

# 340B Drug Pricing Program for Family Planning Providers

NFPRHA NATIONAL CONFERENCE 2020

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# TRAINING ROADMAP

- Provider and Patient Eligibility
- Interaction with Medicaid
- Termination/close-out
- Compliance considerations
- Case study exercises

# The 4-1-1 on 340B

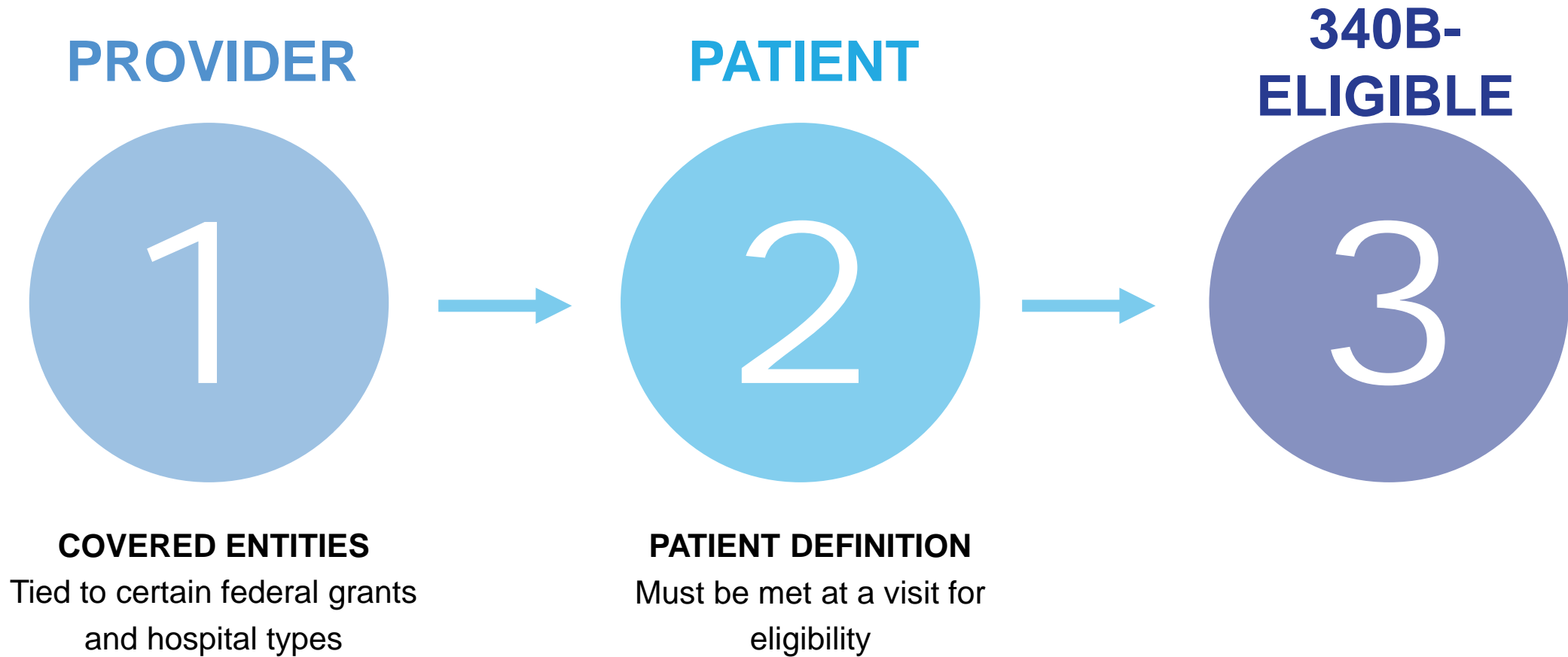
**ENACTMENT** Passed as part of Veteran's Health Care Act of 1992 to provide discounts on outpatient drugs to certain provider entities

**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

# Eligibility: Two Step Process





A photograph of four healthcare professionals, two men and two women, standing in front of a hospital building. They are all wearing blue scrubs and have their arms crossed, smiling at the camera. The image is overlaid with a semi-transparent blue filter. The text 'PROVIDER ELIGIBILITY' is written in large, white, bold, sans-serif capital letters across the center of the image.

