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October 30, 2020

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20510
340B@help.senate.gov

The Honorable Greg Walden
Republican Leader
U.S. House of Representatives Committee on Energy and Commerce
2322 Rayburn House Office Building
Washington, D.C. 20515
340B@mail.house.gov

Dear Chairman Alexander and Ranking Member Walden:

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, nearly 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 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 channel distortions within the U.S. pharmaceutical distribution and reimbursement system.

As I will explain, these distortions:

- Overcharge uninsured patients for their 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 president of [Pembroke Consulting, Inc.](#), a management consulting and research firm based in Philadelphia. For more than 20 years, I have consulted on channel, trade, payer, pharmacy, and other commercial issues in the pharmaceutical industry. I am also CEO of [Drug Channels Institute](#) (DCI), a Pembroke Consulting subsidiary that provides management education for and about the pharmaceutical industry.

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 pharmacy benefit managers (PBMs).

For years I've been studying the economics of the complex and opaque intersection of the 340B program and the pharmacy industry. Over the past eight years, I have published more than 70 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.

According to the data provided by HRSA, discounted purchases made under the program totaled at least \$29.9 billion in 2019¹—an increase of 23% from the \$24.3 billion in 2018. What’s more, I have found that since 2014, purchases under the program have grown at an average rate of 27% per year. Over the same period, manufacturers’ net drug sales have grown at an average annual rate of less than 5%.²

Hospitals account for 86% of total 340B purchases, according to data provided to me from Apexus.³

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. I estimate that the 340B program has grown to account for more than 8% of the total U.S. drug market and as much as 16% of manufacturer’s total rebates and discounts for brand-name drugs.

2) The number of external 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.⁴

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.⁵
- As of July 2020, I found nearly 28,000 unique pharmacy locations acting as 340B contract pharmacies.⁶ That’s a more than 21-fold increase in just 10 years.
- These pharmacies have more than 112,000 contractual relationships with more than 8,000 340B covered entities. About three-quarters of these covered entities are disproportionate share and children’s hospitals.

This growth means that almost half of the U.S. pharmacy industry now profit from the 340B program, which was designed as a narrow support to certain hospitals and providers.

¹ Fein, Adam J., [New HRSA Data: 340B Program Reached \\$29.9 Billion in 2019; Now Over 8% of Drug Sales](#), *Drug Channels*, June 9, 2020. Note that the data from Apexus include only indirect sales made via wholesalers. The \$29.9 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.

² *Medicine Spending and Affordability in the United States*, IQVIA Institute for Human Data Science, 2020, 5

³ Email communication from Apexus, February 16, 2016.

⁴ Health Resources and Services Administration, [Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services](#), *Federal Register*, March 5, 2010.

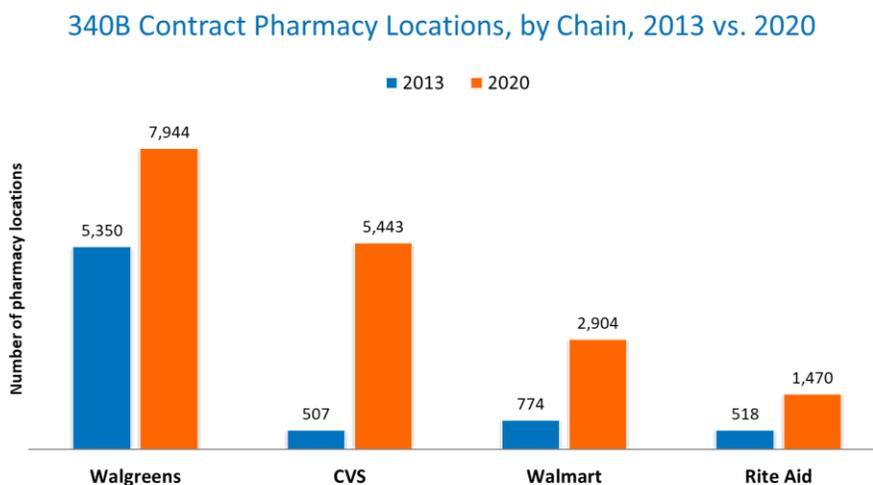
⁵ U.S. Government Accountability Office, [Status of Agency Efforts to Improve 340B Program Oversight](#), May 15, 2018.

