340 Drug Pricing Program for Family Planning Providers

NFPRHA WINTER MEETING 2019

National Family Planning & Reproductive Health Association

Training Roadmap

- Provider and Patient Eligibility
- Medicaid and 340B
- 340B Termination
- Elements of Compliance
- Case study exercises

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 drugs to Medicaid, must offer same products to 340B "covered entities" at a discounted rate

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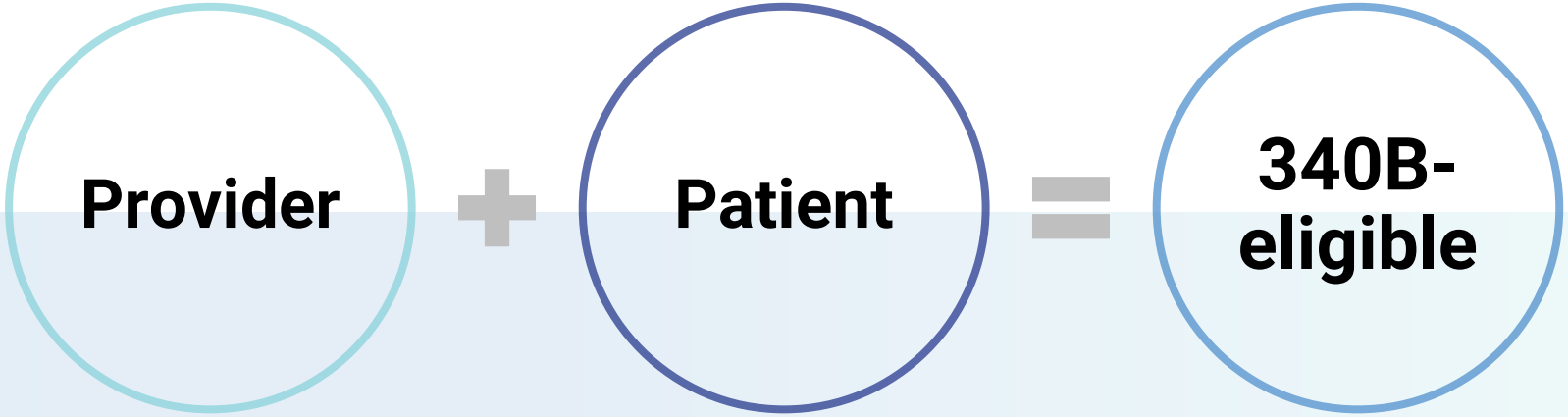
Eligibility: Who Qualifies?



COVERED ENTITIES
Tied to certain grants or hospital types

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

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340B Provider Eligibility

HOW TO QUALIFY AS A 340B COVERED ENTITY

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Provider Eligibility Requirements

- Receive funds from one of the designated grants: Title X, 318, 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.

318 Eligibility

- Historically: Grantees and subgrantees of CDC STD grant (STD PCHD)

- Recently redefined: Recipients or subrecipients of any CDC grant that uses 318 legislative authority
  - Includes 30 CDC grants supporting prevention, surveillance, and treatment of HIV, Hepatitis B and C, and other STDs

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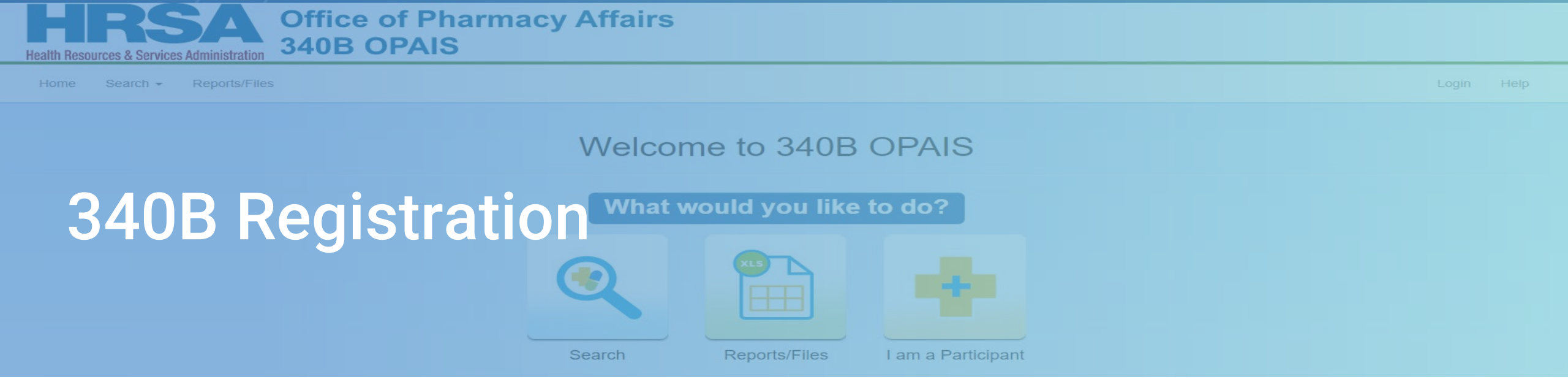

340B Registration

- 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
- 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

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

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Discussion Questions

- An organization withdrew from Title X in July 2019 and registered under the 318 STD program during the October registration period. When will the new site be eligible to purchase and dispense 340B drugs again?

