

Disclosures

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AETC Program National Centers and HIV Curriculum

- **National Coordinating Resource Center** – serves as the central web –based repository for AETC Program training and capacity building resources; its website includes a free virtual library with training and technical assistance materials, a program directory, and a calendar of trainings and other events. Learn more: <https://aidsetc.org/>
- **National Clinician Consultation Center** – provides free, peer-to-peer, expert advice for health professionals on HIV prevention, care, and treatment and related topics. Learn more: <https://nccc/ucsf.edu>
- **National HIV Curriculum** – provides ongoing, up –to-date HIV training and information for health professionals through a free, web –based curriculum; also provides free CME credits, CNE contact hours, CE contact hours, and maintenance of certification credits. Learn more: www.hiv.uw.edu

340B Basics

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KITCHEN



Learning Objectives

- Provide introduction to the 340B Drug Pricing Program
- Outline covered entity eligibility requirements
- Discuss 340B compliance cornerstones and registration
- Review best practices in program oversight

Due to the nature of Apexus' role as HRSA's 340B prime vendor, it is a neutral organization that supports all 340B Program stakeholders and will not be discussing political dynamics and legal challenges facing the program.

Program Intent

“ 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)



June 7, 2023

340B Drug Pricing Program Overview

Federal program requiring **manufacturers** to provide discounted prices on **medications** to certain **health care providers**

- Manufacturers that participate in the Medicaid Drug Rebate Program (to receive state Medicaid coverage) must also offer their drugs through the 340B Program
- Affected medications are called covered outpatient drugs (CODs), as defined in Section 1927(k)(2) of the Social Security Act
- Eligible providers, known as covered entities (CEs), must comply with program requirements

340B Savings

Entities save on drug costs by purchasing 340B drugs at a reduced price for eligible patients

- Example: physician administers drug to 340B eligible patient at an outpatient clinic

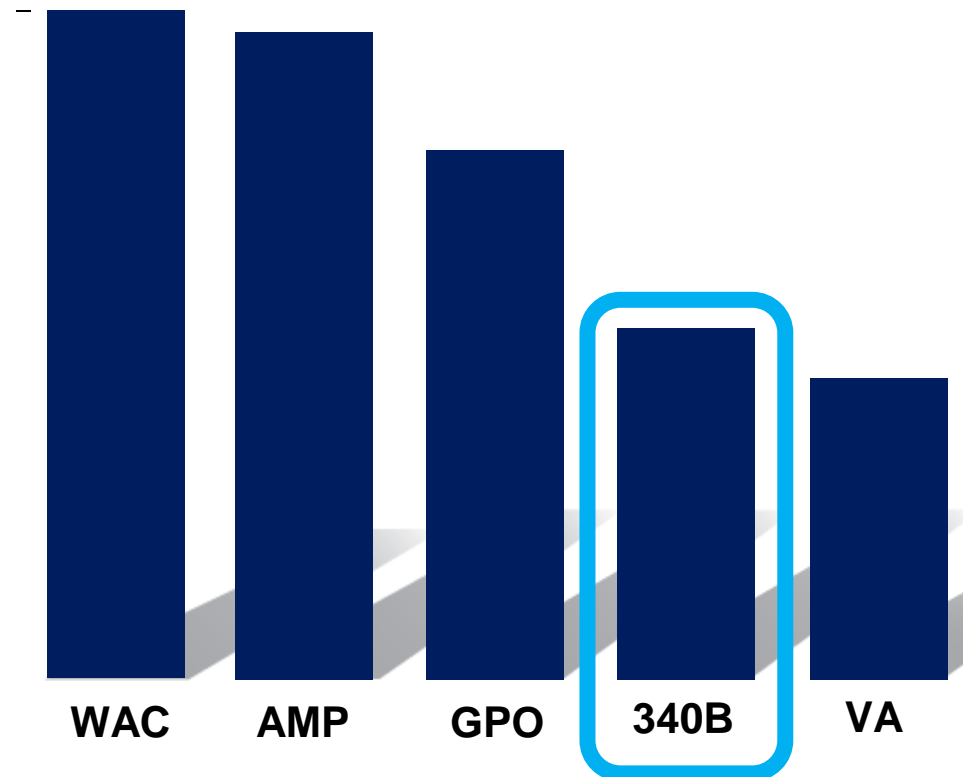
Non-340B acquisition cost: \$100
– 340B acquisition cost: \$70
\$30 savings

- Some examples of entity services meeting the intent of the program or grant program requirements include community benefit, charity care, drug access programs, free clinics, health fairs, and sliding fee scales



340B Ceiling Price

Manufacturers will not charge a price that is higher than the 340B ceiling price



Covered Outpatient Drugs (CODs)

