Oncology Value Watchdog Report: 340B Drug Pricing Program

March 2016
Many drug manufacturers are expected to see a significant revenue impact from the increasing number of 340B-eligible entities.

340B Program mandates huge discounts for drugs sold to eligible entities.

AMP for 340B-Non-Eligible Entities: 100%

AMP for 340B-Eligible Entities: 77%

As 340B-eligible sites grow, manufacturers will have to sell larger amounts of discounted drugs.

Number of 340B sites:

<table>
<thead>
<tr>
<th>Year</th>
<th>Actual</th>
<th>Projected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>2010</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>2011</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>2012</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>2013</td>
<td>24</td>
<td>28</td>
</tr>
<tr>
<td>2014</td>
<td>28</td>
<td>31</td>
</tr>
<tr>
<td>2015</td>
<td>31</td>
<td>31</td>
</tr>
<tr>
<td>2016</td>
<td>33</td>
<td>33</td>
</tr>
<tr>
<td>2017</td>
<td>34</td>
<td>34</td>
</tr>
<tr>
<td>2018</td>
<td>35</td>
<td>35</td>
</tr>
</tbody>
</table>

340B sales as percentage of total pharma sales:

- 2013: 5%
- 2019E: 8%

Source: PhRMA, BRG, 340B sites, AMP: Average Manufacturer Price.
340B discounted sales have grown at a CAGR of 12.56% over the past 18 years, and will continue to grow.

The original intent of this program was to stretch limited federal resources to provide more and better care to the uninsured and compensate hospitals that treat a disproportionate share of them.

Release of 340B Program Mega Guidance

- Contract pharmacies permitted
- MMA changes DSH calculation for rural hospitals
- ACA extends eligibility CAH’s cancer centers; multiple contract pharmacies allowed for all covered entities
- Section 340B of the PHSA enacted
- Family planning centers made eligible for 340B
- Eligibility expanded to children’s hospitals
- Release of 340B draft of Mega Guidance

Estimated sales through the 340B Program at discounted price*

- Source: BRG Report, Drug Channels, RAND; PHSA: Public Health Services Act; MMA: Medicare Modernization Act; ACA: Affordable Care Act; CAH: Critical access hospitals, *Participation as of December 31st of each year; for 2015, all entities participating as of March are included
- Source: Avalere Health analysis of the 340B Database, opanet.hrsa.gov, 340B Reform, Mega Guidance; CAGR is calculated for 340B-Participating Sites, 2004-2015
- *BRG Report, (Number interpreted from illustration in the BRG report)

However, due to laxity in the program, many hospitals which didn’t meet the original 340B criteria, also became eligible.
Executive Summary

What is the 340B Drug Pricing Program?
- 340B is a federal program instituted to encourage hospitals with disproportionate shares of uninsured patients to continue providing services to the patients by reducing the financial burden

How is it evolving?
- The program has rapidly grown over the last several years due to continued expansion of practice eligibility

Who is eligible?
- 340B eligibility of a provider site of care (covered entities) is selected based on the estimated Disproportionate Share Hospital (DSH) inpatient percentage of the entity
- Covered outpatient drugs – whether intended for self-administration or administration by a clinician – are eligible for 340B discounts
- Eligible patients have their health records maintained by the covered entities and can access the drugs purchased at 340B discounted price in the outpatient care settings of the covered entities

What type of discounts are provided?
- Average manufacturer price is discounted by 23.1% for brand prescription drugs and 13% for generics

Why reform may be needed?
- Findings from audits on 340B have raised questions about the actual utilization of these discounts
- HRSA and drug manufacturers have now participated in the monitoring and lobbying efforts to bring the necessary reforms in the 340B Program

Source: Health Resources and Services Administration (HRSA)
Contents

- 340B Overview
- Eligibility and Business Models
- Rebate Calculation
- Loopholes/Shortcomings
- Oncology and 340B
340B is a federal discount program formulated to empower select providers by providing discounts on outpatient prescription drugs

340B primary stakeholders

Drug manufacturers

Drug purchase

340B-covered entities

GPO/PVP

Drugs dispensed by pharmacies

at discounted prices in outpatient settings

Eligible drugs to eligible patients

Drug manufacturers

Medicaid participants sell drugs at ceiling price determined by 340B to the providers at 25-50% discount on AWP

Covered entities/providers

Non-profit HCOs with federal designations – or receiving funding from federal programs – provide discounted drugs to patients

