340B 101
Taking Into Account Entire Supply Chain

Biopharmaceutical Companies

Providers

Payers and PBMs
Medicine Spending is in Line with Other Health Care Services

Note: Total retail sales include brand medicines and generics. Centers for Medicare & Medicaid Services
Data Show Medicine Spending Growth Declining

<table>
<thead>
<tr>
<th>Year</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td>5.2%</td>
<td>3.8%</td>
<td>Below 1%</td>
</tr>
<tr>
<td></td>
<td>5%</td>
<td>3.2%</td>
<td>5%</td>
</tr>
<tr>
<td></td>
<td>9%</td>
<td></td>
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2016 Data

2017 Data
Nearly 40% of the List Price is Rebated Back to Payers, the Government and Other Stakeholders

Brand companies retain just 63% of list price spending on medicines

Rebates, discounts and fees keep increasing

- 2013: $67.0B
- 2014: $84.6B
- 2015: $106.4B

- Brand Companies
- Market Access Rebates and Discounts
- Statutory Rebates and Fees
- Supply Chain Entities
Patients’ Out-of-Pocket Spending is Growing Faster Than Underlying Medical Costs

Savings Aren’t Always Shared with Patients

More than half of commercially insured patients' out-of-pocket spending for brand medicines is based on the full list price.

Cost sharing for nearly 1 in 5 brand prescriptions is based on list price.

52%

48%

39%

13%

- Copay
- Deductible
- Coinsurance

Amundsen Consulting Group study.
A hospital is paid 2.5 times what the biopharmaceutical company, who brought the medicine to market, receives.

*Analysis does not take into account the impact of the 340B program.*

The 340B Program Continues to Expand

### 340B Hospital Participation

<table>
<thead>
<tr>
<th>Year</th>
<th>Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1992</td>
<td>51</td>
</tr>
<tr>
<td>2002</td>
<td>151</td>
</tr>
<tr>
<td>2017</td>
<td>2,357</td>
</tr>
</tbody>
</table>

### 340B Sales Volume

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>$2.65B</td>
</tr>
<tr>
<td>2016</td>
<td>$16.1B</td>
</tr>
</tbody>
</table>

### For-Profit Retail Pharmacy Participation

<table>
<thead>
<tr>
<th>Year</th>
<th>Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>279</td>
</tr>
<tr>
<td>2010</td>
<td>6,293</td>
</tr>
<tr>
<td>2017</td>
<td>51,963</td>
</tr>
</tbody>
</table>

By 2021, the 340B program will effectively surpass today’s spending on drugs in the Part B program.

As noted by economists, the 340B program causes many 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 and payers
- GAO has cited the incentives to prescribe more and more expensive drugs at 340B hospitals
- Rapid program growth may be affecting market prices for prescription medicines

### How Hospitals & Clinics Qualify to Participate in 340B

<table>
<thead>
<tr>
<th>340B Grantee Eligibility</th>
<th>340B Hospital Designation</th>
<th>340B Hospital Eligibility</th>
</tr>
</thead>
</table>
| • Clinics and other entities qualify largely based on the receipt of a federal grant from HHS  
• Grant is provided to support care for vulnerable populations  
• Grantees use the program as intended | • Applies to the hospital or clinic *not* the patient  
• Hospital or clinic may claim steep discounts on outpatient drugs dispensed to all patients whether insured or uninsured  
• **340B hospitals are not required to pass discounts along to uninsured or low-income patients** | • 340B hospital eligibility is for non-profit hospitals and based in part on how many low-income Medicare and Medicaid patients a hospital admits  
• Congress intended for this to be a proxy for safety-net hospitals treating a lot of uninsured patients  
• **Not based on charity care or uninsured patients served, allowing wealthy hospitals to qualify** |
Hospitals and Grantees Have Different Requirements for Use of 340B

Participating grantees use revenue from 340B and other sources to help vulnerable patients. Hospitals face no such requirements.

340B Requirements

- Provide care to a vulnerable community on an income-based, sliding-fee scale
- Reinvest any additional resources into services for vulnerable patients
- Meet federal reporting requirements on use of 340B revenue

Grantees

Hospitals
How 340B Discounts Work

1. Manufacturer provides 340B hospital with discounted drug

2. 340B hospital provides medicines to patients, including those with commercial insurance

3. Commercial insurer or Medicare reimburses at full negotiated rate; hospital keeps difference as profit

How 340B discount works for $1000 drug:

- **$900** Total reimbursement for drug from commercial insurer or Medicare
- **+$100** 10% coinsurance received from patient
- **-$600** 340B purchase price for drug from manufacturer

**$400** profit for 340B entity

Where does this profit go?

25-50% average discount

Average discount from Apexus 340B Prime Vendor Program 340B Price/Covered Outpatient Drugs
340B: Past and Present

45% of All Medicare Acute Hospitals Participate in 340B

1992
340B was envisioned as a small 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 true safety-net hospitals.

Early 2000s – Present
Overly broad guidance, historically weak oversight and other factors led to dramatic program growth, driven by the participation of large hospitals in the 340B program.

