² *Id.*; see also ASPE Brief at 2–3 & ref. 2.

for 340B drugs in the normal course and use those greater profit margins to subsidize other unfunded areas of their operations. Because certain 340B providers, such as small community health centers, may not have in-house pharmacies, HRSA issued sub-regulatory guidance in 1996 permitting 340B providers to “contract” with outside pharmacies (i.e., Contract Pharmacies), and to allow 340B inventory to be dispensed through such Contract Pharmacies. *See* 61 Fed. Reg. at 43,549.

Initially, HRSA restricted 340B providers to contracting with only a single Contract Pharmacy. *Id.* at 43,551. In 2010, however, HRSA dramatically shifted the 340B Contract Pharmacy landscape by permitting 340B providers to maintain an unlimited number of Contract Pharmacy relationships. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010). In the wake of this HRSA guidance, for-profit pharmacies, especially those owned or affiliated with PBMs, have developed businesses that generate revenue from substantial 340B drug discounts. The 2010 guidance opened the door for the largest and most sophisticated for-profit PBMs to earn revenue through a federal drug-pricing program intended to support safety-net care.

B. The Pharmacy Benefit Manager Landscape

PBMs are fiscal intermediaries that administer and manage drug benefits on behalf of health insurance plans. PBMs are primarily responsible for processing and paying prescription drug claims submitted by providers on behalf of covered beneficiaries. The largest PBMs unilaterally dictate the 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.

The largest PBMs are owned or affiliated with the nation’s largest health insurance companies. These PBMs also own or are affiliated with retail, mail-order and/or specialty pharmacies. Today, three PBMs control nearly 80 percent of the prescription drug market: Caremark, ESI, and OptumRx.¹³ Each of these PBMs also shares common ownership with a major insurer and specialty and/or mail-order pharmacy. Caremark is owned by CVS Health, which also owns health insurer Aetna¹⁴ and CVS retail, mail order, and specialty pharmacies.¹⁵ Health insurer Cigna owns ESI,¹⁶ which operates its own mail-order pharmacy,¹⁷ and Accredo Health, Inc., which operates Accredo Specialty Pharmacy.¹⁸ Insurance company

¹³ Adam Fein (“Fein”), Drug Channels (“DC”), *The Top Pharmacy Benefit Managers of 2024: Market Share and Key Industry Developments* (March 31, 2025) <https://www.drugchannels.net/2025/03/the-top-pharmacy-benefit-managers-of.html> (last accessed October 13, 2026).

¹⁴ Aetna/CVS Health, <https://www.aetnacvshealth.com/> (last accessed October 13, 2026).

¹⁵ CVS Health, Neighborhood Pharmacy, <https://www.cvshealth.com/services/pharmacy/neighborhood-pharmacy.html> (last accessed October 13, 2026); CVS Health, Specialty Pharmacy, <https://www.cvshealth.com/services/pharmacy/specialty-pharmacy.html> (last accessed October 13, 2026).

¹⁶ 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/> (last accessed October 13, 2026).

¹⁷ Express Scripts, <https://www.express-scripts.com/rx> (last accessed October 13, 2026).

¹⁸ Accredo by Evernorth, <https://www.accredo.com/> (last accessed October 13, 2026).

UnitedHealth Group owns OptumRx,¹⁹ which owns OptumRx Specialty Pharmacy.²⁰

C. The Exponential Growth of Contract Pharmacies Has Caused Further Reliance on PBMs

Since 2010, the number of Contract Pharmacies participating in 340B and the number of arrangements these Contract Pharmacies maintain with 340B providers have grown exponentially. In January 2010, less than 1,300 locations participated as Contract Pharmacies.²¹ However, by mid-2025, there were 32,069 locations for Contract Pharmacies participating in 340B—representing nearly 60% of all U.S. retail, mail, long-term care and specialty pharmacies—and accounting for 229,531 contractual relationships with 340B providers.²² Between 2010 and 2020, the number of Contract Pharmacy arrangements with 340B providers grew by 4,228%,²³

¹⁹ Optum - About Us, <https://www.optum.com/en/about-us.html> (last accessed October 13, 2026).