Eligible patients

Individuals undergoing treatment at the covered entities are eligible to receive the drugs purchased at 340B discounted prices

One-third of all hospitals in the United States are in the 340B Program, accounting for almost half (46%) of outpatient drug spending by all U.S. hospital facilities

Source: Clinical oncology, snhpa, hrsa.gov, American action; OPA: Office of Pharmacy Affairs; HRSA: Health Resources and Services Administration; PPA: Pharmaceutical Pricing Agreement; AWP: Average Wholesale Price; HCO: Health Care Organizations; PBM: Pharmacy Benefit Manufacturer; GPO: Group Purchasing Organizations; PVP: Prime Vendor Program; HCP: Health Care Practitioner

© 2016 ZS Associates | CONFIDENTIAL
Recent amendments are exacerbating the alarming growth of 340B Program coverage and total drug sales under the program.

Why such a rapid expansion?

1. **Greater use of contract pharmacies**
   - Sub-regulatory guidance issued in 2010, eliminated the limitation of single-contract pharmacy, enabling all 340B entities to contract with multiple outside pharmacies approved by OPA and listed in 340B database.
   - 20% of retail pharmacies have now become contract pharmacies for 340B institutions.

2. **Increase in Medicaid coverage**
   - Higher Medicaid enrollment under the Affordable Care Act (ACA) has contributed to a larger share of hospitals qualifying for 340B based on their DSH percentage.
   - Medicaid coverage of the population has increased from 13% in 1996 to 19.5% by 2014.

3. **Expansion of eligible hospitals**
   - Patient Protection and ACA added new categories of eligible hospitals in March 2010:
     - Critical access hospitals
     - Sole community hospitals
     - Rural referral centers
     - Free-standing children’s hospitals
     - Free-standing cancer hospitals

Given expansion of eligible entities with increased enrollment of the patients under Medicaid, manufacturers have been put in a position to expand discounting accordingly.

Source: Rxobserver, Cancernetwork, 340breform, Americanbar, Medicaid coverage, *BRG Report, 340B Reform
The 340B Prime Vendor Program (PVP) has been designed to secure sub-340B ceiling prices for the covered drugs to maximize additional savings.

### What is PVP Apexus?

- Apexus is **HRSA's designated prime vendor for 340B**, which has established a national network of wholesalers to facilitate price negotiations for PVP contract portfolio.
- All registered entities under the 340B PVP will have access to the PVP-negotiated sub-ceiling prices on medications covered under 340B Program.
- Prime vendor will overlay the PHS/340B ceiling price for each NDC in the sub-340B PVP contract portfolio.
- 87% of 340B-covered entities are members of the PVP.

### Role of Apexus

- **Secure sub-ceiling discounts** on branded and generic outpatient drugs for participating 340B entities through negotiating with manufacturers.
- **Contract for other value-added products and services** not covered under 340B Program such as: vaccines and medical devices.
- **Support stakeholders’ 340B-compliant operations** by providing education and technical assistance.
- **Establish distribution solutions and networks** to improve drug access.

Apart from oncology centers, PVP participants also include entities treating tuberculosis, HIV programs, the CHCs, Disproportionate Share Hospitals (DHS), family planning entities, etc.³

Contents

- 340B Overview
- Eligibility and Business Models
  - Rebate Calculation
  - Loopholes/Shortcomings
  - Oncology and 340B
A prescription is eligible for 340B discounts when the following criteria are met:

The covered entities sell the covered drugs at the discounted rate in the outpatient settings to all eligible patients regardless of their payer status, so even privately insured patients can receive benefits.*

<table>
<thead>
<tr>
<th>PROVIDERS</th>
<th>PATIENTS</th>
<th>DRUGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>- HCOs with certain federal designations or receiving funding from federal programs</td>
<td>- Patients who are treated in outpatient settings by HCP employed by 340B-eligible entity</td>
<td>- Outpatient drugs whether intended for self or physician administration, including oral drugs that can be distributed through contract pharmacies</td>
</tr>
<tr>
<td>- DSH adjustment percentage above 11.75% or 8%, depending on type of hospital</td>
<td>- Patients with health records maintained by covered entities</td>
<td>- Growth in white bagging also adds to 340B rebate liabilities</td>
</tr>
</tbody>
</table>

Source: [White Bagging, hrsa.gov](https://hrsa.gov), *RAND*; HCO: Health care organization; DSH: Disproportionate Share Hospital.*
340B eligibility of a provider is decided based on estimated Disproportionate Share Hospital (DSH) inpatient percentage

<table>
<thead>
<tr>
<th>DSH inpatient percentage</th>
<th>=</th>
<th>Medicare Part A SSI days</th>
<th>+</th>
<th>Medicaid, Non-Medicare days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total Medicare days</td>
<td></td>
<td>Total inpatient days</td>
</tr>
</tbody>
</table>

The calculation is based solely on inpatient utilization, and thus is not an ideal proxy for 340B as it is limited to outpatient drugs.