# PROVIDER ELIGIBILITY

QUALIFYING AS A 340B COVERED ENTITY

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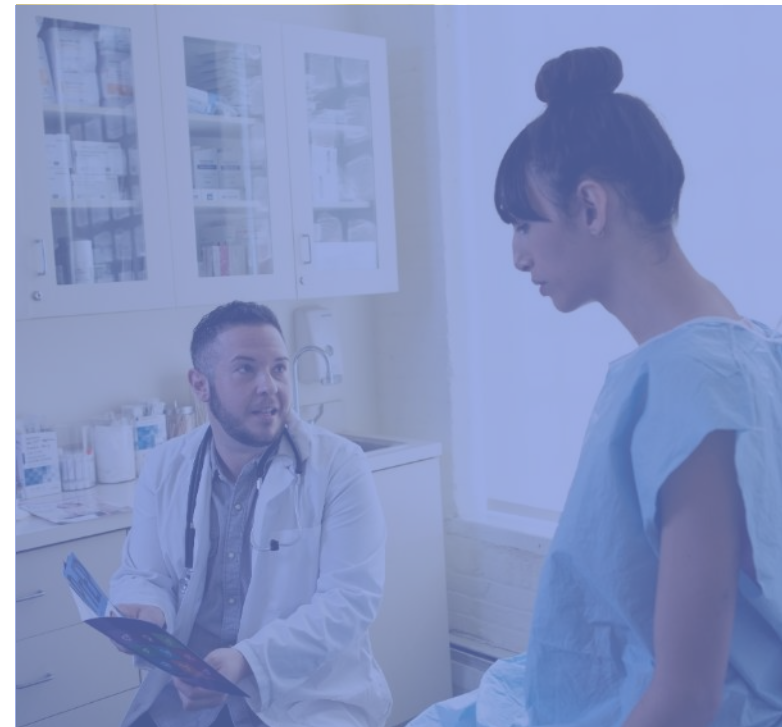
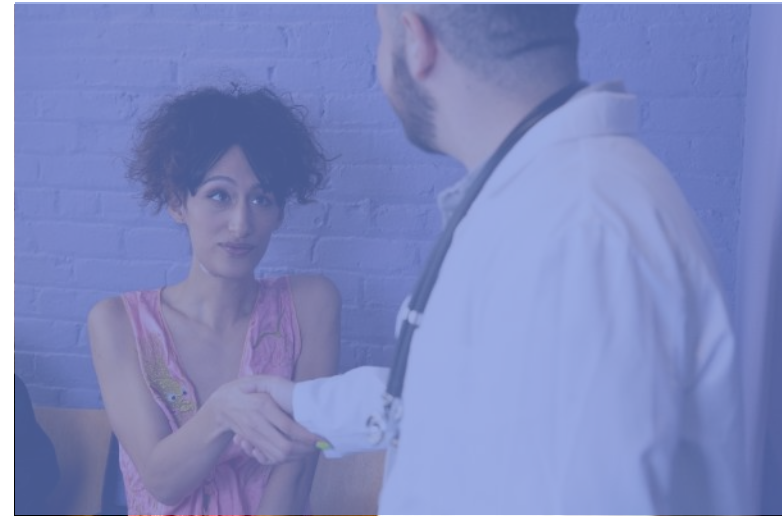
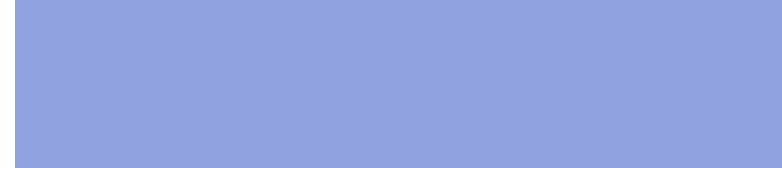
# ELIGIBILITY REQUIREMENTS

- Receive funds from one of the designated grants: Title X, CDC 318, Ryan White, FQHC 330 grants (+ FQHC look-alikes), etc.\*
- Registered in 340B OPAIS
- Recertify annually
- Ongoing commitment to compliance

\* 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 authorized under section 318 of PHS
  - Includes 30 CDC grants for prevention, surveillance, and treatment of HIV, Hep B and C, and other STDs



PROVIDERS

Welcome to 340B OPAIS

# REGISTRATION

What would you like to do?



