340B: Past and Present

“The [340B] program was intended to offer affordable medicines to providers focused on low-income Americans, but has now expanded far beyond the original set of providers identified.”
- Alex Azar, Secretary of Health and Human Services, March 2018

340B was envisioned as a safety-net program to address unintended consequences of the 1990 Medicaid drug rebate statute by reinstating deep discounts that pharmaceutical manufacturers had voluntarily provided to certain clinics and hospitals treating low income and/or uninsured patients.

Overly broad guidance, historically weak oversight and other factors led to dramatic program growth, driven by the participation of large hospitals and for-profit pharmacy chains in the 340B program. Today, 45 percent of all Medicare acute hospitals participate in 340B.
340B Has Grown Dramatically, Including Via For-Profit Pharmacies

<table>
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<tr>
<th>340B Sales Volume</th>
<th>340B Hospital Participation</th>
<th>For-Profit Retail Pharmacy Arrangements</th>
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<tr>
<td>2005  $2.40B</td>
<td>1992 45</td>
<td>2002 288</td>
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<td>2019  $29.90B</td>
<td>2002 143</td>
<td>2010 6,118</td>
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<td>2020 2,580</td>
<td>2020 109,114</td>
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Sales at the 340B price, via Apexus, the HRSA-designated Prime Vendor, as reported by Drug Channels, June 2020; Hospital Participation: Health Resources and Services Administration, Office of Pharmacy Affairs 340B Database, May 2020; Contract pharmacies: BRG analysis of the HRSA OPA Database, May 2020.
As noted by economists, the 340B program causes many uninsured and/or low income patients to pay more out of pocket because …

Consolidation in the health care market partially driven by perverse incentives in 340B causes costs to go up for patients

GAO and Milliman have cited the incentives to prescribe more and more expensive medicines at 340B hospitals

Rapid program growth may be affecting market prices for prescription medicines
“List prices for drugs are likely higher than they otherwise would be “to offset revenue losses incurred as a larger number of drug sales become eligible for 340B discounts (and thus fewer drugs are sold at full price).”

—RENA CONTI AND PETER BACH

“The current nature of 340B is such that it is quite possible for the program’s benefits to be diverted to unintended purposes, unrelated to supporting care for low-income patients …”

ALEX AZAR, Secretary of the Department of Health and Human Services

 “[The 340B program] will ultimately end up increasing health care costs for everyone, as patients are shifted from cheaper, community-based care to more expensive hospital settings ...”

STEPHEN PARENTE, University of Minnesota

“[In the absence of reforms] the trend toward consolidation will continue to drive up the cost of commercial insurance.”

PETER BACH & RH JAIN, Memorial Sloan Kettering
A Closer Look at Contract Pharmacies
The original intent of contract pharmacies was to help covered entities without their own in-house pharmacy. Today, large DSH hospitals now have large, expansive networks of contract pharmacies, greatly expanding hospital – and for-profit pharmacy – access to 340B discounts (and profits).

HRSA stated in guidance that it would allow covered entities without their own in-house pharmacy to access 340B discounts through a contract with a single retail pharmacy.

The “contract pharmacy” policy was dramatically expanded under HRSA’s 2010 contract pharmacy guidance to allow 340B entities to have an unlimited number of contract pharmacy arrangements.
2010 Guidance Spurred Rapid Growth in Number of Contract Pharmacy Arrangements

- The number of contract pharmacy arrangements has grown by more than 4,000% since the 2010 guidance.
- Currently, over 27,000 distinct pharmacies participate in the 340B program, and each one may have arrangements with multiple entities.
- 2014 OIG and 2018 GAO studies found few hospitals passed 340B discounts on to uninsured patients at contract pharmacies.

For-Profit Pharmacies Now Taking a Large Slice of the Pie

- 75% of contract pharmacies are chain pharmacies
- 60% of contract pharmacies are represented by CVS, Walgreens, Walmart, Rite-Aid, and Kroger
- More than 20% of contract pharmacy arrangements are between 340B entities and the five largest specialty pharmacies, which are owned by PBMs

340B Contract Pharmacy Arrangements Are Clustered Around Metropolitan Centers, Fewer in Rural Areas

Some hospitals have as many as 400 contract pharmacy arrangements with pharmacies as far as 1,000 miles away from the DSH hospital itself.

Each dot represents a covered entity hospital. Dots for hospitals with contract pharmacies (orange) have been scaled to reflect the number of active contract pharmacy relationships for that hospital.
How For-Profit Retail Pharmacies Profit off of 340B

Here’s how it works when 340B discounted medicines are shipped to for-profit retail pharmacies through contract pharmacy arrangements:

Uninsured patient gets sick
Uninsured patient gets treated at a 340B hospital
Patient goes to 340B contract pharmacy and fills prescription at full retail price ($100)
Due to 340B discount, hospital gets $50 from drug manufacturer, which it can share with the pharmacy

The hospital and pharmacy profit while the patient may see no direct benefit from the 340B discount
Patient may not see benefit
### Government Reports Note Contract Pharmacies Create Complications and Have Little Oversight

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<td>• Contract pharmacy arrangements create complications for program compliance for covered entities around diversion and/or duplicate discounts.</td>
<td>• Weaknesses in HRSA’s oversight impede its ability to ensure compliance with 340B program requirements at contract pharmacies.</td>
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<td>• OIG found some covered entities do not offer the discounted price to uninsured patients at contract pharmacies.</td>
<td>• Hospitals are more likely to use contract pharmacies than grantees – at least one hospital had 439 contract pharmacy arrangements.</td>
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<td>• Without adequate oversight, the complications created by contract pharmacy arrangements introduce vulnerabilities to the 340B program.</td>
<td>• GAO found less than half of hospitals provide 340B discounts to uninsured, low-income patients at some or all of their contract pharmacies.</td>
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<td>• Contract pharmacies often earn larger fees from brand prescriptions as compared to generics.</td>
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Contract Pharmacy Arrangements Born Out of Guidance

- **Agency guidance** refers to statements that interpret laws or regulations or announce agency policy and that are not issued through notice-and-comment rulemaking.

- Unlike laws and regulations, agency guidance **cannot impose any binding requirements** on the public and lack the force and effect of law.

- HRSA’s contract pharmacy doctrine is guidance – contract pharmacies are not mentioned in the 340B law or in any regulations. HRSA statements about contract pharmacies **cannot bind covered entities or manufacturers** and, therefore, cannot be the basis for any enforcement actions.