The 340B Program and Considerations for PDABs

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Disclaimer and Conflict of Interest Disclosure

My comments today are my own and **do not represent the Minnesota Prescription Drug Affordability Board**, or the **University of Minnesota School of Public Health**

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340B is Complicated but PDABs Need to Understand

The **objectives of PDABs and 340B** organizations may **directly conflict** because the size of the 340B subsidy depends on **drug prices**

Research suggests the **340B subsidy does not always translate to better access** for patients because the program is **poorly targeted**

The 340B Drug Discount Program Defined

Manufacturers provide **upfront discounts** on **outpatient drugs** to qualifying **clinics and hospitals** in exchange for coverage in Medicaid.

HRSA states the goal is to “stretch scarce federal resources as far as possible **reaching more eligible patients** and providing **more comprehensive services**.”

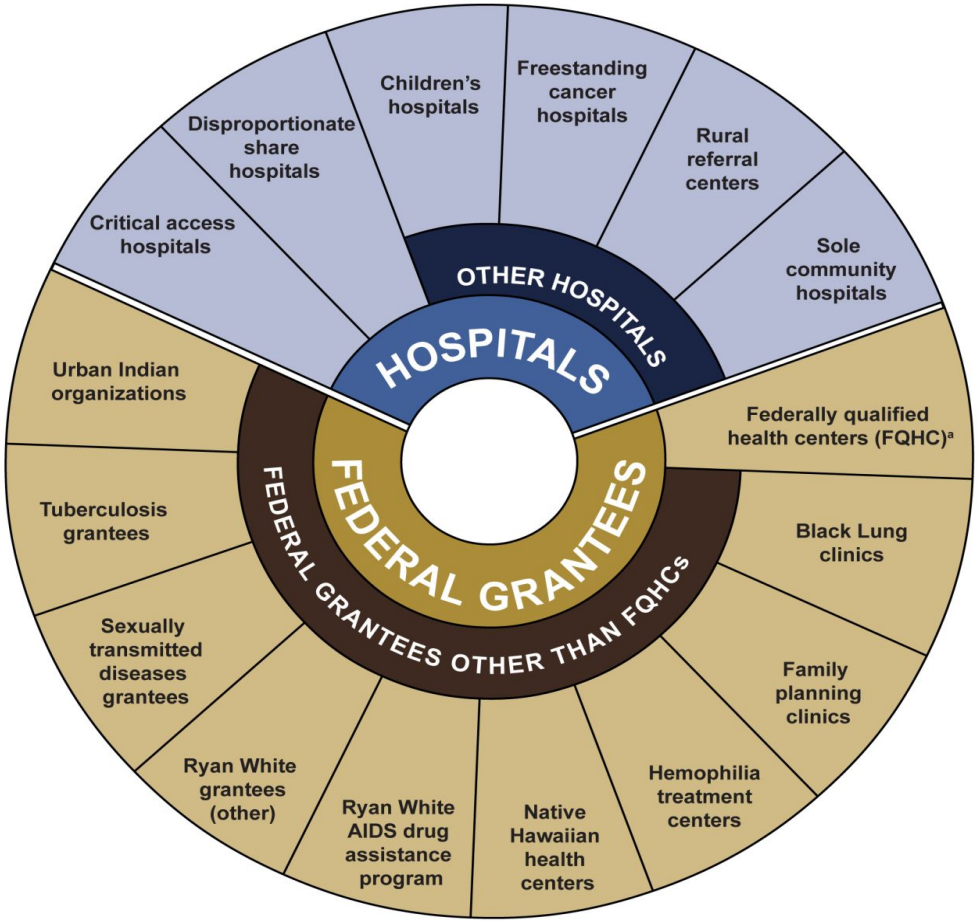
Source: HRSA

An Accident of History?

1990 **Medicaid Drug Rebate** granted Medicaid agencies "**best price**," triggering significant **price increases** on other payers, especially **safety-net organizations.**

340B intended to **extend discounts similar to Medicaid rebates** to safety-net organizations to **prevent loss of services to patients who rely on the safety-net**.

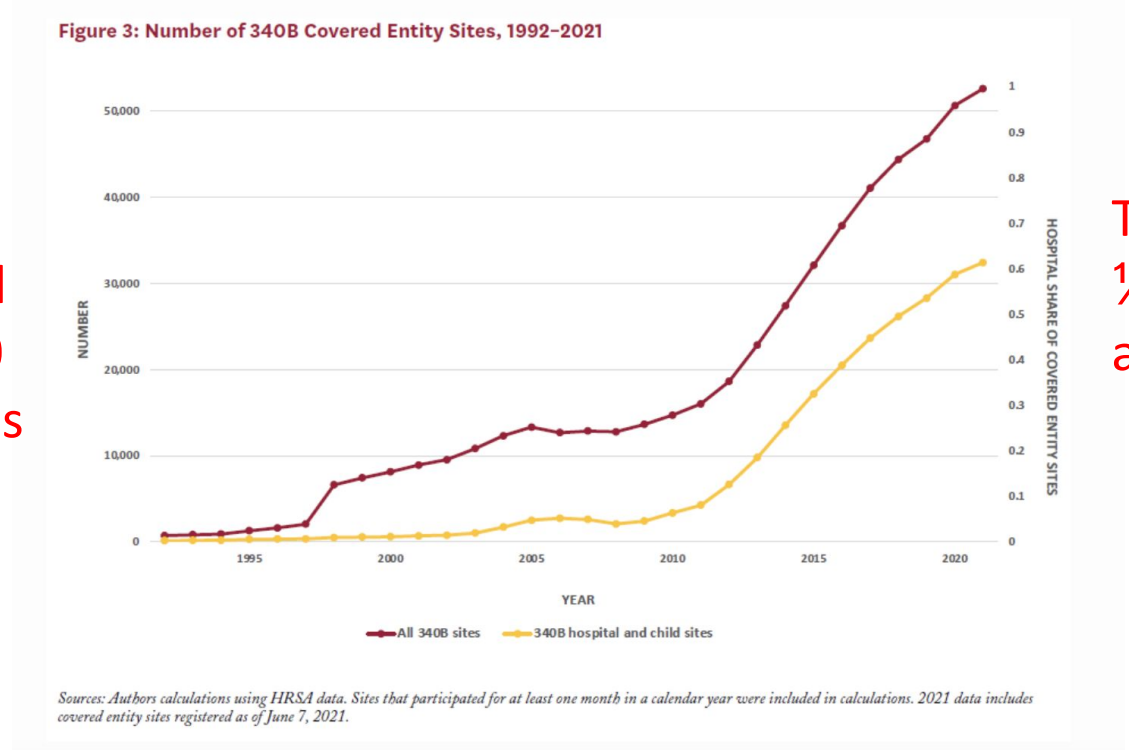
“Covered Entities”



