

Vermont & the 340B Drug Pricing Program

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340B Drug Pricing Program

What is it?

The program, created by Congress, requires manufacturers who participate in the Medicaid rebate program to provide discounts to 340B eligible hospitals and other providers.

Who can participate?

Publicly owned or non-profit hospitals with contracts to provide care to uninsured patients. In 2010, expanded to many hospital types as well as FQHCs and HRSA grantees.

Why does it exist?

The 340B Program was created in the early 1990s to stretch scarce federal resources in order to support hospitals in providing comprehensive medical services.

340B Drug Pricing Program

What are the limits?

Hospitals can only purchase 340B drugs for use by hospital patients in an outpatient setting.

Who pays?

No taxpayer funds are used for 340B. The drug manufacturing industry pays for the program.

According to the AHA, the cost of 340B discounts accounts for less than 2% (less than \$10 billion) of the United States revenue of drug manufacturers, which is expected to exceed \$500 billion in 2020.

The industry spends approximately \$20 billion per year on marketing.

340B Entities in Vermont

- 89 entities in Vermont are qualified and registered with the 340B Program, as well as grant funded programs (STD programs, Planned Parenthood, hemophilia treatment center, etc.)
- This includes all Vermont hospitals and all or most FQHCs

340B & Third-Party Reimbursement

For most payers, the reimbursement amount paid to hospitals and pharmacies is the same regardless of whether the drug is purchased with 340B discounts or not. The additional margin between the payment and the 340B purchase price is then used to reinvest in clinical services to support the nonprofit missions of the covered entities.

Program Elements & Savings

- Mixed use and outpatient sites: Drugs are hospital / clinic administered and purchased by hospital and provided exclusively to outpatients.
- Contract pharmacies: Agreements with retail pharmacies allow CEs to provide them with 340B drugs for covered entity patients. Pharmacies receive a dispensing fee and forward transaction revenue to CE.
- In-house retail and mail order pharmacies: Receives drugs through 340B program to be dispensed to CE patients.

Recent Developments

- Drug industry groups argue that the discounts on medications were intended to be passed along to patients and contend that non-profit hospitals are using 340B to support huge profit margins
- Not true – program was intended as a lifeline for safety net hospitals, who are struggling with historically low margins
- The current administration in Washington D.C. has supported several proposals targeted at the 340B community, particularly community health centers
 - CMS pays 340B hospitals 30% less for drugs billed to Medicare Part B and redistributes payments to other, often for-profit, hospitals and entities
 - An executive order will force FQHCs to pass 340B prices on to patients (who already receive sliding scale pricing)
- These efforts deprive 340B covered entities of funding that supports basic medical services as well as community-oriented programs
- Many manufacturers in 2020 have withdrawn discounts from contract pharmacies, costing covered entities tens of millions of dollars in critically needed funding
 - This figure is as high as \$25 million per year for UVM Health Network hospitals; only a month ago this was \$16 million but it continues to grow
- Ryan White clinics, community health centers and hospitals have each separately sued to enforce the law against manufacturers

340B reduces health care costs in Vermont

- Hospitals and other providers depend on 340B to preserve patient access to critical health care services
- Some hospitals use 340B dollars to provide direct aid through patient assistance programs
- For the UVM Health Network's Vermont hospitals in FY2019, the savings amount was over \$100 million
- The Health Network's actual margin for Vermont in FY2019 was \$41 million (2.5%)
- Without 340B, health care in Vermont would look very different and cost Vermonters a great deal more

Medication cost containment efforts

- Hospital Formulary
 - Controls what medications the hospital will purchase to provide to patients in the hospital or at an outpatient clinic
 - A committee of physicians and pharmacists (Pharmacy & Therapeutics) and others review the efficacy, safety and cost of drugs proposed to enter the formulary
 - Most powerful hospital tool for containing unnecessary drug costs and identifying alternatives (therapeutic equivalents) that are equally effective at lower costs
 - Formulary selection also offers hospitals the opportunity to negotiate for lower prices from manufacturers

