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July 28, 2023

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building 509
Washington, DC 20510

The Honorable Benjamin L. Cardin
United States Senate
Hart Senate Office Building
Washington, DC 20510

Via email: Bipartisan340BRFI@mail.senate.gov

Dear Senators Thune, Stabenow, Moore Capito, Baldwin, Moran, and Cardin:

I appreciate the opportunity to present my views about the federal 340B Drug Pricing Program.

Congress created the 340B Drug Pricing Program in 1992 with the vague goal of helping providers "stretch scarce federal resources" by requiring manufacturers to offer steep drug discounts to certain covered entities—hospitals and other designated healthcare providers.

Covered entities increasingly rely on external (or contract) commercial pharmacies to extend 340B pricing to a broad set of patients. As I document below, more than half of the country's retail, mail, and specialty pharmacies now profit from the 340B program. However, there is no requirement that the billions of dollars in 340B pharmacy discounts are used appropriately, no obligation to share discounts with indigent patients, no fair-market-value standards for pharmacies' fees, and zero transparency around the profits earned by the billion-dollar public companies that dominate 340B pharmacy networks.

Consequently, the program's good intentions have been overwhelmed by middlemen that pocket discounts while forcing patients, employers, and the Medicare program to pay more for prescription

drugs. The unmanaged and unregulated growth of contract pharmacies is also causing significant distortions within the U.S. pharmaceutical distribution and reimbursement system.

As I will explain, these distortions:

- Overcharge uninsured and financially needy patients for prescriptions
- Require patients with commercial and Medicare Part D insurance to pay for the 340B funds earned by covered entities and contract pharmacies
- Permit large, public pharmacy and insurance companies to profit inappropriately from 340B discounts at the expense of needy and uninsured patients
- Curb manufacturers' willingness to offer rebates to Medicare Part D and commercial payers, raising net drug costs for these payers

I conclude with a set of policy recommendations for the contract pharmacy program.

QUALIFICATIONS

First, a few words about my industry experience and knowledge of these issues. I am an expert in the complex economic interactions within the U.S. pharmacy distribution and reimbursement system. I earned my Ph.D. in Managerial Science and Applied Economics from the Wharton School of Business at the University of Pennsylvania. I am CEO of Drug Channels Institute (DCI), a leading source of industry research about pharmaceutical economics and the drug distribution system.

DCI's products are purchased by numerous participants in the U.S. healthcare system, including manufacturers, wholesalers, pharmacies, health systems, physician practices, insurers, pharmacy benefit managers (PBMs), consulting firms, investment companies, technology companies, law firms, industry associations, group purchasing organizations, individual healthcare providers (physicians, pharmacists, nurses, etc.), and others.

I write the widely read *Drug Channels* website. There, I analyze the latest news and research affecting pharmaceutical economics and the drug distribution system. *Drug Channels* attracts a large, diverse audience throughout the pharmaceutical and healthcare industries. I also research and write detailed annual industry reports on the economics of pharmacies, wholesalers, and PBMs.

For years I've been studying the economics of the complex and opaque intersection of the 340B program and the pharmacy and PBM industries. Over the past 10 years, I have published more than 80 articles about the 340B program in *Drug Channels* and other publications.