Source: GAO

340B Program Scope has Grown Significantly

Began with ~5,600 Federal clinics and ~50 public hospitals



Today it's about ⅓ Federal clinics and ⅔ hospitals

340B Accounted for $66B in Purchases in 2023

340B Drug Pricing Program, Purchases by Covered Entities, 2022

Entity type	Total 2022 purchases at 340B discounted prices	Share of total 2022 purchases	Change in total purchases vs. 2021
Hospital			
• Disproportionate Share Hospitals	$41,818,751,617	77.9%	+22.0%
• Children's Hospitals	$1,662,587,169	3.1%	+25.0%
• Rural Referral Centers	$1,327,392,962	2.5%	+13.1%
• Critical Access Hospitals	$743,195,969	1.4%	+19.7%
• Sole Community Hospitals	$516,652,406	1.0%	+14.4%
• Free-standing Cancer Centers	$420,119,631	0.8%	+38.2%
Subtotal	$46,488,699,754	86.5%	+21.8%
Federal Grantee			
• Consolidated Health Center Programs	$2,766,861,692	5.2%	+24.9%
• Ryan White HIV/AIDS Program Grantees	$2,583,009,095	4.8%	+18.5%
• Sexually Transmitted Disease Clinics	$1,200,458,142	2.2%	+37.8%
• Comprehensive Hemophilia Treatment Center	$317,598,376	0.6%	+65.3%
• All other	$359,191,705	0.7%	+26.2%
Subtotal	$7,227,119,010	13.5%	+25.8%
Total	$53,715,818,764	100.0%	+22.3%

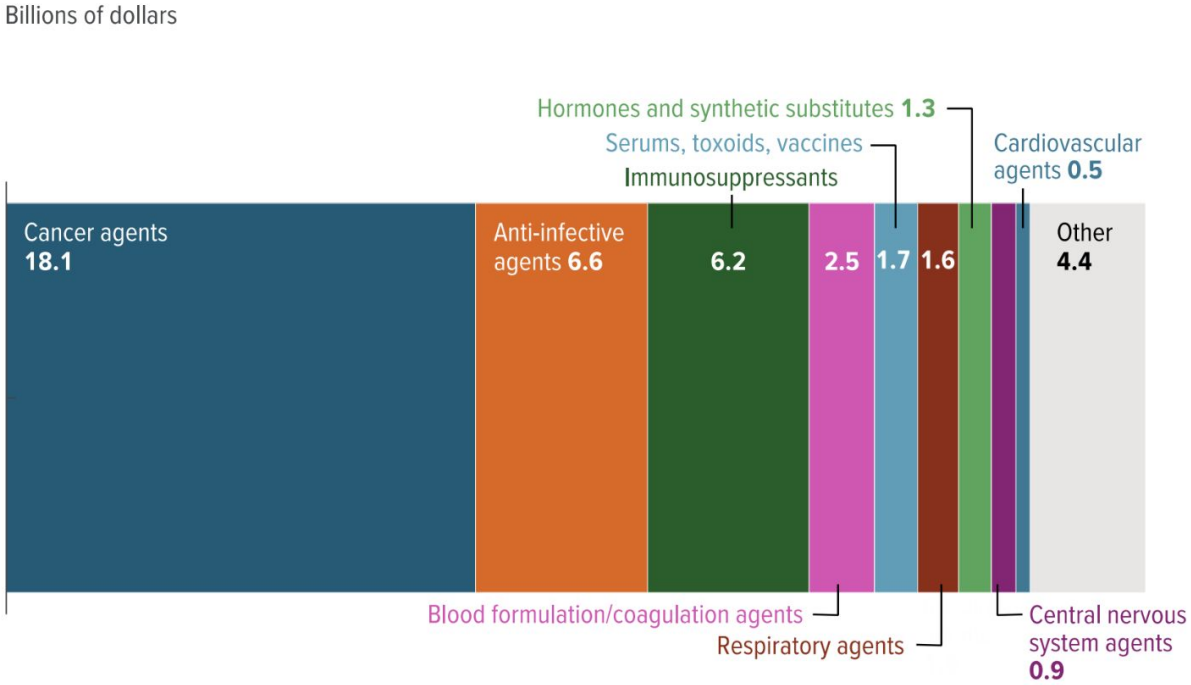
Source: Drug Channels Institute analysis of data from Health Resources and Services Administration. Purchases exclude sales made directly to healthcare institutions by manufacturers and some sales by specialty distributors. Data for purchases at discounted prices show value of purchases at or below the discounted 340B ceiling prices.

Mostly through hospitals

Far less through grantees

Source: HRSA 2023, 2024 via Drug Channels

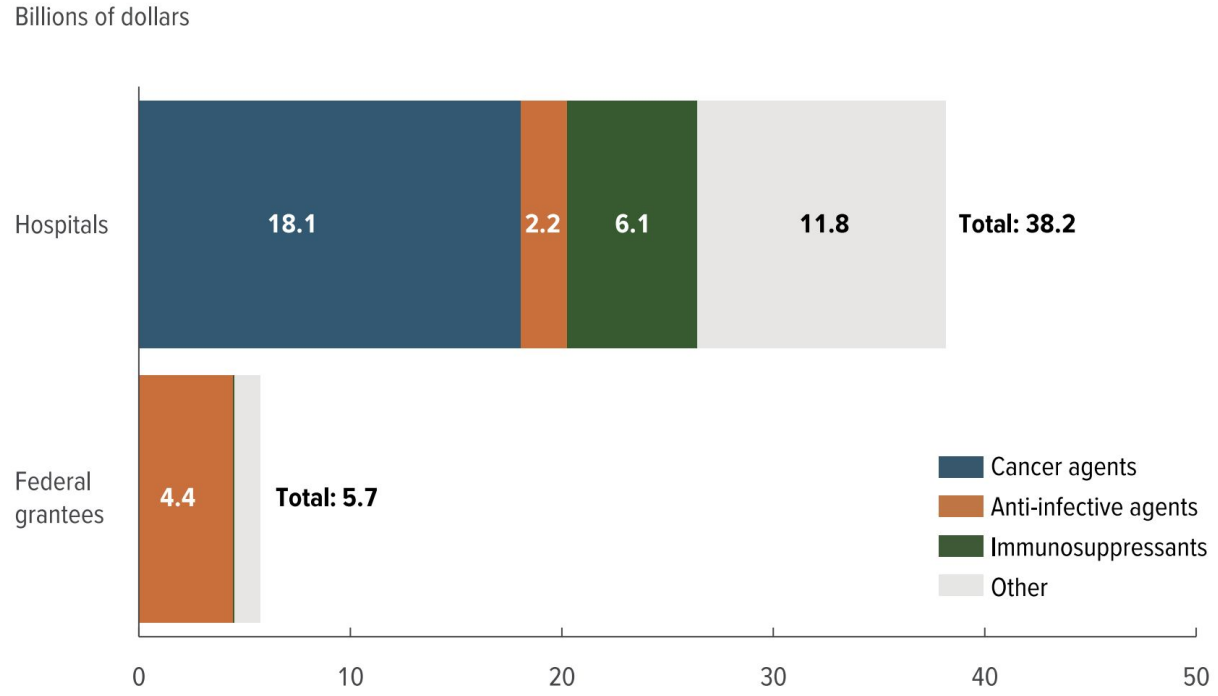
340B Concentrated in Certain High-Cost Drugs in 2021