²⁰ Optum, Specialty Pharmacy, <https://www.optum.com/en/pharmacy-services/specialty-pharmacy.html>, (last accessed October 13, 2026).

²¹ Fein, DC, *The 340B Contract Pharmacy Market in 2025: Big Chains and PBMs Tighten Their Grip*, <https://www.drugchannels.net/2025/06/340b-contract-pharmacy-market-in-2025.html> (last accessed October 13, 2026).

²² *Id.*

²³ Aaron Vandervelde et al. (“Vandervelde”), BRG, *For-Profit Pharmacy Participation in 340B Program*, at 4 (Oct. 2020), https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf (last accessed October 13, 2026); see also AIR340B (“AIR340B”), *The Impact and Growth in 340B Contract Pharmacy Arrangements – Six Years Later*, at 1, <https://340breport.com/wp-content/>

with each 340B hospital utilizing 22 different Contract Pharmacies on average.²⁴

This expansion has coincided with an *increasing* reliance on PBMs. As of mid-2025, the five largest companies accounted for approximately 76.1% of all Contract Pharmacy relationships.²⁵ Those companies—CVS Health, Walgreens, Walmart, ESI (Cigna) and OptumRx (UnitedHealth)—include large retail chains as well as businesses affiliated with the largest PBMs. Between just 2020 and 2025, the three largest PBMs dramatically increased the number of PBM-affiliated Contract Pharmacy relationships—for CVS/Caremark from approximately 23,000 to 77,000, for ESI/Cigna from approximately 6,000 to 15,000, and for OptumRx/UnitedHealth from approximately 3,000 to 13,000.²⁶

340B represents a substantial share of national drug purchasing. One estimate placed 2025 sales at approximately \$170 billion at list prices.²⁷ 340B has grown three times faster than the non-340B drug market between 2018 and 2025.²⁸ Contract Pharmacy

uploads/2024/05/AIR340B_340B-Contract-Pharmacies.pdf (last accessed October 13, 2026).

²⁴ Vandervelde, at 7.

²⁵ Fein, DC, *The 340B Contract Pharmacy Market in 2025: Big Chains and PBMs Tighten Their Grip*, <https://www.drugchannels.net/2025/06/340b-contract-pharmacy-market-in-2025.html> (last accessed October 13, 2026).

²⁶ *Id.*

²⁷ Chuan Sun et al., IQVIA, *The Cost of 340B to State Employee Health Plans*, Feb. 2026, <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2026/the-cost-of-340b-to-state-employee-health-plans.pdf> (last accessed October 13, 2026).

²⁸ Rory Martin and Harish Karne and Shanyue Zeng, IQVIA, *The Size and Growth of the 340B Program in 2025*,

expansion is one important consideration of the program’s growth. Program-wide purchasing figures alone do not establish how much of that growth is attributable to Contract Pharmacies, how much is retained by PBM affiliates, or whether patient access has improved.

D. Contract Pharmacy Expansion Does Not Necessarily Improve Affordability or Coordinated Cancer Care

The exponential growth of Contract Pharmacies, on its own, would not be an issue if it resulted in increased access and affordability of care to patients of 340B providers. But financial help for patients is “*negatively correlated*” with growth of Contract Pharmacies.²⁹ The “growth of contracts with 340B hospitals [is] uncorrelated with uninsured rates, poverty rates, or areas of medical underservice.”³⁰ In direct contradiction to the spirit of 340B—serving poor neighborhoods and patients—following HRSA’s reversal of its one-Contract-Pharmacy policy, “the percentage of 340B pharmacies in the *lowest* income neighborhoods *declined by 5.6%*.”³¹ Conversely, “the

<https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2026/iqvia-size--growth-of-340b-in-2025-white-paper-2026.pdf> (last accessed October 13, 2026).

