

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, of which I am Vice Chair

Ventures, Commonwealth
Fund, the NIH, CMS, the
Minnesota Department of
Health, and Health Affairs
Scholar

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"

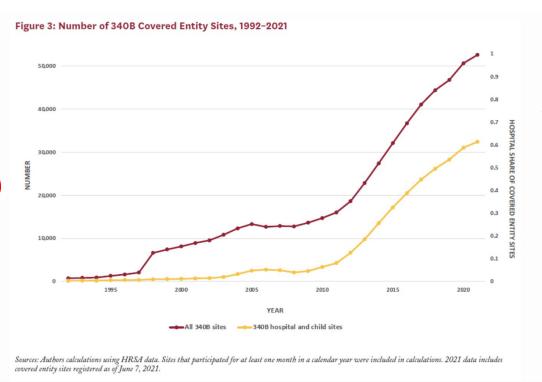


Source: GAO



340B Program Scope has Grown Significantly

Began with ~5,600 Federal clinics and ~100 public hospitals



Today it's about 1/3 Federal clinics and 2/3 hospitals

340B Accounted for \$66B in Purchases in 2023

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

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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

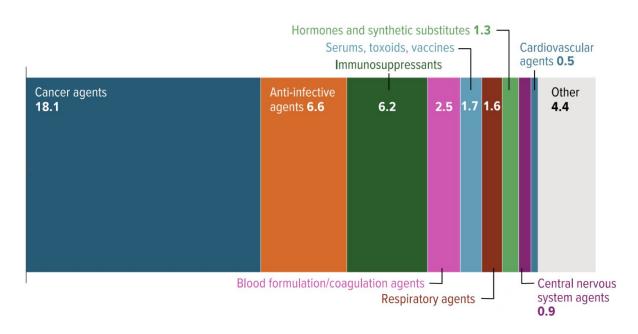
Far less through grantees

Source: HRSA 2023, 2024 via Drug Channels



340B Concentrated in Certain High-Cost Drugs in 2021

Billions of dollars

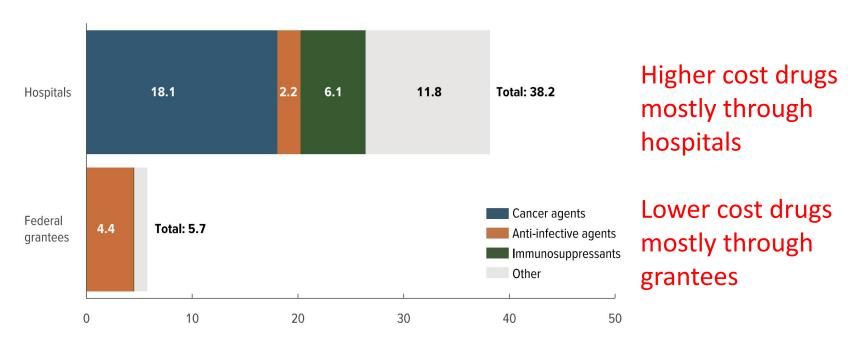


Source: CBO 2024



340B Concentrated in Certain High-Cost Drugs in 2021

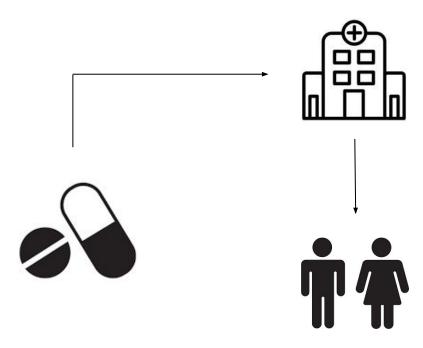
Billions of dollars



Source: CBO 2024



How the 340B Subsidy Benefits Participants



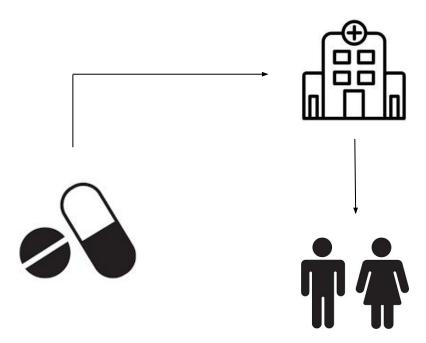
Without 340B

- \$100 Cost of drug
- + \$0 Reimbursement
- + \$0 Co-payment
 - \$100

With 340B