US spending on cancer drugs ~$75B in 2021

Source: CBO 2024

340B Concentrated in Certain High-Cost Drugs in 2021

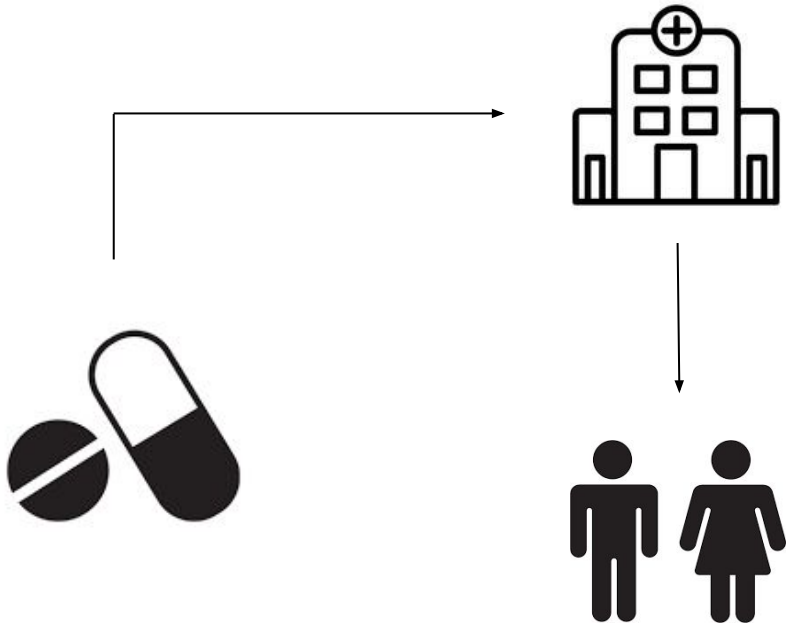


Higher cost drugs mostly through hospitals

Lower cost drugs mostly through grantees

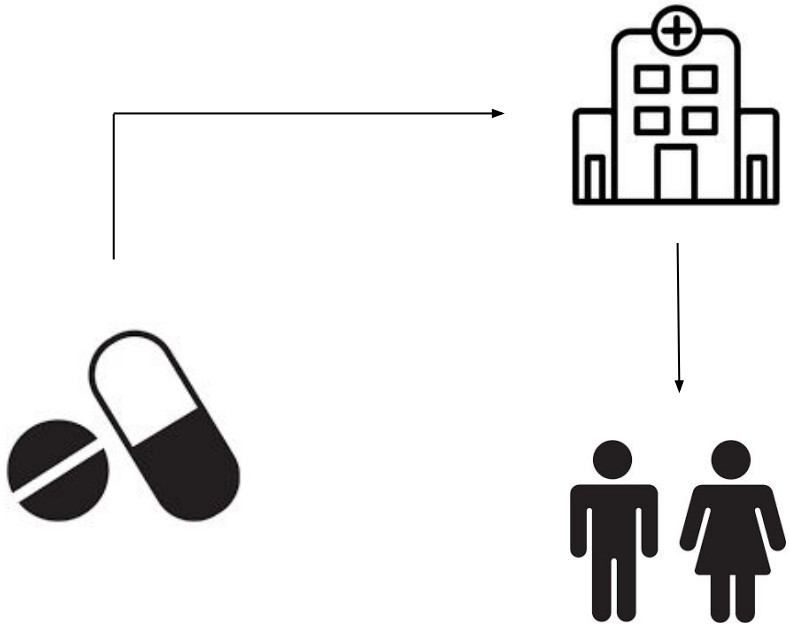
Source: CBO 2024

How the 340B Subsidy Benefits Participants



340B designed to **benefit** the **participants**, who are *assumed* to **pass benefits** to **patients**

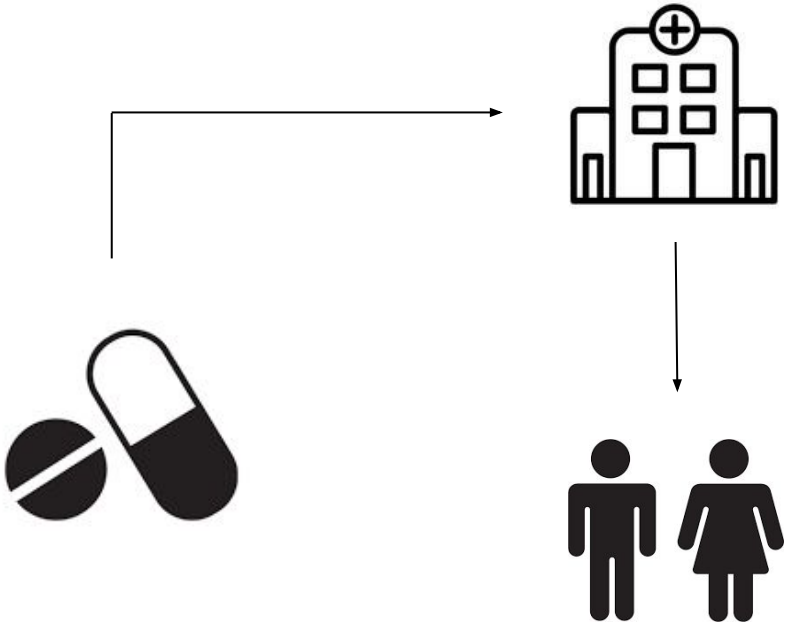
How the 340B Subsidy Benefits Participants



Without 340B	With 340B
- $100 Cost of drug	- $60 Cost of drug
+ $0 Reimbursement	+ $0 Reimbursement
+ $0 Co-payment	+ $0 Co-payment
- $100	- $60

Reduce losses by $40

How the 340B Subsidy Benefits Participants



Without 340B	With 340B
- $100 Cost of drug	- $60 Cost of drug
+ $90 Reimbursement	+ $90 Reimbursement
+ $10 Co-payment	+ $10 Co-payment
$0	+ $40

Generate $40 of Revenue*

How Much Revenue does 340B Generate?

62J.461 340B COVERED ENTITY REPORT.