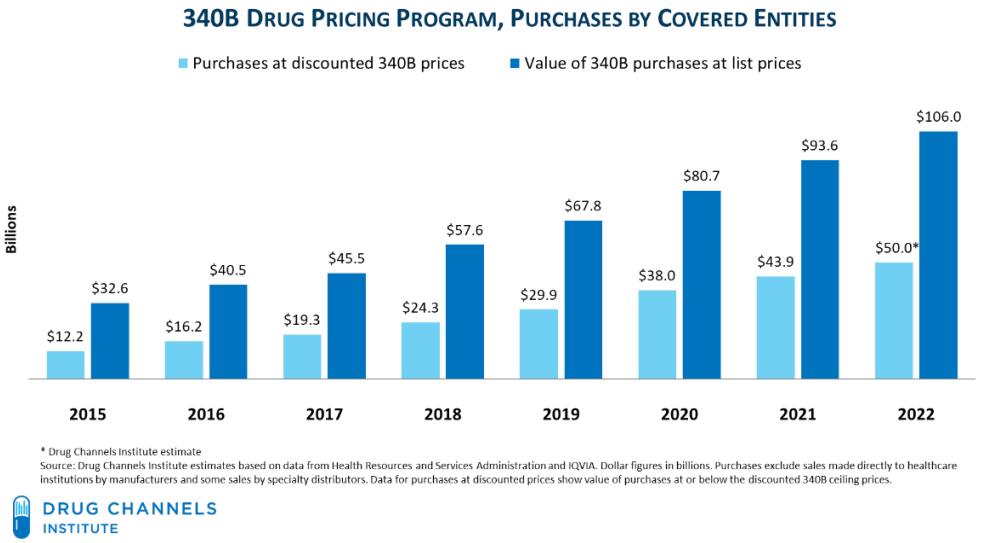
I. MARKET OBSERVATIONS

Below are the results of my research into the 340B programs and contract pharmacies.

1) The 340B Drug Pricing Program is a large and growing part of the U.S. pharmaceutical market.

In recent years, the Health Resources and Services Administration (HRSA) has provided *Drug Channels* with data measuring the 340B program. Apexus, the HRSA-designated Prime Vendor, reports these data to HRSA. I have obtained these data through multiple Freedom of Information Act (FOIA) requests. For years, the publication of these FOIA requests on *Drug Channels* was the primary public source of program information on covered entities' purchases under the 340B program.[1]

The chart below summarizes these data along with figures from IQVIA on the value of 340B purchases at drug list prices.



According to the data provided by HRSA, the 340B program has undergone skyrocketing growth:

- Discounted purchases made under the program totaled at least $43.9 billion in 2021.[2] The value of net drug purchases under the 340B program now exceeds the value of net purchases of the nation's Medicaid outpatient drug market, which was $39.6 billion in 2021.[3]

[1] Drug Channels News Roundup, September 2022, Drug Channels, September 27, 2022.
[2] The 340B Program Climbed to $44 Billion in 2021—With Hospitals Grabbing Most of the Money, *Drug Channels*, August 15, 2022. Note that the data from Apexus include only indirect sales made via wholesalers. The $43.9 billion figure is therefore less than the actual total of 340B purchases at discounted prices. That's because the Apexus data exclude an unknown amount of manufacturer sales made directly to healthcare institutions and some sales by specialty distributors.
[3] Office of the Actuary in the Centers for Medicare & Medicaid Service, National Health Expenditures (historical), December 2022.

- From 2015 to 2021, purchases under the program have grown at an average rate of 24% per year. Over the same period, manufacturers' net brand-name drug sales (excluding COVID-19 vaccines) grew at an average annual rate of less than 4%.[4]

- The wholesale acquisition cost (WAC) list price value of 340B purchases was $93.6 billion in 2021.[5] 340B purchases at list prices were $106 billion for 2022.[6]

- For 2021, the list-to-340B gap—the difference between purchases at list prices and purchases at 340B discounted prices—grew to $49.7 billion (= $93.6 minus $43.9). That is $7.0 billion higher than the 2020 gap. This figure approximates the money collected by 340B covered entities.

Many partisan supporters try to minimize 340B's share of the total U.S. market. In reality, the many years of above-market growth have made the 340B program into a significant and growing part of the industry. Some 340B advocates have even argued that "drug companies are cutting 340B," but the data tell a different story. Billions more in payments and spreads cannot be considered a cut.

2) The number of external contract pharmacies in the 340B program has skyrocketed.

A covered entity can purchase and dispense 340B drugs through internal and external (contract) pharmacies. In 2010, HRSA permitted eligible entities (including those that have an in-house pharmacy) to access 340B pricing through multiple contract pharmacies.[7]

Since this change in guidance, 340B covered entities have dramatically expanded their use of contract pharmacies:

- In 2010, there were fewer than 1,300 contract pharmacies.[8]

- As of mid-2023, DCI counted 33,043 unique locations acting as 340B contract pharmacies for 340B covered entities.[9] That's a more than 25-fold increase—a figure far beyond HRSA's wildest dreams from 2010.