In order to be a 340B-eligible hospital, hospitals must have a DSH adjustment percentage above a certain threshold, typically either 11.75% or 8%, depending on the type of hospital.

Source: Rxobserver, drugchannels, cms.gov

*Patients entitled to both Medicare Part A and SSI: Supplemental Security Income benefits
In addition to affiliated outpatient sites of care, non-profit hospitals – owned or operated by state or local governments – can be eligible for 340B

<table>
<thead>
<tr>
<th>340B eligible hospital</th>
<th>DSH inpatient percentage threshold</th>
<th>GPO prohibition</th>
<th>Orphan drug exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disproportionate Share Hospital (DSH)</td>
<td>&gt;11.75%</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Children’s Hospital</td>
<td>&gt;11.75%</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Free-Standing Cancer Hospitals</td>
<td>&gt;11.75%</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Critical Access Hospital (CAHs)</td>
<td>NA</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Sole Community Hospital (SCH)</td>
<td>≥8%</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Rural Referral Center (RRC)</td>
<td>≥8%</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Under GPO prohibition, the covered entity cannot purchase a 340B-covered outpatient drug from GPO. Orphan drugs are excluded from scope of covered outpatient drugs subject to 340B discounts.

Outpatient sites of care:
- Federally qualified health centers (FQHCs)
- Hemophilia treatment centers
- Native Hawaiian health centers
- FQHC look-alikes
- Ryan HIV/AIDS program grantees
- Family planning clinics
- Public housing primary care clinics
- Sexually transmitted disease clinics
- Tuberculosis clinics
- Black lung clinics
- Black lung clinics

Source: HRSA/OPA, snhpa.org, snhpa, healthcareforminsights, SNHPA, GPO: Group purchasing organization; Prohibition, obroncology
Covered entities renew certification on an annual basis and the updated list is shared by the Office of Pharmacy Affairs every quarter.

Facilities that believe they meet the criteria of a “covered entity” can apply to participate in the 340B Program by submitting their applications at least **one month in advance** of the beginning of the next calendar quarter, which is when OPA updates the list of covered entities on its website.

Covered entities must **recertify their eligibility annually** and should immediately notify OPA about the change in their eligibility status and stop purchasing drugs through the 340B Program.

Manufacturers should be concerned about unqualified entities continuing to receive 340B discounts.

Source: hrsa.gov; snhpa.org. Recertification: OPA: Office of Pharmacy Affairs
With certain restrictions, providers can expand 340B-eligible facilities or become 340B-eligible through collaboration with existing 340B entities

<table>
<thead>
<tr>
<th>Business Models</th>
<th>Direct Ownership and Operation</th>
<th>Hospital/Physician Group Affiliations</th>
<th>Hospital/ Hospital Affiliations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Collaboration</td>
<td>340B entity purchases or establishes a new outpatient clinic</td>
<td>Medical practice enters into an affiliation with a 340B entity</td>
<td>340B entity and non-340B entity establish a new 340B clinic</td>
</tr>
</tbody>
</table>
| Eligibility | ▪ Outpatient clinic must be on site or located within 35 miles of the main hospital campus  
▪ Clinical services must be fully integrated between the covered entity and the clinic  
▪ The hospital must include the facility in a filed Medicare cost report | ▪ The medical practice would not be eligible to purchase or dispense 340B drugs as the rights are retained by the 340B hospital (they may however refer to the hospital in order for the discounts to be retained) | ▪ Clinic must satisfy Medicare provider-based requirements  
▪ Clinic should be located on the main campus of the 340B hospital or may be leased from the non-340B entity, as an outpatient department for 340B hospital |

HRSA’s emphasis on the Medicare provider-based rules for hospital-covered entities has led to significant delays before new hospital locations can access 340B pricing

Source: PubMed
Patients must receive health care services other than drugs from the 340B-covered entity in order for them to count towards 340B eligibility.