²⁹ Bruce Levinson, *Measuring the Effectiveness of the 340B Program*, at 4, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3284078 (last accessed October 13, 2026).

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> (last accessed October 13, 2026).

³¹ Dr. John K. Lin et al., *Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug*

percentage of 340B pharmacies in the *highest* income neighborhoods increased by 5.0%.³² These findings raise questions about how closely network expansion tracks the needs of low-income and uninsured patients; neighborhood income alone does not establish the insurance status of the patients served. For example, a May 2024 report by the North Carolina State Treasurer found that despite the marked expansion of Contract Pharmacies, jumping from six within North Carolina in 2010 to 1,059 in 2022, it primarily involved an expansion into ***wealthier*** neighborhoods, serving communities that were 41.5% more affluent than in 2012.³³ Further, between 2010 and 2020, the distance between hospital 340B providers and their Contract Pharmacies has increased dramatically, from an average of 34 miles to an average of 334 miles.³⁴ In some instances, a Contract Pharmacy can be in a different state thousands of miles away from the 340B provider.³⁵

Mississippi presents the same concern in concrete form. Of 446 contract pharmacies intended to serve

Pricing Program by Neighborhood Socioeconomic Status, JAMA (June 17, 2022), <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530> (last accessed October 14, 2026).

³² *Id.* (suggesting that economic opportunity cannot justify the disparity in the decline of 340B Contract Pharmacies in poor neighborhoods because “the percentage of non-340B pharmacies in the same neighborhood increased by 1.3%”).

³³ State Treasurer of North Carolina, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program*; <https://www.shpnc.org/documents/overcharged-state-employees-cancer-drugs-and-340b-drug-price-program/download?attachment> (last accessed October 14, 2026).

³⁴ Vandervelde, at 7.

³⁵ *Id.* at 4.

needy Mississippi patients, 100 are outside the State; some are in Hawaii and California.³⁶ Fifty-one percent are located in high-income districts, despite an 18.0% statewide poverty rate.³⁷ Half of the contract pharmacies associated with the Mississippi hospitals with the most contract pharmacies are outside Mississippi: the University of Mississippi Medical Center has 148, including 56 out of state (38%); Singing River Health System has 95, including 56 out of state (59%); and North Mississippi Medical Center has 84, including 51 out of state (61%).³⁸ The leading contract pharmacy by contracts is Optum Pharmacy 705, LLC (Optum/UnitedHealth), followed by Walgreens locations.³⁹ Out-of-state specialty and mail-order pharmacies can serve Mississippi patients but these figures warrant scrutiny of whether the arrangements meet demonstrated patient needs.

Another collateral consequence of the rapid expansion of Contract Pharmacy relationships with 340B providers is that independent community practices and pharmacies, such as independent community oncology practices, are being crowded out of the market.⁴⁰ PBM restrictions on network

³⁶ Pioneer Institute, *340B Program Requires Federal Reform: 340B in Mississippi*, <https://pioneerinstitute.org/wp-content/uploads/Mississippi-2025.pdf> (last accessed October 14, 2026).

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ See, e.g., Nikpay, Sayeh S., et al., *Hospital-Physician Consolidation Accelerated in the Past Decade in Cardiology, Oncology*, Health Affairs. July 2018. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1520> (last accessed October 14, 2026).

participation and reimbursement can place independent providers at a disadvantage.

ASPE identifies oncology as a setting in which these incentives are especially consequential.⁴¹ Its review explains that hospitals can generate substantial revenue by acquiring oncology practices and converting them into hospital-affiliated sites, and cites research associating new 340B participation with higher oncology-drug episode spending among commercially insured patients.⁴² The report connects higher spending with costs borne by patients and employers.⁴³ These findings underscore why preserving affordable community cancer care is relevant to assessing the practical consequences of the challenged mandate.