⁶ Fein, Adam J., [Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?](#), *Drug Channels*, July 14, 2020.

The 340B program is now approaching the size of the nation’s Medicaid outpatient drug market, which was projected to be \$34.9 billion in 2019.⁷ 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) Large, for-profit pharmacy companies are the primary operators of contract pharmacies.

Four large pharmacy chains—Walgreens, CVS, Walmart, and Rite Aid—account for nearly two-thirds of the program’s contract pharmacy locations. These companies have dominated contract pharmacies for years. The chart below shows the growth in 340B participation for these companies since my first analysis, in 2013.⁸ In line with overall program growth, the largest chains have dramatically increased the number of their locations acting as 340B contract pharmacies.



Source: Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database. Data show number of unique contract pharmacy locations as of July 1, 2020. Company totals are computed from combined banners (store names) in the database.

- Walgreens remains the dominant 340B contract pharmacy participant. As of mid-2020, we found that nearly 8,000 Walgreens locations act as 340B contract pharmacies. The chain therefore accounts for more than one-quarter of all contract pharmacy locations.
- CVS has dramatically increased its participation in the 340B program. About half of all CVS locations are now 340B contract pharmacies. The company’s growth has been facilitated by CVS Health’s acquisition of Wellpartner, a provider of 340B contract pharmacy services.
- Other major retail chains—Walmart, Rite Aid, Kroger, and Albertsons—account for more than 6,000 additional 340B contract pharmacy locations. Thousands of independent pharmacies and small chains participate, too.

⁷ Office of the Actuary in the Centers for Medicare & Medicaid Service, [National Health Expenditures \(projected\)](#), March 2020.

⁸ Fein, Adam J., [Walgreens Dominates 340B Contract Pharmacy Mega-Networks](#), *Drug Channels*, July 16, 2013.

4) For-profit, insurer-owned specialty pharmacies now play a significant role in the 340B program.

Specialty pharmaceuticals (also known as specialty drugs) are brand-name or generic drugs for patients undergoing intensive therapies for such chronic, complex illnesses as cancer, rheumatoid arthritis, multiple sclerosis, and HIV. Specialty drugs accounted for slightly more than 2% of all U.S. outpatient prescriptions, but more than one-third of the pharmacy industry's total revenues.

The country's largest specialty pharmacies are fully or partially owned by large, vertically integrated organizations that offer health insurance, manage pharmacy benefits, operate pharmacies, and deliver medical care to patients.⁹

The four largest specialty pharmacies are operated by CVS Health's Caremark business, Cigna's Express Scripts business, UnitedHealth Group's OptumRx business, and Walgreens Boots Alliance/Prime Therapeutics.¹⁰ Drug Channels Institute estimates that these four companies account for more than 70% of prescription revenues from pharmacy-dispensed specialty drugs.¹¹

Our research has documented these insurers' deep involvement in the 340B program:

- As of mid-2020, specialty locations associated with the top four specialty pharmacies are operating a combined 224 locations that act as contract pharmacies for 340B covered entities.¹² CVS Health and UnitedHealth also operate an additional 78 infusion sites that function as 340B contract pharmacies.
- These 302 locations have more than 17,000 contractual relationships with covered entities. Most of the relationships are with disproportionate share hospitals and children's hospitals. Thus, specialty pharmacies and infusion sites account for 15% of total contract pharmacy relationships with 340B hospitals and other covered entities. Yet they represent only 1% of 340B contract pharmacy locations.
- Each specialty pharmacy location has dozens or even hundreds of contract pharmacy relationships. This is unsurprising, because specialty pharmacies typically fill prescriptions from a central location and then deliver the products directly to a patient's home. For example, the typical CVS Specialty location has agreements with 225 covered entities; a typical Accredo pharmacy has agreements with 159 covered entities; and a typical AllianceRx Walgreens Prime location has agreements with 618 covered entities.