Search



Reports/Files



I am a Participant

- Four annual registration periods (1<sup>st</sup> 15 days of each calendar quarter)
- Must include grant number in registration
- Registration effective first day of following calendar quarter
  - Prohibited from buying and dispensing 340B drugs until effective date
- Registration ideally done at the service site level



# RECERTIFICATION



- Must recertify annually during the designated time
- Authorizing official contact by email
- Failure to recertify will result in termination from the 340B program

# DISCUSSION QUESTIONS

- An organization withdrew from Title X in July 2019 and registered under the 318 STD program during the October 2019 registration period. When will the 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 per year must that organization complete recertification?



# 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)



- Patient eligibility is ONLY governed by the 340B patient definition
- NOT dependent on patient's coverage status or source
- If patient definition is met, ANY drug prescribed at that visit can be 340B-priced
- Because of 3<sup>rd</sup> prong, patient eligibility will change depending on which funding stream qualified the provider for 340B

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# WHEN NOT TO USE 340B DRUGS

- In an inpatient setting; 340B is only for outpatient drugs
- When patient receives no health care service other than the administration or dispensing of a drug (except refills from an eligible Rx)
  - Example: selling emergency contraception on a walk-in basis from the front desk

# 318 STD ELIGIBILITY

- Patients should, at a minimum, have a sexual health history and a discussion of STD risk factors
- Receive any STD testing and treatment warranted, per CDC STD guidelines



PATIENTS

# CASE STUDY

- Emily is a patient with private health insurance coverage. She comes into 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?



# CASE STUDY

- Libby has an appointment at a CDC 318 STD-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?

A photograph of a family of three—a woman, a man, and a young child—standing outdoors in what appears to be a park or field. The woman is on the left, smiling and looking towards the child. The man is on the right, also smiling and looking down at the child. The child is in the center, wearing a light-colored zip-up jacket and looking up at the camera with a smile. The entire image is overlaid with a semi-transparent blue filter. The title text is centered over the image.

# MEDICAID AND 340B

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# LINKED PROGRAMS

- Medicaid drug rebate program (MDRP) requires drug mfrs to pay a “rebate” to Medicaid agencies
- Manufacturers are protected from paying a rebate on a drug already sold at a 340B discount
- Rules for giving 340B drugs to Medicaid patients are more complex

