



America's Voice for Community Health Care



NATIONAL ASSOCIATION OF
Community Health Centers

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.



NATIONAL ASSOCIATION OF
Community Health Centers

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.



NATIONAL ASSOCIATION OF
Community Health Centers

**For further information about NACHC and
America's Health Centers**

Visit us at www.nachc.com



NATIONAL ASSOCIATION OF
Community Health Centers

NACHC 340B Webinar Series

Part 1: Basics of the 340B Drug Pricing Program

Cynthia (Cindy) R. DuPree
Partner, Draffin & Tucker, LLP
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

Medicaid Drug Rebate Program - 1990

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.



340B Drug Program - 1992

Congress then created the 340B Drug Program to protect certain clinics and hospitals (known as **covered entities**) from significant drug price increases.

340B Drug Program - 1992

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**”.

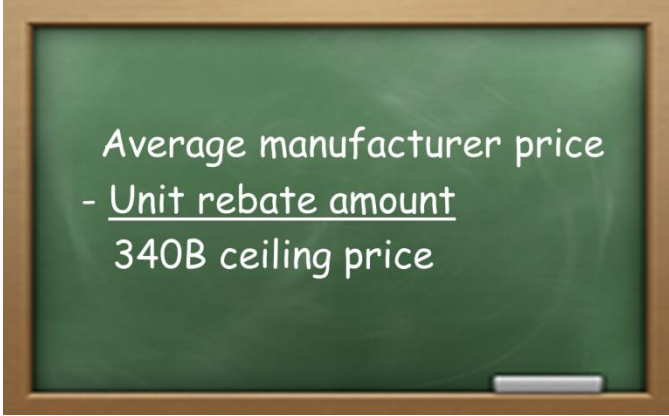
Ceiling price calculation

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*

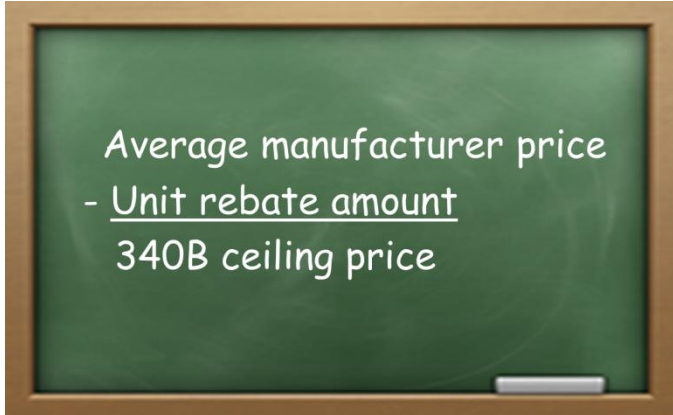

$$\begin{array}{r} \text{Average manufacturer price} \\ - \text{Unit rebate amount} \\ \hline \text{340B ceiling price} \end{array}$$

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

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


$$\begin{array}{r} \text{Average manufacturer price} \\ - \text{Unit rebate amount} \\ \hline \text{340B ceiling price} \end{array}$$

Ceiling price calculation

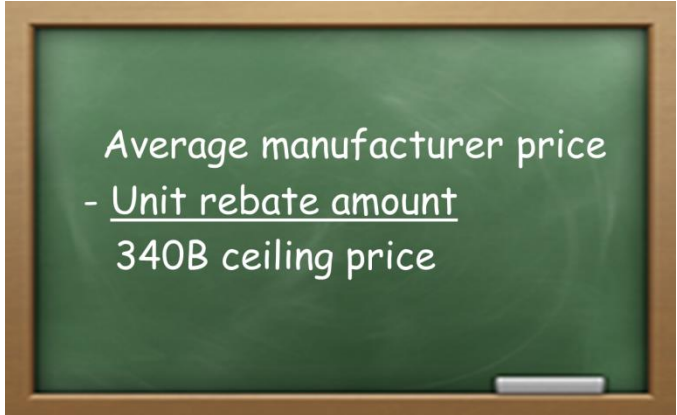
Average manufacturer price	\$1.00
minus: <u>Unit rebate amount*</u> (Brand)	<u>.23</u>
340B ceiling price for one pill	<u>\$.77</u>

*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.

Ceiling price calculation

HRSA (Health Resources Services Administration) calculates the ceiling prices each quarter.



Average manufacturer price
- Unit rebate amount
340B ceiling price

Verification of 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

12/01/2015 10:09 AM

[Show Details](#)

Security: 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 to 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,

Jose Rodriguez, CPhT

340B Call Center Specialist

Apexus | 340B Prime Vendor Program

290 East John Carpenter Freeway

Irving, Texas 75062

APEXUSANSWERS@340BPVP.com | www.340BPVP.com

| 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.

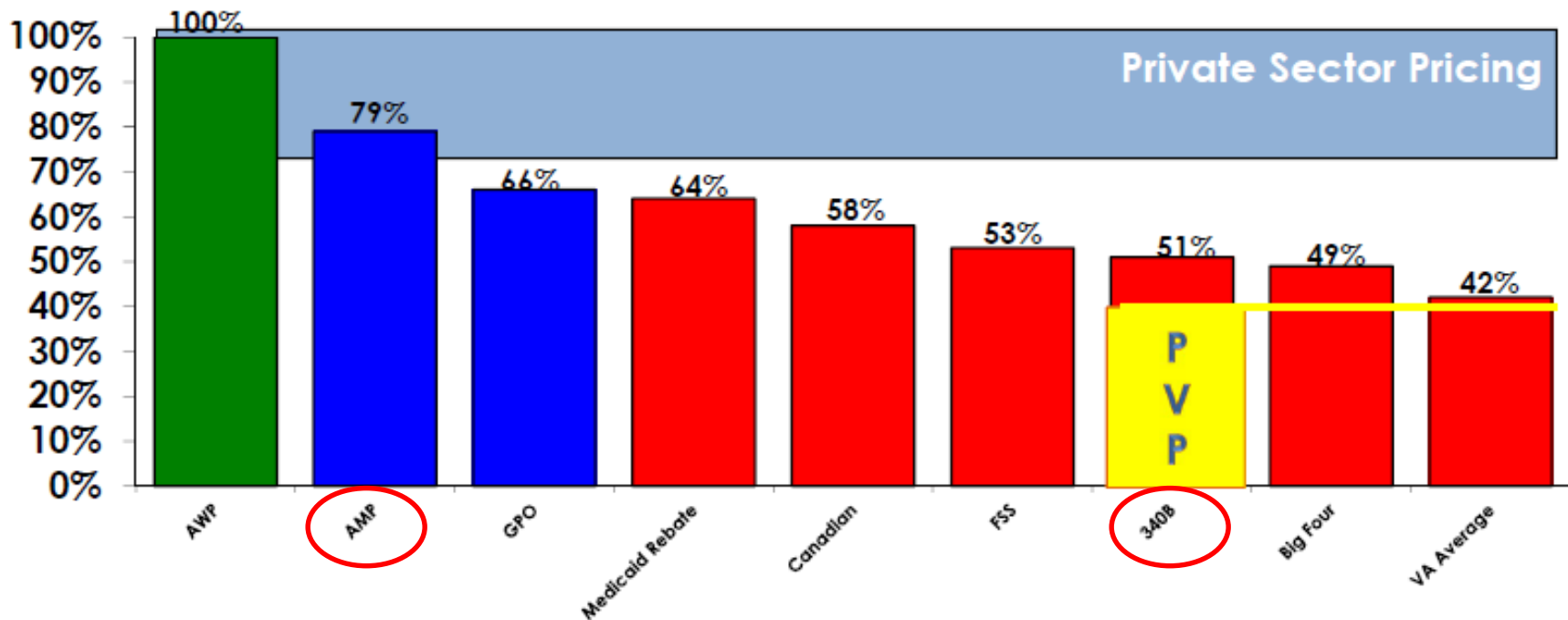
Why do FQHCs participate?