- These more than 33,000 pharmacies have 194,016 contractual relationships with 9,585 340B covered entities, i.e., there are more than 194,000 unique contract pharmacy/covered entity relationships. The number of contractual relationships has grown more quickly than has the

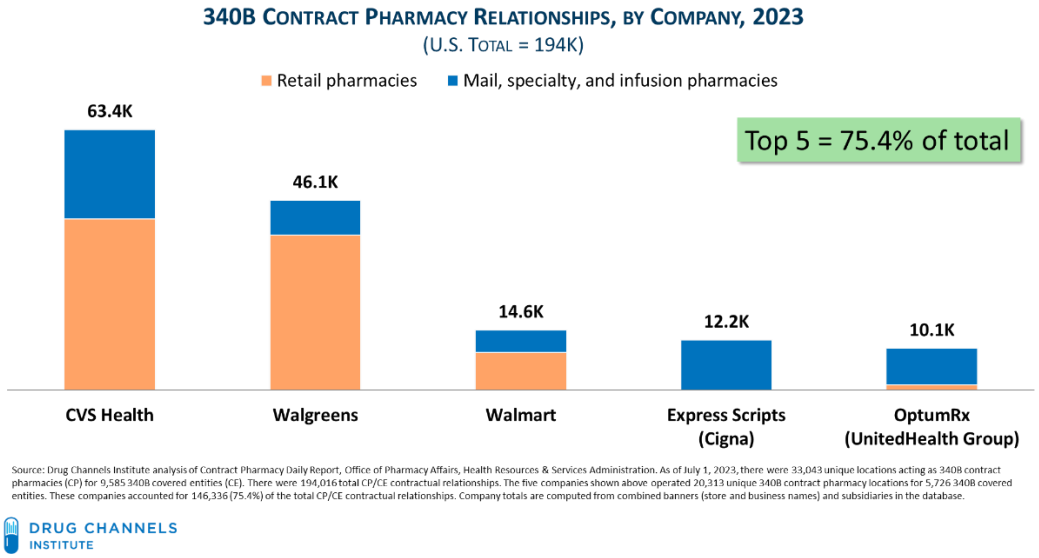
[4] The Use of Medicines in the U.S. 2022, IQVIA Institute for Human Data Science, 2022, 47.
[5] 340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect, IQVIA, April 5, 2022.
[6] The 340B Drug Discount Program Exceeds $100B, 2023, 4.
[7] Health Resources and Services Administration, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, *Federal Register*, March 5, 2010.
[8] U.S. Government Accountability Office, Status of Agency Efforts to Improve 340B Program Oversight, May 15, 2018.
[9] EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market, *Drug Channels*, July 11, 2023.

number of contract pharmacy locations. Since our 2022 analysis, the number of contractual pharmacy relationships has grown by about 25,500 relationships (+15%).

This growth means that most of the U.S. pharmacy industry now profit from the 340B program, which was designed as a narrow support to certain hospitals and providers. Unlike Medicaid, the pharmacy component of 340B doesn't have—and has never had—a regulatory infrastructure. That's because the 2010 notice bypassed the usual rulemaking and comment procedures.

3) Five multi-billion-dollar, for-profit, publicly traded pharmacy chains and PBMs dominate the 340B contract pharmacy market.

Five public companies—CVS Health, Walgreens, Cigna (via Express Scripts), UnitedHealth Group (via OptumRx), and Walmart—account for 75.4% of total number of 340B contract pharmacy relationships with covered entities.[10] That's an increase from the top five's share of 73.2% for 2022.



These companies are among the largest U.S. pharmacies by prescription revenues.[11] They are also among the largest, vertically integrated organizations that offer health insurance, manage pharmacy benefits, operate pharmacies, and deliver medical care to patients.[12]

[10] EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market, *Drug Channels*, July 11, 2023. The biggest retail chain pharmacies—Walgreens, CVS Health, Walmart, Rite Aid, Kroger, and Albertsons—account for a majority of the 340B program's total contract pharmacy locations. However, the number of locations provides a misleading picture of the 340B contract pharmacy marketplace. A typical retail pharmacy location operates as a contract pharmacy for fewer than five covered entities, while a typical mail and specialty location operates as a 340B contract pharmacy for hundreds of covered entities.