§ Subdivision 1. **Definitions.** (a) For purposes of this section, the following definitions apply.

(b) "340B covered entity" or "covered entity" means a covered entity as defined in United States Code, title 42, section 256b(a)(4), with a service address in Minnesota as of January 1 of the reporting year. 340B covered entity includes all entity types and grantees. All facilities that are identified as child sites or grantee associated sites under the federal 340B Drug Pricing Program are considered part of the 340B covered entity.

(c) "340B Drug Pricing Program" or "340B program" means the drug discount program established under United States Code, title 42, section 256b.

(d) "340B entity type" is the designation of the 340B covered entity according to the entity types specified in United States Code, title 42, section 256b(a)(4).

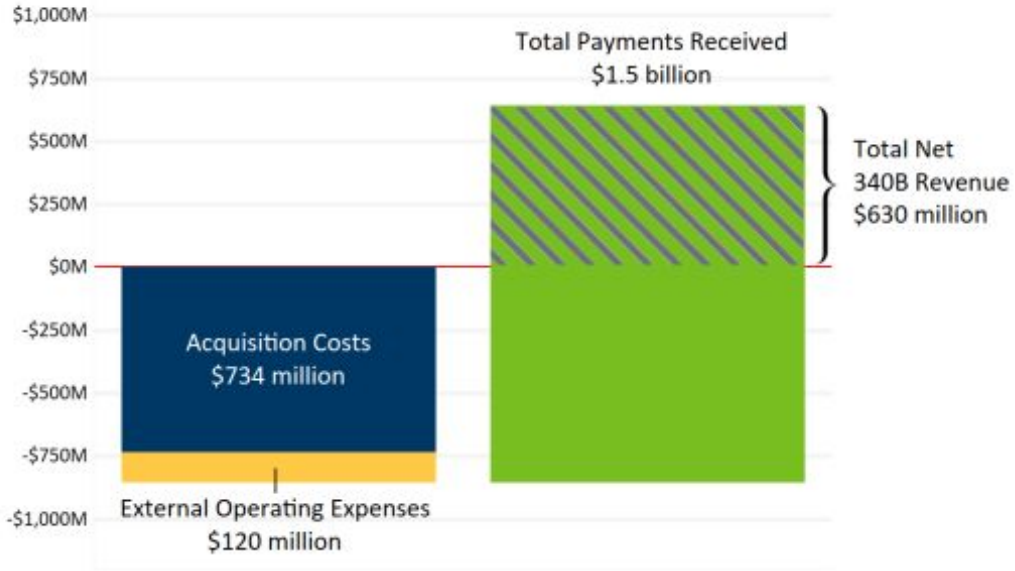
(e) "340B ID" is the unique identification number provided by the Health Resources and Services Administration to identify a 340B-eligible entity in the 340B Office of Pharmacy Affairs Information System.

(f) "Contract pharmacy" means a pharmacy with which a 340B covered entity has an arrangement to dispense drugs purchased under the 340B Drug Pricing Program.

(g) "Pricing unit" means the smallest dispensable amount of a prescription drug product that can be dispensed or administered.

Source: MN Statute 62J.461

Results from Minnesota's 2023 Covered Entity Report



Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

$766M in gross 340B revenue generated in Minnesota in 2023

Source: MN MDH

340B Revenue by Payer

Payer Type	Drug Fills (Count)	% of Drug Fills	Payments Received ($)	Net 340B Revenue ($)	% of Net 340B Revenue	Average Net 340B Revenue Per Drug Fill ($)
Commercial	1,921,639	42%	908,854,110	343,236,687	54%	179
Medicare	1,107,475	24%	351,595,699	197,064,198	31%	178
Minnesota Health Care Programs (MHCP)	932,441	20%	169,854,222	86,587,184	14%	93
Other	640,023	14%	53,538,210	3,374,283	1%	5
Total	**4,601,577**	**100%**	**1,483,842,241**	**630,262,352**	**100%**	**137**

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

Source: MN MDH

340B Revenue by Entity Type

Major Entity Type	Covered Entity (CE) Grouping	Covered Entities (count)	Drug Fills (Count)	Acquisition Costs ($)	External Operating Costs ($)	Payments Received ($)	Net 340B Revenue ($)	Average Net 340B Revenue per CE ($)	Average Net 340B Revenue per Drug Fill ($)
Hospital	General Acute Care Hospitals (DSH)	24	2,707,505	566,390,065	86,038,210	1,158,173,156	505,744,881	21,072,703	187
Hospital	Critical Access Hospitals	72	940,380	39,684,338	12,493,446	111,802,360	59,624,576	828,119	63
Hospital	Other Hospitals	8	406,605	32,011,520	5,937,312	74,252,756	36,303,924	4,537,990	89
Grantee	Disease Specific Federal Grantees	66	232,763	86,270,048	11,488,781	118,490,487	20,731,659	314,116	89
Grantee	Safety-Net Federal Grantees	19	314,324	9,193,241	4,072,928	21,123,482	7,857,313	413,543	25
	Total	**189**	**4,601,577**	**733,549,211**	**120,030,677**	**1,483,842,241**	**630,262,352**	**3,334,721**	**137**

Source: MDH, Health Economics Program analysis of 2023 data reported by Covered Entities under the Minnesota 340B Covered Entity Report.

Source: MN MDH

340B Revenues Net of Fees by Drug Family

Rank by net 340B revenue	Drug family	Brand name(s)	Biologic	Primary indication	Total fills (count)	Total net 340B revenue ($)	Average net 340B revenue per fill ($)
1	Adalimumab	Humira	Yes	Immunology	3,593	12,233,752	3,405
2	Elexacaftor-Tezacaftor-Ivacaftor	Trikafta	No	Cystic fibrosis	2,465	9,737,952	3,950
3	Apixaban	Eliquis	No	Blood thinner	17,335	9,679,212	558
4	Semaglutide	Ozempic	No	Anti-diabetic	11,201	6,373,377	569
5	Etanercept	Enbrel	Yes	Immunology	578	3,899,862	6,747
6	Dornase Alfa	Pulmozyme	Yes	Cystic fibrosis	988	3,740,182	3,786
7	Somatropin	Norditropin	Yes	Growth hormone	1,219	3,459,801	2,838
8	Avalglucosidase Alfa-ngpt	Nexviazyme	Yes	Pompe disease	68	2,662,632	39,156
9	Semaglutide (Weight Management)	Wegovy	No	Weight loss	2,051	2,433,566	1,187
10	Rivaroxaban	Xarelto	No	Blood thinner	3,586	2,010,046	561

Source: MN MDH

Mixed Peer Review Findings on if 340B Benefits Patients

Federal grantee clinics increase provision of safety-net care (Watts et al. 2024, Nikpay et al. 2022)

