

Disclosures

- *This program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U1OHA30535 as part of an award totaling \$4.2m. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.*
- *“Funding for this presentation was made possible by cooperative agreement U1OHA30535 from the Health Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.”*
- *This content is owned by the AETC, and is protected by copyright laws. Reproduction or distribution of the content without written permission of the sponsor is prohibited, and may result in legal action.*



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 Implementation: FQHCs and Grantees

Jangus Whitner, PharmD, MHA, BCACP, 340B ACE
340B Policy & Compliance Director
Apexus

Apexus®

340B[®]
Prime Vendor
PROGRAM
Managed by Apexus



Objectives

- Review 340B compliance considerations important to grantees
- Discuss available resources for helping maintain a compliant program
- Review frequently asked questions from grantees and discuss solutions



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.



340B Program Considerations for Grantees

Opening a New Site

■ Eligibility and Registration

- Sites of grantees administered by HRSA (FQHCs, direct RW or HTC) must be added to the Electronic Handbook (EHB) prior to registration in 340B OPAIS
- Eligibility of other grantees not administered by HRSA will be verified with the granting agency

■ Multiple sites under same grant

- FQHCs = associated sites
- Other grantees = each site receives a unique 340B ID

What steps need to be taken before the clinic can begin using 340B?



Ensuring Compliant Practices

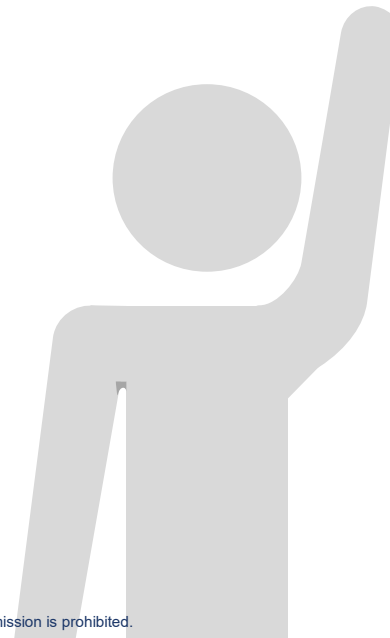
- **Inventory management practices**
 - Physical or virtual replenishment inventory models for clinic-administered, owned pharmacies, and contract pharmacies
 - Are all patients treated 340B eligible?
 - Pharmacies (and even clinic locations) may hold inventory for multiple 340B grantees
- **Clinic inventory models**
 - Often not pharmacy managed and harder to maintain auditable records; may require paper logs



Put in chat:

Which inventory model do you use?