Defined in
Section
1927(k)(2) of
the Social
Security Act



- Outpatient drugs
- Over-the-counter drugs (with prescription)
- Clinic-administered drugs
- Biologics & insulin



Entities should maintain relevant policies and procedures explaining how this definition is applied to their operations

Covered Entity Eligibility



June 7, 2023

Eligible Covered Entities

Hospitals

- Disproportionate Share Hospitals (DSH)
- Children's Hospitals (PED)
- Critical Access Hospitals (CAH)
- Free-standing Cancer Hospitals (CAN)
- Rural Referral Centers (RRC)
- Sole Community Hospitals (SCH)

Grantees

- **Federally Qualified Health Centers**
 - Health Center Program Award Recipients and Look-Alikes (FQHC, FQHC-LA)
 - Native Hawaiian Health Centers (NH)
 - Tribal/Urban Indian Health Centers (IHS)
- **Ryan White HIV/AIDS Program (RW)**
- **Specialized Clinics**
 - Black Lung Clinics (BL)
 - Hemophilia Treatment Centers (HTC)
 - Title X Family Planning Clinics (FP)
 - Sexually Transmitted Disease Clinics
 - Tuberculosis Clinics (TB)



Grantee Eligibility

Federal funding/designation determines 340B eligibility for grantees as listed within the statute

- *Includes federal grantees from HRSA, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service*