⁹ Fein, Adam J., [Insurers + PBMs + Specialty Pharmacies + Providers: Will Vertical Consolidation Disrupt Drug Channels in 2020?](#), *Drug Channels*, December 12, 2019.

¹⁰ Prime Therapeutics is a PBM owned by 18 Blue Cross and Blue Shield health plans. Note that Prime now outsources many of its PBM functions to Cigna's Express Scripts business. See: Fein, Adam J., [Prime Therapeutics Deepens Its Reliance on Express Scripts: Our Four Takeaways From Their New Pharmacy Relationship](#), *Drug Channels*, October 15, 2020.

¹¹ Fein, Adam J., [The Top 15 Specialty Pharmacies of 2019: PBMs Stay On Top](#), *Drug Channels*, April 28, 2020.

¹² Fein, Adam J., [PBM-Owned Specialty Pharmacies Expand Their Role In—and Profits From—the 340B Program](#), *Drug Channels*, July 21, 2020.

5) 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.

Based on my analysis of HRSA data,¹³ about 500 healthcare providers (6% of covered entities with contract pharmacies) account for more than 40% all contract pharmacy relationships. These providers have built networks averaging 99 pharmacies. Six large health systems have networks with more than 300 contract pharmacies.

The table below summarizes our findings about contract pharmacy networks. In addition to the mega-networks, a further 2,000 providers have networks with 11 to 50 pharmacies, accounting for 40% of contract pharmacy arrangements. By contrast, 70% of all 340B covered entities that utilize contract pharmacies have small networks with 10 or fewer pharmacy locations.

340B Covered Entities, By Number of Contract Pharmacies, July 2020

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 Network Size
One pharmacy	1,856	23%	1,856	2%	1
2 to 10 pharmacies	3,764	47%	17,393	15%	5
11 to 50 pharmacies	1,964	24%	45,501	40%	23
50 to 100 pharmacies	482	6%	47,948	43%	99
Total	8,066	100%	112,698	100%	14

Source: Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database (7/1/20).

These networks are seemingly designed to enrich certain covered entities and pharmacies, not to help needy and uninsured patients. 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 hospitals monitor out-of-state mail and specialty pharmacies.

II. CHANNEL DISTORTIONS FROM 340B CONTRACT PHARMACIES

I believe that the growing use of contract pharmacies leads to at least five significant problems in the U.S. drug distribution and reimbursement system. I have outlined some of these issues in a peer-reviewed article¹⁴ and in a recent *Wall Street Journal* opinion piece.¹⁵

¹³ Drug Channels Institute analysis of OPA Daily Contract Pharmacy Database (7/1/20)

¹⁴ Fein, Adam J., [Challenges for Managed Care from 340B Contract Pharmacies](#), *Journal of Managed Care and Specialty Pharmacy*, March 2016.

¹⁵ Fein, Adam J., [The Federal Program That Keeps Insulin Prices High](#), *The Wall Street Journal*, September 10, 2020.

1) Needy patients do not always benefit from prescriptions filled at 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.¹⁶
- 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.¹⁷

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 determinations of 340B eligibility across covered entities.¹⁸ 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."¹⁹

2) Most prescriptions at hospitals' 340B contract pharmacies are dispensed to insured patients.

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

¹⁶ Office of Inspector General, [Contract Pharmacy Arrangements in the 340B Program](#), February 2014.

¹⁷ U.S. Government Accountability Office, [Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement](#), June 2018.

¹⁸ Office of Inspector General, [Contract Pharmacy Arrangements in the 340B Program](#), OEI-05-13-004311G. February 4, 2014.

¹⁹ U.S. Government Accountability Office, [Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement](#), September 2011.

and paid by such third-party payers as Medicare Part D and commercial health plans. (Medicaid prescriptions are excluded by statute.)

