

340b Overview for NC Local Health Departments

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919-270-0820

Objectives:

- Understand basic concepts and definitions of the 340b program
- Identify policies and procedures that should be maintained and the available resources to support
- Gain knowledge of common issues with 340b compliance and how to avoid them

340b University – On Demand

- <https://www.340bpvp.com/340b-university/online-learning>

Concepts

Intent of 340b

- Permits eligible safety net providers “to stretch scarce Federal Resources as far as possible, reaching more eligible patients and providing more comprehensive services.”
 - Provides discounts on outpatient drugs to certain safety-net covered entities.
 - Average savings of 25-50%
 - Savings may be used to:
 - Reduce price of pharmaceuticals for patients.
 - Expand services offered to patients.
 - Provide services to more patients.
 - Manufacturers that participate in Medicaid must also participate in the 340B Program.

340b Acronyms

- Acronym guide - <https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-acronym-Guide.pdf>
- HRSA - Health Resources and Services Administration - an agency of the U.S. Department of Health and Human Services, is the primary Federal agency for improving health care to people who are geographically isolated, economically or medically vulnerable
 - <https://www.hrsa.gov/>
- Apexus - the only national 340B call center verified and endorsed by the HRSA - <https://www.340bpvp.com/>

340b Acronyms

- OPA – Office of Pharmacy Affairs – the office within HRSA responsible for the 340b program.
- OPAIS – Office of Pharmacy Affairs Information system– the official database for the 340b program
 - <https://340bopais.hrsa.gov/>

340b key terms

- <https://www.340bpvp.com/Documents/Public/340B%20Tools/340b-glossary-of-terms.pdf>
- 340b ID
- Covered Entity (CE)
- Authorizing Official (AO)
- Primary Contact (PC)
- Registration
- Recertification
- Patient Definition
- Contract pharmacy
- Duplicate discount
- Material breach

Covered Entity Types

- Health Centers
 - Federally Qualified Health Centers ← A few LHDs are FQHCs.
 - Federally Qualified Health Center Look-Alikes
 - Native Hawaiian Health Centers
 - Tribal / Urban Indian Health Centers
 - Ryan White HIV/AIDS Program Grantees
 - Hospitals
 - Children's Hospitals
 - Critical Access Hospitals
 - Disproportionate Share Hospitals
 - Free Standing Cancer Hospitals
 - Rural Referral Centers
 - Sole Community Hospitals
 - Specialized Clinics
 - Black Lung Clinics
 - Comprehensive Hemophilia Diagnostic Treatment Centers
 - Title X Family Planning Clinics
 - Sexually Transmitted Disease Clinics
 - Tuberculosis Clinics
- { All LHDs have all 3 of these CD types.

Registration vs. Recertification vs. Open Enrollment

- Registration - the process of adding a covered entity, outpatient facility, or contract pharmacy to the 340B program that is not already participating.

Registration vs. Recertification vs. Open Enrollment

- Recertification - Once a site has been registered and is listed as active in the 340B program, HRSA is required by statute to conduct annual recertification of participating 340B covered entities' information listed in the HRSA 340B Database. As part of this process, an authorizing official from each 340B entity certifies basic information about the entity and its 340B compliance. Recertification is done at different points in the year by entity-type. HRSA will notify the listed Authorizing Official and Primary Contact when the recertification for their entity type is approaching.

Registration vs. Recertification vs. Open Enrollment

- Open Enrollment – the window in which a covered entity can make changes (such as adding or deleting a contract pharmacy) or a new site can be added. Open enrollment is on the following schedule:

Register	Start Date
January 1-15	April 1
April 1-15	July 1
July 1-15	October 1
October 1-15	January 1

340b Patient Definition

- Patients must receive health care services other than drugs from the 340B covered entity.
- An individual is a patient of a 340B covered entity only if:
 - the covered entity has **established a relationship** with the individual, such that the covered entity maintains records of the individual's health care; **and**
 - 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**
 - 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 covered entity 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.

