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 Implementation: FQHCs and Grantees

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340B Policy & Compliance Director

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
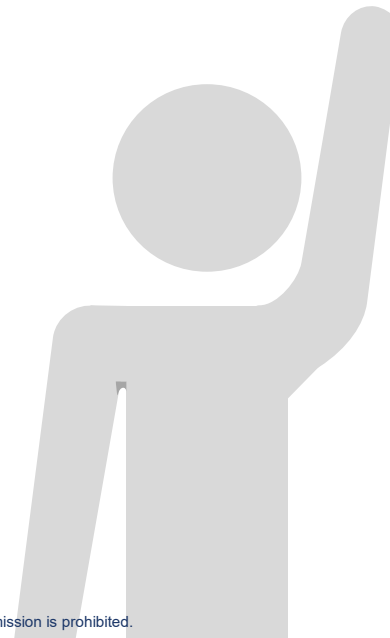
Transferring 340B Inventory

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 Practice[1]

Covered outpatient drug order/ prescription

| Outpatient status | Patient health record | Entity-prescriber relationship | Consistent with scope of grant (grantees only) |

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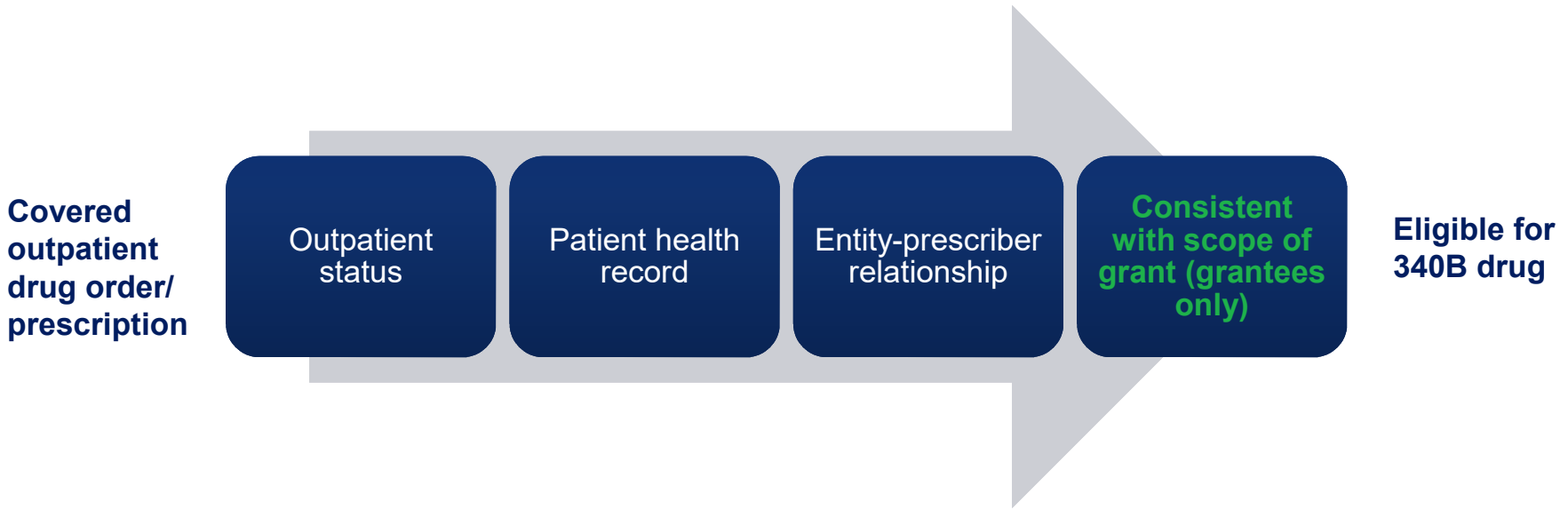
Covered entities carving out Medicaid must ensure that 340B drugs are not billed to Medicaid fee-for-service

[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.