ARGUMENT

A. The Lack of Regulation Regarding the Exponential Growth of Contract Pharmacies Has Allowed PBMs to Siphon the 340B Profits Intended for Charity Care

“The enormous growth in 340B Contract Pharmacy arrangements seems to boil down to a *single* factor: *outsized profit margins*.”⁴⁴ Limited transparency into PBM-affiliated Contract Pharmacy arrangements makes it difficult to determine how much of the financial benefit supports patients and Covered Entities, and how much is retained by commercial

⁴¹ ASPE Brief at 6–7 & refs. 29–31.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Vandervelde at 4 (emphasis added).

intermediaries.⁴⁵ In turn, this means that growth in Contract Pharmacy arrangements does not itself establish increased financial assistance for patients in need. It can also create a lucrative source of revenue for large corporations.

ASPE's discussion of Contract Pharmacies further supports scrutiny of the financial interests protected by Mississippi's law. The report recognizes that these pharmacies can serve providers without in-house pharmacies and offer convenient pickup locations.⁴⁶ It also describes concerns that rapid expansion reflects revenue seeking, that Contract Pharmacies retain part of the financial benefit, and that the arrangements increase diversion risks.⁴⁷ This distinction is central to COA's position: a Contract Pharmacy can improve access, but the existence or expansion of a contractual relationship does not itself demonstrate lower patient costs or better care.

Indeed, based on the terms of their contracts with 340B providers, Contract Pharmacies retain a substantial portion, generally 25-35%, of total 340B discounts,⁴⁸ but there is no requirement that Contract

⁴⁵ 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> (last accessed October 14, 2026).

⁴⁶ ASPE Brief at 5–6.

⁴⁷ *Id.*

⁴⁸ Fein, DC, *Exclusive: Five Pharmacy Chains and PBMs Dominate 2022's Still-Booming Contract Pharmacy Market*, <https://www.drugchannels.net/2022/07/exclusive-five-pharmacies-and-pbms.html> (last accessed October 14, 2026); *see also* Minnesota Department of Health, *340B Covered Entity Report*:

Pharmacies use those discounts to help patients.⁴⁹ Typically, 340B providers pay the Contract Pharmacy a flat fee for each eligible prescription dispensed, which generally ranges from \$6-\$15, but can be upwards of \$1,750 per prescription.⁵⁰ Additionally, some 340B providers “also agree[] to pay [Contract] Pharmacies a percentage of the revenue generated by each [340B] prescription,” which can be as much as 20%.⁵¹ With these favorable reimbursements, the average profit margin for Contract Pharmacies on 340B claims for brand name drugs was estimated at 72%, compared with just 22% for non-340B brand name drug claims.⁵² These estimates illustrate the potential financial incentive to obtain 340B prescriptions.

1. PBM-Affiliated Pharmacies Comprise a Disproportionate Share of Contract Pharmacies and Retain Billions in 340B Discounts Annually

The Contract Pharmacies participating in 340B are primarily not independent pharmacies. Rather, large for-profit pharmacy chains account for a substantial majority of Contract Pharmacy relationships; several

Report to the Legislature, <https://www.health.state.mn.us/data/340b/docs/2024report.pdf> (last accessed October 14, 2026).

⁴⁹ GAO, GAO-18-480, *Drug Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, (June 2018), at 31, <https://bit.ly/3vKXcxg> (“GAO 2018”) (noting that 57% of surveyed hospital-CEs provided *no 340B discounts* to patients receiving their prescriptions at Contract Pharmacies) (last accessed October 14, 2026).

⁵⁰ *Id.* at 26.

⁵¹ *Id.* at [ii], 27.