Hospitals Participating in 340B

<table>
<thead>
<tr>
<th>Year</th>
<th>Hospitals Participating</th>
</tr>
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<tbody>
<tr>
<td>1992</td>
<td>51</td>
</tr>
<tr>
<td>2002</td>
<td>151</td>
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<tr>
<td>2017</td>
<td>2,357</td>
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</tbody>
</table>

Health Resources and Services Administration: Office of Pharmacy Affairs 340B Database.
340B Has Shifted Over Time
Now Vast Majority of 340B Sales Are to Hospitals

Total Sales at 340B Price:
$2.65 Billion in 2004

- Grantees: 55%
- Hospitals: 45%

Total Sales at 340B Price:
$16.2 Billion in 2016

- Grantees: 13%
- Hospitals: 87%

Mathematica, The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities, August 2004
Apexus, 340B Health Summer Conference, July 2016
340B Key Issues
Key Areas for Future Reform

- Patient Definition
- Hospital Eligibility
- Contract Pharmacy
- Patient Costs
Program Lacks Definition of a 340B Patient

• No 340B program requirement that 340B discounts be passed on to patients

• No way for a patient to know if their prescription qualifies as a 340B discounted drug

• Hospitals can profit from 340B discounts for patients due to lax program rules

“HRSA’s current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B.”

GOVERNMENT ACCOUNTABILITY OFFICE

“[There is] a lack of clarity on how HRSA’s patient definition should be applied in contract pharmacy arrangements.”

OFFICE OF INSPECTOR GENERAL

Two previous administrations proposed guidance that would have added greater clarity around the definition of a 340B patient.
Does the Program Use the Right Metrics?

- Formula for DSH eligibility is based on insured populations

- Analysis by MedPAC shows that the DSH adjustment percentage:
  - Is poorly targeted to hospitals’ shares of uncompensated care
  - Does not reflect the percentage of uninsured patients treated by a hospital

- The hospital eligibility metric is an inpatient metric but 340B is an outpatient program
Most 340B Hospitals Provide Little to Below Average Levels of Charity Care

Distribution of 340B Hospitals by Level of Charity Care as a Percent of Patient Costs Provided

- Above Average Charity Care
- Below Average Charity Care

64% of 340B hospitals have CHARITY CARE RATES below the 2.2% national average for all hospitals
How For-Profit Retail Pharmacies Take Advantage of 340B

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

1. Uninsured patient gets sick
2. Uninsured patient gets treated at a 340B hospital
3. Patient goes to 340B contract pharmacy and fills prescription at full retail price ($100)
4. Hospital gets $50 back from drug manufacturer, which it shares with the pharmacy

The hospital and pharmacy profit while the patient may see no direct benefit from the 340B discount.
2014 Department of Health and Human Services Office of the Inspector General report found few of the hospitals in their study passed 340B discounts on to uninsured patients at contract pharmacies.
Incentives for Hospitals to Buy Up Physician Offices

- HRSA guidance permits outpatient prescriptions written at hospitals' offsite outpatient facilities (physician offices) to be eligible for 340B discounts, but there is no basis in the statute for including these offsite facilities in the program.

- Ability to profit off "spread" between the 340B price and reimbursed amount incentivizes 340B hospitals to buy up community-based practices, resulting in higher costs to patients.

"[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

"[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....."

STEPEHN PARENTE, University of Minnesota

Incentives to Prescribe More Expensive Medicines

**GAO:** “Medicare beneficiaries were prescribed more drugs, more expensive drugs, or both, at 340B DSH [disproportionate share] hospitals.”

Average Per Beneficiary Medicare Part B Drug Spending in 2008 and 2012

- **2008:**
  - 340B Hospital: $58
  - Non-340B Hospital: $27

- **2012:**
  - 340B Hospital: $144
  - Non-340B Hospital: $60

GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, June 2015
Incentives to Shift Delivery of Physician-Administered Medicines to More Expensive Hospital Settings

Site of Care for Breast Cancer Drug Therapies Reimbursed in Medicare Part B

<table>
<thead>
<tr>
<th>Year</th>
<th>340B Hospitals</th>
<th>Non-340B Hospitals</th>
<th>Physician Offices</th>
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</thead>
<tbody>
<tr>
<td>2008</td>
<td>11%</td>
<td>73%</td>
<td>17%</td>
</tr>
<tr>
<td>2009</td>
<td>13%</td>
<td>70%</td>
<td>18%</td>
</tr>
<tr>
<td>2010</td>
<td>15%</td>
<td>67%</td>
<td>18%</td>
</tr>
<tr>
<td>2011</td>
<td>19%</td>
<td>64%</td>
<td>17%</td>
</tr>
<tr>
<td>2012</td>
<td>24%</td>
<td>58%</td>
<td>18%</td>
</tr>
<tr>
<td>2013</td>
<td>28%</td>
<td>53%</td>
<td>19%</td>
</tr>
<tr>
<td>2014</td>
<td>32%</td>
<td>50%</td>
<td>19%</td>
</tr>
<tr>
<td>2015</td>
<td>33%</td>
<td>49%</td>
<td>18%</td>
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Hospital Consolidation and For-Profit Pharmacies Expected to Fuel Future 340B Growth

From 2016 to 2021, the 340B program is estimated to increase by more than 40 percent.

Key Areas for Future Reform

**Patient Definition**

**Problem:** Lack of clarity around what constitutes a 340B patient enables hospitals to game the system.

**Solution:** Clearer rules needed to create an enforceable set of standards.

**Hospital Eligibility**

**Problem:** Current metric does not focus program on true safety-net hospitals.

**Solution:** Update eligibility metrics so that true safety-net hospitals are eligible.

**Contract Pharmacy**

**Problem:** For-profit pharmacies gaining revenue with no benefit for patients.

**Solution:** Administration should revisit Obama-era guidance that vastly expanded the program with no accountability that patients are helped.

**Patient Costs**

**Problem:** Program incentives raise costs for patients.

**Solution:** Limit hospital abuse of program and require sliding-fee scale to ensure that low-income and/or uninsured patients benefit from discounts.