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Entity–Prescriber Relationship

Eligible providers who are "floaters"

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

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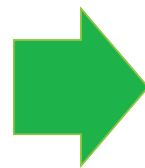
Pharmacy should have means to verify patient is a patient of the covered entity

- 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

1. Patient sees 340B eligible primary HCP

2. Referral request noted in patient's medical record

3. Patient has referral visit and receives prescription

4. Referral visit summary sent to 340B eligible primary HCP

5. Referral visit summary placed in patient's medical record
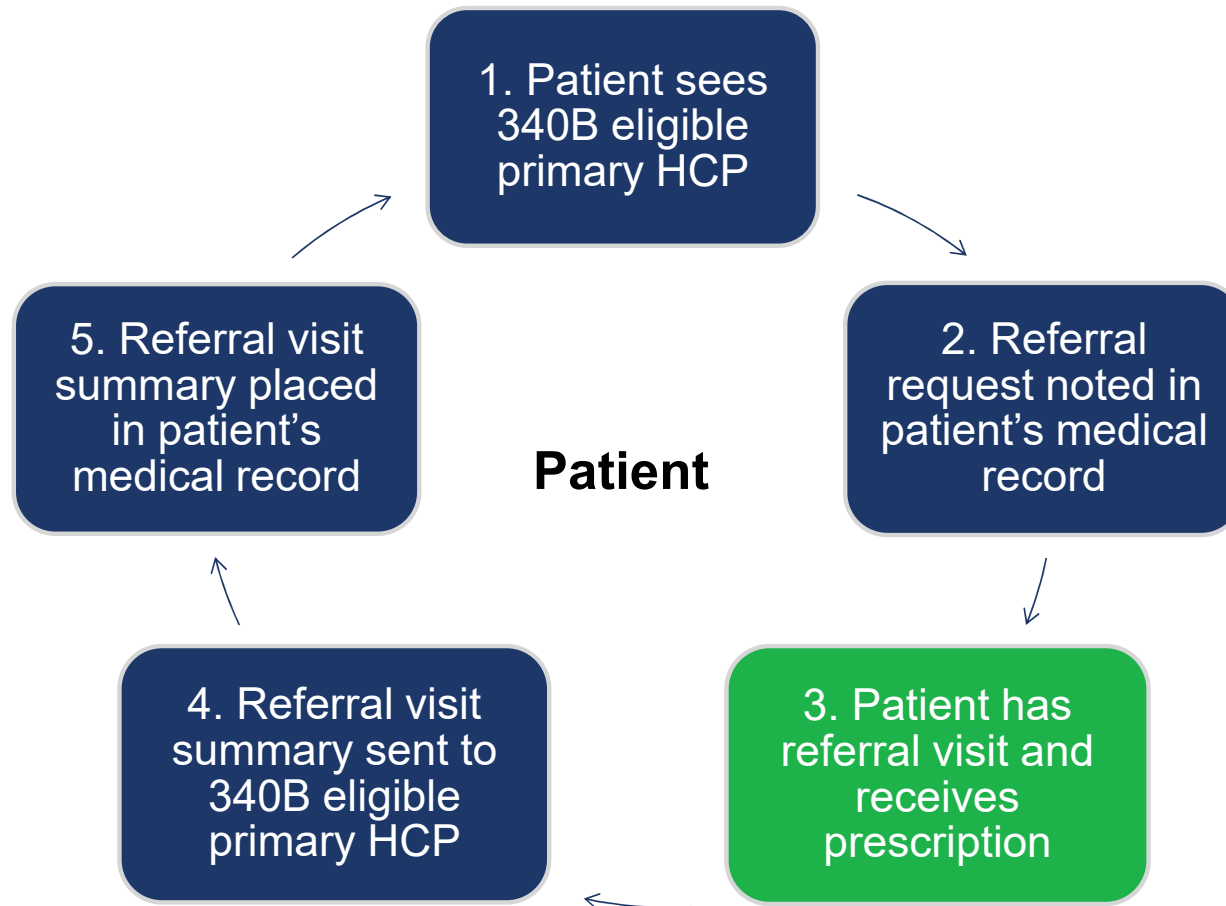
Patient

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

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

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 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