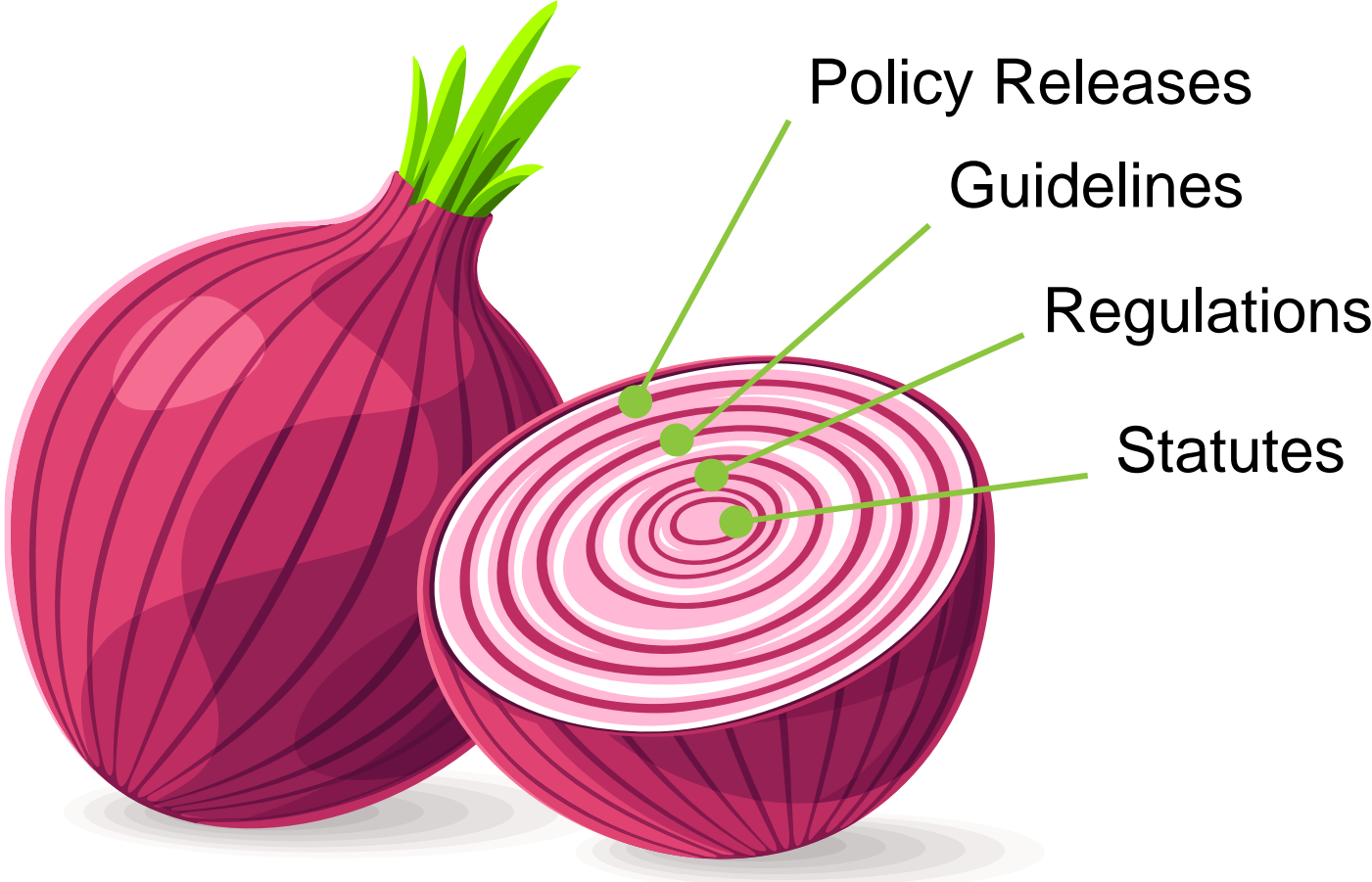


Covered Entity Compliance Cornerstones



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Layers of 340B Policy



Major 340B Compliance Areas

- Covered Entities
 - Prevent diversion to ineligible patients
 - Medicaid duplicate discount prohibition
 - Annual recertification

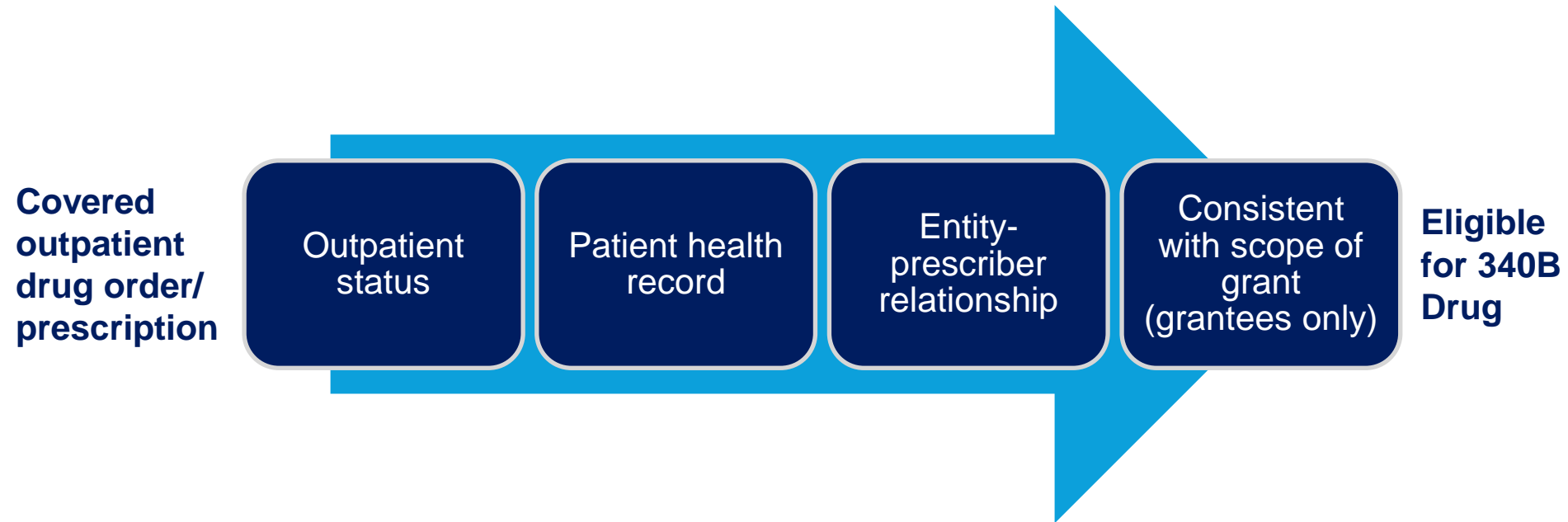
- Manufacturers
 - Offer to sell CODs at 340B ceiling price

Prevent Diversion to Ineligible Patients

- Entities must not resell or transfer 340B drugs to ineligible patients
- Patient definition¹:
 - Records of individual's care
 - Health care services, health care professional
 - Employed by, under contractual or other arrangements (referral)
 - Entity has responsibility for care
 - Service received is consistent with funding or designation status (grantees)
 - Services are more than dispensing

¹ An individual registered in a state-operated or -funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHS Act will be considered a “patient” of the covered entity for purposes of this definition if so registered as eligible by the state program.