[11] The Top 15 U.S. Pharmacies of 2022: Market Shares and Revenues at the Biggest Companies, *Drug Channels*, March 8, 2023.

[12] Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers: A May 2023 Update, Drug Channels, May 10, 2023.

These data also highlight the complex ways in which the 340B program interacts with the pharmacy and PBM industries:

- Walgreens and CVS Health remain the two most active 340B contract pharmacy participants. Each company has more than 8,200 locations participating as 340B contract pharmacies. They each are partnered with more than 3,000 340B covered entities.

- Two large PBMs—the Express Scripts business of Cigna and the OptumRx business of UnitedHealth Group—are among the most active participants when measured by the number of 340B contract pharmacy agreements with covered entities. Each company has partnered with about 1,500 340B covered entities.

- The three largest PBMs—CVS Health, Express Scripts, and OptumRx—collectively have about 230 mail, specialty, and infusion pharmacy locations acting as 340B contract pharmacies. Combined, these locations have nearly 43,000 relationships with covered entities. Consequently, the big three PBMs' non-retail pharmacies account for less than 1% of 340B contract pharmacies—but 22% of 340B contract pharmacy relationships.[13]

As I discuss below, these contract pharmacy operators' total estimated gross profits from the 340B program were nearly $3 billion in 2023.

4) Hundreds of covered entities have established contract pharmacy mega-networks.

Many covered entities have relatively small 340B contract pharmacy networks. However, some hospitals have built extraordinarily large networks. The table below summarizes our findings about contract pharmacy networks.[14]

340B Covered Entities, By Number of Contract Pharmacies, 2023

Number of 340B contract pharmacies in network	340B covered entities	Share of 340B entities with a 340B contract pharmacy	Total number of 340B contract pharmacy relationships	Share of 340B contract pharmacy relationships	Average contract pharmacy network size
1 pharmacy	2,359	25%	2,359	1%	1
2 to 10 pharmacies	3,629	38%	16,357	8%	5
11 to 50 pharmacies	2,453	26%	61,684	32%	25
51 to 100 pharmacies	747	8%	50,419	26%	67
More than 100 pharmacies	398	4%	63,197	33%	159
Total	9,586	100%	194,016	100%	20

Source: Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database (July 1, 2023).

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[13] Note that OptumRx also operates more than 700 community pharmacies. Most of these locations are operated by Genoa Healthcare, which OptumRx acquired in 2018.
[14] Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database (7/1/23)

These data highlight the scope and scale of contract pharmacy arrangements:

- About 400 healthcare providers (4% of covered entities with contract pharmacies) account for one-third all contract pharmacy relationships. These providers have built networks averaging 159 pharmacies. Twelve large health systems have networks with more than 300 contract pharmacies each.
- In addition to the mega-networks, a further 3,200 providers have networks of 11 to 100 pharmacies, accounting for 58% of contract pharmacy arrangements. These providers have built networks with dozens of pharmacies.

- By contrast, 62% of all 340B covered entities that utilize contract pharmacies have small networks with 10 or fewer pharmacy locations.

Multiple peer-reviewed academic studies suggest that these networks are seemingly designed to enrich certain covered entities and pharmacies, not to help needy and uninsured patients:

- Contract pharmacy growth has been concentrated in affluent and predominantly White neighborhoods, whereas the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods has declined.[15]

- 340B hospitals were less likely to use contract pharmacies in areas with higher uninsured rates and in medically underserved areas.[16]

- Both hospitals and federal grantees were less likely to use contract pharmacies located in neighborhoods where low-income patients were likeliest to live.[17]

There are no regulations or guidance on network size or how 340B entities should monitor such large networks. These covered entities are not required to justify such large networks on the basis of access needs for uninsured, underinsured, and needy populations. We also do not know how or if covered entities monitor out-of-state retail, mail, and specialty pharmacies.