340b and Medicaid

- Prevention of duplicate discounts
- Carve in – use 340b purchased medications on Medicaid patients and bill with the UD modifier
- Carve out – use NON-340b purchased medications on Medicaid patients and Medicaid seeks the rebate
- Must bill Medicaid at actual acquisition cost

Material Breach

- Sample Statement: [Entity Name] defines a material breach of compliance as a violation(s) that exceeds [threshold indicator – see examples below*]. Such violations require self-disclosure. Violations identified through internal self-audits, independent external audits, or otherwise that [meet or] exceed this threshold, and that remain non-correctable within the entity-defined period timeframe of review, will be immediately reported to HRSA (at 340Bselfdisclosure@hrsa.gov) and applicable manufacturers using the following self-disclosure report template:
<https://www.340bpvp.com/Documents/Public/340B%20Tools/self-disclosure-to-hrsa-and-manufacturer-template.docx>

Material breach thresholds examples

- *Examples of threshold indicators (use one or more in each definition to be applied within entity-defined review period timeframe of review):
 1. X% of total 340B purchases or impact to any one manufacturer
 2. \$X (fixed amount), based upon total outpatient or 340B spend, or impact to any one manufacturer
 3. X% of total 340B inventory (units)
 4. X% of audit sample
 5. X% of prescription volume/prescription sample
 6. Will not self-correct within x months

Select one quantity and one time frame for local policy

Policies

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<https://www.340bpvp.com/education/340b-tools/>

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340B Tools

Apexus PVP has developed a number of tools to help covered entities operationalize 340B Program compliance guidelines. Tools are grouped by type of covered entity. Find 340B tools such as templates for policies and procedures, registration, audit and compliance plans, and additional resources to ensure 340B program integrity.

Each of the available tools has been reviewed by [HRSA](#). They are based on best practice sites from across the country and [HRSA FAQs](#). These tools are meant to be a guide and should be carefully considered and updated based on your particular site's needs.

- GPO Prohibition Hospitals**
DSH, PED, CAN
- Rural Hospitals**
CAH, RRC, SCH
- Community Health Centers**
CH, FQ, FQHC, FQHCLA, NH
- Grantees**
STD, RW, HM, FP, BL, TB, MH, UI
- All Tools**



Policy and Procedure Manuals

- Grantee – Title X Family Planning Sample Policy and Procedure Manual (FP)
 - Grantees – Hemophilia Treatment Center Sample Policy and Procedure Manual (HM)
-

Registration

- Contract Pharmacy Medicaid Carve-In Checklist
-

Auditing/Compliance

Entity

- Self-Audit: Policy and Procedure
- Self-Audit: Contract Pharmacy

HRSA

- Self-Disclosure to HRSA and Manufacturer Template
 - Establishing Material Breach Threshold
 - 340B Ceiling Price Unavailable/Incorrect 340B Ceiling Price Notification for HRSA
 - HRSA Audits of Entities
 - Sample HRSA 340B Audit Data Request for Covered Entities
-

Policies and Procedures

- Eligibility – entity and patient
- Roles and responsibilities
- Enrollment, recertification, change requests
- Inventory management
- Duplicate discount prevention
- Contract pharmacy if applicable
 - <https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>
- Material breach
- Self audits

Policy and Procedure Manuals

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Registration

- Contract Pharmacy Medicaid Carve-In Checklist
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Auditing/Compliance

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- 
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<https://www.340bpvp.com/education/340b-tools/>

Self Audits

ols/

Community Health Centers
CH, FQ, FQHC, FQHCLA, NH

Oversight

- [340B Oversight Best Practices Dashboard](#)

Auditing/Compliance

Entity

- [Self-Audit: Eligibility \(CHC/FQHC\)](#)
- [Self-Audit: Prevention Duplicate Discounts \(CHC/FQHC\)](#)
- [Self-Audit: Prevention of Diversion \(CHC/FQHC\)](#)
- [Self-Audit: Policy and Procedure \(CHC/FQHC\)](#)
- [Self-Audit: Contract Pharmacy](#)