- 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?





Intent of Program

To permit covered entities “to stretch scarce Federal resources as far as possible, reaching more **eligible*** patients and providing more comprehensive services.”

H.R. Rep. No. 102-384(II), at 12 (1992)

*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.

OMB No.: 0915-0285, Expiration Date: 9/30/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration		FOR HRSA USE ONLY	
		Grant Number	Application Tracking #
FORM 5A: SERVICES PROVIDED (REQUIRED SERVICES)			
Service Type	Service Delivery Methods		
	Direct (Health Center pays)	Formal Written Contract/ Agreement (Health Center pays)	Formal Written Referral Arrangement (Health Center DOES NOT pay)
General Primary Medical Care			
Diagnostic Laboratory			
Diagnostic Radiology			
Screenings			
Coverage for Emergencies During and After Hours			
Voluntary Family Planning			
Immunizations			
Well Child Services			
Gynecological Care			
Obstetrical Care			
• Prenatal Care			



Document use of 340B savings

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?





Covered entities

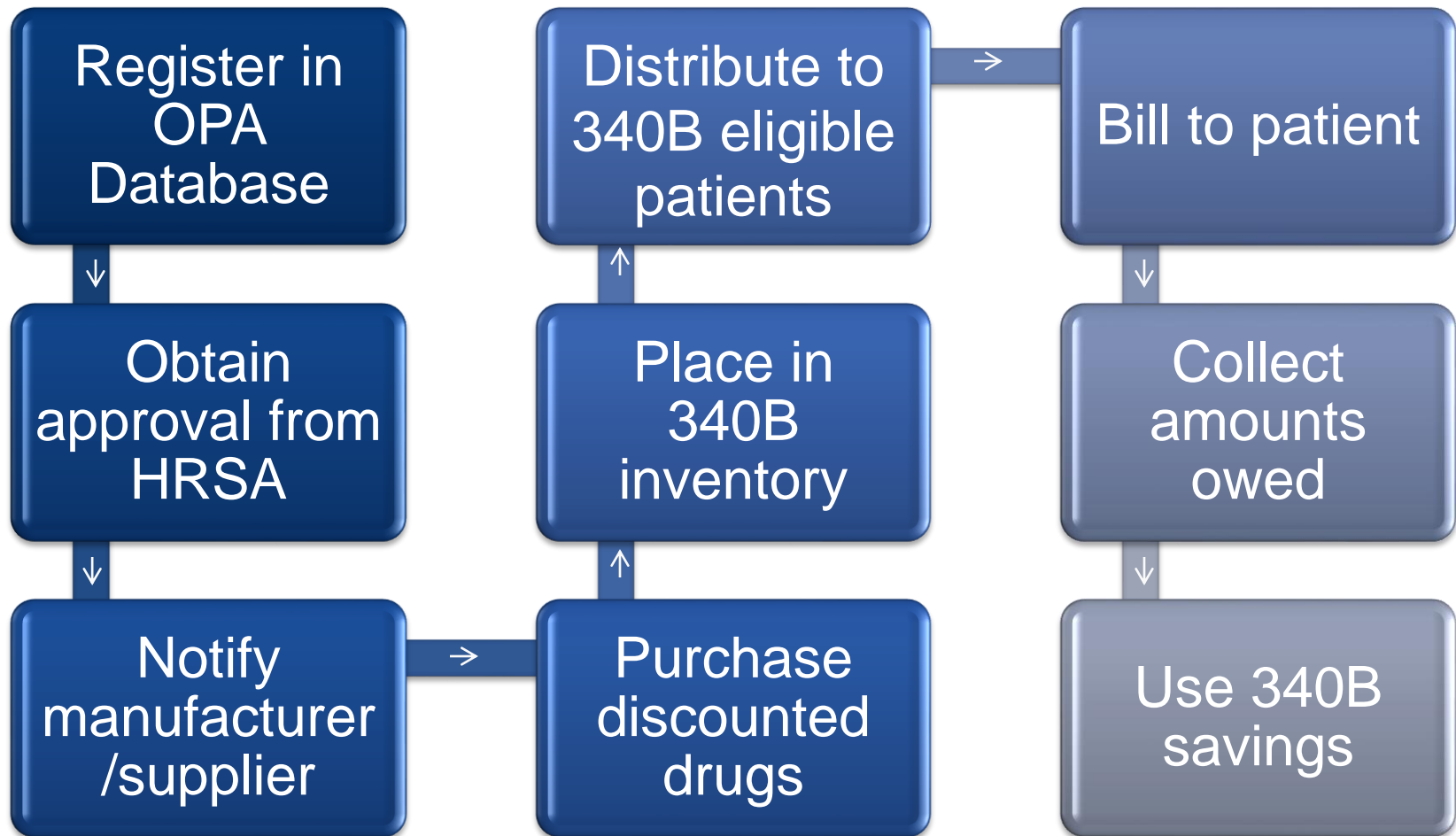
A non-profit healthcare organization, that meets certain Federal designations, or receives specific types of Federal funding may participate.

