340b Overview for NC Local Health Departments

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919-270-0820

Disclosures

- 1.5 NCPD Contact Hours and up to 1.5 CPH Recertification Credits may be earned upon successful completion.
- For successful completion, participants must attend the entire educational activity and complete the online course evaluation. There will be no partial credit awarded.
- No relevant financial relationship exists for anyone in the position to control the content for this activity.
- No commercial support has been received for this activity (only if applicable).
- The Public Health Nursing Institute for Continuing Excellence is approved as a provider of nursing continuing professional development by the North Carolina Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
- This independent study will be available for completion until 2/1/2025
- The evaluation will close on 2/15/2025 at 5:00 p.m.
 - **Please Note:** This will be your only option to receive evidence of the NCPD contact hours and CPH Recertification Credits. You will need to save this certificate.

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:

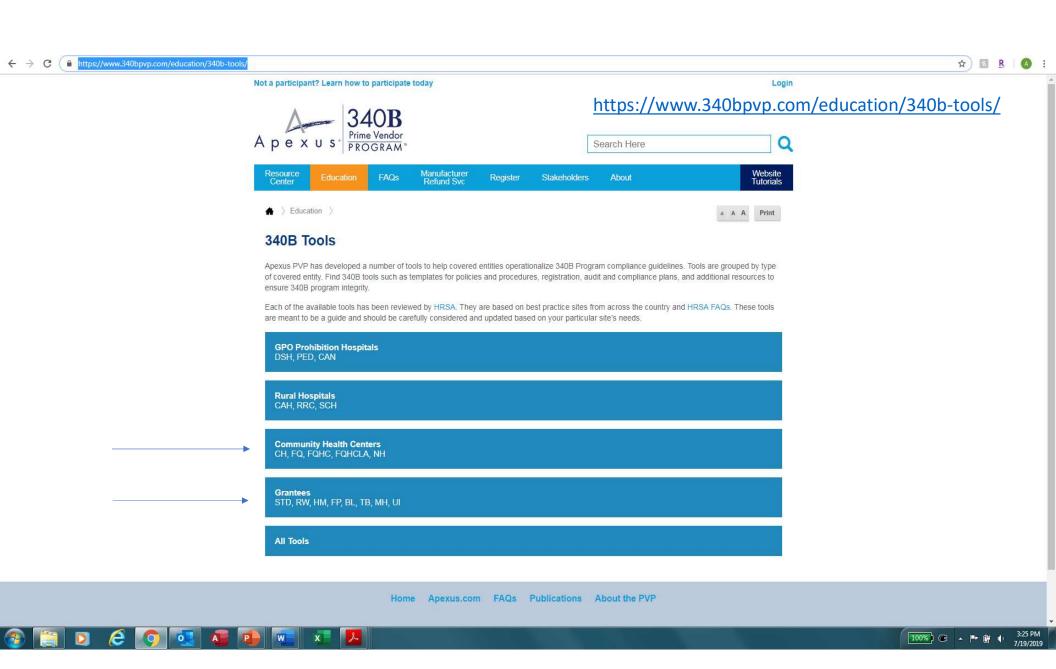
https://www.340bpvp.com/Documents/Public/340B%20Tools/self-disclosure-to-hrsa-and-manufacturer-template.docx

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



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

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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/

Self Audit: Prevention of Diversion

Compliance Element: Prevention of Diversion

Section 340B of the Public Health Service Act prohibits the resale, or other transfer, of a 340B drug to a person who is not a patient of the entity. Covered entities are responsible for maintaining an accurate patient eligibility determination system, including tracking and accounting all of 340B drugs at the covered entity to ensure that diversion has not occurred.

PATIENT ELIGIBILITY VERIFICATION

Table 1

- For each of the 20 administrations/dispenses selected in step 2c of the instructions (page 1) and for the date range selected in step 1 of the instructions, verify patient eligibility by validating the dispense/administration record against the entity's health care record
- Validate that the prescription/drug order is the result of a health care service included in the scope of grant and
 was provided to a covered entity patient at an eligible site by an eligible provider such that the covered entity
 documents its responsibility for care in its health care record

Table 1

340B Eligibility Determination Verification Table Time period tested: begin date to end date													
		The state of the s			The second second		ibility for)			
(1) Sample ID (prescription	(2) Date dispensed/	(3) Drug dispensed/ administered/ prescribed from eligible location?		(4) Drug dispensed/ administered/ prescribed from location with a 340B ID?		(5) Drug dispensed/ administered as a result of a service included in the scope of grant?			ELIGIBLI	(7) DRUG and VISIT documented in covered entity's health care record?			
number or dispense tracking number)	administered							(A) Employed/ contracted?				(B) Documented referral?	
		YES	NO	YES	NO	YES	NO	YES	NO	YES	NO	YES	NO
													50
		5.			2	-	3						
				8 8	20								2 22
		20											