New 340B participation among hospitals is **not associated with safety-net engagement** on average (Nikpay et al. 2021, Desai et al. 2022)

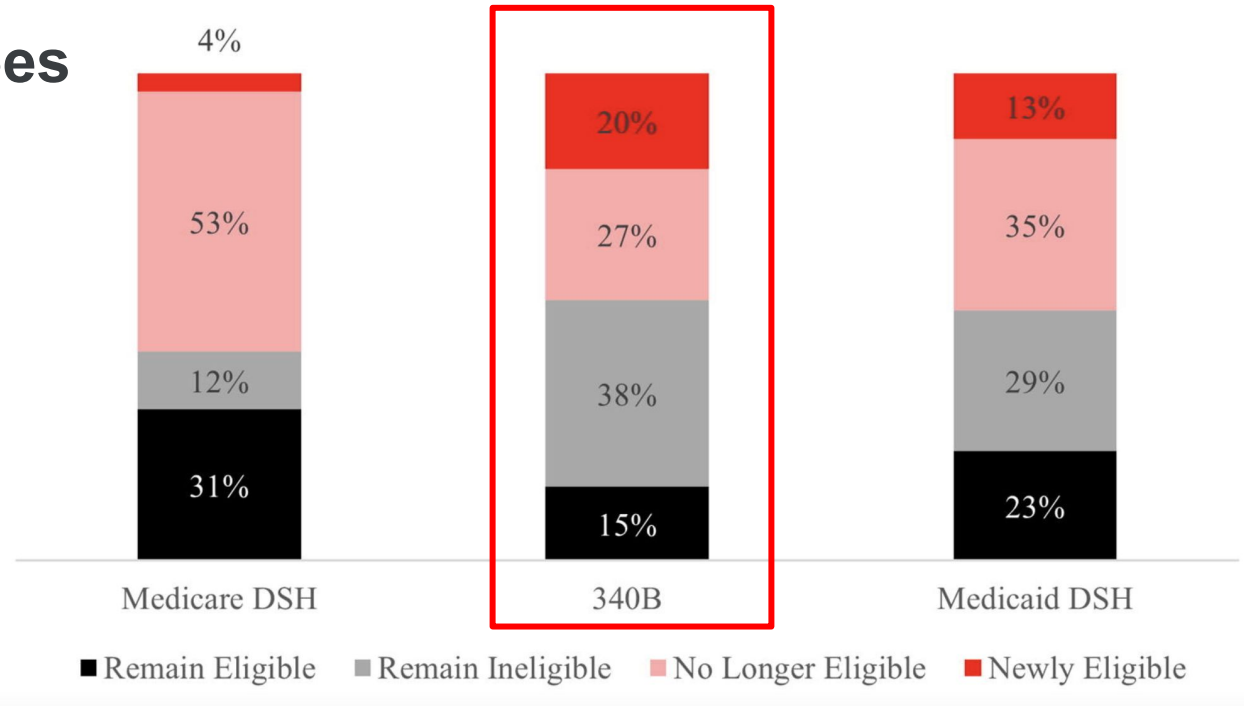
Public hospitals are an exception (Owsley et al. 2023)

Source: Watts et al. 2024, Owsley et al. 2024, Nikpay et al. 2020, Desai et al. 2021

Why Mixed Results? Poor Program Targeting

Most **federal grantees must** provide care **regardless of cost**

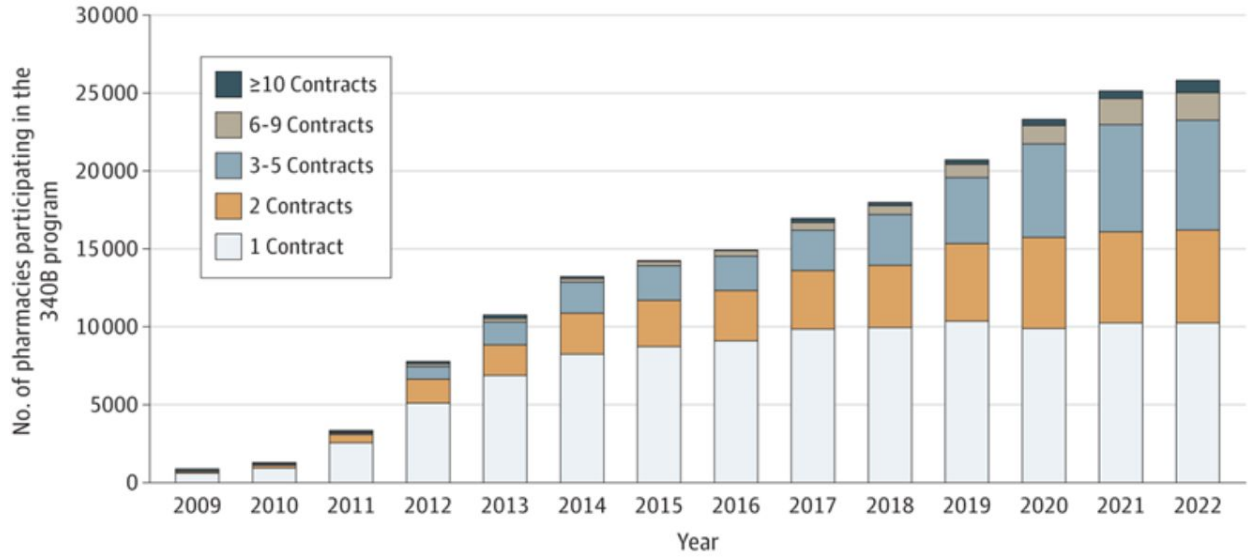
Most **hospitals** face **weaker**, voluntary **requirements**



Source: Nikpay 2022

Increasing Role of Large, Outside, For-Profit Parties

Figure 1. Distribution of Contract Pharmacy Depth Among Retail Pharmacies From 2009 to 2022