Recommended quarterly, but should meet the CE specific auditing needs

<https://www.340bpvp.com/education/340b-tools/>

Grantees

STD, RW, HM, FP, BL, TB, MH, UI

Auditing/Compliance

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- Self-Disclosure to HRSA and Manufacturer Template
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Operational/Purchasing

- 340B Manual Dispense Tracking Log
- Controlled Substance Ordering System (CSOS) Compliance Considerations

OPAIS

← → ↻ 🔒 https://340bopais.hrsa.gov/coveredentitysearch ☆ 📄 📄 📄 📄

U.S. Department of Health and Human Services HRSA OPA

HRSA Office of Pharmacy Affairs

Health Resources & Services Administration 340B OPAIS

Home Search Reports/Files Login Help

Covered Entity Search Criteria

Keyword <input type="text" value="Enter the text to search"/> <small>Searches the following fields: Name, SubName, 340B ID, Site ID, MPN, Grant Number, Address Line 1, Address Line 2, City.</small>	Entity Type <input type="text" value="All"/>	Entity Classification <input type="text" value="All"/>	Grant/Provider Number <input type="text"/> <small>Searches both Medicare Provider Number and Grant Number fields.</small>
340B ID <input type="text"/>	Entity Name <input type="text"/>	Site ID <input type="text"/>	
City <input type="text"/>	Advanced Query Options <input type="text"/> <small>Populates Start or Termination Date fields with quarterly dates.</small>	Participating <input type="text" value="All"/> <small>Select All or No to include entities with a future start date in the search results.</small>	
State <input type="text" value="All"/> <ul style="list-style-type: none">AlabamaAlaskaAmerican SamoaArizonaArkansasCalifornia	Zip <input type="text"/>	Start Date From <input type="text"/> To <input type="text"/>	Edit Date From <input type="text"/> To <input type="text"/>
	Termination Date From <input type="text"/> To <input type="text"/>	Registration Date From <input type="text"/> To <input type="text"/>	

Friday, July 19, 2019 3:12 PM ApexusAnswers@340bpvp.com | 1-888-340-2787 OMB Number: 0915-0327, Expiration: 08/31/2019

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CE ID Number
and Type

Start, Termination, Last Edit
Dates

<input type="checkbox"/>	CAH341326-10	CAH	Angel Medical Center	Angel Medical Center Pain Clinic / Pain Management	120 Riverview Street	Franklin	NC	07/01/2017	04/01/2019	04/01/2019
<input type="checkbox"/>	CAH341326-11	CAH	Angel Medical Center	Angel Medical Center - Cancer Care of Western North Carolina	834 Depot Street	Franklin	NC	10/01/2018	04/01/2019	04/01/2019
<input type="checkbox"/>	CHC28348-05	CH	APPALACHIAN MOUNTAIN COMMUNITY HEALTH CENTERS	Franklin Community Health Center	100 Thomas Heights, Suite 206	Franklin	NC	10/01/2016	01/01/2019	01/01/2019
<input type="checkbox"/>	DSH340012	DSH	ANGEL MEDICAL CENTER, INC.		120 RIVERVIEW STREET	FRANKLIN	NC	07/01/2008	07/01/2009	06/30/2009
<input type="checkbox"/>	DSH340016C	DSH	HARRIS REGIONAL HOSPITAL	CENTER FOR FAMILY MEDICINE	55 HOLLY SPRINGS PARK DRIVE	FRANKLIN	NC	10/01/2013	10/01/2014	09/11/2014
<input type="checkbox"/>	FP287341	FP	MACON COUNTY HEALTH DEPARTMENT		1830 LAKESIDE DRIVE	FRANKLIN	NC	01/01/1998		05/06/2019
<input type="checkbox"/>	STD28734	STD	MACON COUNTY HEALTH DEPARTMENT		1830 LAKESIDE DRIVE	FRANKLIN	NC	01/01/2009		05/03/2019

STD28734 MACON COUNTY HEALTH DEPARTMENT (Active)

Print

Name MACON COUNTY HEALTH DEPARTMENT
Subdivision Name
Type Sexually Transmitted Diseases
340B ID STD28734
Grant Number 5H25PS004349-04
Nature of Support Direct Funding (dollars received from CDC or an intermediate organization)
 Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