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

Auditing/Compliance

Entity

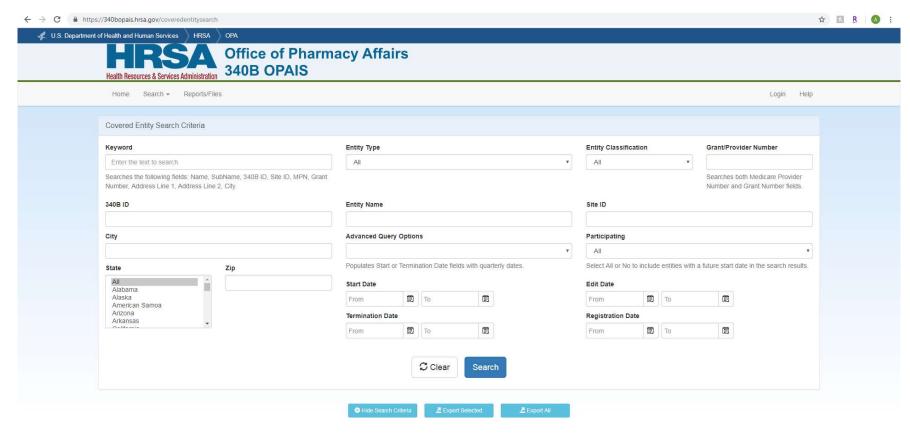
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Operational/Purchasing

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



ApexusAnswers@340bpvp.com | 1-888-340-2787

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OPAIS

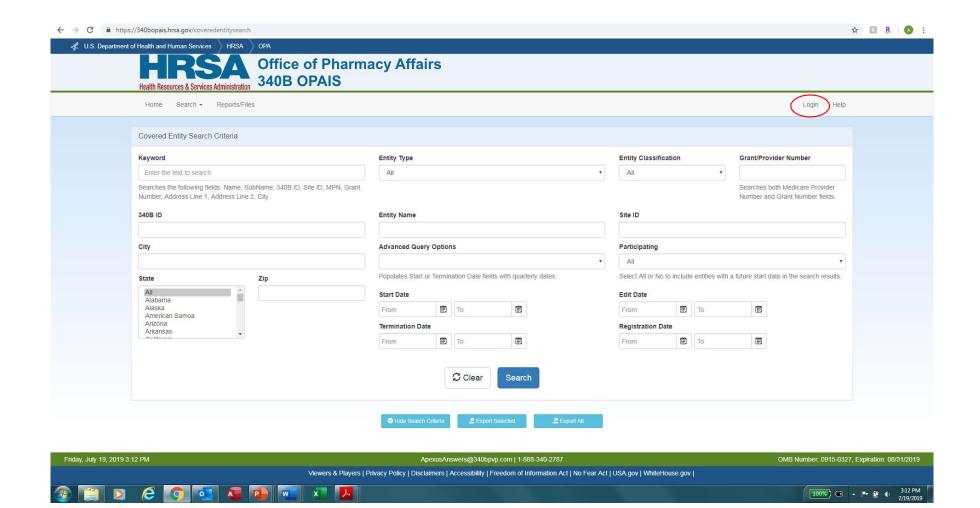
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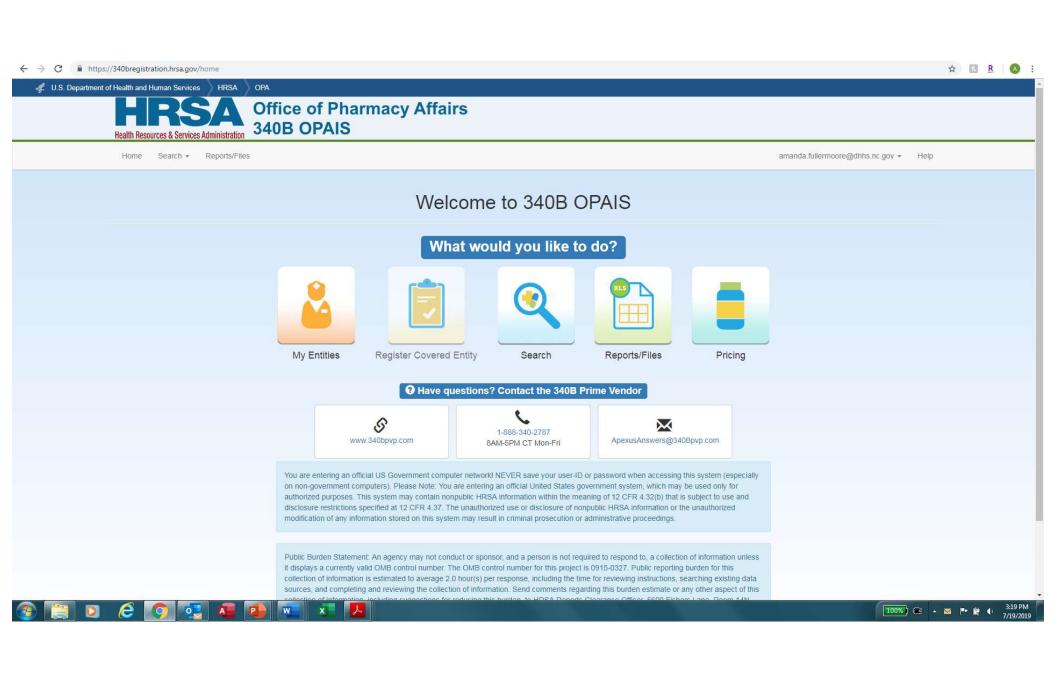
Start, Termination, Last Edit Dates