### Patient requirements for 340B eligibility

<table>
<thead>
<tr>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients should have their health records maintained by the covered entity</td>
</tr>
<tr>
<td>Patient is treated by an HCP, who is either employed by the covered entity or provides health care under contractual or other arrangements (for example: referral for consultation)</td>
</tr>
<tr>
<td>Patient receives services for which grant funding or FQHC look-alike status has been provided to the entity*</td>
</tr>
</tbody>
</table>

**Does not include:** Patients receiving services like dispensing of a drug for subsequent self-administration or administration in the home-setting.

**Exception:** Patients registered in a state-operated or funded ADAP that receives federal Ryan White funding.

All three requirements must be met in order for the patient to “count” towards the entity becoming eligible.

Source: hrsa; FQHC: Federally qualified health center; ADAP: AIDS Drug Assistance Program; HCP: Health care professional

*DSH entities are exempted from this requirement.
Eligible outpatient drugs, whether intended for self-administration or administration by a clinician, are eligible for discounts under 340B

### Eligible Drugs

- Outpatient drugs
- FDA-approved prescription drugs
- Prescribed OTC drugs
- Prescribed biological products (other than vaccines)
- FDA-approved insulin
- Clinic-administered drugs within eligible facilities
- ER drugs
- Drugs in other ambulatory care settings (example: day surgery)

### Ineligible Drugs

- Vaccines*
- Orphan Drugs for RRC, SCH and CAH

Inpatient drugs may also be included as a part of impact of PPACA#

---

The program requires drug manufacturers to extend discounts on outpatient drugs, including oral drugs that can be distributed through contract pharmacies as well as physician-administered drugs

*Aggressive discounts have been negotiated for vaccines and others not covered by PVP
# Details in speaker notes; Source: DPC, Critical Access Hospital (CAHs), Rural Referral Center (RRC), Sole Community Hospital (SCH)
Source: hisci-net.org, HRSA/OPA list of eligible drugs, Drug eligibility and oral drugs, OTC: Over-the-counter, ER: Emergency Room
Contents

- 340B Overview
- Eligibility and Business Models
- Rebate Calculation
- Loopholes/Shortcomings
- Oncology and 340B
As a result of the 340B program, average manufacturer price is discounted by 23.1% for brand prescription drugs and 13% for generics.

Rebate offered is the percentage of AMP per unit or difference between AMP and manufacturer’s best price, whichever yields a lower price.

- **URA for brand prescription drugs on AMP:** 23.1%
- **URA for generics and OTC on AMP:** 13%
- **URA brand-name pediatric drugs and clotting factor on AMP:** 17.1%

### 340B Ceiling Price Formula

340B price = \( [\text{AMP} - \text{URA}] \times \text{Drug package size} \)

An additional amount is subtracted from the drug price, due to the CPI penalty.

### Illustration*

Source: HRSA, 340B rebate snhpa.org, HRSA Program requirements, Price, 340B PVP, *RAND

GPO: Group Purchasing Organizations, URA: Unit Rebate Amount, AMP: Average Manufacturer Price, CPI-U: Customer Price Index Urban
Customer Price Index penalty is charged to discourage manufacturers from what the government would deem to be excessive price increases

Additional discount is built into URA for brand-name drugs if AMP increases faster than the Customer Price Index Urban (CPI-U) rate of inflation

- Manufacturers of single source/innovator multiple source drugs are required to pay an additional rebate for increases in AMP that outpace inflation (as determined by CPI-U)
- A manufacturer will determine if an additional rebate (also known as the CPI-U penalty) is owed by comparing a “benchmark” AMP with the comparison period AMP\(^2\)
- The benchmark AMP is calculated by adjusting the baseline AMP by the change in CPI-U over the appropriate period

If the comparison period AMP is greater than the benchmark AMP, an additional rebate is due

- Amount of the additional rebate is the amount by which the comparison period AMP exceeds the benchmark AMP
- **Calculation**
  
  \[
  \text{CPI adjusted price} = \text{AMP current} - (\text{CPI-U current}/\text{CPI-U baseline}) \times \text{AMP baseline}
  \]
- Reformulated drugs are subject to inflation penalty based on original drug’s launch price adjusted by CPI-U