- An FQHC also receives Title X funds and is registered for 340B under both programs (has 2 unique 340B IDs). How many times annually must that organization recertify?

Patient Eligibility

340B PATIENT DEFINITION

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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 will change depending on which funding stream qualifies the provider for 340B**

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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

318 STD Patient Eligibility

- A patient should receive a sexual health history and discussion of STD risk factors with a provider at every visit
- Receive any STD testing and treatment warranted, per CDC STD Guidelines, from that sexual health history

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Case Study

- Emily is a patient with private health insurance coverage. She comes in to a Title X-funded health center, wants to initiate a new contraceptive method, and chooses the NuvaRing.
  - Can the NuvaRing dispensed at the visit be 340B-priced?
  - Emily is a smoker and says she wants to quit. She is interested in trying a smoking cessation drug at this visit. Can that drug be 340B-priced?
  - What about if the health center has CDC 318 and not Title X?

Case Study

- Libby has an appointment at a CDC STD 318-funded health center. Her provider completes a full sexual health history and counsels her on STD prevention during the course of a well-woman exam. Libby decides that she wants to change her contraceptive method and get an IUD.
    - Can the IUD be 340B-priced?

Medicaid and 340B

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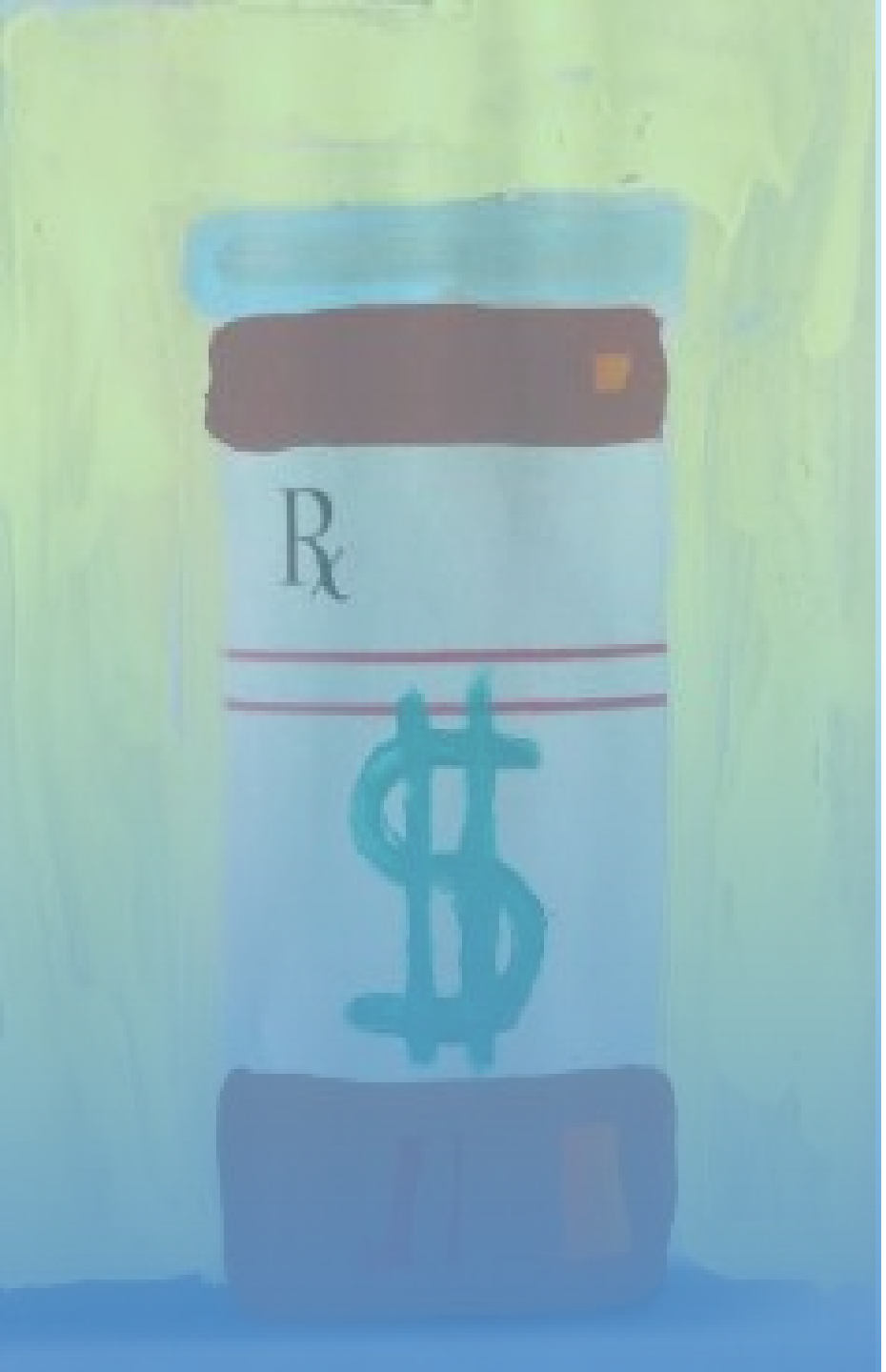
Links between Medicaid and 340B