⁵² Vandervelde, at 3.

of the largest participants are affiliated with major PBMs.⁵³ These integrated corporations, especially over the last five to ten years, have grown to own a significant majority of Contract Pharmacy relationships.⁵⁴ As of mid-2025, the top five companies, including the largest PBMs (Caremark, ESI, and OptumRx) and pharmacy giants Walgreens and Walmart control 76.1% of all Contract Pharmacy relationships through their owned or affiliated Contract Pharmacies.⁵⁵ Each of these entities operates or is affiliated with a PBM.⁵⁶ Additionally, more than 90% of Walgreens and CVS Health locations serve as Contract Pharmacies.⁵⁷ In fact, CVS Health is the

⁵³ Karen Mulligan, PhD, University of Southern California, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, (Oct. 14, 2021) at 4, https://schaeffer.usc.edu/wp-content/uploads/2024/10/USC_Schaeffer_340BDrugPricingProgram_WhitePaper.pdf (noting that “[l]arge retail pharmacy chains—Walgreens, CVS, Walmart, and Rite Aid are disproportionately represented among Contract Pharmacies”) (last accessed October 14, 2026); *see also* GAO 2018, at 20 (noting 75% of Contract Pharmacy arrangements are held by “chain pharmacies”).

⁵⁴ Fein, DC, *The 340B Contract Pharmacy Market in 2025: Big Chains and PBMs Tighten Their Grip*, <https://www.drugchannels.net/2025/06/340b-contract-pharmacy-market-in-2025.html> (last accessed October 14, 2026).

⁵⁵ *Id.*; *see also* GAO 2018, at 20-21 (noting approximately 75% of 340B Contract Pharmacies are chain pharmacies, notwithstanding that chain pharmacies represent scarcely half of all pharmacies nationwide).

⁵⁶ *See* https://ncpa.org/sites/default/files/2024-05/VerticalBusiness_2024_040324.pdf (last accessed October 14, 2026).

⁵⁷ Fein, DC, *The 340B Contract Pharmacy Market in 2025: Big Chains and PBMs Tighten Their Grip*, <https://www.drugchannels.net/2025/06/340b-contract-pharmacy-market-in-2025.html> (last accessed October 14, 2026).

largest Contract Pharmacy participant in the 340B Program, with an estimated 77,000 Contract Pharmacy relationships, out of nearly 230,000 nationally.⁵⁸

A 2022 analysis reported that, in addition to their retail pharmacies, Caremark, ESI, and OptumRx collectively owned 500 mail order, specialty, and infusion pharmacies that acted as Contract Pharmacies.⁵⁹ Demonstrating the outsized control the PBMs have over the overall 340B Contract Pharmacy market, these 500 Contract Pharmacies had a combined 35,000 contractual arrangements with 340B providers.⁶⁰ These 500 mail, specialty, and infusion pharmacies owned by or affiliated with the three largest PBMs accounted for only 1.5% of all Contract Pharmacy *locations*, but 15% of the total number of Contract Pharmacy *relationships*.

The rapid rise of Contract Pharmacies may be explained, in part, by the large PBMs' use of their enormous, outsized market leverage and discriminatory practices to pressure Covered Entities, including those that have their own in-house pharmacies, to use PBM-affiliated Contract Pharmacies. For example, some PBMs have implemented practices termed "discriminatory reimbursement" against Contract Pharmacies owned by 340B providers, or have outright excluded them from the PBMs' networks.⁶¹

⁵⁸ *Id.*

⁵⁹ Fein, DC, *Exclusive: Five Pharmacy Chains and PBMs Dominate 2022's Still Booming Contract Pharmacy Market*, <https://www.drugchannels.net/2022/07/exclusive-five-pharmacies-and-pbms.html> (last accessed October 14, 2026).

⁶⁰ *Id.*

⁶¹ See America's Essential Hospitals, *340B State Policy: Combating Discriminatory Payer Practices*, <https://essential>

The above Contract Pharmacy relationships translate to substantial profits from 340B for the PBMs' parent conglomerates. The cited Nephron analysis estimated that, in 2023, CVS Health Contract Pharmacies retained \$1.08 billion of 340B drug discounts; Walgreens Contract Pharmacies retained \$1.04 billion; ESI Contract Pharmacies retained \$663 million; and OptumRx Contract Pharmacies retained \$337 million.⁶² Collectively, in 2023, Walgreens, Caremark, ESI, and OptumRx retained \$3.12 billion in 340B discounts.