Applying Patient Definition in Practice¹

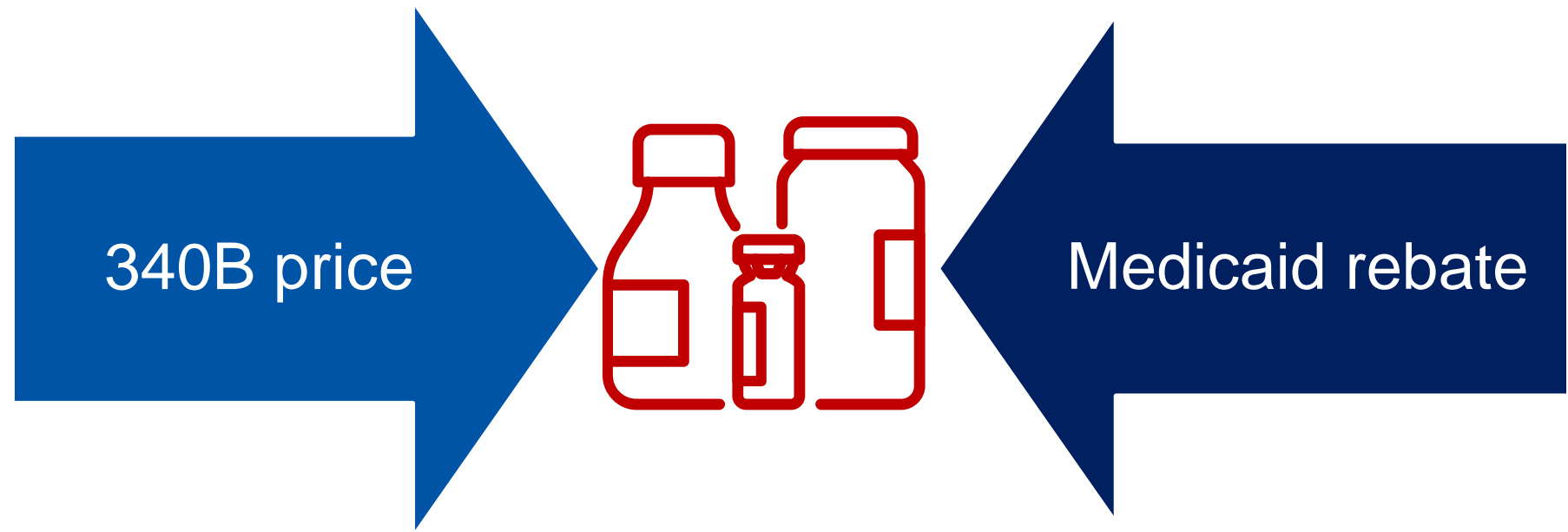


Covered entities carving out Medicaid must ensure 340B drugs are not billed to Medicaid

¹ An individual registered in a state-operated or -funded AIDS drug purchasing assistance program receiving financial assistance under Title XXVI of the PHS Act will be considered a “patient” of the covered entity for purposes of this definition if so registered as eligible by the state program.

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Duplicate Discount Prohibition



Avoiding Duplicate Discounts

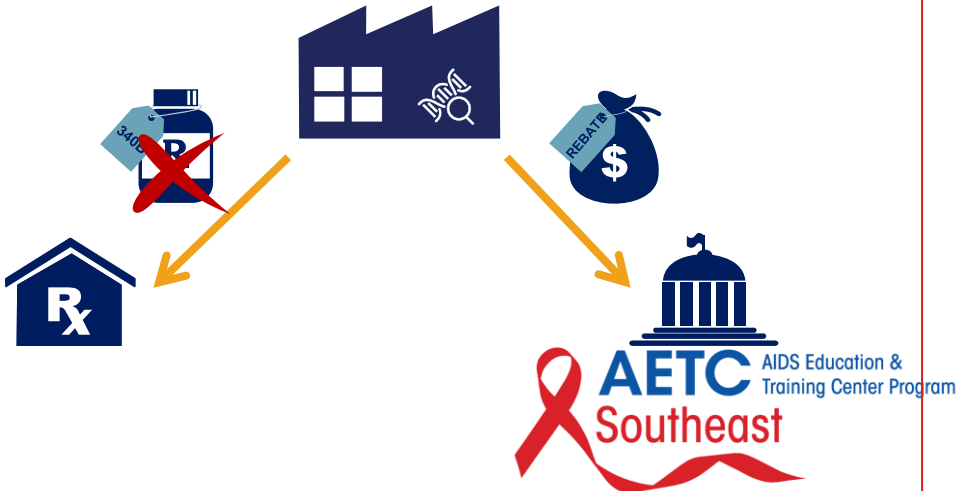
Carve In

- Covered entity purchases drugs for Medicaid patients **with** an upfront 340B discount
- State Medicaid programs **cannot** seek an MDRP rebate



Carve Out

- Covered entity purchases drugs for Medicaid patients **without** an upfront 340B discount
- State Medicaid programs **can** seek an MDRP rebate directly from the manufacturer