FQHCs and FQHC look-alikes are both eligible.

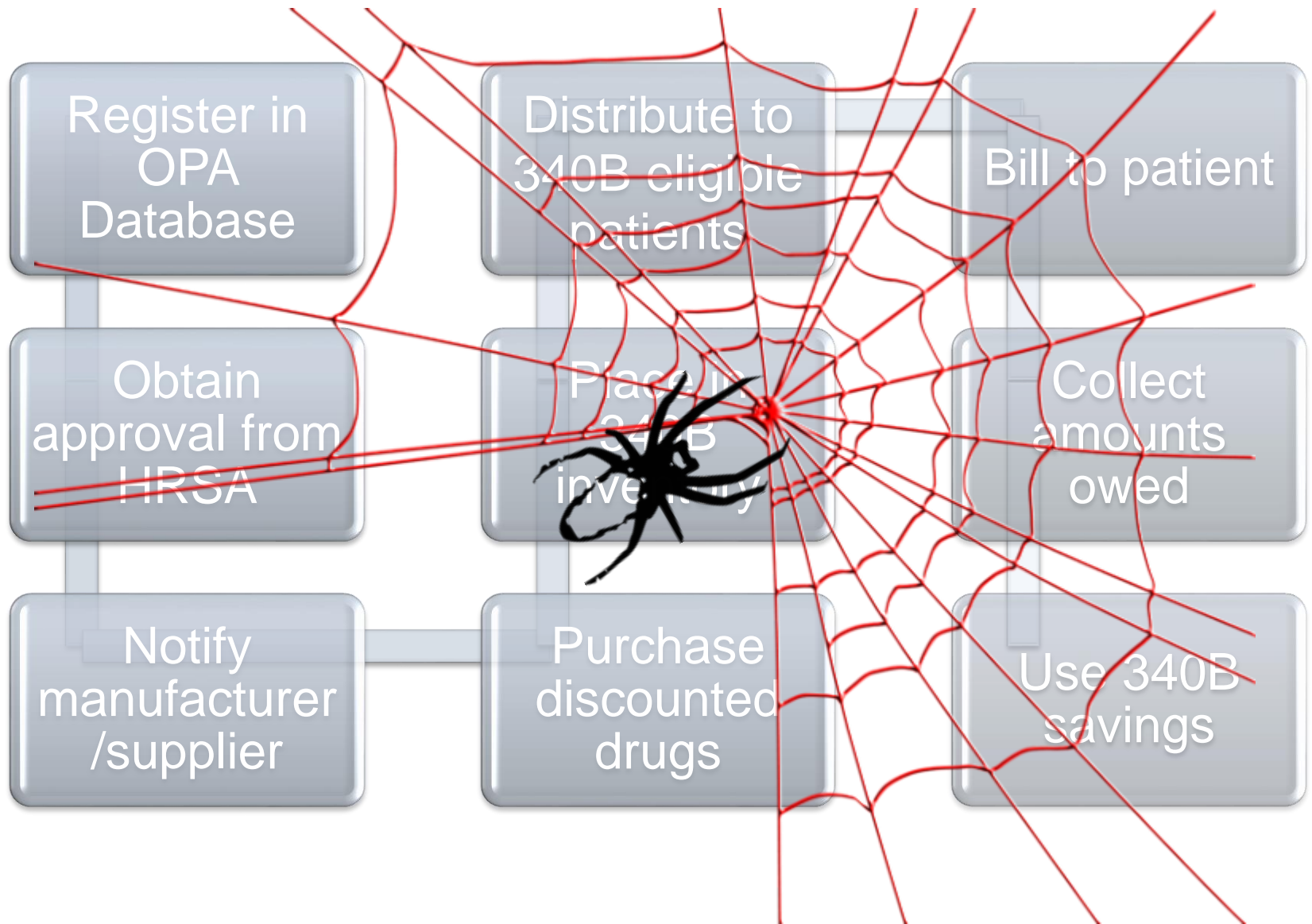
How does the Program work?



340B process flow



COMPLIANCE ISSUES!



How do you register?



Where to register

Web-based

HRSA Office of Pharmacy Affairs
340B Database

Home | Search | Register | Change Request | Reports/Files

Welcome to 340B Drug Pricing Program Database

WHAT WOULD YOU LIKE TO DO?

Search Register Change Request Reports/Files

HAVE QUESTIONS?
Contact the 340B Prime Vendor

ApexusAnswers@340bvp.com 1-888-340-2787 www.340bvp.com

SAM-5PM CT Mon-Fri

<https://opanel.hrsa.gov/340B/default>

Quarterly registration “windows”

Registration Period	Effective Date
January 1 - 15	April 1
April 1 - 15	July 1
July 1 - 15	October 1
October 1 - 15	January 1

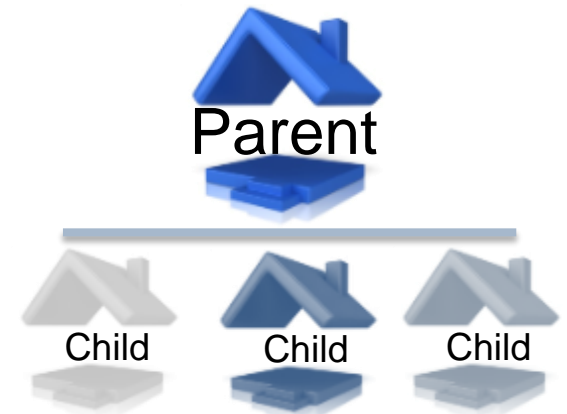
Information needed



- ✓ 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:

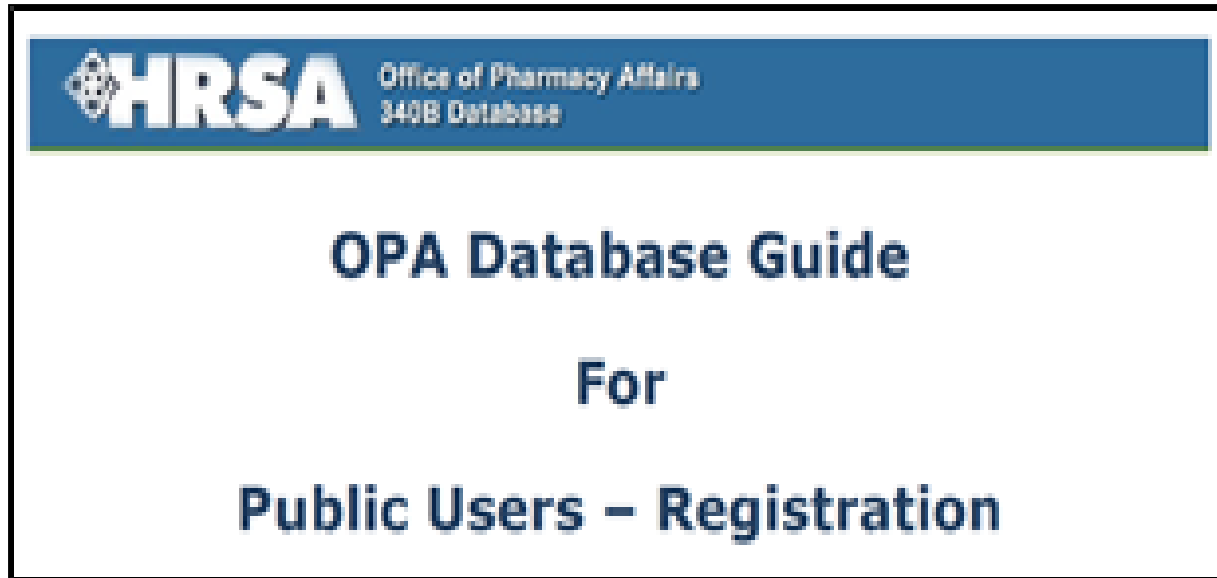
- (1) all information listed on the 340B Program database for the covered entity will be complete, accurate, and correct;
- (2) the covered entity will meet all 340B Program eligibility requirements;
- (3) the covered entity will comply with all requirements and restrictions of Section 340B of the Public 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 of the 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://opanel.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



OPA DATABASE GUIDE

FOR


PUBLIC USERS - RECERTIFICATION

https://opanel.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?



Current definition

(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

Health Resources and Services Administration

[0905–ZA92]

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Notice.

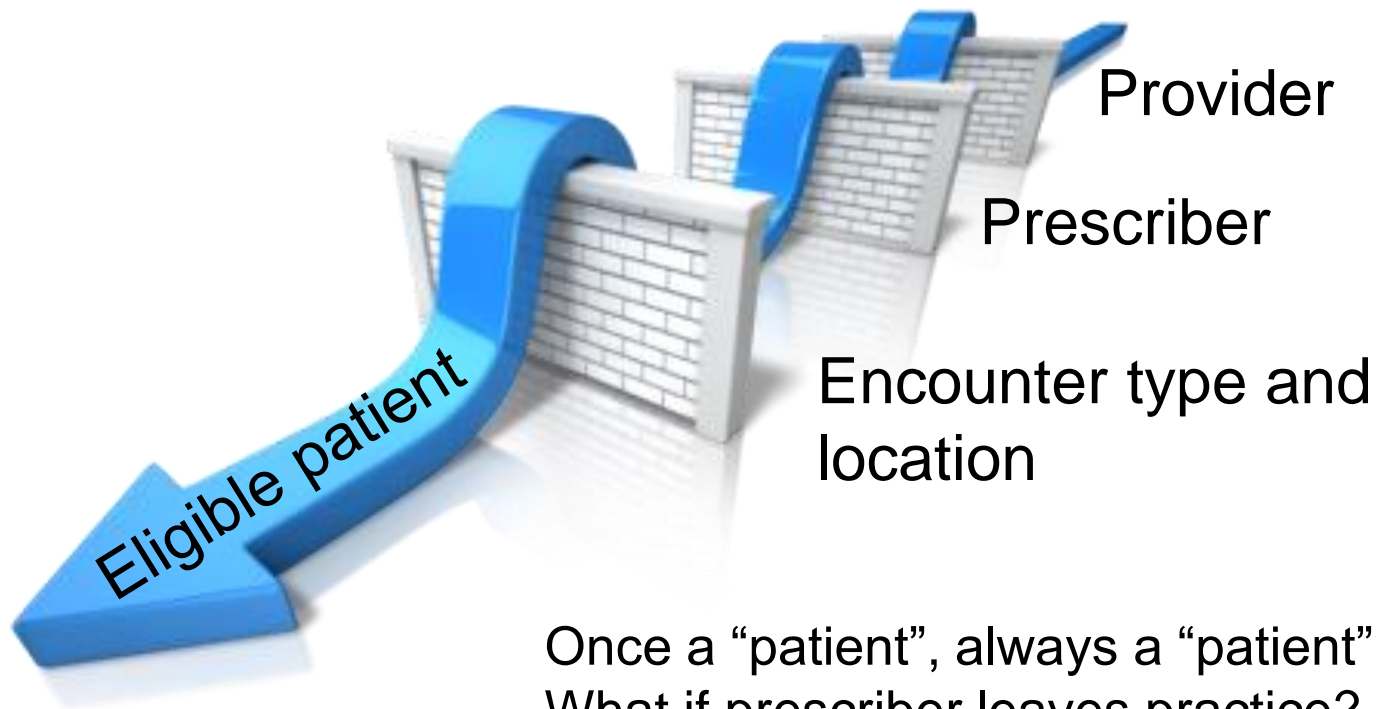
61 Fed. Reg. 55156, October 24, 1996

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



- 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 & 340B

Employees must meet the qualifying patient definition, same as any other patient.

FAQ ID: 1435

Last Modified: 09/15/2014

Q: Are employees of a covered entity eligible to receive 340B drugs?