2. PBMs and Contract Pharmacies Have Indicated that Reductions to Their 340B Contract Pharmacy Footprint Would Significantly and Materially Affect Overall Profitability

340B has become a significant profit center for for-profit corporations owning PBMs and Contract Pharmacies. The annual reports of CVS Health and Walgreens Boots Alliance ("WBA") confirm that 340B profits are material to their business operations and warn that restrictive Contract Pharmacy policies enacted by drug manufacturers will negatively impact their bottom lines. *See e.g.*, CVS Health Corporation 2026 Form 10-K at 22 (stating that a reduction in its 340B contract pharmacy business could "materially

hospitals.org/wp-content/uploads/2022/07/340B-State-Snapshot-August-2022.pdf (noting "common examples" of PBM discriminatory practices including two-tier pricing, excluding 340B pharmacies from PBM networks, imposing additional fees, and other administrative burdens) (last accessed October 14, 2026).

⁶² Nephron Research, *340B Pharmacy Tailwind / Manufacturer Headwind Poised to Reverse in 2H 2023*, <https://nephronresearch.com/340b-pharmacy-tailwind-manufacturer-headwind-poised-to-reverse-in-2h-2023/> (last accessed October 14, 2026).

and adversely affect the Company.”); WBA, Form 10-K FY 2021, p. 22 (“[c]hanges [. . .] in connection with the federal 340B drug pricing program, could also significantly reduce [WBA’s] profitability.”). These disclosures confirm that Contract Pharmacy arrangements have material commercial significance. They do not establish that an expansion of those arrangements necessarily improves patient access.

B. The Profit Opportunities Presented by 340B and Contract Pharmacies Have Incentivized PBMs to Drive Out Unaffiliated Providers to the Detriment of Patients

The substantial profit opportunities for PBM-affiliated Contract Pharmacies have further spurred PBM attempts to divert patient volume to their own affiliated Contract Pharmacies and drive unaffiliated Contract Pharmacies out of the market. PBMs have engaged in exclusionary and discriminatory tactics against unaffiliated providers participating in 340B. PBMs are also known to pay lower reimbursement rates to non-affiliated and independent pharmacies. Indeed, a recent audit performed by the Tennessee Department of Commerce and Insurance reported that Caremark “used reimbursement practices that led to higher payments for prescription medications dispensed at the PBM-affiliated retail, mail order, and specialty pharmacies than payments made to the non-affiliated” pharmacies.⁶³

PBMs also employ restrictive networks and overly burdensome admission requirements. In the specialty

⁶³ See https://tnpharm.org/wp-content/uploads/CaremarkReportAuditPackage_20260212.pdf at page 6 (last accessed October 14, 2026).

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.⁶⁴ Indeed, some PBM networks are effectively closed to any pharmacy unaffiliated with PBMs.⁶⁵ Specialty and mail order prescriptions also account for a significant portion of 340B claims revenue. This has become dominated by PBMs, which can impose specialty network application and approval requirements that exclude otherwise qualified independent pharmacies.⁶⁶ For example, when PBMs deny unaffiliated pharmacy applications, they often require them to wait a year or more before they can reapply. PBMs also require applying pharmacies to demonstrate a broad level of expertise in dispensing a wide range of specialty medications in numerous therapeutic classes.⁶⁷

⁶⁴ Fein, DC, *Independents Outshine PBMs in Manufacturers' Exclusive Specialty Pharmacy Networks*, <https://www.drugchannels.net/2024/04/independents-outshine-pbms-in.html> (last accessed October 14, 2026); 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), at 29-37 https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (last accessed October 14, 2026).

⁶⁵ *Id.*

⁶⁶ 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) at 29-37, https://communityoncology.org/wp-content/uploads/2022/02/COA_FL_PBM_Expose_2-2022.pdf (last accessed October 15, 2026).