- Physical inventory
- Neutral/virtual replenishment inventory
- Both



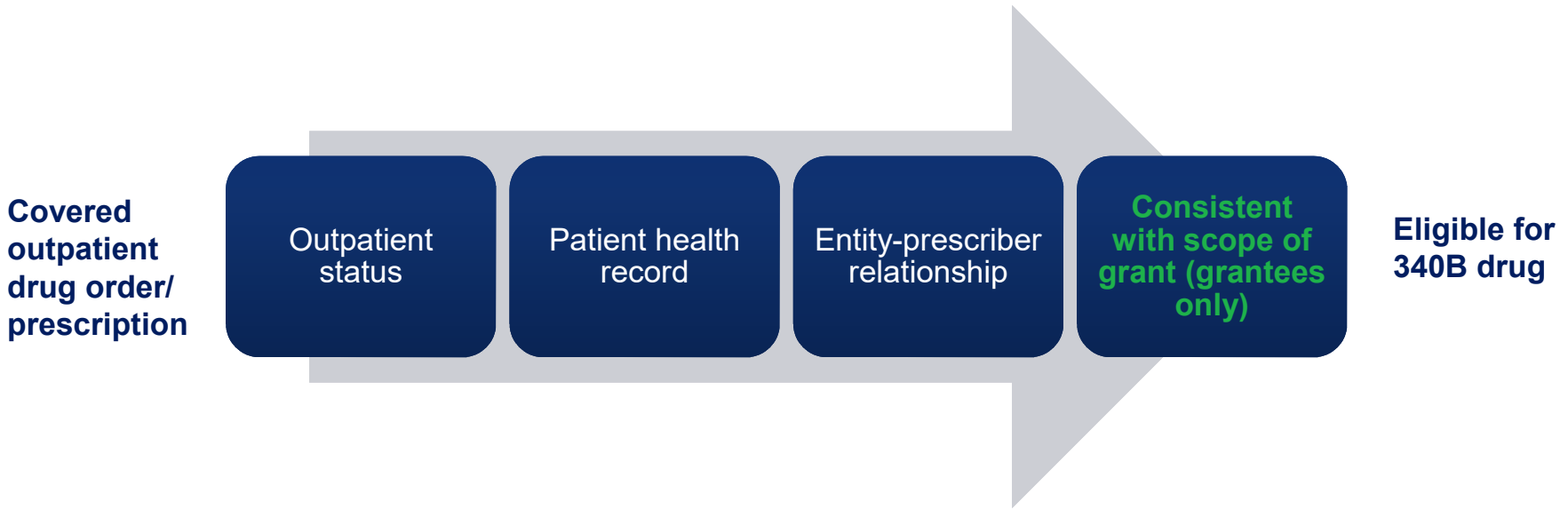
Transferring 340B Inventory

340B purchase alignment with 340B ID

- FQHCs/FQHC-LAs may transfer 340B drugs between the main site and associated sites in 340B OPAIS
- Other grantees (e.g., STD clinics) may be a part of the same organization but individual clinics have different 340B IDs
 - Sites that would like to use a combined purchasing model (all sites under a single grant wanting to purchasing off one 340B account) should contact HRSA for approval
 - Grantee Combined Purchasing and Distribution Request for HRSA
 - Primarily seen in state grantees



Applying Patient Definition in Practice¹



Covered entities carving out Medicaid must ensure that 340B drugs are not billed to Medicaid fee-for-service

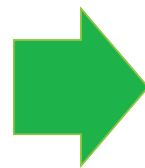
¹ An individual registered in a state-operated or -funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a “patient” of the covered entity for purposes of this definition if so registered as eligible by the state program.



Entity–Prescriber Relationship

Eligible providers who are “floaters”

Covered entity maintains a list of providers who could prescribe from non-covered entity