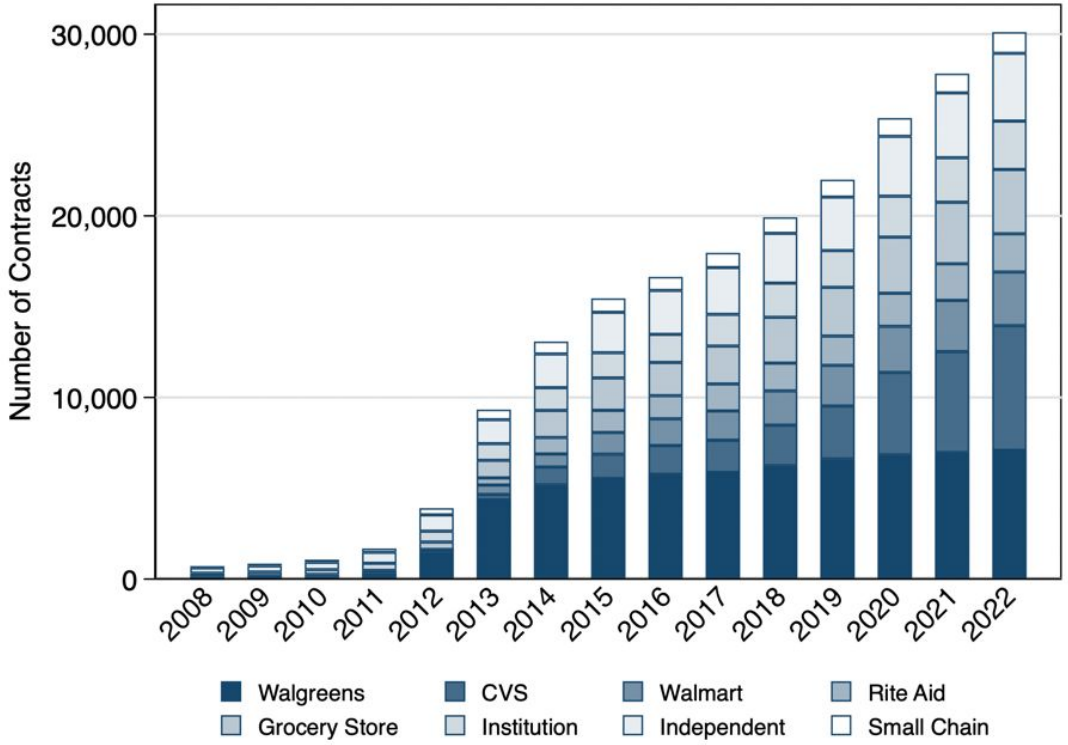


~40% of US retail pharmacies have >=1 contract

Source: Nikpay et al. 2022

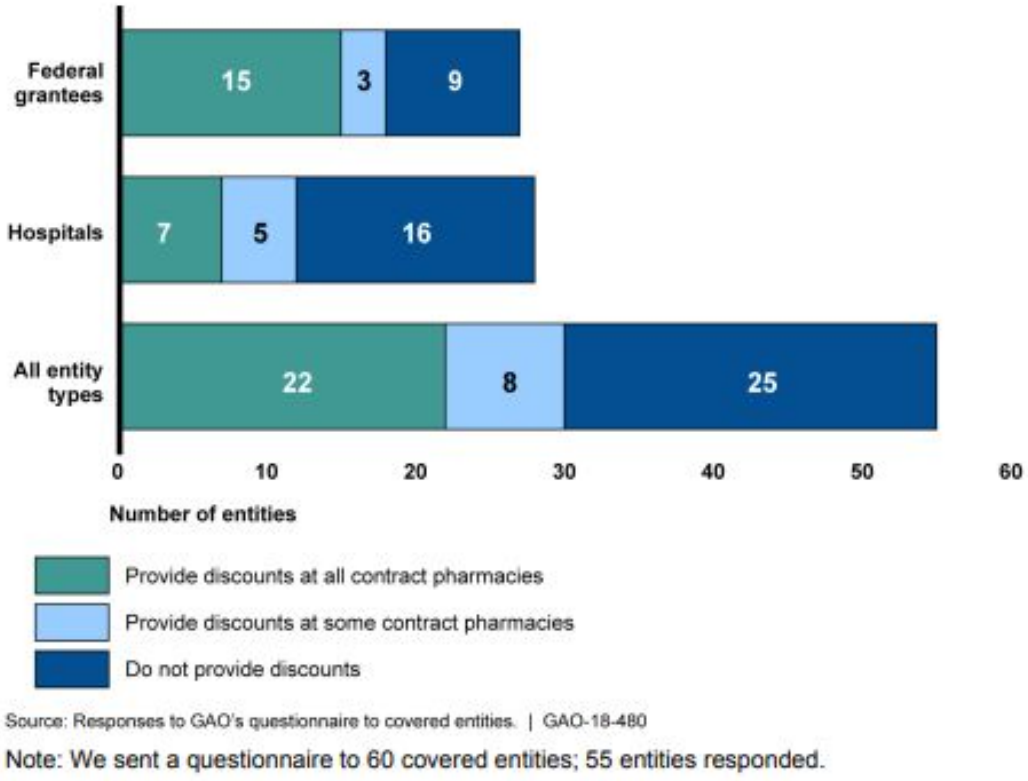
Increasing Role of Large, Outside, For-Profit Parties