- \$60 Cost of drug
- + \$0 Reimbursement
- + \$0 Co-payment
 - \$60

How the 340B Subsidy Benefits Participants





Without 340B

- \$100 Cost of drug
- + \$90 Reimbursement
- + \$10 Co-payment

\$0

With 340B

- \$60 Cost of drug
- + \$90 Reimbursement
- + \$10 Co-payment

+ \$40

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



Results from Minnesota's 2023 Covered Entity Report



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

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

Source: MIN WIDE, EKSA



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, HRSA



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, HRSA



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)

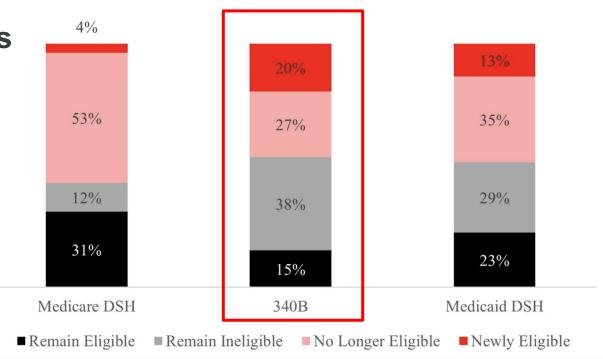
Source: Watts et al. 2024, Owsley et al. 2024, Nikpay et al. 2020, Desai et al. 2021



Why Mixed Results? Poor Program Targeting

Most federal grantees must provide care regardless of cost

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

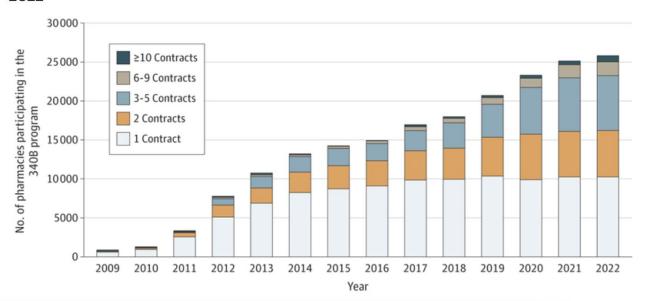


Source: Nikpay 2022



Increasing Role of Large, Outside, For-Profit Parties

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



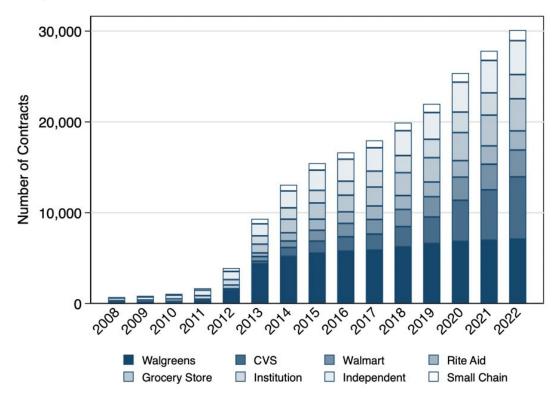
~40% of US retail pharmacies have >=1 contract