Pharmacy should have means to verify patient is a patient of the covered entity

- Provider alone may not be enough
- Ensure additional screening

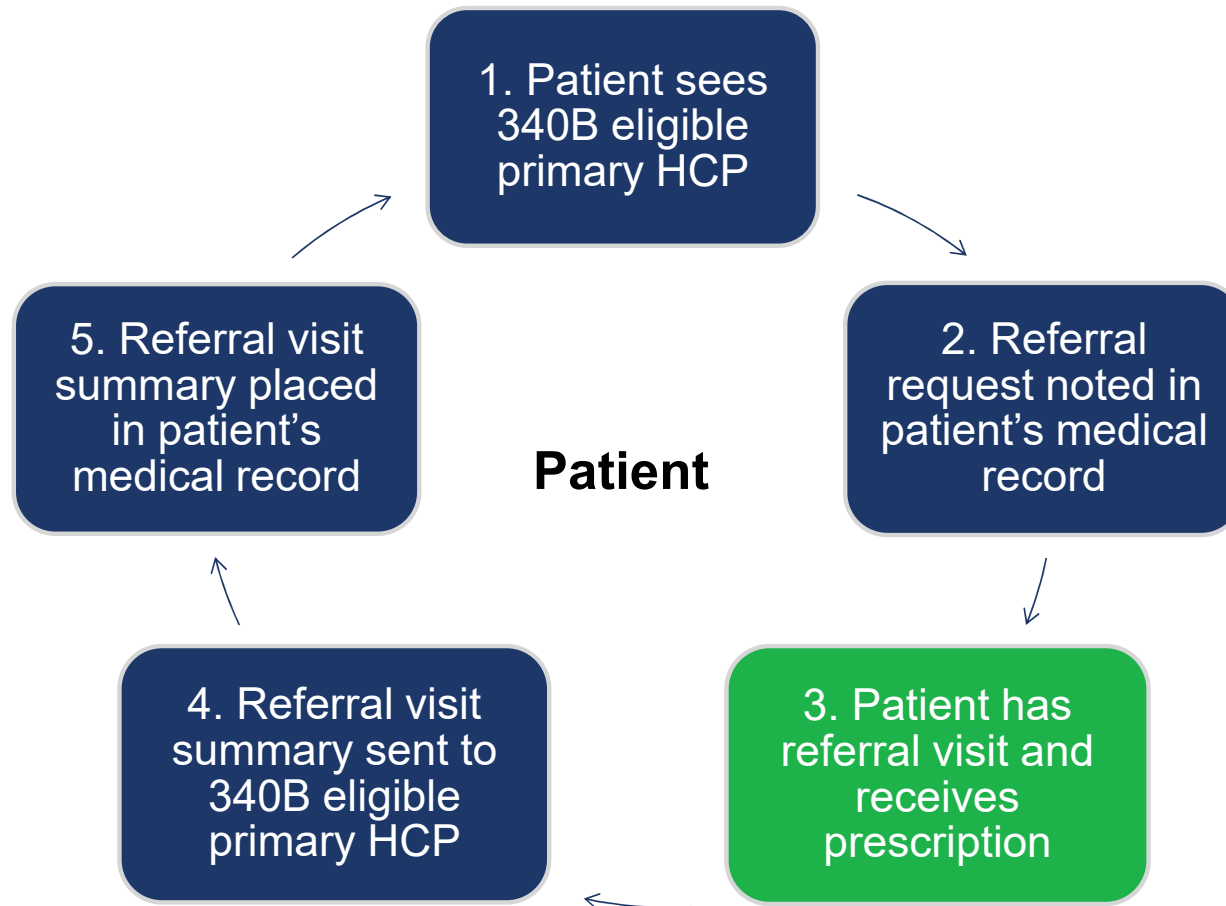
340B Eligibility via Referral

- Q.** If we refer a patient to an outside clinic, can we fill the patient's prescriptions from our 340B clinic?
- A.** A covered entity may refer an individual for consultation to an outside clinic not registered for the 340B Program and consider that patient 340B eligible only if the individual receives health care 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 (61 Fed. Reg. 55156 (October 24, 1996)). If the covered entity can document that it retained responsibility for the health care services provided to the referred individual, then that individual may be eligible to receive 340B drugs from the covered entity. How a covered entity counts referrals under the 340B Program should be addressed in its written policies and procedures.

FAQ: 1493



Best Practice Referral Documentation



Medicaid: Should We Carve In or Out?

Case: FQHC has a clinic setting where all patients seen are eligible. It is having trouble meeting the state Medicaid fee-for-service (FFS) billing requirements for 340B claims. What should it do?

- Choose to carve out?
 - Maintaining a non-340B inventory for Medicaid FFS patients
 - How many medications are used in this setting?
- What if we just don't bill for the medications used?
 - If Medicaid FFS is billed at an all-inclusive rate, entity should answer “yes” to Medicaid billing question (carve in)
 - If Medicaid FFS is not billed at all, entity should answer “no” to the Medicaid billing question (carve out)



Multiple Eligibility Types

- **A single site may register as more than one grantee type**
- **Each registered entity must continue to meet eligibility and compliance requirements**
 - What is additional benefit from registering as more than one?
 - What additional recordkeeping/compliance requirements would apply?