⅔ of contract pharmacy relationships with top 4 pharmacy chains



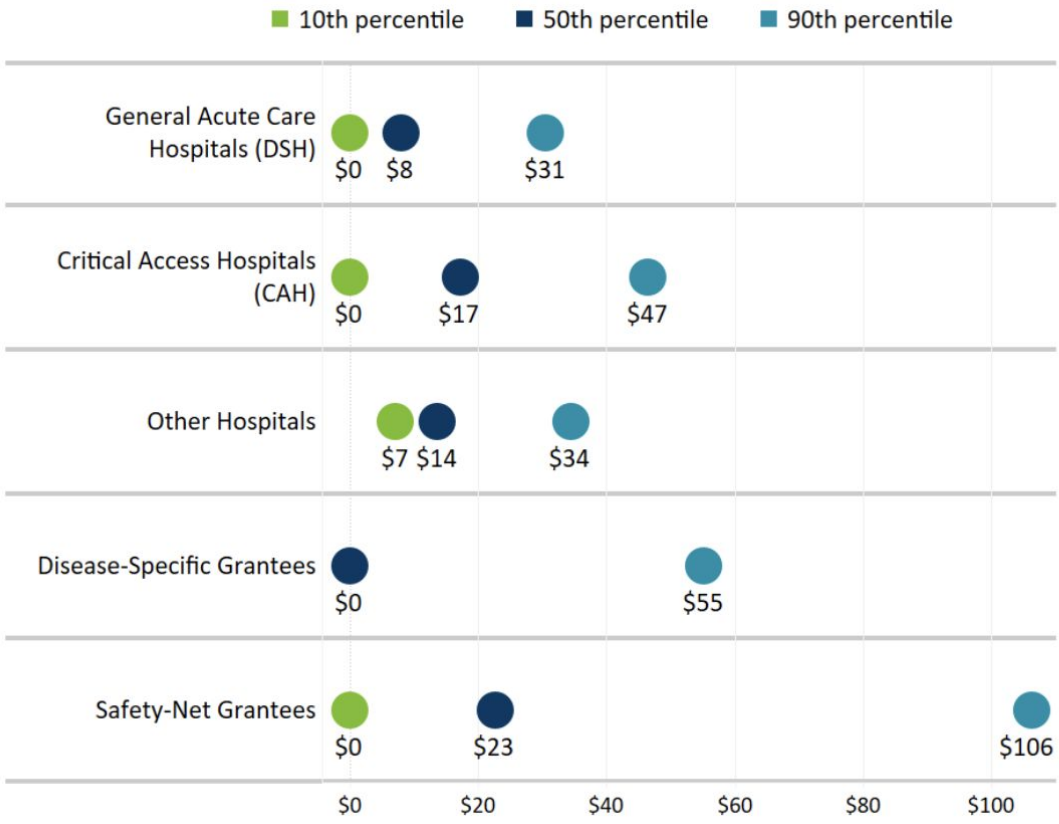
Source: McGlave et al. 2024

Contract Pharmacies Don’t Always Pass Discounts to Indigent Patients

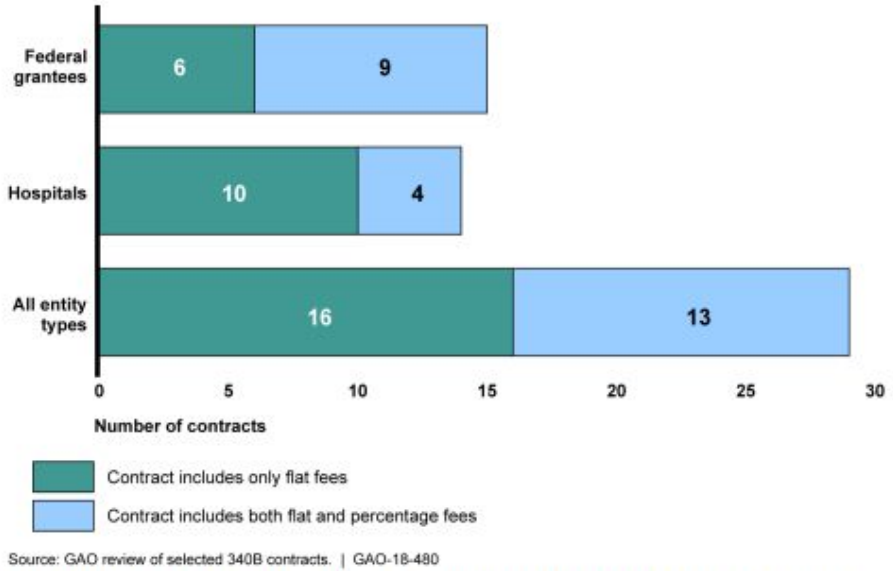


Source: GAO 2018

Outside Fees Paid per $100 of 340B Revenue from the Minnesota Covered Entity Report



Contract Pharmacies Also Take Fees



GAO Sample of 30 Contracts

Flat fee range: $6 - $15

+ for branded drugs: $5 - $7

+ for specialty drugs: $75 - $1,750

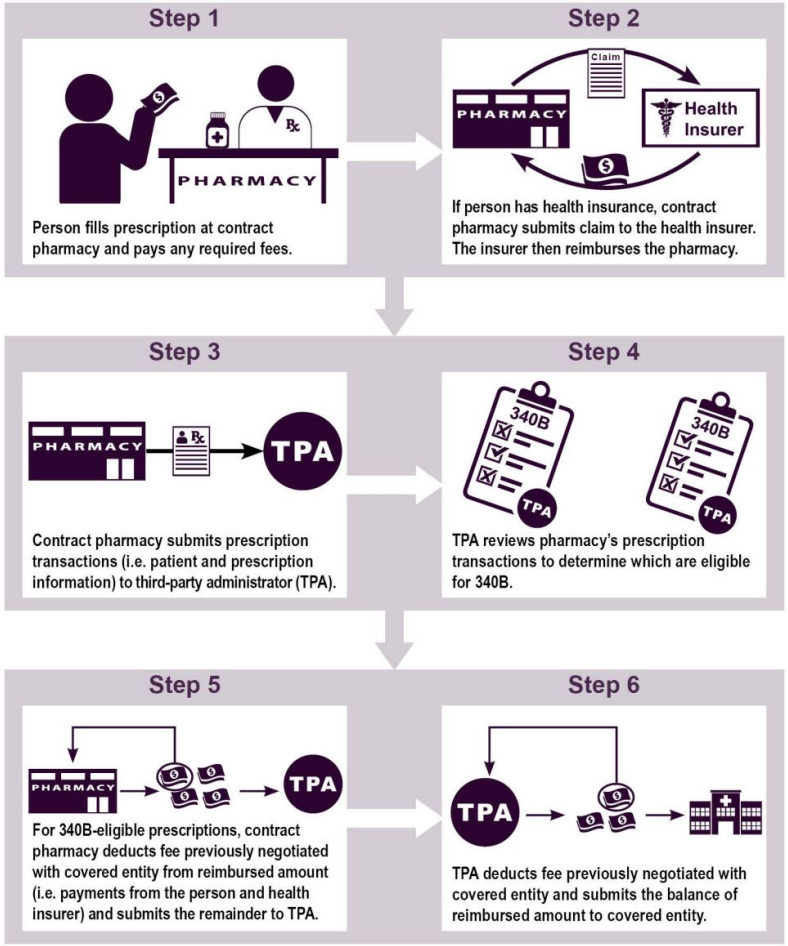
Fees higher for insured patients

Fees negotiated with pharmacies

Source: GAO 2018

Third Party Administrators also Also Take Fees

80% of providers use TPAs
Fees per prescription: $3.50 - $10
Fees per contract too

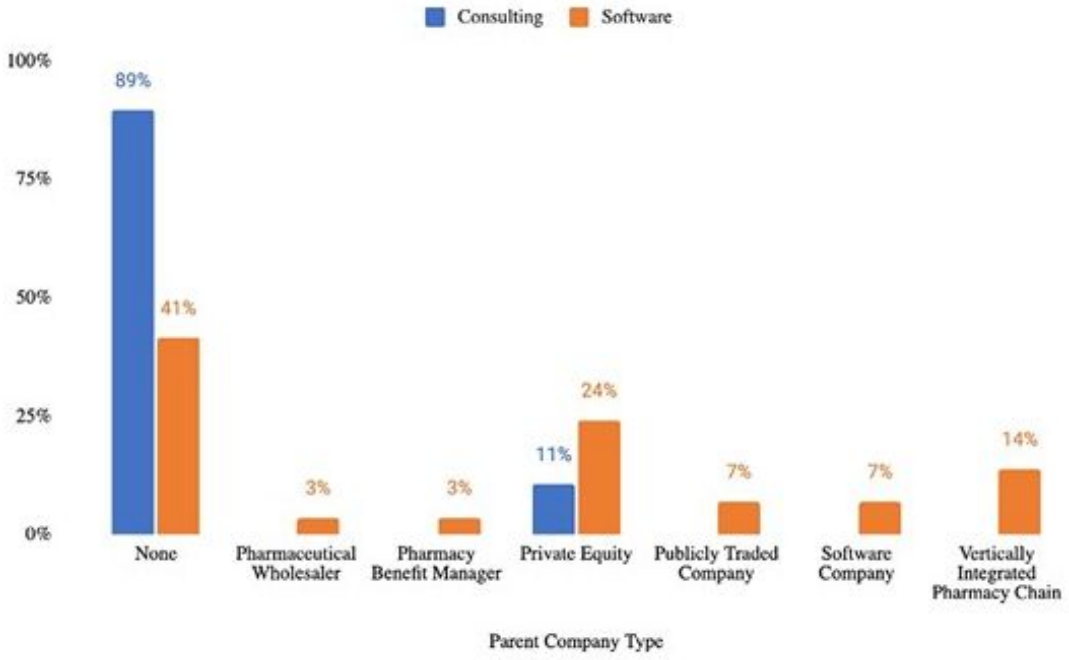


Source: GAO 2018

Third Party Administrator Ownership

TPAs that provide software solutions often owned by private equity or vertical health care entities