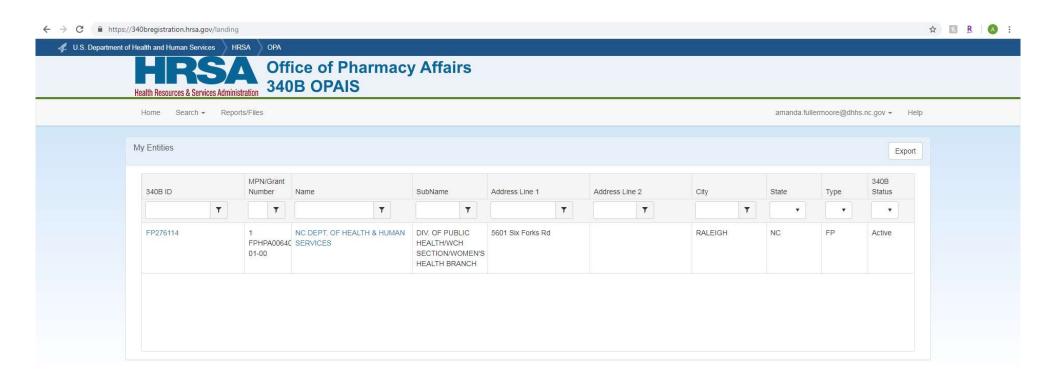
0	CAH341326-10	CAH	Angel Medical Center	Angel Medical Center Pain Clinic / Pain Management	120 Riverview Street	Franklin	NC	07/01/2017	04/01/2019	04/01/2019
0	CAH341326-11	CAH	Angel Medical Center	Angel Medical Center - Cancer Care of Western North Carolina	834 Depot Street	Franklin	NC	10/01/2018	04/01/2019	04/01/2019
0	CHC28348-05	СН	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
	DSH340012	DSH	ANGEL MEDICAL CENTER, INC.		120 RIVERVIEW STREET	FRANKLIN	NC	07/01/2008	07/01/2009	06/30/2009
	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
0	FP287341	FP	MACON COUNTY HEALTH DEPARTMENT		1830 LAKESIDE DRIVE	FRANKLIN	NC	01/01/1998		05/06/2019
0	STD28734	STD	MACON COUNTY HEALTH DEPARTMENT		1830 LAKESIDE DRIVE	FRANKLIN	NC	01/01/2009		05/03/2019