Establishing and Maintaining Compliance

Where to Find Help

The screenshot shows the '340B Compliance Tools and PVP Resources' page. At the top left is the '340B Prime Vendor PROGRAM' logo. A navigation bar includes links for 'COVERED ENTITIES', 'MANUFACTURERS', 'DISTRIBUTION', '340B UNIVERSITY', 'HRSA FAQs', 'RESOURCE CENTER', 'ABOUT 340B & PVP', and 'APEXUS ANSWERS'. A 'LOGIN' button is in the top right. The main heading is '340B Compliance Tools and PVP Resources', followed by a sub-heading: 'The Prime Vendor has developed 340B Compliance Tools to help out put 340B policy into practice. Access Prime Vendor Program Resources available only to PVP participants to support purchasing decisions.' Below this is a search bar with the placeholder text 'Search by keyword or subject'. The section '340B Compliance Tools' is described as 'Created by the PVP and HRSA-reviewed' and includes a disclaimer: 'These tools are intended to be a guide and should be carefully reviewed and modified based on your specific needs. Tools include policy and procedure templates, auditing plans, and additional resources to promote 340B Program integrity.' Four tool categories are listed in a grid, each with a plus sign icon: 'GPO PROHIBITION HOSPITALS (DSH, PED, CAN)', 'GRANTEES (STD, RW, HM, FP, BL, TB, MH, UI)', 'COMMUNITY HEALTH CENTERS (CH, FQ, FQHC, FQHCLA, NH)', and 'RURAL HOSPITALS (CAH, RRC, SCH)'. The tool categories are highlighted with orange boxes.

340Bpvp.com/Tools



Finding the Tools for You

- **New to the program?**
 - Glossary of 340B terms
 - Getting started in 340B checklist
 - Policy and procedure templates
 - Dispense tracking log example

- **Looking for additional resources to support a compliant program?**
 - Self-audit tools (policy and procedure, eligibility, diversion, duplicate discount, contract pharmacy)
 - Split-billing software configuration considerations
 - HRSA and manufacturer disclosure examples



Tools Spotlight

Getting Started in 340B Checklist			
Category	Task	How To/Resource	Links
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	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.	
CR - 3	Identify all areas within the CE that will be using 340B and create map of all areas	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 - 4	Determine which inventory model(s) will be used at your site(s)	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.	On-Demand Module: 340B Drug Delivery
CR - 5	Assess need for third-party administrator (TPA) software for areas with replenishment inventory models	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 - 6	Develop entity-specific policies and procedures	Prior to going live, entities should have policies and procedures that outline how they will align to core elements of the program. Entities may need to assess certain areas mentioned in this tool early in the process when determining operational infrastructure. At registration, CEs will need to articulate which states and which NPIs are using 340B. IMPORTANT: Implementation of software can take up to 6 months, so this process should be started early.	340B Tool: Sample Policy and Procedures Manual On-Demand Module: 340B & Medicaid, Medicare, Medicaid Reimbursement

340B PVP Tools Medicaid Exclusion File (MEF) Checklist



Purpose: This tool is a checklist of common errors reflected in the Medicaid Exclusion File (MEF) that can increase a covered entity's risk of causing duplicate discounts. As a best practice, covered entities should review their 340B Office of Pharmacy Affairs Information System (OPAIS) and MEF on a quarterly basis.

Background: Incorrect information in 340B OPAIS will be reflected in the extracted MEF and could result in duplicate discounts or inaccurate database findings. **Action steps** when recognizing an error should include determining whether the error caused any state to inappropriately submit a manufacturer rebate claim and, if so, whether the claim was paid by the manufacturer (a duplicate discount). The covered entity would need to reach out to the manufacturer in good faith to resolve the issue and determine if the infraction met the material breach threshold needed to self-report to HRSA.

- Core Understandings:**
- "Carve-in" describes a covered entity, child site (hospital), or associated site (FQHC / FQHC-LA) that dispenses 340B drugs to Medicaid patients.
 - National Provider Identifier (NPI) numbers referenced in this document are type-2 (organizational) and not tied to an individual.
 - Covered entities are responsible for providing each Medicaid state it plans to bill for 340B drugs and the associated billing number(s) for each of its sites listed on 340B OPAIS. Some states have placed additional requirements regarding the prevention of duplicate discounts.
 - (Hospitals) If a parent and child site both carve-in using the same NPI number, BOTH the parent and child should each roster that NPI number.