Figure 1.



Source: Nikpay and Halvorson 2023

New Contract Pharmacy Laws

62J.96 ACCESS TO 340B DRUGS.

Subdivision 1. **Manufacturers.** A manufacturer must not directly or indirectly restrict, prohibit, or otherwise interfere with the delivery of a covered outpatient drug to a pharmacy that is under contract with a 340B covered entity to receive and dispense covered outpatient drugs on behalf of the covered entity, unless the delivery of the drug to the pharmacy is prohibited under the 340B Drug Pricing Program.

Subd. 2. **Definitions.** (a) For purposes of this section, the following definitions apply.

(b) "340B covered entity" has the meaning provided in section 340B(a)(4) of the Public Health Service Act.

(c) "Covered outpatient drug" has the meaning provided in section 1927(k) of the Social Security Act.

(d) "Manufacturer" has the meaning provided in section 151.01, subdivision 14a.

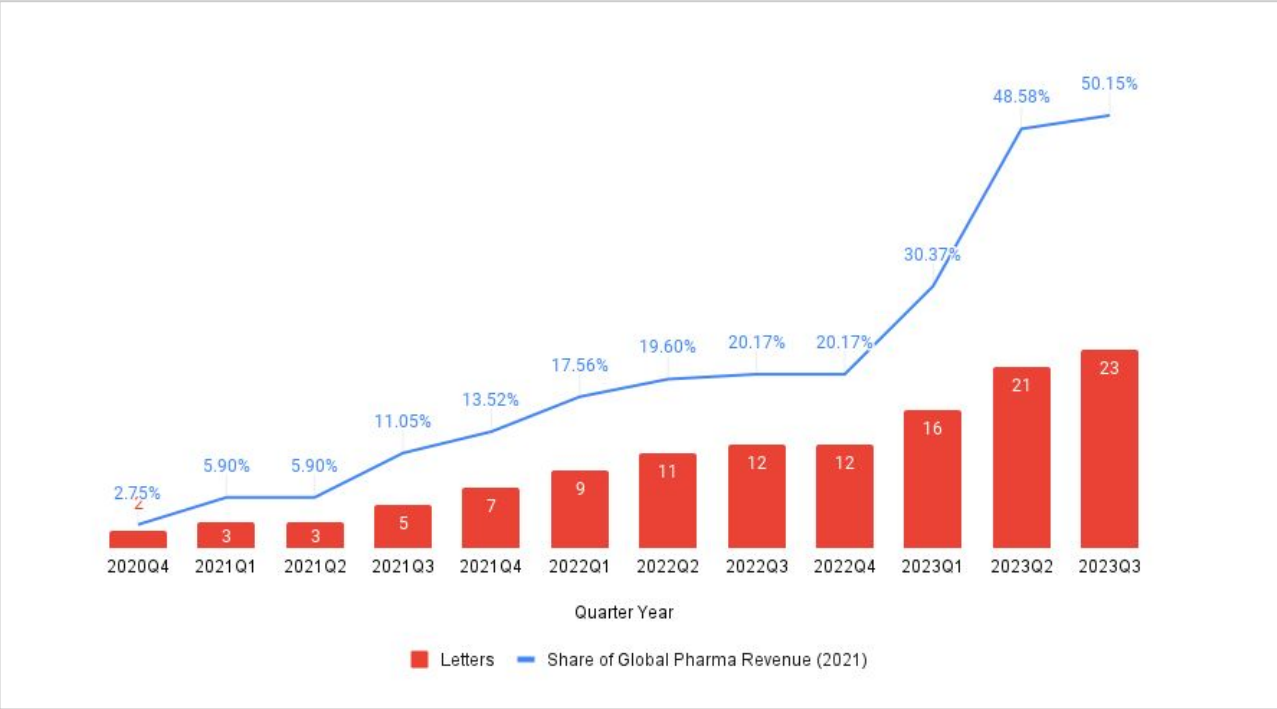
Subd. 3. **Expiration.** This section expires July 1, 2027.

History: *2024 c 121 art 4 s 3*

Source: Minnesota Statute Sec. 62J.96

Contract Pharmacy Restrictions

Cumulative Letters and Restricted Share of Global Pharmaceutical Revenue, 2020 - 2023



Source: Quinones and Nikpay (2024) - manuscript available on request

Laws Prevent Plans from Varying Reimbursements

(f) A pharmacy benefit manager or health carrier must not prohibit an entity authorized to participate in the federal 340B Drug Pricing Program under section 340B of the Public Health Service Act, United States Code, title 42, chapter 6A, or a pharmacy under contract with such an entity to provide pharmacy services from participating in the pharmacy benefit manager's or health carrier's provider network. A pharmacy benefit manager or health carrier must not reimburse an entity or a pharmacy under contract with such an entity participating in the federal 340B Drug Pricing Program differently than other similarly situated pharmacies. A pharmacy benefit manager that contracts with a managed care plan or county-based purchasing plan under contract with the commissioner of human services under chapter 256B or 256L must comply with this paragraph only if the entity or contracted pharmacy can identify all claims eligible for 340B drugs at the time of initial claims submission at the point of sale. This paragraph does not preclude a pharmacy benefit manager that contracts with a managed care plan or county-based purchasing plan under contract with the commissioner of human services under chapter 256B or 256L from reimbursing an entity or pharmacy identified in this paragraph at a lower rate for any prescription drug purchased by the entity or pharmacy through the federal 340B Drug Pricing Program.

Source: Minnesota Statute Sec. 62W.07

Should UPLs Exempt 340B Covered Entities?

PDABs must weigh:

Increased affordability of **specific prescription drugs** targeted for the UPL against ***possible*** **decreased affordability of care** overall

The answer should probably depend on whether covered entities **pass discounts to patients** or **provide significant amounts of safety-net care**

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