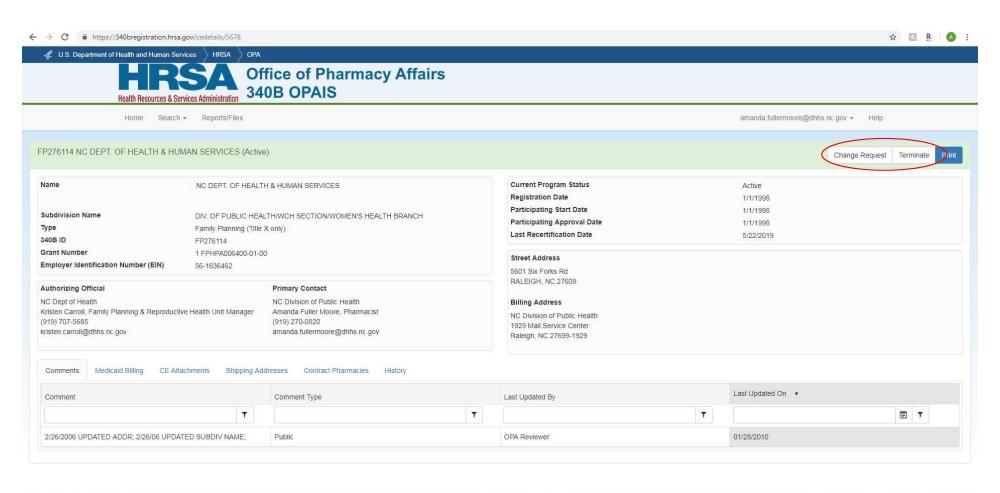
09/03/2013

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



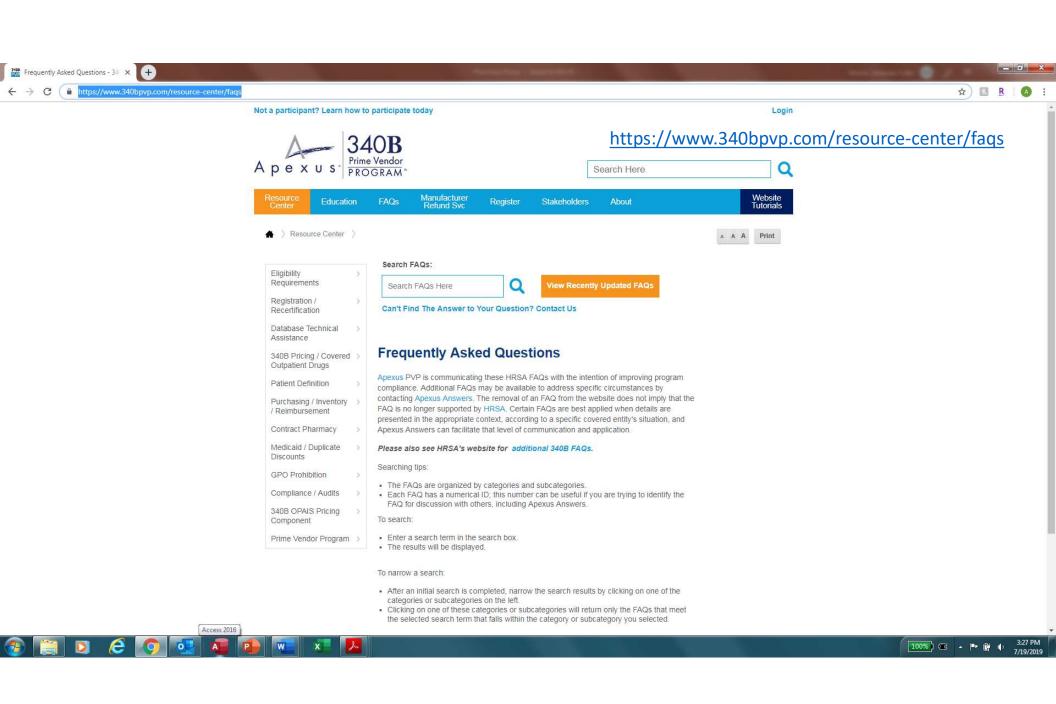


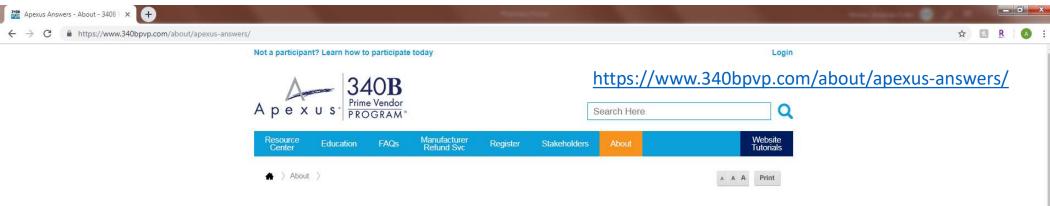






Resources





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 guestion, it will forward the issue to HRSA for clarification.

Call: 888.340.BPVP (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



You may earn continuing education hours for your professional discipline by completing the evaluation for this activity. Your thoughtful responses provide important information that allows the PHNICE to continue its mission of providing quality professional development opportunities at free or reduced cost.

You must complete the activity evaluation to receive a certificate of completion. Everyone should save/print a completion certificate for their records.

The educational activity evaluation will be open from **until February 16**, **2025**.

A professional development certificate will be provided to all individuals that complete the evaluation by the deadline. **Please Note:** This will be your only option to receive evidence of the professional development contact hours and/or CPH Recertification Credits. You will need to save this certificate.

To complete the evaluation, go to

https://www.surveymonkey.com/r/0269Pretest

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