America’s Voice for Community Health Care
America’s Voice for Community Health Care

The National Association of Community Health Centers (NACHC) represents Community and Migrant Health Centers, as well as Health Care for the Homeless and Public Housing Primary Care Programs and other community-based health centers.

Founded in 1971, NACHC is a nonprofit advocacy organization providing education, training and technical assistance to health centers in support of their mission to provide quality health care to medically underserved populations.
The NACHC Mission

To promote the provision of high quality, comprehensive and affordable health care that is coordinated, culturally and linguistically competent, and community directed for all medically underserved populations.
For further information about NACHC and America’s Health Centers

Visit us at www.nachc.com
NACHC 340B Webinar Series

Part 1: Basics of the 340B Drug Pricing Program

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January 20, 2016
This is the first in a series of four webinars. Today we will focus on 340B Basics. Due to the number of callers, and the complexity of the 340B Program, please limit questions to the material covered in today’s webinar.

We will compile all unanswered questions from today’s webinar and respond to them as soon as possible.
What is the 340B Drug Program?
340B Program

- Program that allows certain entities to buy drugs at discounted prices
- Savings from lower drug costs can then be used to expand FQHC services or reduce charges to patients
Required drug manufacturers to have a rebate agreement with the government in order for their drugs to be covered under Medicaid.
Although drug manufacturers offered the rebates, provider costs for other discounted drugs rose dramatically.
Congress then created the 340B Drug Program to protect certain clinics and hospitals (known as **covered entities**) from significant drug price increases.
A second agreement was signed by the drug manufacturers which limited the amount that could be charged to covered entities for drugs.

This is known as the “ceiling price”.
Ceiling price calculation

Average manufacturer price
- Unit rebate amount
340B ceiling price
Ceiling price calculation

Average Manufacturer Price (AMP)

• Unit price, net of discounts, that distributors pay for the retail community pharmacies

Average manufacturer price
- Unit rebate amount
340B ceiling price
Ceiling price calculation

Unit Rebate Amount (URA)
- Percentage discount allowed off of the AMP
- Calculated by the Centers for Medicare and Medicaid Services
- Based on drug classes

<table>
<thead>
<tr>
<th>Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand</td>
<td>23.1%</td>
</tr>
<tr>
<td>Generic</td>
<td>13.0%</td>
</tr>
<tr>
<td>Clotting Factor</td>
<td>17.1%</td>
</tr>
<tr>
<td>Exclusively Pediatric</td>
<td>17.1%</td>
</tr>
</tbody>
</table>
## Ceiling price calculation

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Average manufacturer price</td>
<td>$1.00</td>
</tr>
<tr>
<td>minus: Unit rebate amount* (Brand)</td>
<td>$0.23</td>
</tr>
<tr>
<td>340B ceiling price for one pill</td>
<td>$0.77</td>
</tr>
</tbody>
</table>

*Brand 23.1%  
Generic 13.0%  
Clotting Factor 17.1%  
Exclusively Pediatric 17.1%

Calculation example does not consider other factors such as best price, consumer price index and base line AMPs.
HRSA (Health Resources Services Administration) calculates the ceiling prices each quarter.

Average manufacturer price
- Unit rebate amount
  340B ceiling price
RE: How to verify a 340b ceiling price [ ref: _00Dj0KRDh._500j07qpi5:ref ]
ApexusAnswers to: cdupree@draffin-tucker.com
Sent by: noreply@salesforce.com

To ensure privacy, images from remote sites were prevented from downloading.  Show Images

Good morning Cindy,

Thank you for contacting Apexus Answers, OPA has mentioned they would like to make the ceiling price available on the public website, however they did not set a specific time frame when that would happen. Secondly if you have access yo our secure PVP website, some manufacturers have provided us with their ceiling price. The ceiling price can be found under the reports tab if you log in and also the 340B price file that the big four wholesaler report to Apexus can also be found under the reports tab.

I hope this is helpful please let me know if you have any further questions.

Warmest Regards,

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| 888.340.2787
What’s the benefit?

• The FQHC benefits by saving the difference between the usual drug cost and the 340B cost. (340B savings)

• Many insurers will continue to pay the FQHC the normal reimbursement rate for the drug, regardless of the 340B reduced cost.
Why do FQHCs participate?

• 340B savings enable the covered entities to provide increased services to patients.
• FQHCs can offer lower prescription costs.