Medicaid Environment – Types of Claims

Retail

- Mostly for self-administration or home infusion
- Billed in real time through pharmacy point of sale system (using NCPDP standards)



Institutional

- Provider/facility/clinic-administered drugs
- Billed at later date through 837I electronic transmission (e.g., CMS-1450 aka UB-04)



Medicaid Environment – Payer Types

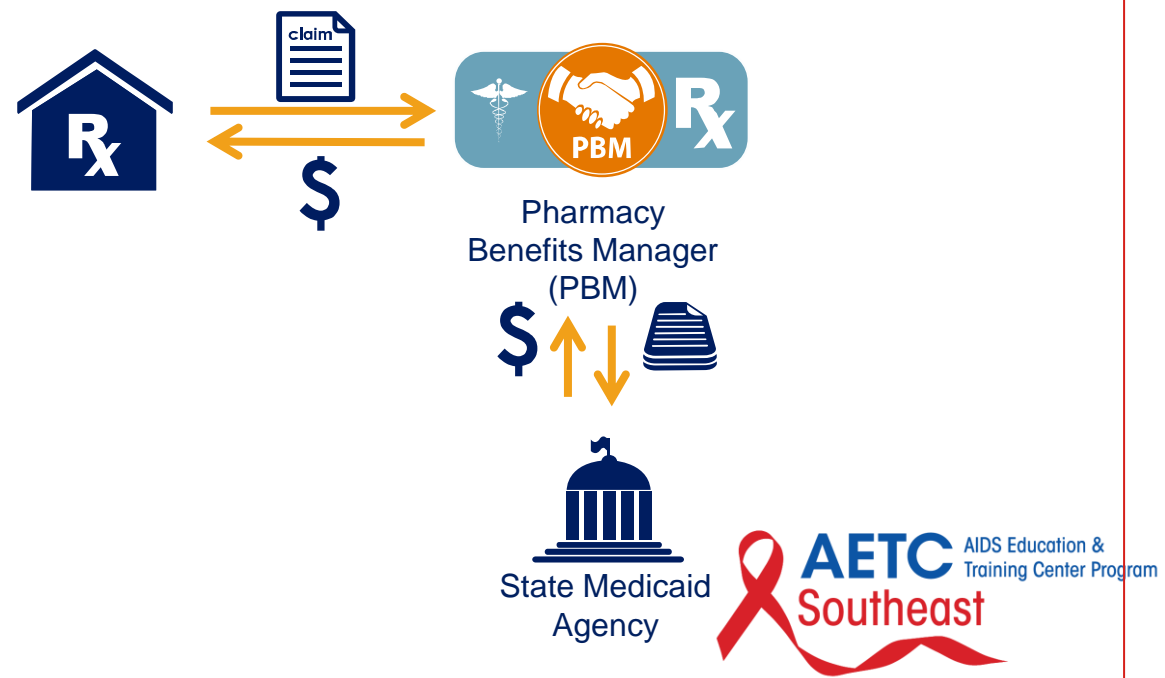
Fee-For-Service (FFS)

Managed directly by state agency



Managed Care Organizations (MCOs)

Managed by third party contracted by state



HRSA, CMS, and State 340B Policy



HRSA Policy for Covered Entities

- Prevent duplicate discounts
- List Medicaid FFS billing information on 340B OPAIS, reflected on the HRSA Medicaid Exclusion File (MEF)
- Bill according to state policy



CMS Federal Policy for States

- Collect rebates on claims
- Establish process for 340B drugs to avoid duplicate discounts



State Policy for Covered Entities

- Adhere to Medicaid 340B drug billing and reimbursement policy to prevent duplicate discounts

Registration and Recertification

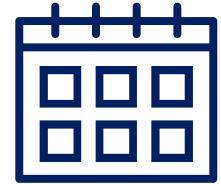


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Grantee 340B Registration

- Grantees must provide their federal grant number when registering for the 340B Program
 - Grantee eligibility verified either through the HRSA Electronic Handbook (EHB) or validation with Project Officer/Program Manager
- Importance of EHB changes and timing, especially changes of scope
 - Possibility of chargeback denial and/or wholesaler delivery issues if any discrepancies between EHB, 340B OPAIS, and distributor information

Quarterly Registration Process



Registration Period:	January 1–15	April 1–15	July 1–15	October 1–15
340B Go Live:	April 1	July 1	October 1	January 1

- Quarterly registration
 - Register new entities, entity locations, and/or contract pharmacies
 - Two-week registration periods, quarterly updates made to 340B OPAIS
- Change requests
 - Changes to existing information can be made any time