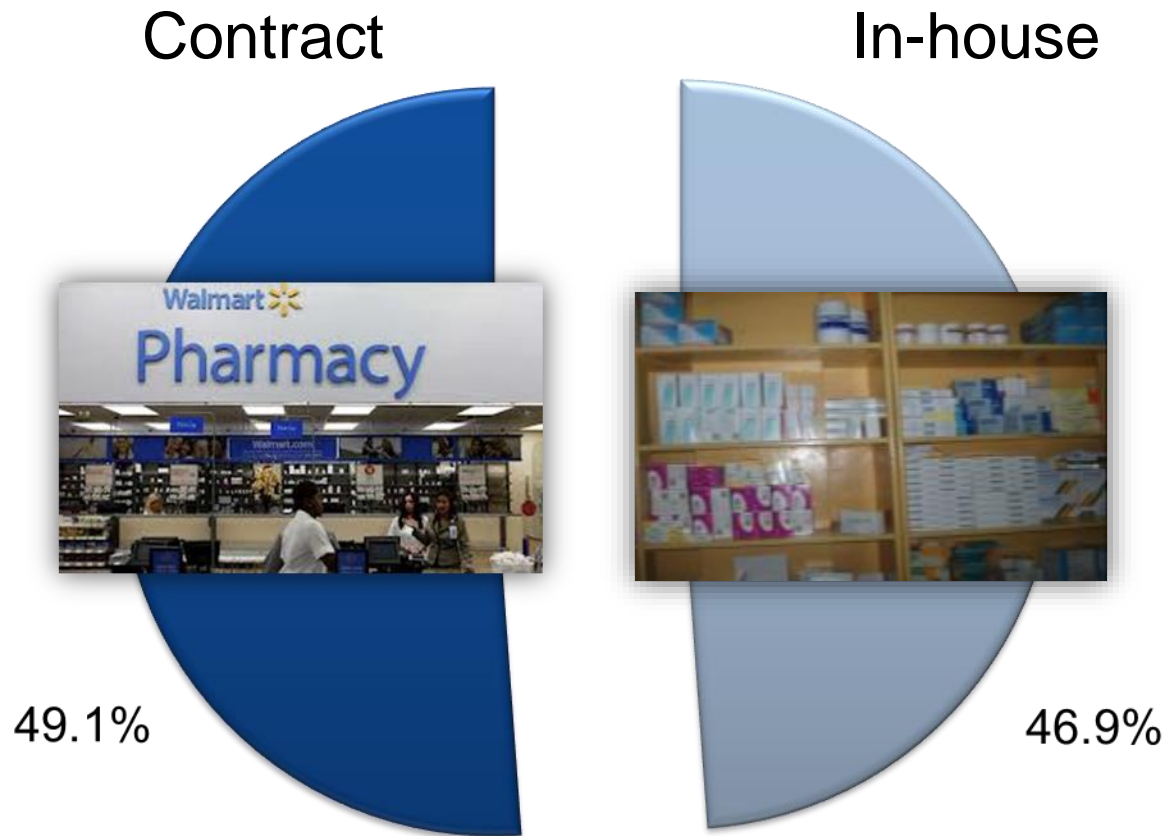
A: Covered entities may only distribute 340B drugs to their employees that meet the patient definition guidelines set forth under the 340B Program. The 340B Program is limited to patients of the covered entity and has never been a general employee pharmacy benefit or self-insured organization pharmacy benefit. Evidence of an employer relationship or insurer relationship alone is insufficient to determine 340B patient eligibility.

Source: Apexus FAQ

How are 340b drugs distributed
to patients?



Drug delivery models



Source: 2011 NACHC survey

How do you
track 340B inventory?



Types of 340B inventory systems



Physically separate



Virtual model

Types of inventory systems

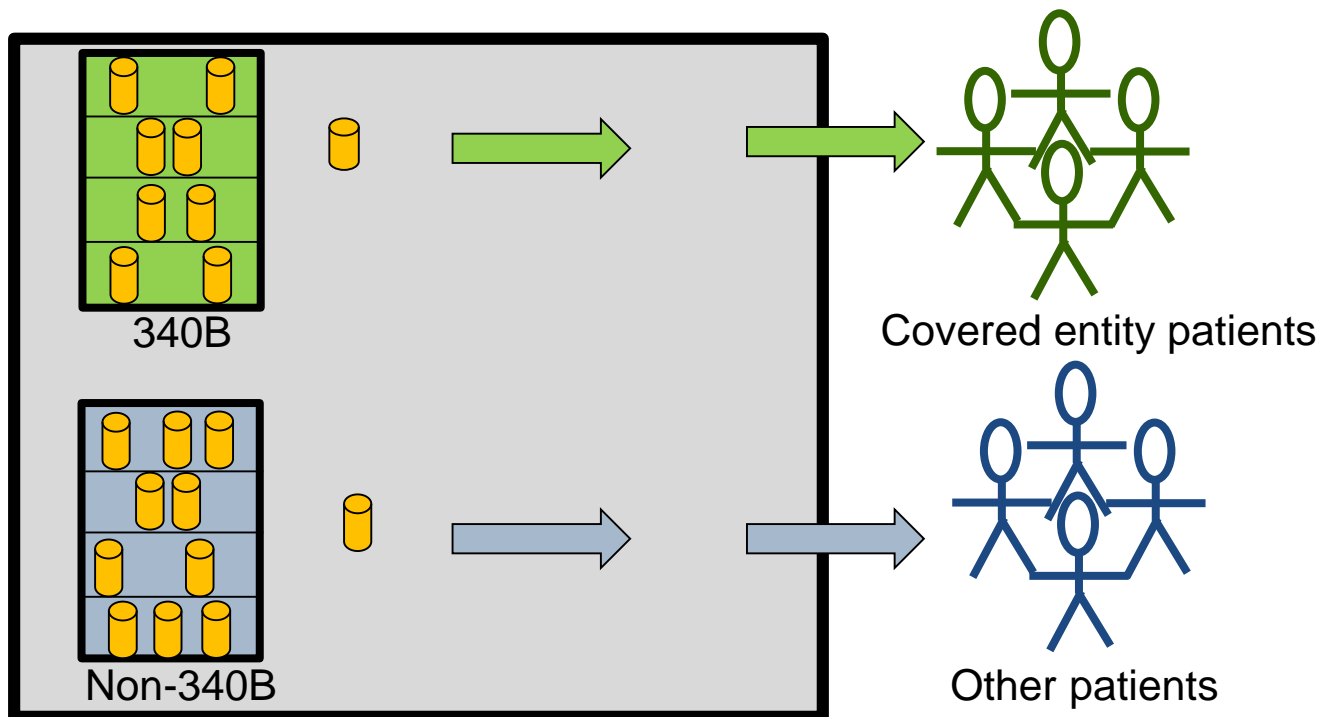
Physically separate

- 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)



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.