- 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
- Medicaid Exclusion File entries are tied to NPIs



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

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Discussion Questions

- Do you know whether your organization is carved in or carved out? Do you think the organization's practice matches your carve in/out selection?

- Do you know what policies (if any) your state Medicaid agency has implemented regarding billing for 340B drugs?
  - New resource on state policies: https://www.340bpvp.com/resource-center/medicaid

340B Termination

CONSIDERATIONS FOR MAKING THE TRANSITION

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Termination process

- Immediately upon withdrawal from Title X or loss of any qualifying funding source, entities must notify HRSA through OPAIS of termination from 340B

- Inventory options
  - Return or destroy
  - Contact manufacturers and get permission in writing for continued use/transfer
  - Request permission from HRSA for inventory transfer (if you have other 340B eligibility)

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Discussion Questions

- An entity notifies OPA that it is withdrawing from Title X effective March 4, 2020. When should the entity terminate their Title X 340B ID with HRSA?
    - When does the entity have to stop purchasing 340B-priced drugs under its Title X 340B ID?
    - When does the entity have to stop dispensing 340B-priced drugs purchased under its Title X 340B ID?

Case Study

- Agency XYZ withdrew from the Title X program in July 2019. The agency also has 340B access under the 318 program. What are the agency's options for handling the 340B inventory on its shelves purchased under its 340B account?
  - What if the agency has no other access to 340B? What are the options for handling its existing 340B inventory?

340B Compliance

ALL STAFF HAVE A ROLE TO PLAY

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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
  - This does not apply to FQHCs in a parent-child relationship if the transfer is happening between two child sites or between the parent and a child site.

- Dispensing/administering 340B drugs in an inpatient setting

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EPT and 340B

EXPEDITED PARTNER THERAPY

- 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.

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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

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ELEMENTS OF 340B COMPLIANCE

1
Robust policies and procedures

2
Regular internal audits and quality control

3
Regular training of all pertinent staff

4
Check/update 340B database quarterly

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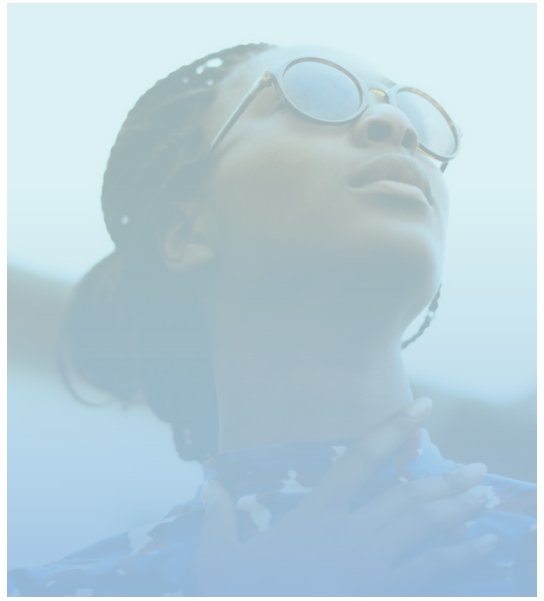
Policies and Procedures

- 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



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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

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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 Study

- Simon is a patient at health department A, which qualifies for 340B with 318 STD funds. He tests positive for syphillis and needs bicillin. Health department A does not have any bicillin in its 318 340B inventory?
  - Can health department A pull a specific ADAP patient's bicillin, relabel it, and dispense it to Simon instead?
  - Can health department A call another 340B entity and request bicillin from them?

Case Study

- FQHC 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 FQHC D bring its 340B inventory of drugs with them to the alternate site to dispense?

Case Study

- A Title X health center conducts internal 340B audits quarterly. The entity's established material breach threshold is if diversion or duplicate discount are identified in more than 5 records in a 100-record chart review. The entity carves out for Medicaid patients.
  - In the course of one of these audits, 10 charts for Medicaid patients in a 100-record chart review indicate those patients were dispensed 340B-priced medications. What actions should the entity take?

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Thank you!

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QUESTIONS?