Medication cost containment efforts cont'd

- Patient adherence programs and pharmacist MTM
- Real-time benefit check information at point of prescribing
- Value based care and Accountable Care Organizations
- Group purchasing arrangements



Appendix

Definitions

Purchasing Bases

- **WAC:** Wholesaler Acquisition Cost - a published purchase price from a wholesaler with no additional discounts (beyond volume) or contracts applied
- **340B:** Provides mandated discounts of 30-50% off the WAC cost of the drug
- **GPO:** Group Purchasing Organization, for-profit company with independent purchasers (like hospitals, pharmacies, etc.) as clients, negotiates group discounts on drugs and other items.

Definitions

Reimbursement Bases

- **AWP:** Average Wholesale Price, a tracked sales price (from for-profit vendors, such as MediSpan). Not the price a pharmacy pays. Usually, WAC + 20%. Used by most commercial PBMs as an element of reimbursement formula.
- **NADAC:** National Average Drug Acquisition Cost. Medicaid agencies pay no more than this amount, in aggregate, to pharmacies for dispensing drugs.
- **MAC:** Maximum Allowable Cost, a list of drugs with capped reimbursement from a specific third party (commercial insurance, Medicaid, etc.)
- **ASP:** Average Sales Price. Used by CMS to calculate reimbursement for physician or clinic administered drugs. Many 340B entities get ASP – 26% for drugs, instead of ASP + 6% for non-340B entities.

Other

- **Covered Outpatient Drug:** Limiting term for 340B discounts; discounts do not apply to drugs used in an inpatient setting, or to non-drug items. Definition includes drugs dispensed in retail pharmacies, infused drugs or clinic administered drugs.
- **Registered outpatient location:** For drugs prescribed and/or administered outside the four walls of the hospital, to be 340B eligible the location of care must appear with reimbursable expenses on the most recently filed Medicare Cost Report *and* be registered with the federal agency that administers the 340B Program.

Key Regulatory Constraints

- **GPO Prohibition:** Applies to DSH hospitals, prohibits use of covered outpatient drugs purchased through negotiated discount that aggregates volume between entities. Not limited to formal GPO relationships; any grouped discount may violate the prohibition.
- **Duplicate discount prohibition:** Manufacturers are protected from providing both Medicaid rebates and 340B discounts on the same drugs. Medicaid agencies have the power to compel covered entities to turn over discounts; in Vermont, each of our hospitals can elect to either pass on 340B discounts to the state or forego purchasing drugs dispensed to Medicaid patients at 340B rates. This is “*carving in*” or “*carving out*.” For DSH hospitals, carving out means buying the covered outpatient drugs at WAC.

Key Regulatory Constraints

- **Orphan drug exclusion:** Applies to covered entity types created in the Affordable Care Act, including Sole Community Hospital and Critical Access Hospital. Relieves manufacturers from the requirement to provide 340B discounts on drugs with an orphan designation (including virtually all specialty drugs) – but they may do so voluntarily.
- **Government contract:** Private non-profit hospitals must have a contract with a state or local government that requires the hospital to provide care to uninsured patients and those with Medicaid or Medicare coverage.

Program Integrity

- 340B Program covered entities spend significant time, effort and money to maintain compliance with the 340B program regulations and guidance
- Covered entity authorizing official annually certify compliance with all program rules under penalty of False Claims Act prosecution
- Most audit findings relate to technical errors in the federal 340B database that covered entities quickly correct
- HRSA routinely audits covered entities but rarely audits manufacturers (HRSA's target is 200 covered entities and 5 manufacturers per year)
 - In 2019, 4 out of 5 manufacturer audits included serious findings of overcharging above the ceiling price or failing to offer discounts at all
- Despite its requirement in the Affordable Care Act in 2010, HRSA only finalized an administrative dispute resolution process for 340B in December 2020.
- Enforcement action against manufacturers for not offering mandated discounts is extraordinarily rare

DSH Adjustment

For larger hospitals, the DSH adjustment percentage is the key criteria for 340B eligibility. The formula is below.