Recertification



- Entities are required to recertify information in 340B OPAIS annually
 - Certifies that information in 340B OPAIS is accurate
 - Certifies that covered entity is still eligible and meets compliance requirements
- HRSA sends a notification email to authorizing official and primary contact
- The authorizing official performs the recertification online

340B Program Oversight



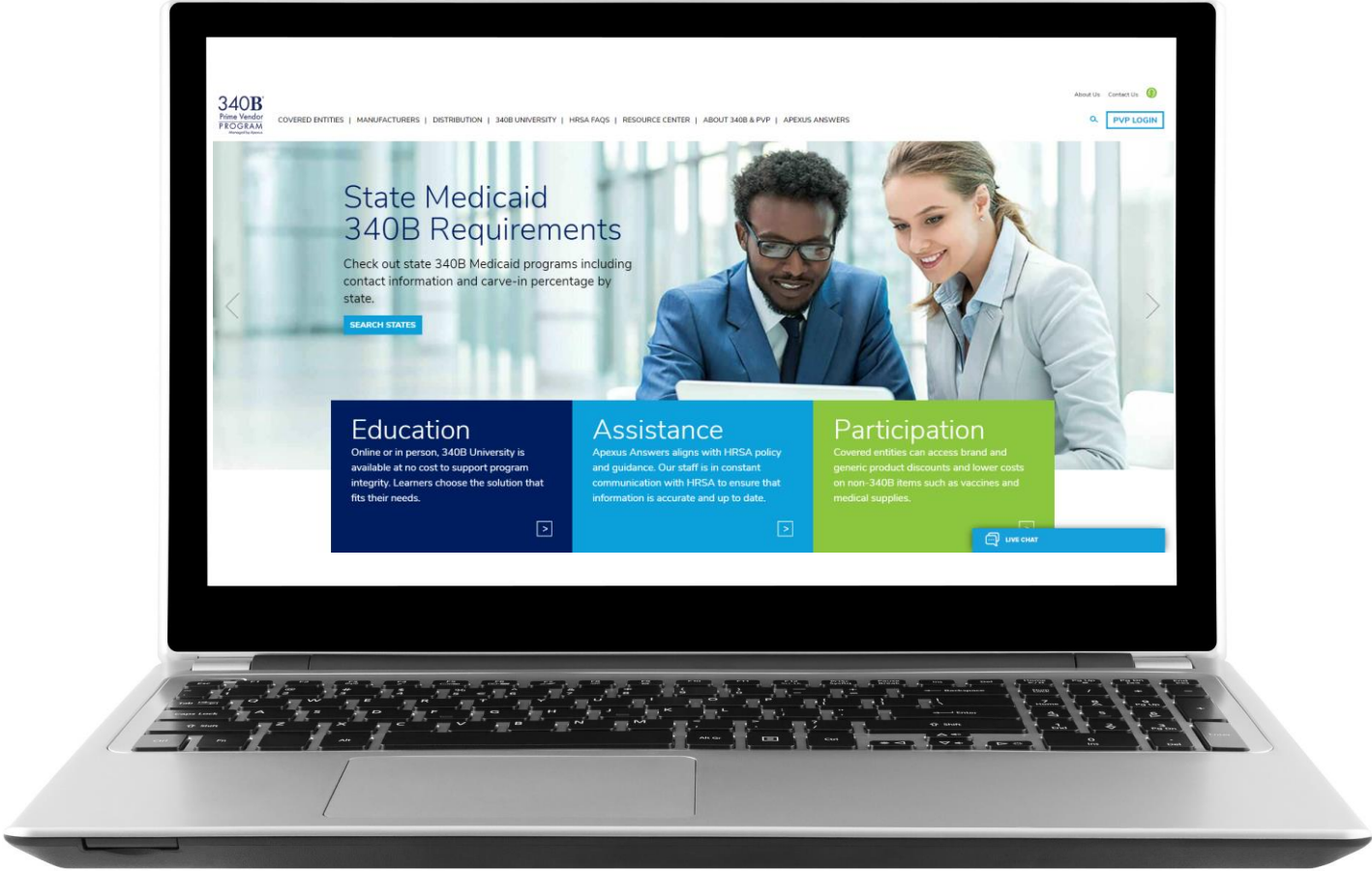
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340B Internal Resources