Virtual inventory tracking

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

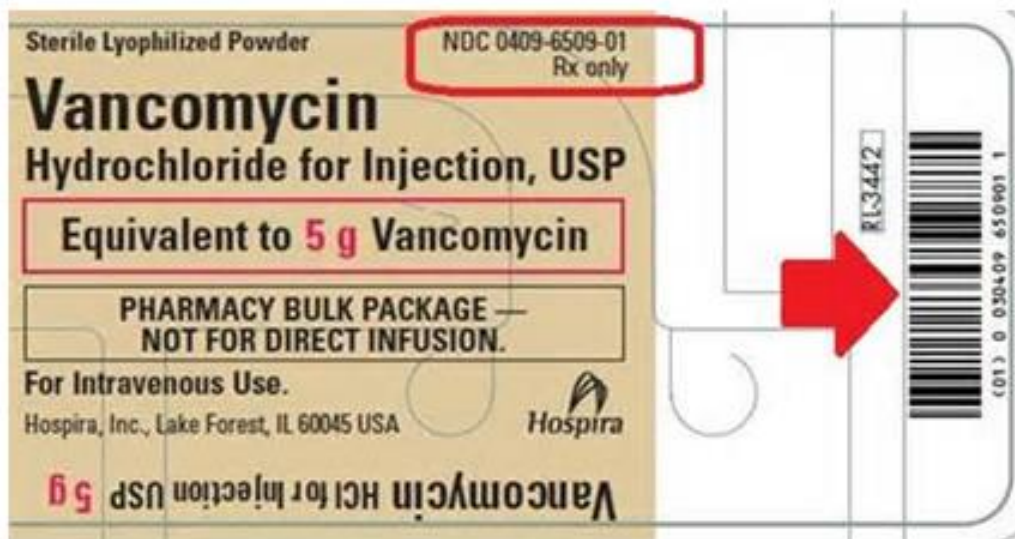
NDC matching is required

National Drug Code – 11 digit number

First 5 digits = manufacturer

Next 4 digits = drug product

Final 2 digits = package size



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?



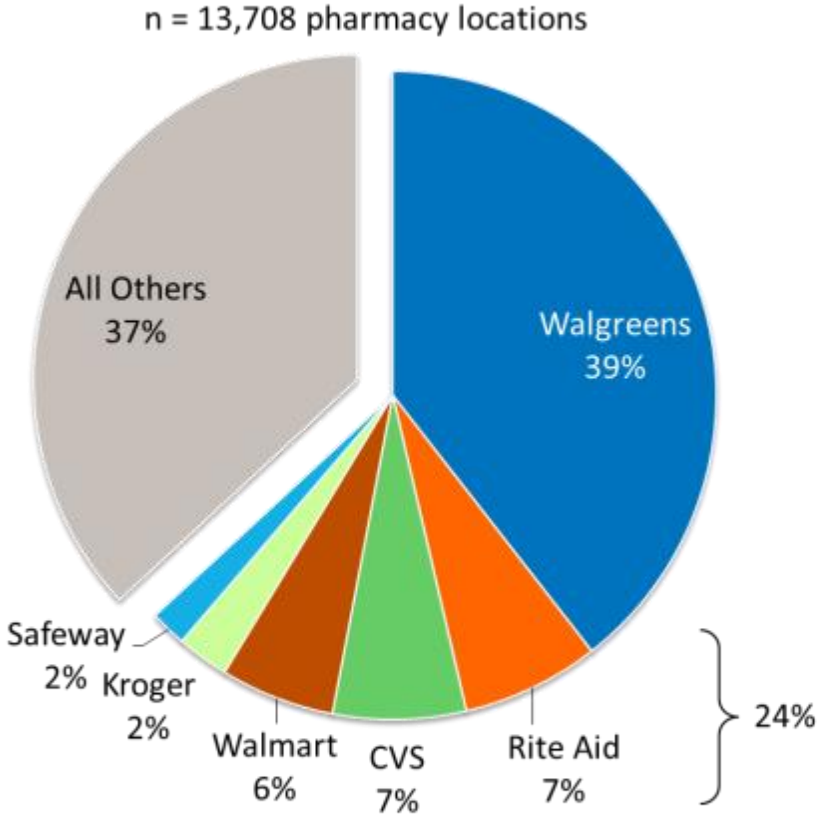
Covered entities that participate in the Program may contract with retail pharmacies to dispense 340B drugs on their behalf.

PHARMACY SERVICES AGREEMENT

THIS PHARMACY SERVICES AGREEMENT, (the "Agreement"), dated as of April 1, 2011, between _____ Pharmacy, Inc. /dba/ _____ Pharmacy, located at _____ ("Pharmacy"), and _____ located at _____ ("Facility").



340B Contract Pharmacy Locations, by Chain, January 2014



Source: Pembroke Consulting analysis of OPA Daily Contract Pharmacy Database (1/3/14). Excludes contracts terminated before 1/3/14.