II. DISTORTIONS FROM 340B CONTRACT PHARMACIES

I believe that the growing use of contract pharmacies leads to at least six significant problems in the U.S. drug distribution and reimbursement system. I have outlined some of these issues in a peer-

[15] Lin, J.K., et al., Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics, JAMA, June 17, 2022.
[16] Nikpay, S., and G. Gracia, Association of 340B Contract Pharmacy Growth With County-Level Characteristics, *The American Journal of Managed Care*, March 10, 2022.
[17] Masia, N., and F. Kuwonza, Income Differences Between Locations of 340B Entities and Contract Pharmacies, *The American Journal of Managed Care*, June 5, 2023.

reviewed journal article,[18] in a *Wall Street Journal* opinion piece,[19] and in articles on the *Drug Channels* website.

1) Many 340B hospitals do not provide discounts to low-income, uninsured patients at their facilities' contract pharmacies.

There is compelling evidence that uninsured and indigent patients do not always benefit from 340B drug discounts earned from third-party or patient paid prescriptions dispensed by contract pharmacies.

The small amount of public information about the operation of 340B contract pharmacy arrangements paints a dismal picture for uninsured patients using hospitals' 340B contract pharmacies:

- The Office of Inspector General (OIG) found that in a sample of 15 hospitals, 10 (67%) required uninsured patients to pay the full, non-340B price, even though hospitals were purchasing the drugs at the deeply discounted 340B price.[20]

- The Government Accountability Office (GAO) found that in a sample of 28 hospitals, 16 (57%) did not provide discounted drug prices to low-income, uninsured patients who filled prescriptions at the hospital's 340B contract pharmacy.[21] In a separate report from 2023, the GAO found that in a sample of 30 hospitals, 14 (47%) did not provide discounts to low-income, uninsured patients at their facilities' contract pharmacies.[22]

Independent studies also raise issues about covered entities' use of contract pharmacies. For example, one study found that most 340B-eligible patients at contract pharmacies do not receive the value of 340B discounts.[23]

These problems stem partly from the ways in which covered entities manage contract pharmacy relationships. Covered entities and their software vendors classify outpatient prescriptions as "340B eligible." They do this via non-public processes that are not subject to formal regulations.

Due to the lack of regulations, different entities have different standards for identifying 340B-eligible prescriptions. The OIG has described four common scenarios that would result in differing

[18] Fein, Adam J., Challenges for Managed Care from 340B Contract Pharmacies, *Journal of Managed Care and Specialty Pharmacy*, March 2016.
[19] Fein, Adam J., The Federal Program That Keeps Insulin Prices High, *The Wall Street Journal*, September 10, 2020.
[20] Office of Inspector General, Contract Pharmacy Arrangements in the 340B Program, February 2014.
[21] Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, U.S. Government Accountability Office, June 2018, 31.
[22] 340B Drug Discount Program: Information about Hospitals That Received an Eligibility Exception as a Result of COVID-19, U.S. Government Accountability Office, May 11, 2023, 16.
[23] Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?, IQVIA, 2022.

determinations of 340B eligibility across covered entities.[24] The OIG notes that "two covered entities may categorize similar types of prescriptions differently, i.e., 340B-eligible versus not 340B-eligible, in their contract pharmacy arrangements."

In a separate report, the Government Accountability Office (GAO) noted, "[S]ome covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care."[25]

2) Medicare and commercial third-party payers fund the profits earned by a 340B covered entity and its contract pharmacy.

By using external pharmacies, a 340B covered entity profits from prescriptions filled by a pharmacy that is not owned or operated by the covered entity. They do this after the prescription has been adjudicated and paid by such third-party payers as Medicare Part D and commercial health plans. Since 340B prescriptions at contract pharmacies cannot be identified at the time of adjudication, Medicare Part D and commercial payers reimburse 340B and non-340B outpatient prescriptions at the same rate.

A covered entity generates 340B funds at contract pharmacies from the difference between:

- The drug's market rate pharmacy reimbursement (paid by a Medicare or commercial plan) plus the patient's out-of-pocket contribution, and

- The drug's discounted 340B price from the manufacturer

Consequently, most 340B-eligible prescriptions filled at contract pharmacies are dispensed to patients who have prescription drug insurance—not to uninsured or financially needy patients.