Illustration*

\[
\text{AMP} = $100
\]

\[
\text{CPI-U Penalty}
\]

\[
\text{340B Ceiling Price} \quad \text{340B ceiling price/ Medicaid Rebate Program price} = $76.90
\]

\[
\text{Unit rebate amount/340B discount}
\]

Source: HRSA, CPI-U Penalty, 340B rebate snhpa.org, HRSA Program requirements, Price, 340B PVP, *RAND
GPO: Group Purchasing Organizations, URA: Unit Rebate Amount, AMP: Average Manufacturer Price, CPI-U: Customer Price Index Urban
Contents

- 340B Overview
- Eligibility and Business Models
- Rebate Calculation
- Loopholes/Shortcomings
- Oncology and 340B
Several factors directly or indirectly affect 340B eligibility, increasing 340B drug volume and abuse of the discounts

Double-Dipping
- Providers resorting to duplication of records to obtain discounts from both Medicaid rebates and 340B Program
- Drug diversion and double reimbursements for single prescriptions

Non-Compliance
- Violation of GPO prohibition by purchasing covered outpatient drugs from a GPO
- 69% of the covered entities provide less charity care than the national average across all hospitals
- Covered entities are using the profits to create monopolistic situations in health care provision

Acquisitions
- Hospitals are increasing the M&A with physician-based settings, community clinics and private cancer centers
  - 340B hospitals were responsible for purchase of approx. 75% community oncology practices in 2012-2013
  - Cleveland Clinic has merged with a three-hospital system and independent community hospitals over the past 12 years, becoming the top-grossing 340B entity (US$11.63B)

Inpatient → Outpatient
- Hospitals are converting the inpatient procedures to outpatient settings to get the benefit of the program or diverting the drugs from this scheme to non-scheme purchases

Source: OncLive, Medscape, Evolving Landscape, Cleveland Clinic, Cleveland clinic USD, health.clevelandclinic.org
GPO: Group Purchasing Organization; M&A: Mergers and acquisitions
# 340B Program Issues

Findings from 340B audits have raised questions about actual utilization of discounts

### Audit results for hospitals – FY12

<table>
<thead>
<tr>
<th>Issue</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Violation of the GPO prohibition (for applicable entities)</td>
<td>42%</td>
</tr>
<tr>
<td>Dispensed drugs to ineligible individuals</td>
<td>36%</td>
</tr>
<tr>
<td>Billing contrary to Medicaid Exclusion File</td>
<td>24%</td>
</tr>
<tr>
<td>Incorrect database records</td>
<td>21%</td>
</tr>
</tbody>
</table>

### Audit results for non-hospitals – FY12

<table>
<thead>
<tr>
<th>Issue</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect database records</td>
<td>39%</td>
</tr>
<tr>
<td>Dispensed drugs to ineligible individuals</td>
<td>33%</td>
</tr>
<tr>
<td>Billing contrary to Medicaid Exclusion File</td>
<td>33%</td>
</tr>
</tbody>
</table>

For Medicare patients, oncology care in the hospital OPD costs 14% more than in a physician office.

This may result in duplication of discounts as well as diversion.

Non-transparent regulations have left the regulatory bodies blindfolded about the outcome of the program.

Source: pharmacist, hrsa.gov, Audit Results of HRSA for FY12, Rxobserver, prnewswire, post-gazette, Clinicaloncology
HRSA and drug manufacturers have participated in monitoring and lobbying efforts to bring reform in the 340B Program

- Conducts audits to scrutinize how 340B funds are spent
- Implements stricter guidelines on patient eligibility
- Clarifies requirements for contract pharmacy arrangements
- Improves program integrity standards and enforcement

Implement strategies to minimize inappropriate provider use. For example, Genentech increased site visits and audits in response to 25% growth in its 340B discounts to US$1 billion a year

- Promotes transparency and accountability by requiring 340B-covered entities to provide comprehensive accounting of the amount of 340B savings* on an annual basis
- Considers changing demographics in oncology care while bringing in policy reforms
- Defines the stakeholders and provides funding for key oversight activities
- Addresses access hurdles to high-quality oncology care

- Suggests that HRSA’s oversight of 340B is inadequate and needs rework
- Assures proper implementation of the 340B Program, in appropriate populations, to prevent abuse

Source: Medscape, Genentech; PharmaCo React; Price hike, * Percentage reinvested into caring for the uninsured, underinsured and Medicaid patients; Celgene.com
Contents