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

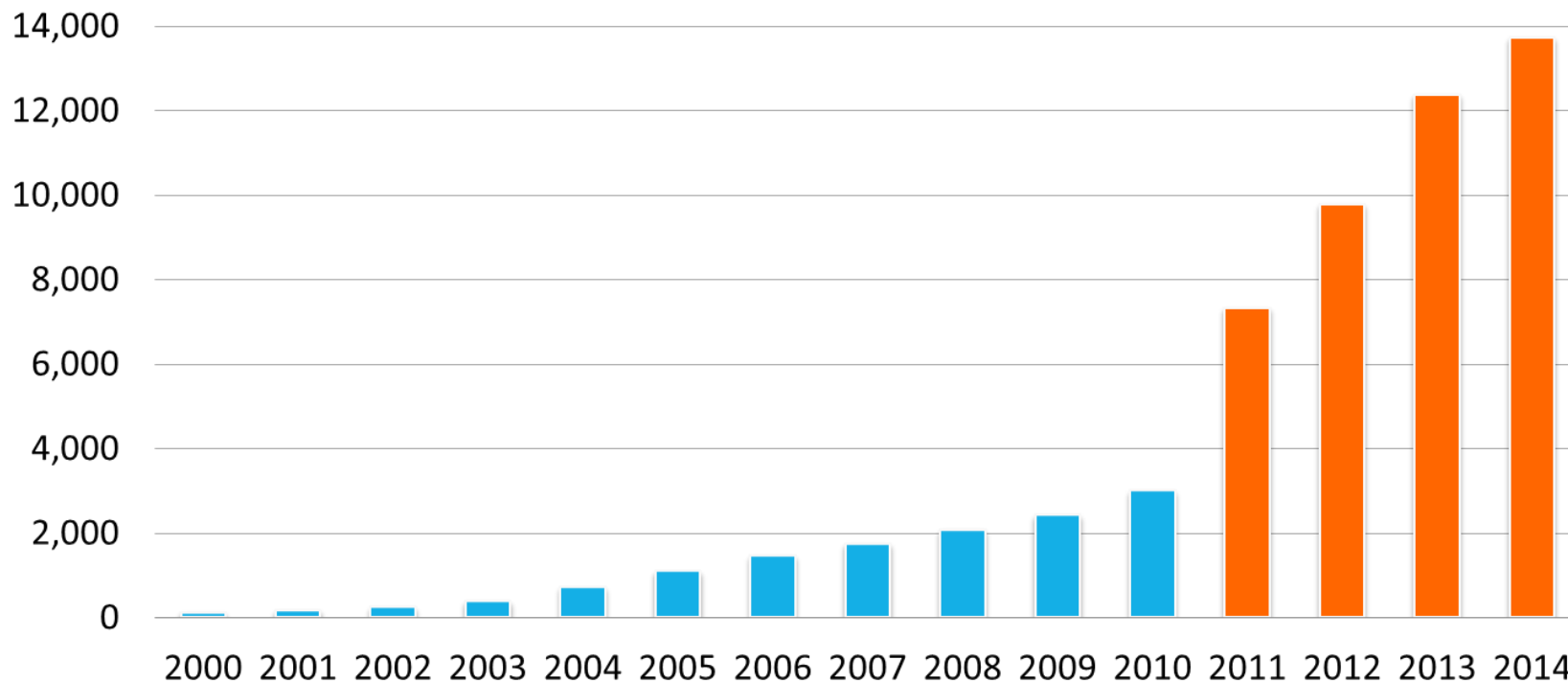


- Provides alternative if no in-house pharmacy is available
- Increases patient access to medications
- Eliminates cost of operating in-house pharmacy

- 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/)





DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



FEB 04 2014

TO: Mary K. Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration
/S/

FROM: Stuart Wright
Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Memorandum Report: *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431

This memorandum report describes selected covered entities' contract pharmacy arrangements and their oversight of those arrangements to prevent (1) diversion of drugs purchased through the 340B Drug Pricing Program to ineligible patients and (2) duplicate discounts through Medicaid.

SUMMARY

Covered entities participating in the 340B Drug Pricing Program (hereinafter referred to as the 340B Program) may contract with pharmacies to dispense drugs purchased through the program (hereinafter referred to as 340B-purchased drugs) on their behalf. Such pharmacies are referred to as contract pharmacies.

According to Health Resources and Services Administration (HRSA) guidance, covered entities that establish contract pharmacy arrangements must oversee these arrangements to prevent diversion of 340B-purchased drugs to ineligible patients and duplicate discounts through Medicaid. Diversion and duplicate discounts are statutorily prohibited. HRSA guidance recommends that covered entities' oversight activities include periodic comparisons of covered entity records and contract pharmacy records, as well as annual independent audits.

The OIG issued a Memorandum Report: *Contract Pharmacy Arrangements in the 340B Program* on February 4, 2014.

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)

Medicaid Drug Rebate Program - 1990

Required drug manufacturers to have a rebate agreement with the government in order for their drugs to be covered under Medicaid



Carve-out

- Does not dispense 340B-purchased drugs to Medicaid patients
- State bills manufacturer for rebate amount

Medicaid Exclusion File



<http://opanet.hrsa.gov/opa/CEMedicaidExtract.aspx>

HRSA Clarification

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Healthcare System Bureau
Office of Pharmacy Affairs



Date: December 12, 2014
NOTICE

340B DRUG PRICING PROGRAM

Release No. 2014-1
(Replaces No. 2013-2 dated February 7, 2013)

CLARIFICATION ON USE OF THE MEDICAID EXCLUSION FILE

This policy release clarifies the use of the 340B Medicaid Exclusion File to prevent duplicate discounts that could result when a drug is discounted under the 340B Drug Pricing Program (340B Program) and subject to a Medicaid rebate. This policy release only applies to Medicaid fee-for-service (MFFS) and further addresses the Health Resources and Services Administration's (HRSA) oversight role.

Background

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act (PHSA), "Limitation on Prices of Drugs Purchased by Covered Entities." The Office of Pharmacy Affairs (OPA) within HRSA administers the 340B Program.

Section 340B of the PHSA requires that participating pharmaceutical manufacturers charge covered entities a price for covered outpatient drugs that does not exceed the 340B ceiling price, as specified in the statute. Section 340B(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a rebate under the Medicaid drug rebate program (MDR program) for the same drug. The MDR program is administered by the Centers for Medicare & Medicaid Services (CMS). While CMS and HRSA have worked collaboratively to ensure compliance with the duplicate discount prohibition, HRSA is specifically responsible for the enforcement of covered entity compliance with this requirement.

340B Medicaid Exclusion File

Pursuant to section 340B(a)(5)(A)(ii), HRSA and CMS, collaborated to establish the 340B Medicaid Exclusion File as the mechanism to prevent duplicate discounts for drugs subject to

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?