What's more, a 340B entity only profits when prescriptions are paid at nondiscounted rates. That's why covered entities have opposed third-party payers' efforts to establish differential reimbursement rates and lobbied states to pass laws prohibiting so-called "discriminatory pricing." One expert on hospital finances recently described the 340B program in the following way: "This 'buy low, sell low' program has evolved into a 'buy low, sell high' program that enables eligible hospitals to generate profits by providing these drugs to well-insured patients."[26]

[24] Contract Pharmacy Arrangements in the 340B Program, Office of Inspector General, February 4, 2014, 14
[25] Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, U.S. Government Accountability Office, September 2011.
[26] Bai, G., et al, Do Nonprofit Hospitals Deserve Their Tax Exemption?, *The New England Journal of Medicine*, July 20, 2023.

3) Managed Medicaid programs can also provide prescription profits to 340B covered entities.

The 340B statute prohibits manufacturers from having to provide a discounted 340B price and a Medicaid drug rebate for the same drug. This prohibition on duplicate discounts applies to traditional Medicaid arrangements as well as Medicaid programs operated by managed care organizations, also known as managed Medicaid.

However, states that shift from a managed care (carved-in) to a fee-for-service (carved-out) Medicaid pharmacy program will reduce the revenues that 340B covered entities and their contract pharmacies earn.[27] That's because federal government regulations require fee-for-service state Medicaid programs to adopt acquisition cost pharmacy reimbursement.[28]

Some states have adopted fee-for-service Medicaid pharmacy programs that use actual acquisition cost as the basis for reimbursement to prescriptions dispensed by 340B covered entities.[29] By using actual 340B acquisition cost, the state eliminates the risk of a duplicate discount while ensuring that the benefit of the 340B discounts accrue to the state Medicaid program, rather than the 340B covered entity.

These shifts to fee-for-service pharmacy benefits have become controversial and the subject of several lawsuits by covered entities.[30] That's because covered entities have been earning 340B contract pharmacy profits at the expense of state Medicaid programs.

4) Patients covered by commercial insurance and Medicare Part D pay for the 340B funds earned by covered entities and contract pharmacies.

As a matter of principle, an underinsured or indigent patient should not pay hundreds or thousands of dollars out-of-pocket for a drug that a large, multi-billion-dollar health system bought at a deep discount. However, this appears to happen regularly under the 340B program.

A patient with commercial or Medicare Part D insurance can't detect that their prescription is eligible for 340B pricing. The pharmacist at a contract pharmacy can't tell, either. That's because the determination is made weeks or months later. Consequently, the 340B covered entity requires insured patients to pay more for their prescriptions at contract pharmacies so the covered entity can generate 340B funds.

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[27] Almeter, P.J., et al., Pharmacy benefit manager reform within Medicaid Managed Care: The pursuit of a model that preserves the intent of the 340B program, *American Journal of Health-System Pharmacy*, September 2022.
[28] Medicaid Program; Covered Outpatient Drugs; Final Rule, *Federal Register*, February 1, 2016.
[29] Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State, Centers for Medicare & Medicaid Services.
[30] New York Implements Medicaid Drug Benefits Transfer, 340B Entities Say Fight Isn't Over, *340B Report*, April 4, 2023.

Patients therefore don't benefit from 340B discounts. Instead, they are expected to pay their health plans' full out-of-pocket costs. Patients taking specialty and brand-name drugs often have out-of-pocket costs tied to coinsurance or within the deductible phase. They therefore pay full price—or a percentage of full price—for drugs that are sold to 340B covered entities at deep discounts. Thus, an insured patient could pay thousands of dollars out of pocket—even as the 340B hospital and its contract pharmacy generate substantial profits.

For instance, I estimate that a commercially insured patient with coinsurance can be responsible for one-third of the total profit earned by the 340B hospital and the contract pharmacy.[31] If the patient had a high deductible plan, then 100% of the 340B savings would come from the patient. Note that these examples illustrate a single prescription. Many patients also have annual deductibles that would increase the patient's contribution to the 340B industry participants.
This reasoning also applies to Medicare patients. Like commercial plans, Medicare Part D plans often use percentage cost sharing instead of fixed dollar copayments for drugs on higher tiers. Medicare beneficiaries, unlike those in most private insurance plans, can face high out-of-pocket prescription drug costs if they reach the catastrophic coverage limit.[32] (Out-of-pocket obligations will be capped with the implementation of the Inflation Reduction Act of 2022.)