- 340B Overview
- Eligibility and Business Models
- Rebate Calculation
- Loopholes/Shortcomings
- Oncology and 340B
ACA envisioned an expanded prescription drug discount program to improve 340B integrity and patient access to oncology medications

<table>
<thead>
<tr>
<th>Expand and improve program</th>
<th>Ensure improved access</th>
<th>Drive down costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>By one estimate, the ACA will increase demand for medical oncologists by an additional 130 full-time clinical care oncologists per year by 2025, due to insurance access</td>
<td>Expand the program to include the drugs used for inpatient service by enrolled hospitals</td>
<td>Key focus areas of ACA in oncology care includes:</td>
</tr>
<tr>
<td></td>
<td>Facilitate enrolled hospitals to obtain inpatient drugs through a group purchasing agreement or the 340B PVP</td>
<td></td>
</tr>
</tbody>
</table>

* Providers could use 340B purchasing discounts for oncology practices that they have acquired while still charging expensive facility-level prices to commercial payers

The ACA has increased access to care for oncology patients yet also seeks to improve the way care is delivered by providers

Source: ASCO 2014 Report; AJMC, OBRoncology, PVP: Prime Vendor Program
ACA: Affordable Care Act
Impact of 340B is significant when evaluating the relative growth in oncology drug reimbursement

Total Part B drug reimbursements for oncology drugs for 340B hospitals has increased by 123% from 2010 to 2013, while increasing only 31% for non-340B hospitals

340B hospitals realize sizeable profits on Medicare and commercial reimbursement of oncology drugs

DSH hospitals are driving acquisition activity of community oncology practices, leading to doubling the size of their oncology services and gaining huge profits on Part B reimbursement

Source: communityoncology, Celgene Report on Acquisitions of Community Practices
Manufacturers need to keep vigil on the evolving 340B landscape and evaluate the implications of the reforms

- Large providers hold considerable bargaining power, leading to dipping margins for manufacturers
- Providers have the incentive to consolidate to extend 340B status
- Contract pharmacies are also gaining bargaining power as they consolidate

The government continues to extend coverage to affordable care
- Apexus has gained significant bargaining power as HRSA's exclusive 340B prime vendor

Impact of Different Stakeholders

Source: cancernetwork.com

**Identify which customers are 340B-eligible**
- Purchase data sources that “flag” 340B-eligible accounts and download updated entity list on a quarterly basis
- Make 340B eligibility status a consistent discussion topic for field personnel engaging in account profiling discussions

**Factor in 340B eligibility to forecasting**
- Make assumptions about average percentage of discount application
- Understand the flow of money and the business model in which eligible entities are operating
- Continue to monitor local consolidation trends and potential changes

**Understand stakeholder economics for their products and competitors**
- Understand the impact of 340B status on physicians’ prescription decisions for eligible vs. ineligible drugs
- Properly take advantage of the improved access through 340B entities and mitigate risk of larger discounted volume
APPENDIX SLIDES
340B participating sites have increased over the past 10 years with DSH constituting approx. 80% share of the total sales under the 340B Program.
Amount spent on 340B drugs by covered entities tripled from 2005-2013

Note: Includes all 340B drugs purchased by covered entities from wholesalers and some (but not all) 340B drugs purchased directly from manufacturers. The Health Resources and Services Administration estimates that these numbers account for 90% to 95% of total 340B sales.

Source: Apexus, Medpac
Cumulating count of newly enrolled 340B hospitals is increasing with non-DSH enrollment superseding DSH enrollment.

Source: communityoncology
Covered entities purchase the drugs and get billed. Drugs are shipped directly to contract pharmacy.

**Flow of funds and drugs under 340B Pricing Program**

1. Eligible patient fills scripts at in-house or contract pharmacy.
2. Pharmacy submits replenishment purchase order to 340B entity.
3. Pharmacy submits replenishment purchase order to 340B entity.
4. DSH submits replenishment purchase order to manufacturer or wholesaler.
5. Manufacturer replenishes pharmacy stock (ship-to/bill-to).
6. DSH pays manufacturer or wholesaler for pharmacy stocks (ship-to/bill-to).
7. Pharmacy pays total reimbursement (minus contract pharmacy fees).
8. DSH receives total reimbursement (minus contract pharmacy and vendor fees).