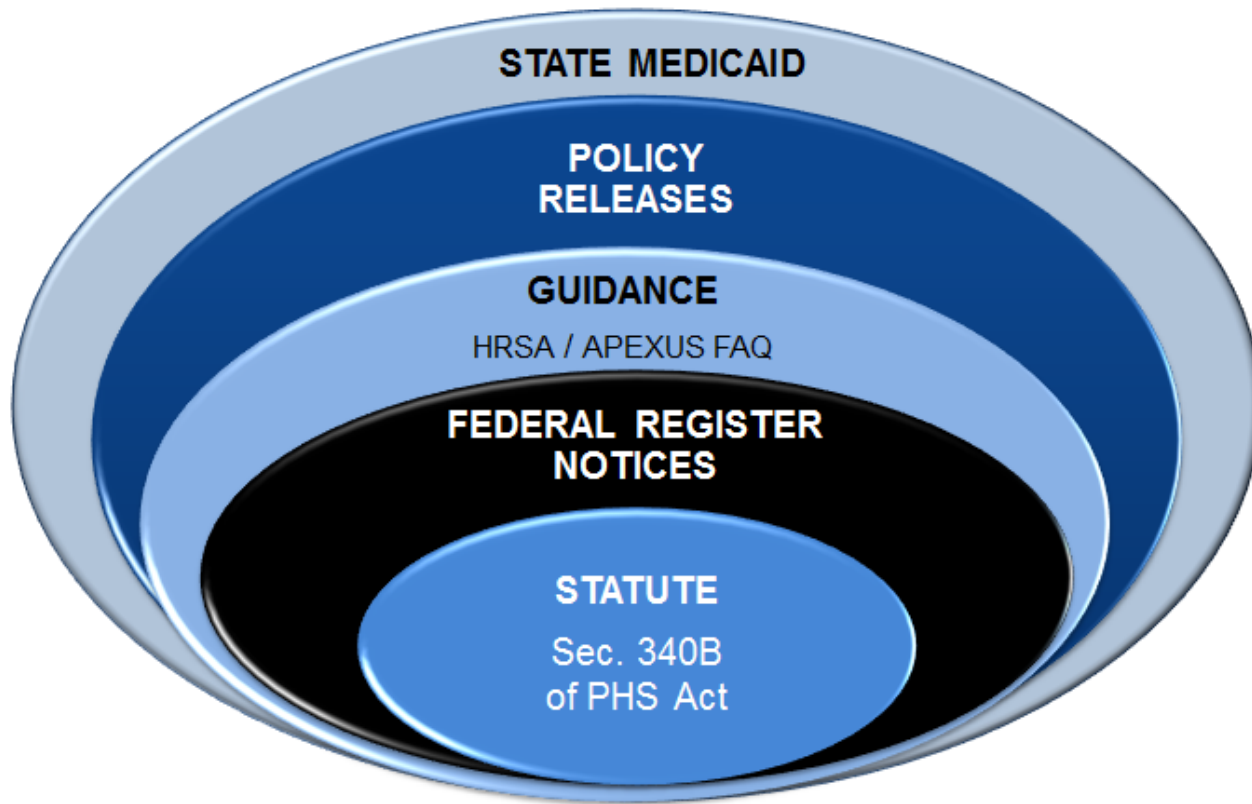


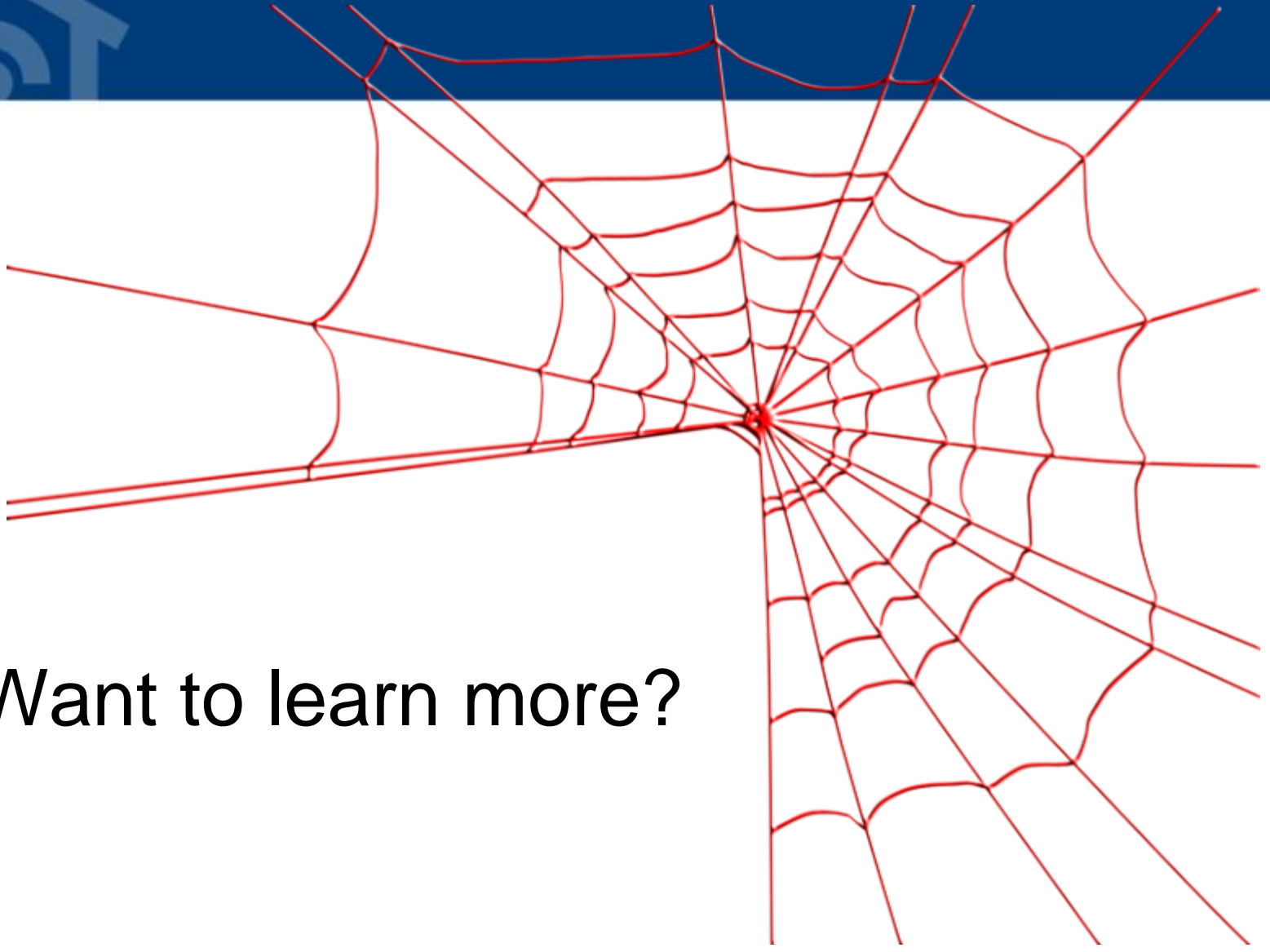
HRSA Assessing Impact of Court Decision On Proposed 340B 'Mega-Rule,' Official Says

HRSA Issues 340B Program Omnibus Guidance

"By Overturning 340B Orphan Drug Rule, Court Could Stifle Future HRSA Rulemaking ."

Program 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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NACHC and America's Health Centers

www.nachc.com