According to a NACHC study, FQHC’s drug costs could increase by a minimum of 41% if 340B pricing was not used.
Relative Pricing

Adapted from a slide by Safety Net Hospitals for Pharmaceutical Access
Source: Data derived from Prices for Brand-Name Drugs Under Selected Federal Programs, Congressional Budget Office (June 2005)
Prime Vendor Program

• By participating in the 340B Prime Vendor Program, covered entities can save more on the cost of drugs.
• The PVP can negotiate prices even lower than the ceiling price. (sub-ceiling prices)
How can 340b savings be used?
To permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible* patients and providing more comprehensive services.”


*340B patient eligibility criteria does not require that the patient is indigent or qualifies for a sliding fee scale discount.
Use of 340B savings?

- Law does not specify further.
- Savings may be passed on to the patient.
  - Drug Discount Cards
  - Sliding Fees
- Savings may go into operations to expand programs and services.
FQHCs

Are statutorily required to invest all revenues, including 340B, into activities that are approved under their HRSA/Bureau of Primary Health Care Scope of Project and advance their charitable mission.
Policies and procedures should discuss use of the savings and how such use supports intent of Program.

- Are savings passed directly to patients?
- Are savings used in programs to benefit the low-income and underserved populations?
Who can participate in the 340B Program?
A non-profit healthcare organization, that meets certain Federal designations, or receives specific types of Federal funding may participate.

FQHCs and FQHC look-alikes are both eligible.
How does the Program work?
Register in OPA Database → Obtain approval from HRSA → Notify manufacturer/supplier → Purchase discounted drugs → Place in 340B inventory → Distribute to 340B eligible patients → Bill to patient → Collect amounts owed → Use 340B savings
COMPLIANCE ISSUES!

- Register in OPA Database
- Obtain approval from HRSA
- Notify manufacturer / supplier
- Distribute to 340B eligible patients
- Place in 340B inventory
- Purchase discounted drugs
- Bill to patient
- Collect amounts owed
- Use 340B savings
How do you register?
Where to register

Web-based

https://opanet.hrsa.gov/340B/default
## Quarterly registration “windows”

<table>
<thead>
<tr>
<th>Registration Period</th>
<th>Effective Date</th>
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</thead>
<tbody>
<tr>
<td>January 1 - 15</td>
<td>April 1</td>
</tr>
<tr>
<td>April 1 - 15</td>
<td>July 1</td>
</tr>
<tr>
<td>July 1 - 15</td>
<td>October 1</td>
</tr>
<tr>
<td>October 1 - 15</td>
<td>January 1</td>
</tr>
</tbody>
</table>
Information needed

- Authorizing official
- Primary Contact
- Tax ID#
- Grant Number
- Address of clinic sites
- Medicaid billing #
- Contract pharmacy information
Parent and child sites

- The main FQHC site is the “parent”.
- Delivery sites at different physical addresses from parent are known as “child sites”.
- Each site must be separately registered.
Attestation

Authorizing Signature

The undersigned represents and confirms that he/she is fully authorized to legally bind the covered entity and certifies that the contents of any statement made or reflected in this document are truthful and accurate. The undersigned further acknowledges the 340B covered entity’s responsibility to abide by the following:

As an Authorized Official, I certify on behalf of the covered entity that:

(1) all information listed on the 340B Program database for the covered entity will be complete, accurate, and correct;
(2) the covered entity will meet all 340B Program eligibility requirements;
(3) the covered entity will comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines, including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient or a covered entity;
(4) the covered entity will maintain auditable records demonstrating compliance with the requirements described in paragraph (3) above;
(5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described in (3) above;
(6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement will be performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);
(7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and
(8) the covered entity acknowledges that if there is a breach of the above that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.

In addition, I have read all applicable registration instructions and I am aware that my registration will not be reviewed if the required supporting documents are not submitted today.

☑ By checking this box, I confirm that I have read the above statements and fully understand my obligations.

Signed By Official
More registration information

https://opanet.hrsa.gov/opa/Manuals/Public/CE7RegisterCE.pdf
What is recertification?
Why recertify annually?

• Opportunity to review and update OPA database
• Re-attest to compliance
• No recertification…..no participation!
When to recertify?

FQHCs usually recertify in February.
More recertification information

https://opanet.hrsa.gov/opa_mod/manuals/Public/CERecertify.pdf
What drugs can be discounted under 340B?
Covered 340B drugs

- FDA approved prescription drugs
- OTC drugs written on a prescription
- Biological products dispensed only by prescription
- FDA-approved insulin

No vaccines!
Who is an eligible patient?
(C) Definition of a Patient

An individual is a “patient” of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care; and

2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and

3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity.

Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a “patient” of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
Multiple hurdles

Provider
Prescriber
Encounter type and location

Once a “patient”, always a “patient”? What if prescriber leaves practice? How many refills are eligible? What about referrals? Is there a need for underlying diagnosis to be treated during encounter?
Employees must meet the qualifying patient definition, same as any other patient.

Source: Apexus FAQ
How are 340b drugs distributed to patients?
Drug delivery models

Contract: 49.1%
In-house: 46.9%

Source: 2011 NACHC survey
How do you track 340B inventory?
Types of 340B inventory systems

- Physically separate
- Virtual model
Types of inventory systems

Physically separate

- Often used for in-house pharmacies.
- One inventory can be used if all patients are 340B eligible.
- Two inventories will be needed, separate 340B and non-340B, if some patients are ineligible for 340B program.
- Patient eligibility is determined at time of drug dispense or administration.
Physical inventory

Pre-purchased inventory model (physical inventory)

340B

Covered entity patients

Non-340B

Other patients
Types of inventory systems

Virtual model

• Used mostly in contract pharmacy arrangements.
• 340B and non-340B inventory is commingled.
• Patient eligibility is retrospectively determined.
• Tracking software will be needed.
In a virtual, commingled inventory, drugs are designated 340B after the drug is purchased and dispensed.

- Tracking system will be necessary.
- Must be tracked and replenished by National Drug Code (NDC) number.
NDC matching is required

National Drug Code – 11 digit number
First 5 digits = manufacturer
Next 4 digits = drug product
Final 2 digits = package size

Sterile Lyophilized Powder
Vancomycin Hydrochloride for Injection, USP
Equivalent to 5 g Vancomycin
Pharmacy Bulk Package – Not for Direct Infusion.
For Intravenous Use.
Hospira, Inc., Lake Forest, IL 60045 USA
Vancomycin HCl for Injection USP 5g

NDC 0409-6509-01
Rx only

11 digit code
00409-6509-01
Why is NDC matching important?

National Drug Code – 11 digit number
- First 5 digits = manufacturer
- Next 4 digits = drug product
- Final 2 digits = package size

A manufacturer does not want to give a rebate to the State, or a discount on replenishment, if the drug dispensed was not purchased from that manufacturer.
What is a contract pharmacy?
Covered entities that participate in the Program may contract with retail pharmacies to dispense 340B drugs on their behalf.

PHARMACY SERVICES AGREEMENT

THIS PHARMACY SERVICES AGREEMENT, (the “Agreement”), dated as of April 1, 2011, between Pharmacy, Inc. /dba/ (“Pharmacy”), and (“Facility”).
340B Contract Pharmacy Locations, by Chain, January 2014

n = 13,708 pharmacy locations

Walgreens 39%
All Others 37%
Safeway 2%
Kroger 2%
Walmart 6%
CVS 7%
Rite Aid 7%

24%

Note: This chart appears as Exhibit 96 in the 2013-14 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2014. (http://drugchannelsinstitute.com/products/industry_report/pharmacy/)
Pros and cons - contract pharmacy

- Provides alternative if no in-house pharmacy is available
- Increases patient access to medications
- Eliminates cost of operating in-house pharmacy

- Reduces amount of 340B savings
- Requires tracking software
- Increases compliance concerns
Total Number of 340B Contract Pharmacies, 2000-2014

Data show contract pharmacies as of July of each year. For 2014, data show contract pharmacies as of January.

Source: Avalere Health (2000-2012); Pembroke Consulting (2013-2014)

Note: This chart appears as Exhibit 95 in the 2013-14 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2014. (http://drugchannelsinstitute.com/products/industry_report/pharmacy/)
340B and Medicaid
Who gets the 340B savings on Medicaid patients?

**Carve-in**
- Dispense 340B-purchased drugs to Medicaid patients
- Bill Medicaid program

Must following individual State’s billing rules for 340B drugs

Example:
(Acquisition cost + processing fee)

**Carve-out**
- Does not dispense 340B-purchased drugs to Medicaid patients
- State bills manufacturer for rebate amount
Medicaid Exclusion File

Medicaid managed care patients are considered Medicaid patients.

Entities must have separate Medicaid numbers if some sites carve-in and some carve-out or are not otherwise 340B eligible sites.
What and where are the 340B rules?
By Overturning 340B Orphan Drug Rule, Court Could Stifle Future HRSA Rulemaking.

HRSA Issues 340B Program Omnibus Guidance.

Want to learn more?
NACHC Information

• NACHC website guidance
• Upcoming webinars

1/27 – Contract Pharmacy
2/03 – Recent Developments
2/10 – Compliance/Self-audits
For more information or questions:
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