Medicare DPP Formula

Medicare DPP =	Medicare/Supplemental Security Income Days	+	Medicaid, Non-Medicare Days
	_____		_____
	Total Medicare Days		Total Patient Days

If the DSH percentage falls below the required threshold when the Medicare Cost Report is submitted at the end of February each year, the hospital must exit the 340B Program effective immediately. In some cases, it may be possible to re-register as a different type of entity.

3rd Party Administrators

A 3rd party administrator (TPA) is a software and service provider that assists 340B covered entities with implementing the 340B program. The TPA receives data from both hospitals and pharmacies to help determine 340B eligibility, purchase drugs, and process payments.





340B DRUG PRICING PROGRAM

PROTECTING THE SAFETY NET

For more than 20 years, Congress has provided relief from high prescription drug costs through the 340B Drug Pricing Program. The program requires participating pharmaceutical companies to sell covered outpatient drugs at a discount to eligible health care organizations. To be eligible, hospitals must serve a disproportionate share of uninsured and low-income patients. This program gives patients better access to drugs they need and helps hospitals enhance care capabilities by stretching scarce federal resources.

Small Program, Big Benefits



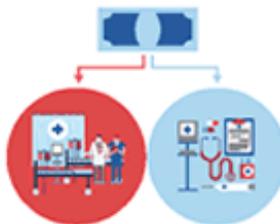
2%

Portion of the United States' \$374 billion in annual drug purchases made through the 340B program

\$3.8 BILLION

Total annual savings for 340B eligible providers

340B creates valuable savings on outpatient drug expenditures to reinvest in patient care and health activities to benefit the communities they serve. It also saves money for state and federal governments.



62%

Percentage of all uncompensated care provided by 340B hospitals

340B increases access to care for our most vulnerable populations - participating hospitals provided \$28.6 billion in uncompensated care in 2013.



Who Are 340B Hospitals?



About **half** are urban; half are rural.



929 (43.4%) are critical access hospitals (CAHs).



Located in **1,529 or 47%** of all US counties.

340B Hospitals Meet Rigorous Requirements

340B ELIGIBILITY

Hospitals must:

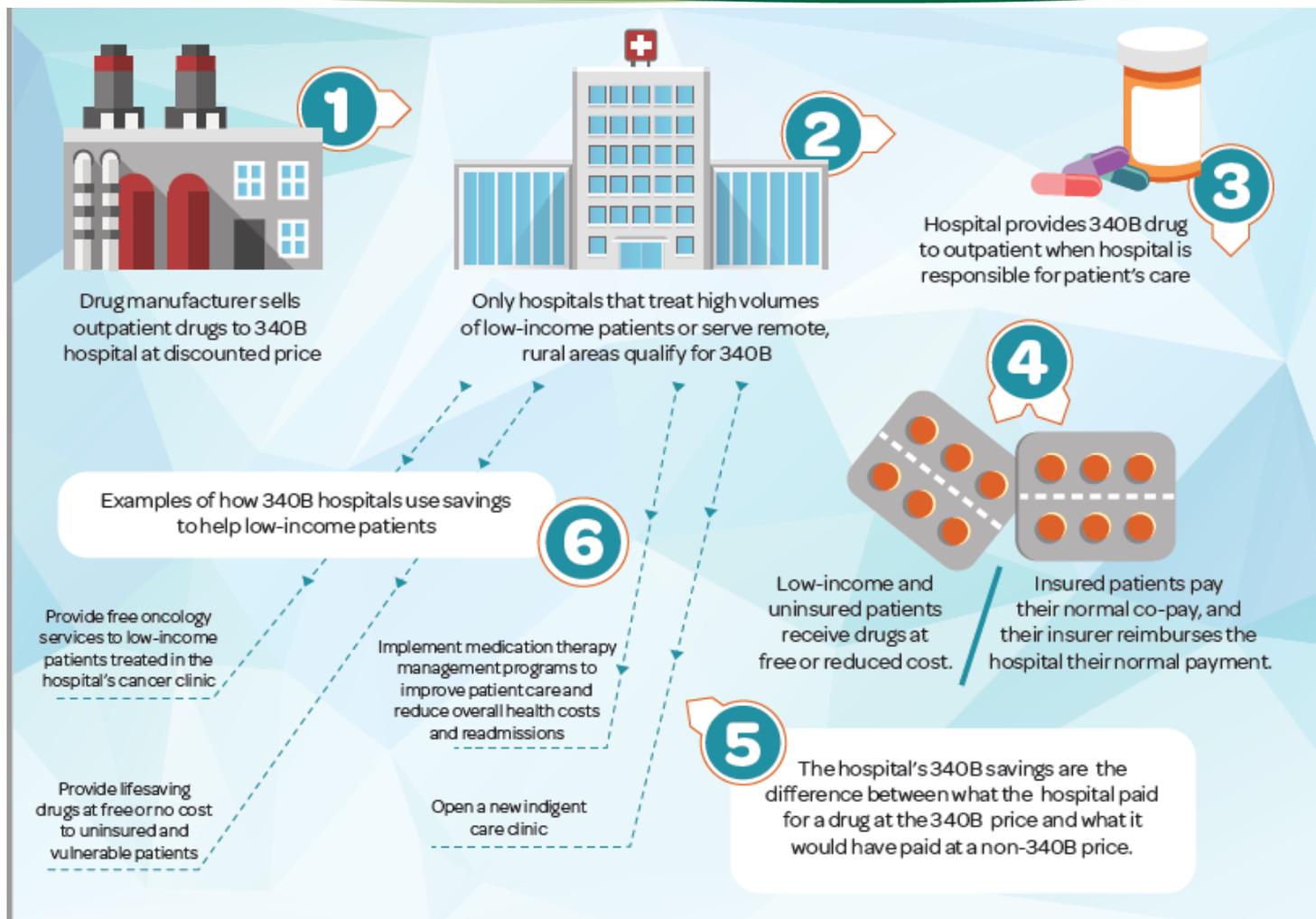
- ✓ Be designated as a not-for-profit hospital.
- ✓ Be classified as a Children's Hospital, Cancer Hospital, Sole Community Hospital, Rural Referral Center, Critical Access Hospital or a Medicare Disproportionate Share Hospital.
- ✓ Serve a large proportion of uninsured and low-income patients.
- ✓ Undergo random audits by the federal government and pharmaceutical manufacturers.
- ✓ Recertify annually as an eligible 340B provider.
- ✓ Maintain auditable inventories for 340B and non-340B prescription drugs.

PRESERVE THE 340B PROGRAM; PROTECT THE SAFETY NET

SOURCES: HEALTH RESOURCES AND SERVICES ADMINISTRATION; IMS HEALTH; 2013 AMERICAN HOSPITAL ASSOCIATION ANNUAL SURVEY DATA; APEXUS



How 340B Works



340B Entity Types & Eligibility Criteria

Entity Type	Nonprofit/ Government Contract Requirement	DSH%	Subject to GPO Prohibition	Subject to Orphan Drug Exclusion
Disproportionate Share Hospital (DSH)	Yes	>11.75%	Yes	No
Children's Hospital (PED)	Yes	>11.75%	Yes	No
Free-Standing Cancer Hospital (CAN)	Yes	>11.75%	Yes	Yes
Critical Access Hospital (CAH)	Yes	N/A	No	Yes
Rural Referral Center (RRC)	Yes	≥8%	No	Yes
Sole Community Hospital (SCH)	Yes	≥8%	No	Yes