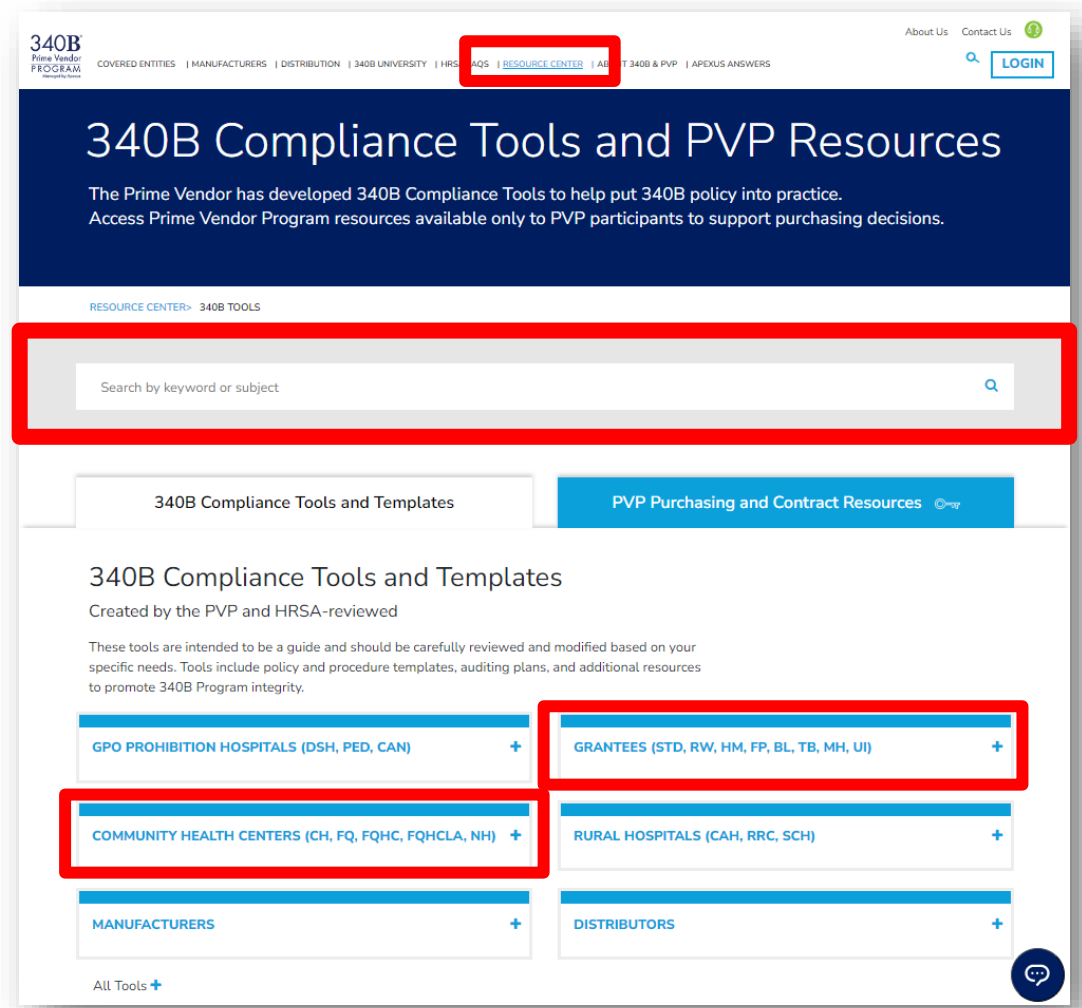
- Dedicated staff responsible for 340B compliance
- Self-audits
 - Ensure readiness for HRSA or manufacturer audit
- Oversight of third parties
 - 340B management systems
 - Contract pharmacies
- Program oversight committee
- Ongoing staff education



Where to Find Help – 340BPVP.com



PVP Tools and Resources



- New Look!
- Improved Search Functionality
- Covered Entity-Specific Resources



PVP Tools and Resources

340B Prime Vendor PROGRAM

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340B Compliance Tools and PVP Resources

The Prime Vendor has developed 340B Compliance Tools to help put 340B policy into practice. Access Prime Vendor Program resources available only to PVP participants to support purchasing decisions.

RESOURCE CENTER > 340B TOOLS

audit

Updated Jan 2023

Independent Audit Request for Proposal Checklist

Self-Audit: Policy and Procedure

Self-Audit: Eligibility (DSH/PED/CAN)

Self-Audit: Prevention of Diversion and GPO Violation (DSH/PED/CAN)

Self-Audit: Prevention of Duplicate Discounts (DSH/PED/CAN)

340B Compliance Tools and Templates

PVP Purchasing and Contract Resources

- Searches all tools by name
- Shows updated tools
- Future enhancements to search key words