Current Program Status Active
Registration Date 12/3/2008
Participating Start Date 1/1/2009
Participating Approval Date 12/4/2008
Last Recertification Date 5/22/2019

Street Address

1830 LAKESIDE DRIVE
 FRANKLIN, NC 28734

Billing Address

Same as Street Address

Authorizing Official

Macon County Public Health
 Carmine Rocco, Interim Health Director
 (828) 349-2420

Primary Contact

Macon County Public Health
 Jennifer Garrett, Director of Nursing
 (828) 349-2466

- Comments
- Medicaid Billing
- Shipping Addresses
- Contract Pharmacies
- History

Comment

Last Updated On ▼

09/03/2013 AO and/or PC updated, this per the arrangement between OPA and the N.C. Department of Health and Human Services

09/03/2013

Covered Entity Search Criteria

Keyword

Searches the following fields: Name, SubName, 340B ID, Site ID, MPN, Grant Number, Address Line 1, Address Line 2, City.

340B ID

City

State

- All
- Alabama
- Alaska
- American Samoa
- Arizona
- Arkansas

Zip

Entity Type

Entity Name

Advanced Query Options

Start Date

From To

Termination Date

From To

Entity Classification

Site ID

Participating

Edit Date

From To

Registration Date

From To

Grant/Provider Number

Searches both Medicare Provider Number and Grant Number fields.

Select All or No to include entities with a future start date in the search results.

Clear Search

Hide Search Criteria

Export Selected

Export All

Welcome to 340B OPAIS

What would you like to do?



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Register Covered Entity



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www.340bpvp.com



1-888-340-2787
8AM-5PM CT Mon-Fri



ApexusAnswers@340Bpvp.com

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Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 2.0 hour(s) per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Deputy Clearance Officer, 5600 Fishers Lane, Room 14N

HRSA Office of Pharmacy Affairs

340B OPAIS

Health Resources & Services Administration

My Entities

Export

340B ID	MPN/Grant Number	Name	SubName	Address Line 1	Address Line 2	City	State	Type	340B Status
FP276114	1 FPHPA0064C 01-00	NC DEPT. OF HEALTH & HUMAN SERVICES	DIV. OF PUBLIC HEALTH/WCH SECTION/WOMEN'S HEALTH BRANCH	5601 Six Forks Rd		RALEIGH	NC	FP	Active

HRSA Office of Pharmacy Affairs

340B OPAIS

Health Resources & Services Administration

FP276114 NC DEPT. OF HEALTH & HUMAN SERVICES (Active)

Change Request Terminate Print

Name	NC DEPT. OF HEALTH & HUMAN SERVICES
Subdivision Name	DIV. OF PUBLIC HEALTH/WCH SECTION/WOMEN'S HEALTH BRANCH
Type	Family Planning (Title X only)
340B ID	FP276114
Grant Number	1 FPHPA006400-01-00
Employer Identification Number (EIN)	56-1636462

Current Program Status	Active
Registration Date	1/1/1998
Participating Start Date	1/1/1998
Participating Approval Date	1/1/1998
Last Recertification Date	5/22/2019

Street Address
 5601 Six Forks Rd
 RALEIGH, NC 27609

Billing Address
 NC Division of Public Health
 1929 Mail Service Center
 Raleigh, NC 27699-1929

Authorizing Official	Primary Contact
NC Dept of Health	NC Division of Public Health
Kristen Carroll, Family Planning & Reproductive Health Unit Manager	Amanda Fuller Moore, Pharmacist
(919) 707-5685	(919) 270-0820
kristen.carroll@dhs.nc.gov	amanda.fuller_moore@dhs.nc.gov

Comments Medicaid Billing CE Attachments Shipping Addresses Contract Pharmacies History

Comment	Comment Type	Last Updated By	Last Updated On
2/26/2006 UPDATED ADDR; 2/26/06 UPDATED SUBDIV NAME;	Public	OPA Reviewer	01/28/2010