- **Product movement**
- **Financial flow**
- **Contract relationship**

- **DSH**
- **Third-Party Payer**
- **Payer**
- **In-House/Contract Pharmacy**
- **340B Contract Pharmacy Split-Billing Vendor**
- **Drug manufacturer/wholesaler**
- **Apexus**

**Drug Channels Institute:**

- Contract pharmacy dispenses drug (non-340B inventory) to 340B entity’s eligible patient.
- When a full package size of the Rx is reached, the pharmacy or vendor orders a 340B drug to replace it.
- Replacement 340B drugs are billed to entity and shipped to contract pharmacy.
- Entity pays contract pharmacy for its services.

**AWP:** Average wholesale price; **DSH:** Disproportionate Share Hospital

# 340B glossary of covered entities (CE) (1/2)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disproportionate Share Hospital (DSH)</td>
<td>Disproportionate Share Hospitals serve a significantly disproportionate number of low-income patients; they receive adjustment payments to provide additional help</td>
</tr>
<tr>
<td>Children’s Hospital</td>
<td>Non-profit hospitals serve individuals under 19 years of age and have a CMS-issued 3300 Series Medicare Provider Number to designate them as Medicare-certified children’s hospital</td>
</tr>
<tr>
<td>Free-Standing Cancer Hospitals</td>
<td>A non-profit entity that is financially and administratively independent (not part of a larger institution). Hospitals are exempt from Medicare’s prospective payment system</td>
</tr>
<tr>
<td>Critical Access Hospital (CAHs)</td>
<td>A hospital certified to receive cost-based reimbursement from Medicare. CAHs are certified under different, more flexible Medicare conditions of participation (CoP) than acute care hospitals</td>
</tr>
<tr>
<td>Sole Community Hospital (SCH)</td>
<td>Typically, these hospitals furnish short-term, acute care and are paid under the Medicare Acute Care Hospital IPPS (Inpatient Prospective Payment System)</td>
</tr>
<tr>
<td>Rural Referral Center (RRC)</td>
<td>A Medicare-participating acute care hospital is classified as an RRC if it is located in a rural area with 275 or more beds available for use during its most recently completed cost reporting period</td>
</tr>
<tr>
<td>Federally Qualified Health Centers (FQHCs)</td>
<td>Community-based health care providers receive funds from the HRSA Health Center Program to provide primary care services in underserved areas</td>
</tr>
<tr>
<td>FQHC Look-Alikes</td>
<td>Community-based health care providers that meet the requirements of the HRSA Health Center Program, but do not receive Health Center Program funding. They provide primary care services in underserved areas, provide care on a sliding fee scale based on ability to pay and operate under a governing board that includes patients</td>
</tr>
</tbody>
</table>

Source: 340B Glossary, Covered Entities
### 340B glossary of covered entities (CE) (2/2)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hemophilia Treatment Centers (HTC)</strong></td>
<td>HTCs that receive HRSA grant funding are expected to provide optimal care using a multidisciplinary team approach that provides accessible, family-centered, continuous, comprehensive, coordinated and culturally effective care for individuals with hemophilia and other bleeding disorders</td>
</tr>
<tr>
<td><strong>Ryan White HIV/AIDS Program Grantees</strong></td>
<td>Grantees receiving federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS, who are uninsured or under-insured</td>
</tr>
<tr>
<td><strong>Family Planning Clinics</strong></td>
<td>Clinics receiving funding from the Title X Family Planning Program to provide contraceptive services, counseling and reproductive health-related preventive services, with priority given to low-income people</td>
</tr>
<tr>
<td><strong>Sexually Transmitted Disease (STD) Clinics</strong></td>
<td>STD Clinics diagnose and treat STDs and receive funding from their state and local health departments through the STD Control Program</td>
</tr>
<tr>
<td><strong>Tuberculosis Clinics</strong></td>
<td>Tuberculosis Clinics receive funding from their state tuberculosis control offices to prevent, diagnose and treat tuberculosis. The Centers for Disease Control and Prevention administer the program</td>
</tr>
<tr>
<td><strong>Black Lung Clinics</strong></td>
<td>Clinics receive funding from the HRSA Black Lung Clinic Program to seek out coal miners, whether they are currently involved in mining or not, and provide services to them and their families, regardless of their ability to pay</td>
</tr>
<tr>
<td><strong>Native Hawaiian Health Centers</strong></td>
<td>Native Hawaiian Health Centers receive Native Hawaiian Health Care Systems Program funding (through the HRSA) to improve the health status of Native Hawaiians by providing access to health education, health promotion and disease-prevention services</td>
</tr>
</tbody>
</table>