Source: Nikpay et al. 2022



Increasing Role of Large, Outside, For-Profit Parties

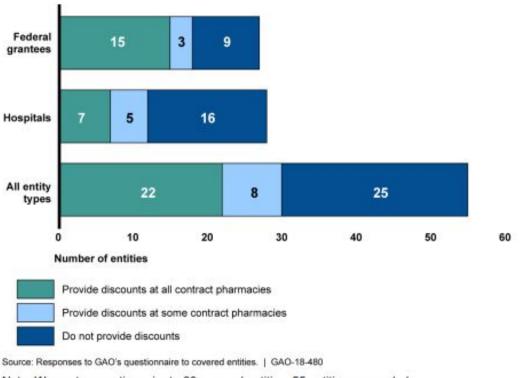
~2/3 of contract pharmacy relationships with top 4 pharmacy chains



Source: McGlave et al. 2024



Contract Pharmacies Don't Always Pass Discounts to Indigent Patients

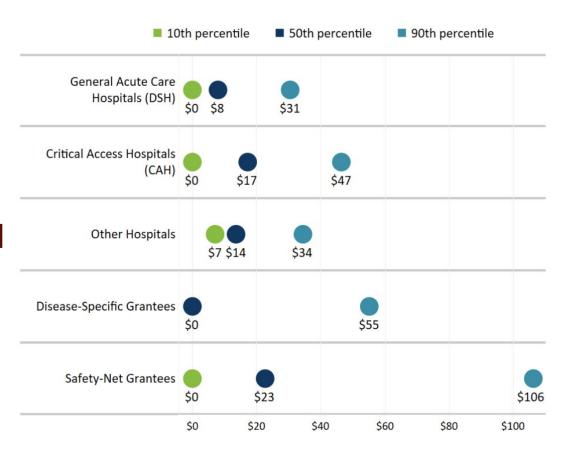


Note: We sent a questionnaire to 60 covered entities; 55 entities responded.

Source: GAO 2018



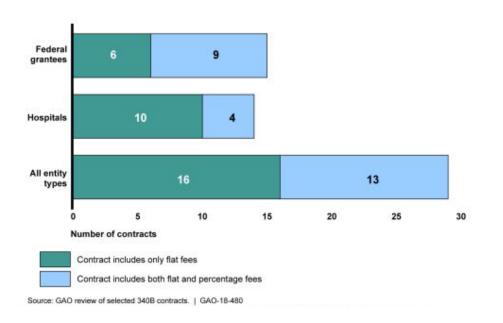
Outside Fees Paid per \$100 of 340B Revenue from the Minnesota Covered Entity Report



Source: MN MDH, HRSA



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

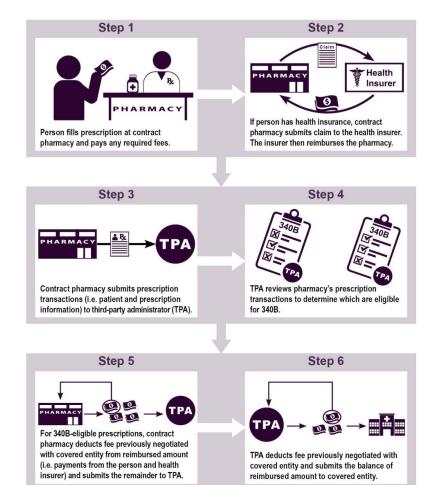
Source: <u>GAO 2018</u>



Third Party Administrators also Also Take Fees

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

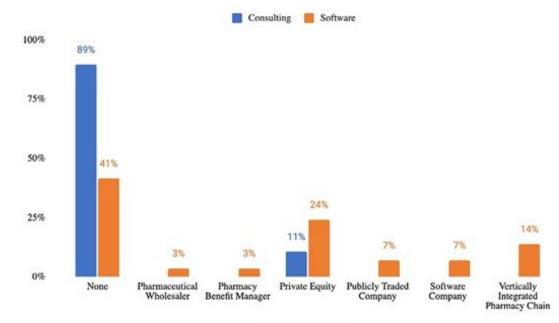
Source: GAO 2018



Third Party Administrator Ownership

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

Figure 1.



Parent Company Type

Source: Nikpay and Halvorson 2023

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 depend on whether covered entities pass discounts to patients or provide significant amounts of safety-net care



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