Resources

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- Database Technical Assistance >
- 340B Pricing / Covered Outpatient Drugs >
- Patient Definition >
- Purchasing / Inventory / Reimbursement >
- Contract Pharmacy >
- Medicaid / Duplicate Discounts >
- GPO Prohibition >
- Compliance / Audits >
- 340B OPAS Pricing Component >
- Prime Vendor Program >

Search FAQs:



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Frequently Asked Questions

Apexus PVP is communicating these HRSA FAQs with the intention of improving program compliance. Additional FAQs may be available to address specific circumstances by contacting [Apexus Answers](#). The removal of an FAQ from the website does not imply that the FAQ is no longer supported by HRSA. Certain FAQs are best applied when details are presented in the appropriate context, according to a specific covered entity's situation, and Apexus Answers can facilitate that level of communication and application.

Please also see HRSA's website for [additional 340B FAQs](#).

Searching tips:

- The FAQs are organized by categories and subcategories.
- Each FAQ has a numerical ID; this number can be useful if you are trying to identify the FAQ for discussion with others, including Apexus Answers.

To search:

- Enter a search term in the search box.
- The results will be displayed.

To narrow a search:

- After an initial search is completed, narrow the search results by clicking on one of the categories or subcategories on the left.
- Clicking on one of these categories or subcategories will return only the FAQs that meet the selected search term that falls within the category or subcategory you selected.

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340B Answers Aligned with HRSA Policy

Assistance with your 340B questions is just a phone call, [email](#), or [chat](#) away. When you have a 340B question, contact Apexus Answers, a free 340B information resource provided by Apexus to promote program integrity for 340B Prime Vendor Program (PVP) participants and other stakeholders.

Apexus Answers is the only Health Resources and Services Administration (HRSA) aligned national 340B call center. When you reach out to Apexus Answers, you can expect to receive an expert answer that aligns with HRSA policy and guidance. Our staff is in constant communication with HRSA to ensure that messaging is consistent. If our staff doesn't have the answer to your question, it will forward the issue to HRSA for clarification.

Call: [888.340.BPVP](tel:888.340.BPVP) ([888.340.2787](tel:888.340.2787)) Email: apexusanswers@340Bpvp.com Chat: [Chat Now](#)

Reasons to contact Apexus Answers:

HRSA 340B Database	Guidance on all 340B policy	Program Eligibility Questions	Covered Outpatient Drugs	Medicaid/ Duplicate Discounts	Annual Recertification	Pricing
Change requests	The patient definition	Covered entities	Definition of Covered Outpatient Drug	State agency contact information	Assistance with login	Sub-WAC Pricing
Registration process	GPO Prohibition	Outpatient facilities	Exclusions; Orphan Drug and GPO Prohibition	Medicaid Exclusion File	Recertify/decertify	Pharmaceutical Pricing Agreement
Locating covered entity resources	Purchasing/Inventory	Contract pharmacies	340Bpvp.com Catalog	General policy	Status of submission/OPA review	Value added products

Please be advised that responses from Apexus Answers are not dispositive with respect to compliance with or participatory status in the 340B Drug Pricing Program. 340B entities are ultimately responsible for 340B program compliance, and Apexus encourages entities to include legal counsel as part of their program integrity efforts.

The responsibility to ensure compliance with 340B program requirements remains with covered entities and manufacturers that participate. Information received from vendors, consultants, and other third parties cannot be assumed to be compliant with HRSA policy.

340b Common issues

- Failure to meet the patient definition
 - The patient definition is not contingent on the clinic in which the patient was seen
 - Transferring inventory to another entity
 - Ordering under the wrong 340b account

340b Common issues

- Inventory
 - Failure to separate inventory by 340b registration
 - Not tracking inventory to the NDC and Lot #
 - Lack of material breach policy
 - Tracking of acquisition cost to ensure proper Medicaid billing

340b Common issues

- Contract pharmacy registrations
 - Can only be completed in open registration windows and are not effective until the next quarter.
 - Required elements of the contract
 - Covered Entity retains all responsibility
- Not all entity types are equivalent

340b University – On Demand

- <https://www.340bpvp.com/340b-university/online-learning>

340b Overview for NC Local Health Departments

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