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. Consequently, covered entities generate 340B funds from the difference between:

- The drug's market rate pharmacy reimbursement (paid by a Medicare or private plan) plus the patient's out-of-pocket contribution, and
- The drug's discounted 340B price from the manufacturer

A 340B entity only profits when prescriptions are paid at nondiscounted rates. Consequently, the vast majority of prescriptions filled at contract pharmacies are dispensed to patients who have prescription drug insurance—not to uninsured or financially needy patients. That's why Medicare and other third-party payers end up being responsible for the balance of the profit earned by a 340B covered entity and the contract pharmacy.

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

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.

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 hospitals at deep discounts. An insured patient could pay thousands of dollars out of pocket—even as the 340B hospital and its contract pharmacy generate substantial profits.

Medicare Part D patients also fund 340B savings. Like commercial plans, Medicare Part D plans often use percentage cost sharing instead of fixed dollar copayments for drugs on higher tiers. Furthermore, Medicare beneficiaries, unlike those in most private insurance plans, can face unlimited out-of-pocket prescription drug costs if they reach the catastrophic coverage limit. Consequently, a significant number of Medicare beneficiaries had very high levels of out-of-pocket spending. More than 1 million Part D enrollees had total drug spending above the catastrophic coverage threshold. They spent an average of \$3,214 out of pocket.²⁰

²⁰ Kaiser Family Foundation, [How Many Medicare Part D Enrollees Had High Out-of-Pocket Drug Costs in 2017?](#), June 2019.

As a matter of principle, a senior on a fixed income should not pay hundreds or thousands of dollars out-of-pocket for a drug that a large health system bought at a deep discount.

The OIG documented a troubling analog in the Medicare Part B program.²¹ 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.

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

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.

Rather than earning traditional dispensing spreads and fees, 340B contract pharmacies earn per-prescription fees paid by the 340B entity.²² These fees can include fixed dollar payments as well as revenue-sharing and profit-sharing arrangements. These arrangements permit for-profit pharmacies to share in the 340B discounts that covered entities earn.

Given 340B prescription profit opportunities, a covered entity can offer—and large pharmacy chains and insurers can demand—overly generous payments. I estimate that contract specialty pharmacies earn profits that are three to four times larger than a specialty pharmacy's typical gross profit from a commercial insurer or Medicare Part D plan.²³ As I discuss above, these profits flow to some of the largest public companies in the U.S.

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.

5) 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." The prohibition on duplicate discounts applies to traditional Medicaid arrangements as well as Medicaid programs operated by managed care organizations, also known as Managed Medicaid.

²¹ Office of Inspector General, [Part B Payments For 340b-Purchased Drugs](#), November 2015, 9.

²² U.S. Government Accountability Office, [Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement](#), June 2018, Appendix I.

²³ Fein, Adam J., [How Hospitals and PBMs Profit—and Patients Lose—From 340B Contract Pharmacies](#), *Drug Channels*, July 23, 2020.

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 recently identified this lack of transparency as one of its top unimplemented recommendations.²⁴

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 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.²⁵ 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.

III. POLICY RECOMMENDATIONS FOR 340B CONTRACT PHARMACIES

Our healthcare system has changed a lot in the 28 years since the 340B program was introduced. 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.

²⁴ Office of Inspector General, [Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs](#), August 2020, 29.

²⁵ National Council for Prescription Drug Programs, [340B Information Exchange, Reference Guide Version 1.0](#). July 2011.

- **Require that contract pharmacy fees be based on fair market value standards.** This would prevent for-profit pharmacies from capturing 340B discounts. 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 ensure that only eligible patients use the contract pharmacy.
- **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. There is compelling evidence that hospitals are double-counting 340B savings against their fundamental legal and statutory community benefit obligations as non-profit organizations.²⁶ Hospitals' community benefit obligations are distinct from any funds received from the 340B program.
- **Require contract pharmacies to identify 340B prescriptions at the time of adjudication (payer prescription approval).** 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.

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²⁶ U.S. Government Accountability Office, [Opportunities Exist to Improve Oversight of Hospitals' Tax-Exempt Status](#), September 2020.