The 4-1-1 on 340B

**ENACTMENT** Passed as part of Veteran’s Health Care Act of 1992 to provide discounts on outpatient drugs to certain provider entities.

**ADMINISTRATION** Office of Pharmacy Affairs (OPA) at the Health Resources and Services Administration (HRSA).

**PURPOSE** Allows safety-net providers to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

**REQUIREMENTS** Manufacturers selling drug to Medicaid, must offer same products to 340B “covered entities” at a discounted rate.
Eligibility: Who Qualifies?

**Provide**er

**Patient**

**340B-eligible**

**COVERED ENTITIES**
Tied to certain grants or hospital types

**PATIENT DEFINITION**
Patients must meet 3-pronged patient definition to qualify for 340B-priced drugs
340B Provider Eligibility

How to be a 340B Covered Entity
Provider Eligibility Requirements

• Receive funds from one of the designated grants: Title X, 318 STD, Ryan White, FQHC Section 330 grants (+ FQHC look-alikes), hemophilia treatment centers, etc.*

• Registered in the 340B database

• Complete annual recertification

• Comply with 340B program requirements

* Some hospitals can also qualify (DSH, children's, free-standing cancer, RRC, CAH, and sole community hospitals.)
Four annual registration periods (January 1-15, April 1-15, July 1-15, October 1-15)

Must include grant number in registration
  - Might need to contact grantee to get grant numbers
  - Title X grant numbers are in the following format: FPHPAXXXXXX

Registration is effective at the beginning of the next calendar quarter
  - Example: Registration submitted during April registration period becomes effective July 1 of that year
  - May not purchase or dispense 340B drugs until registration becomes effective

Ideally, registration is done at the service site level, so each location has its own unique 340B database entry
Elements of 340B Registration

• Select authorizing official (AO) and primary contact (PC)
• Create AO and PC user accounts
• Provide all necessary contact information
• Make Medicaid carve in/carve out selection
Authorizing Officials

- Must be fully authorized to legally bind the entity
- Ultimately responsible for entity’s compliance and annual recertification
- Cannot be the same person as the primary contact
### Annual Recertification

- Must recertify annually during the designated period
- Authorizing official receives email with all necessary info in advance of recertification period
- Failure to recertify will result in termination from the 340B program
Patient Eligibility

340B Patient Definition
PATIENT DEFINITION

1. Established relationship between the patient and the 340B covered entity (usually documented in a medical record)

2. Patient receives health care service(s) from a provider employed by the covered entity (or providing services for the covered entity under contractual or other formal arrangement)

3. Patient receives health care service(s) consistent with the grant through which the covered entity gained 340B eligibility (only applies to non-hospital entities)
Important patient eligibility facts

• Whether a patient is eligible for 340B-priced drugs is **ONLY** governed by the 340B patient definition

• Patient eligibility is **NOT** dependent on the patient’s coverage status or source

• As long as the patient meets the patient definition at a visit, **ANY** drug prescribed at that visit can be 340B-priced

• Patient eligibility is tied to the site where care is received and the visit
When to avoid using 340B drugs

• Anyone in an inpatient setting, including immediate postpartum LARC insertion

• When a patient receives no service other than the administration/dispensing of a drug (except refills from a visit where the patient met the patient definition)

  • Example: Selling emergency contraception on a walk-in basis from the front desk
Medicaid and 340B
Links between Medicaid and 340B

• 340B linked to Medicaid drug rebate program (MDRP)
  • MDRP requires drug manufacturers to pay a “rebate” to Medicaid agencies whenever they pay for/reimburse a provider for an outpatient drug
  • The rebate can’t be collected if the drug was already sold at the discounted 340B price
  • If this happens, it’s called a duplicate discount (we’ll talk about this more later)

• Use of 340B drugs with Medicaid patients is more complicated than patients with any other type of coverage
“Carve in” OR “Carve Out”?