Common Errors	Why is this important?	How can you fix this?
<input type="checkbox"/> Typographical errors; incorrect or transposed national provider identifiers (NPI) or Medicaid provider numbers (MPN).	OPAIS does not validate entries in length or accuracy.	Ask your billing department to review OPAIS-rostered NPI/MPN entries for accuracy. If an error/omission is found, the primary contact (PC) or authorizing official (AO) will need to submit an OPAIS change request.
<input type="checkbox"/> Listing only an MPN, but billing using the NPI.	Historically, MPNs were used by entities to submit state Medicaid claims. Post-HIPAA, all providers are required to obtain and use NPIs when submitting claims to CMS.	Routinely review the MEF with your billing department to ensure that the rostered provider identifier billing information matches your billing practices. If an error/omission is found, the PC or AO will need to submit an OPAIS change request.
<input type="checkbox"/> OPAIS does not reflect <u>all</u> states that receive Medicaid fee-for-service (FFS) claims from your covered entity for drugs purchased at 340B prices.	An entity can choose to dispense 340B drugs to Medicaid patients from multiple states. To do so, the entity must roster the appropriate NPI/MPNs paired with the corresponding state in OPAIS.	Work with your billing department to identify any states that receive Medicaid FFS claims for drugs purchased at 340B prices. Confirm that the appropriate NPI/MPNs on those claims are rostered in OPAIS and paired with the appropriate state.



Program Oversight and Support

- **Multidisciplinary oversight responsibility**
 - Responsible for operational and strategic decision making to ensure integrity of the program
 - Ensure adequate resources to maintain 340B Program compliance and optimization goals
 - Create accountability for compliance measures including auditing and program maintenance
- **Ensuring adequate resources to support the program**



Case: Developing Self-Auditing Strategies

I just got back from 340B University and realized that we need to put a self-audit plan in place—where do I start?

- Create audit plan/calendar based on key compliance areas and locations where 340B is used
- Share with oversight team
- Use tools on [340Bpvp.com](https://www.340bpvp.com) as templates
- Define material breach and process for reporting to manufacturers +/- HRSA for repayment
- Repeat audits on regular schedule



Reporting Noncompliance—Material Breach

- X% of total 340B purchases or impact to any one manufacturer
- \$X (fixed amount), based on total outpatient or 340B spend, or impact to any one manufacturer
- X% of total 340B inventory (units)
- X% of audit sample
- X% of prescription volume/prescription sample



Grantee Frequently Asked Questions

Are community
outreach mobile
services or pop-up
clinics eligible for
340B?



Mobile Clinics and Outreach Services

Ensure that 340B drugs are provided only to eligible patients of the covered entity

- What kind of patient health record is kept by the CE? Is it auditable?
- Is the service consistent with the scope of grant?
- How is inventory maintained?



Our entity recently lost
its 340B eligibility.
How do we handle
340B inventory on the
shelf?



Terminated Covered Entity Inventory

- 340B physical inventory should be returned, destroyed according to state law, or credit/rebilled with manufacturer
- Inventory cannot be transferred from one 340B grantee/covered entity to another 340B grantee/covered entity
- Entities with extenuating circumstances should contact HRSA directly for possible alternatives to this approach



Which types of covered entities can purchase PrEP on 340B?



PrEP

- Patient definition and challenges
 - Scope of grant
- Grantee purchasing medication should be able to meet eligibility requirements



Takeaways

- Grantees have unique needs in complying with the 340B Program
 - Ensure understanding of scope of grant
- 340Bpvp.com contains resources specific to grantee types that can help establish or maintain compliance
- An important step to ensuring compliance is defining practices in policies and procedures





Questions