The OIG documented a troubling analog in the Medicare Part B program.[33] The OIG noted that for many cancer drugs, the Part B beneficiary's coinsurance was greater than the amount a covered entity spent to acquire the drug. In addition to the patient's out-of-pocket coinsurance, hospitals also received additional payments from the Medicare program. This further demonstrates how large hospital systems use seniors to generate 340B funds.

5) External contract pharmacies are profiting inappropriately from 340B discounts.

Rather than earning traditional dispensing spreads and fees, 340B contract pharmacies earn per-prescription fees paid by the 340B entity.[34] These fees can include fixed dollar payments as well as revenue-sharing and profit-sharing arrangements.

High 340B profits allow hospitals to pay inflated fees to their pharmacy partners, which earn margins well above what the patient's insurance company usually pays. Contract pharmacies can earn 25% to 35% of total 340B discounts, which equates to billions of dollars in gross profits. Thus, for-profit pharmacies share in a meaningful portion of the 340B discounts that covered entities earn. These profits accrue primarily to the large, for-profit companies that I identify above.

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[31] How Hospitals and PBMs Profit—and Patients Lose—From 340B Contract Pharmacies, *Drug Channels*, July 23, 2020.
[32] How Will the Prescription Drug Provisions in the Inflation Reduction Act Affect Medicare Beneficiaries?, Kaiser Family Foundation, August 18, 2022. These figures include more than 130,000 Part D beneficiaries who had out-of-pocket obligations above $2,000, but did not reach the catastrophic threshold.
[33] Part B Payments For 340b-Purchased Drugs, Office of Inspector General, November 2015, 9.
[34] Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, U.S. Government Accountability Office, June 2018, Appendix I.

Contract pharmacy fees aren't required to be based on the existing fair market value standards utilized in other federal programs. In fact, when it comes to contract pharmacy fees, there's no guidance at all. Therefore, contract specialty pharmacies can earn profits that are three to four times larger than a pharmacy's typical gross profit from a commercial insurer or Medicare Part D plan.[35]

According to financial analysts at Nephron Research, the five largest contract pharmacy operators' total estimated gross profits from the 340B program were $3.2 billion in 2021.[36] Estimated profits were only $1.1 billion in 2017. This rapid escalation in profits occurred because the larger PBMs and pharmacy chains have accelerated their 340B investments in recent years.

Manufacturers' policy changes have forced the largest public companies to acknowledge the previously-hidden profitability of the 340B program. In May, CVS Health disclosed that 340B contract pharmacy changes would lower its PBM segment profits by $150 to $200 million.[37] Last year, Walgreens disclosed that manufacturers' disruptions to the 340B contract pharmacy market will reduce its profits by about $250 million in the company's 2022 and 2023 fiscal years.[38]

6) The lack of transparency into 340B prescription claims raises costs to Medicare Part D and commercial payers.

Manufacturers cannot identify 340B prescriptions dispensed by contract pharmacies. This disrupts rebate negotiations and raises net drug costs.

The 340B statute prohibits manufacturers from having to provide a discounted 340B price and a Medicaid drug rebate for the same drug, i.e., "duplicate discounts." However, manufacturers often find themselves paying a Medicaid rebate and a 340B discounts for the same prescription. Such double dipping occurs because there is a lack of transparency into claims data that would allow states and manufacturers to apply payment policies correctly. The OIG has identified this lack of transparency as one of its top unimplemented recommendations.[39]

Unlike the provisions in Medicaid, there are no statutory protections for prescriptions paid by commercial third-party payers and Medicare Part D plans. Even if manufacturers negotiate contract language prohibiting duplicate discounts, manufacturers often end up paying rebates on the same prescriptions to commercial payers for products that covered entities purchase at 340B prices. That's