Tools: Getting Started in 340B Checklist

Getting Started in 340B Checklist				
Category	Task	How To/Resource	Links	Prior to Registration
Compliance Related				
CR - 1	Determine site eligibility in anticipation of registration	Once your covered entity (CE) has been determined to meet the eligibility for the 340B Program (https://www.hrsa.gov/opa/eligibility-and-registration/index.html), meet with the individual(s) responsible for maintenance of the Electronic Handbook (EHB) and 330 grant to document eligibility criteria, determine which sites are eligible, and gather supporting documentation for registration. During this process, it may be helpful to start developing a location map for each eligible location within the CE. Work with your reimbursement/billing office to understand what NPIs are used for billing in each location that will be using 340B purchased medications. The 340B Program affects many different departments across the organization. Expertise from multiple departments may be needed to make critical decisions about 340B Program implementation. This list is not all inclusive but includes key departments that best practice sites involve early to make informed decisions. Pharmacy: typically the project owners for implementation, as their department will typically experience the greatest impact Reimbursement: critical to gathering a list of NPIs for registration Billing: important for assessing billing needs for Medicaid and Medicare if 340B product used IT: may be needed if using data feeds for third-party administrator (TPA) software Legal: will help in development of policies and procedures (P&Ps) and key programmatic decisions Compliance: assist in developing self-audit procedures and processes for responding to noncompliance	OPAIS Registration Guide 340B Tool: Self Audit: Eligibility	×
CR - 2	Assemble expertise needed to make implementation decisions	Creating a map of settings that will access 340B (clinic, retail, contract pharmacy) can help new programs understand operational decisions to be made, build appropriate data elements, and communicate effectively with the project team.	340B Tool: 340B Universe Mapping	×
CR - 3	Identify all areas within the CE that will be using 340B and create map of all areas	Broadly, there are three inventory models: replenishment (or neutral) inventory, physical inventory, or hybrid. Determine which model will be used in each area of your CE that will be using 340B medications (see map above) for planning purposes (will affect need for split-billing/third-party administrator [TPA] software). Models may be different based on setting and operational need.	OnDemand Module: 340B Drug Delivery	×
CR - 4	Determine which inventory model(s) will be used at your site(s)	Many CHCs use a TPA for their retail pharmacy locations. This software function in a replenishment inventory by accumulating eligible dispensations and aligning purchasing to help ensure compliance. Sites should understand the general data elements required and assess their own ability to gather the necessary information. IMPORTANT: Implementation of software can take up to 6 months , so this process should be started early.		×
CR - 5	Assess need for third-party administrator (TPA) software for areas with replenishment inventory models			




340BPVP.com/Tools



Tools: 340B Oversight Best Practices and Calculating Program Impact and Use of Savings

340B Oversight Best Practices Dashboard



Purpose: The purpose of this tool is to provide covered entities with a framework for monitoring and communicating 340B oversight based on best practices. The audience for this tool is intended to be the 340B Steering Committee. This template is based on best practices shared by covered entities; it is not an exhaustive list, and can be customized according to the covered entity's specific circumstances.



340BPVP.com/Tools

Calculating 340B Net Financial Impact and Use of Savings



Purpose: This tool is intended to help all types of 340B covered entities understand their 340B net financial impact and document their use of 340B savings. It gives guidance on how to calculate net financial impact as well as articulate benefits provided to the community based on total expense for a variety of services.



Where to Find Help – Apexus Answers

- Apexus Answers provides HRSA-aligned information to promote program integrity
- Tiered levels of response: can handle from basic to complex
- Assistance with your 340B questions is just a phone call, email, or online chat away!

340B Prime Vendor PROGRAM Managed by Apexus

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Apexus Answers

Your source for reliable 340B information that is aligned with HRSA policy, celebrating ten years of service and support.

Apexus Answers Call Center
10
TEN YEARS OF SERVICE AND SUPPORT
2012-2022
APEXUS

Have questions or need help?

If you have questions about the 340B Drug Pricing Program or the Prime Vendor Program (PVP), contact Apexus Answers. This free information resource is available by phone, email, or online chat and offered to PVP participants and all stakeholders.

Apexus Answers, celebrating ten years of service and support, aligns with HRSA policy and guidance. Our staff is in constant communication with HRSA to ensure that information is accurate and up to date. If our staff members don't have the answer to your question, they will anonymously forward it to HRSA for clarification.

Important Information

Apexus Answers is live Monday through Friday, from 8:00 am to 5:00 pm Central Time.

CONTACT US

[Email >](#)

[Chat now >](#)

[Call: 888.340.2787 >](#)

340BPVP.com/Apexus-Answers

Takeaways

- Covered entities and participating manufacturers have 340B program requirements
- Entity eligibility is defined in the 340B statute and requires registration in 340B OPAIS to participate
- Major compliance areas for covered entities include preventing diversion, duplicate discounts prohibition, and recertification
- Resources are available to support program oversight, including Apexus Answers and 340Bpvp.com

Questions



June 7, 2023