- **Carve in** = ALL drugs dispensed to Medicaid patients are 340B
- **Carve out** = NO drugs dispensed to Medicaid patients are 340B
- Entities that carve in are listed in the Medicaid Exclusion File
- Carve in or out is an all-or-nothing decision, at least in fee-for-service Medicaid
- In Michigan, all 340B drugs billed to Medicaid as physician-administered (on the CMS-1500 form) must have a U6 modifier
Medicaid Managed Care

- Not added to 340B program until 2010 in the Affordable Care Act
- No federal recommendation on how to prevent duplicate discount in managed care
340B Compliance
ALL STAFF HAVE A ROLE TO PLAY
Diversion

- Dispensing/administering 340B drugs to a patient that does not meet the 340B patient definition
- Transferring 340B drugs from one covered entity to another covered entity
  - Each unique 340B ID# is considered its own covered entity
- Dispensing/administering 340B drugs in an inpatient setting
Inventory Management

- 340B drugs may not be transferred, sold, donated, etc. outside of the covered entity that purchased those drugs (w/o special HRSA approval)

- Covered entities must be able to track each drug to the grant it was purchased under all the way to the patient

- Inventories must be stored and tracked separately (e.g., 340B vs. non-340B, different grant inventories)
If a patient meets the 340B patient definition at a visit and tests positive for an STD, you may use 340B drugs for EPT.

- The rationale is that EPT is actually a treatment for your patient because it is preventing reinfection.
- Your use of 340B drugs for EPT should be included in your 340B policies and procedures.
Duplicate Discount

• When a Medicaid agency collects a rebate on a drug that was already sold at a 340B price

• Covered entity’s responsibility to prevent duplicate discount by ensuring accurate carve in/carve out decision is reflected in 340B database entry and Medicaid Exclusion File

• In Michigan, must also follow state policy to apply the appropriate modifier to the claim (U6 modifier for physician-administered drugs)
# ELEMENTS OF 340B COMPLIANCE

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<td>Robust policies and procedures</td>
<td>Regular internal audits and quality control</td>
<td>Regular training of all pertinent staff</td>
<td>Check/update 340B database quarterly</td>
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Policies and Procedures

• Definition of patient/services consistent with the grant
• Use of 340B drugs for EPT
• Inventory management practices
• Responsible staff
• Material breach
• Internal audit process and frequency
• Oversight and management of outside vendors
• Medicaid billing procedures
Material Breach

- Material breach = instance of noncompliance

- Responsibility of each covered entity to establish a point at which noncompliance needs to be reported to HRSA and implicated manufacturers, known as a material breach threshold

- Examples of threshold options:
  - X% of total 340B inventory
  - X% of audit sample
  - X% of encounters

- **Consequence of noncompliance** = entity could be required to pay back the discounts to manufacturers
Internal Audits

- Chart reviews
  - Potential diversion or duplicate discount
- Inventory management and tracking
  - Monthly inventory checks
  - Inventory systems checks
- At least annual audits of outside vendors, including contract pharmacies
HRSA Audit Process

- Pre-audit data request
  - 340B policies and procedures
  - 340B drug orders or prescriptions
  - List of providers authorized to write 340B prescriptions at your entity
  - Current 340B drug inventory
  - Listing of contract pharmacies, including contracts
- Onsite audit, including testing on a sample basis of 340B transactions
- If audit results include findings, entity must submit corrective action plan
Case Studies

APPLYING WHAT WE’VE LEARNED TO THE REAL WORLD
Case Study #1

• Simon is a patient at health department A, which qualifies for 340B with 318 STD funds. He tests positive for chlamydia and needs Bactrim. Health department A does not have anymore Bactrim in its 318 340B inventory?

• Can health department A pull a specific ADAP patient’s Bactrim, relabel it, and dispense it to Simon instead?
Case Study #2

- Sally is a family planning patient at health department B, which has Title X funds and is registered for 340B as a family planning entity. She had a family planning visit three months ago, and qualified to receive 340B-priced Depo at that visit.
- This month, Sally goes to health department C, which is also a 340B covered entity. Can her second Depo shot be 340B-priced at health department C if she doesn’t receive any other services that day?
Case Study #3

• Health department D provides STD services every other Tuesday at a local substance abuse treatment center. They are dispensing treatment to those patients who are testing positive for an STD when they go to this alternate site.

• Can health department D bring its 340B inventory of drugs with them to the alternate site to dispense?
Thank you!
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QUESTIONS?