[35] How Hospitals and PBMs Profit—and Patients Lose—From 340B Contract Pharmacies, *Drug Channels*, July 23, 2020. It is unclear how much of these profits are retained by contract pharmacy operators. For example, the companies share a portion of their 340B profits with health plans by accepting lower reimbursement rates for preferred participation in narrow networks.
[36] "New Restrictive 340B Policies Will Weigh on Contract Pharmacy in 2H 2023," Nephron Research, April 17 2023.
[37] CVS Health, Earnings conference call, May 3, 2023, 14. These companies' estimated profits from the program will decline to an estimated $2.9 billion for 2023, due to some pharmaceutical manufacturers' policy changes.
[38] Walgreens Boots Alliance Inc Earnings Call, October 13, 2022, 26.
[39] Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs, Office of Inspector General, 2022, 67.

because manufacturers cannot identify which prescriptions have been dispensed with 340B discounts.

The National Council for Prescription Drug Programs (NCPDP), which sets electronic communication standards for pharmacy care, allows the identification of an individual prescription's status under the 340B Drug Pricing Program.[40] However, hospitals and contract pharmacies have refused to utilize this voluntary standard.

Manufacturers understandably oppose paying 200% in discounts while others in the system make money. Hospitals and pharmacies are fighting requests for data that manufacturers need to verify or track 340B discounts.

Manufacturers would be justified in reducing managed care formulary rebates to offset paying duplicate discounts based on presumed 340B-dispensed claims. Lower rebates to commercial and Medicare Part D plans would raise the net costs of drugs to government and private payers.

The lack of transparency is among the main reasons that manufacturers altered policies regarding 340B discounts available at contract pharmacies. Many manufacturers request or require that the covered entity share deidentified claims data in order for those claims to be eligible for 340B discounted pricing. Many manufacturers have asked covered entities to use a common platform to share claims data.

III. POLICY RECOMMENDATIONS FOR 340B CONTRACT PHARMACIES

Our healthcare system has changed a lot in the 31 years since the 340B program was introduced. As my research indicates, the program needs to be modernized so that it benefits seniors and other patients—while supporting the genuine safety-net services of healthcare providers.

I respectfully offer the following guidelines for improving the operation and accountability of contract pharmacies within the 340B program:

- **Mandate that contract pharmacies for 340B covered entities charge no more than the discounted 340B price to uninsured, underinsured, and vulnerable patients.** There is simply no excuse for overcharging needy patients, per the situations documented by the OIG and GAO. At a minimum, covered entities should use standards for 340B prescription assistance at contract pharmacies that are comparable to the eligibility standards used for charitable medical care services.

- **Require that contract pharmacy fees be based on fair market value standards.** This would prevent for-profit pharmacies from capturing 340B discounts, while still providing

[40] National Council for Prescription Drug Programs, 34ØB Information Exchange, Reference Guide Version 1.Ø. July 2011.

appropriate incentives for pharmacies to participate in the program. It would also protect smaller covered entities that lack negotiating clout with the larger 340B contract pharmacy providers.

- **Revise hospital eligibility for the 340B program to create a clearer patient definition.** As I note above, most prescriptions at 340B contract pharmacies are dispensed to patients with commercial and Medicare Part D insurance. The program should be updated to target benefits towards needy patients and true safety-net providers.

- **Limit the number and geographic scope of contract pharmacy arrangements.** Covered entities are not required to justify large networks on the basis of access needs for vulnerable populations. Smaller, more controlled networks will improve oversight and ensure that only eligible patients use the contract pharmacy.

- **Mandate transparency into the program's size and operations.** I have only been able to access general program information after filing burdensome FOIA requests.

- **Require greater transparency into profits generated by 340B contract pharmacies.** Such a requirement would ensure that discounts provided under the 340B program are being utilized appropriately. Hospitals' community benefit obligations are distinct from any funds received from the 340B program. However, there is compelling evidence that hospitals are double-counting 340B savings against their fundamental legal and statutory community benefit obligations as non-profit organizations.[41]

- **Require contract pharmacies to identify 340B prescriptions at the time of adjudication.** This change would make manufacturers more willing to offer larger rebates to third-party payers.

Please contact me if I can answer any questions or provide additional information.

Sincerely,

Adam J. Fein, Ph.D.
afein@drugchannels.net

[41] U.S. Government Accountability Office, Opportunities Exist to Improve Oversight of Hospitals' Tax-Exempt Status, September 2020.