⁶⁷ *Id.*

These exclusionary practices carry particular consequences in oncology, where ASPE has found that 340B incentives are especially pronounced. Because many cancer drugs are high-cost, clinician-administered drugs eligible for 340B discounts, hospitals can realize substantial revenue by acquiring oncology practices and converting them into hospital-affiliated sites of care.⁶⁸ Among specialties subject to hospital-physician consolidation, oncology experienced the highest rate of growth in vertical integration, reaching 54 percent in 2017.⁶⁹ As these acquisitions increase market share and bargaining power, Covered Entities gain leverage to negotiate higher commercial prices. Those higher prices are borne by commercially insured patients and their employers through increased premiums, deductibles, coinsurance, and other out-of-pocket costs.⁷⁰ ASPE further reported that 340B participation moved physician prescribing toward greater use of pharmaceutical treatments for certain cancers typically treated by surgery, radiation, or conservative management alone.⁷¹

When PBMs exclude independent community oncology practices and their in-office dispensing pharmacies from networks, or reimburse them at discriminatory rates, these pressures compound. Practices that cannot dispense oral cancer drugs to their own patients lose a source of support for local care, leaving them more vulnerable to the hospital acquisitions. Patients, in turn, may be routed to distant PBM-affiliated specialty or mail-order

⁶⁸ ASPE Brief at 7.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

pharmacies, where the treating care team faces additional steps to coordinate treatment initiation, dose changes, refills, and monitoring. The result is a system in which 340B revenue opportunities reward consolidation while patients bear higher costs and more fragmented cancer care.

C. Mississippi's Mandate Protects Commercial Arrangements Without Requiring Demonstrated Patient Benefits

COA supports the safety-net purpose of 340B and reasonable safeguards against diversion, duplicate Medicaid discounts, and opaque financial arrangements. Claims-level verification can improve visibility into eligibility and transactions, but safeguards should also preserve timely access for eligible patients. COA's support for this petition should not be understood as a blanket endorsement of every restriction a manufacturer might adopt. The question here is consequential because state mandates can entrench commercial Contract Pharmacy arrangements without requiring a demonstrated relationship between those arrangements and affordable patient care.

Mississippi's recently enacted H.B. 728 reinforces, rather than corrects, the status quo by protecting and further entrenching reliance on Contract Pharmacies. The Mississippi law provides that a drug manufacturer or distributor "shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health

and Human Services.” Miss. H.B. 728 § 4(1). However, the law defines “340B entity” to include not only the Covered Entity but also “any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.” *Id.* § 2(b). Thus, Miss. H.B. 728’s protections extend to for-profit Contract Pharmacies themselves. Nothing in the law conditions those protections on the discounts, or the revenue they generate, reaching the Covered Entity’s patients, and it adds no reporting or transparency requirements for Contract Pharmacy arrangements.

The practical distinction between protecting a financial relationship and protecting access to treatment must also be considered. A pharmacy’s ability to claim discounted replenishment inventory does not, by itself, establish that a patient can obtain medication sooner, at lower cost, or with better clinical coordination. Nor does limiting a particular arrangement necessarily establish the opposite. The Court should grant review with an understanding of commercial beneficiaries mandates and the absence of a required link between the protected arrangements and demonstrated patient benefits. COA offers the perspective of community oncology practices whose patients depend on affordable, timely, coordinated cancer care.

CONCLUSION

The national growth of state Contract Pharmacy mandates has consequences beyond the financial interests of manufacturers and Covered Entities. Mississippi's law protects arrangements involving powerful commercial intermediaries without requiring that those arrangements lower patient costs or improve access. The resulting implications for patients, independent providers, and the safety net hospitals reinforce the national importance of the question presented. Community Oncology Alliance, Inc. respectfully urges the Court to grant the petition for a writ of certiorari.

Respectfully submitted,

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