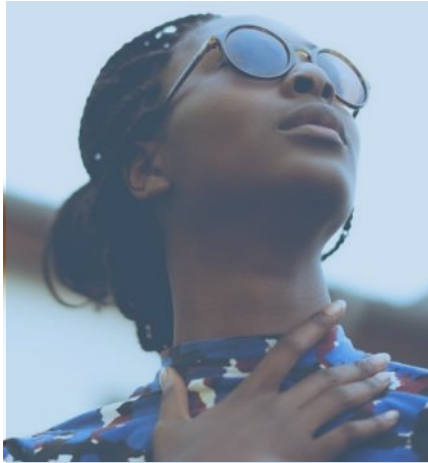


MEDICAID



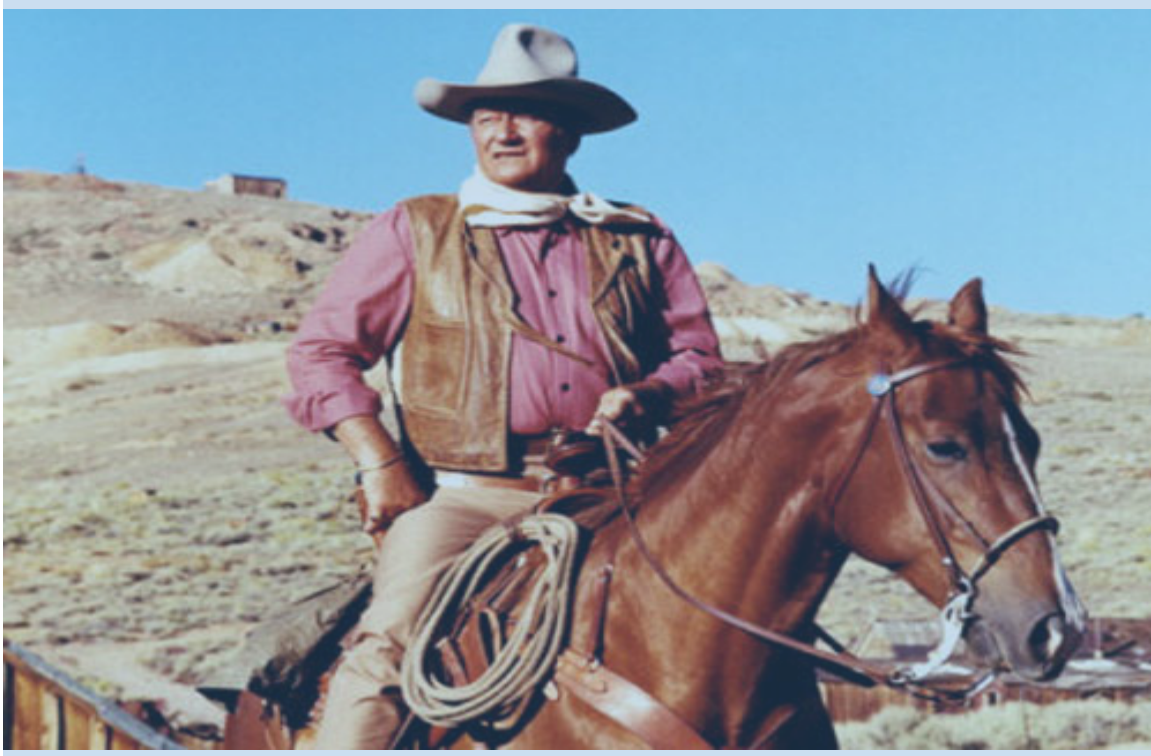
# CARVE IN or CARVE OUT

- Carve in=ALL drugs dispensed to FFS Medicaid patients are 340B
- Carve out=NO drugs dispensed to FFS Medicaid patients are 340B
- All or nothing decision
- Entities that carve in are listed on the Medicaid Exclusion File





# MEDICAID MANAGED CARE



MEDICAID

- Not added to 340B program until 2010 in the Affordable Care Act
- Federal gov't still has not issued any guidance on avoiding duplicate discount in managed care
- States are required to include some mechanism in MCO contracts
- HRSA not requiring repayment if duplicate discount is found in managed care

# DISCUSSION QUESTIONS

- Do you know whether your organization is carved in or carved out? Do you think your organization's practices match your carve in/out selection?
- Do you know what policies (if any are available) your state Medicaid agency has implemented regarding billing for 340B drugs?
  - New resource on state policies: <https://www.340bpvp.com/resource-center/medicaid>





# TERMINATION

CONSIDERATIONS FOR TRANSITIONS

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# TERMINATION PROCESS

- Immediately upon withdrawal from Title X or loss of qualifying funding stream, entities must notify HRSA through OPAIS of termination from the 340B program
- Inventory options
  - Return or destroy
  - Contact manufacturers and request permission to in writing for continued use/transfer
  - Request permission from HRSA for inventory transfer (if you have other 340B ID)



# 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 through OPAIS?
  - 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 August 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 Title X 340B ID?
  - What if the agency has no other access to 340B?

A photograph of three healthcare professionals, two men and one woman, seen from behind as they embrace each other in a brightly lit hallway. They are wearing light blue scrubs. The image is overlaid with a semi-transparent blue filter. The word "COMPLIANCE" is written in large, white, sans-serif capital letters across the center of the image.

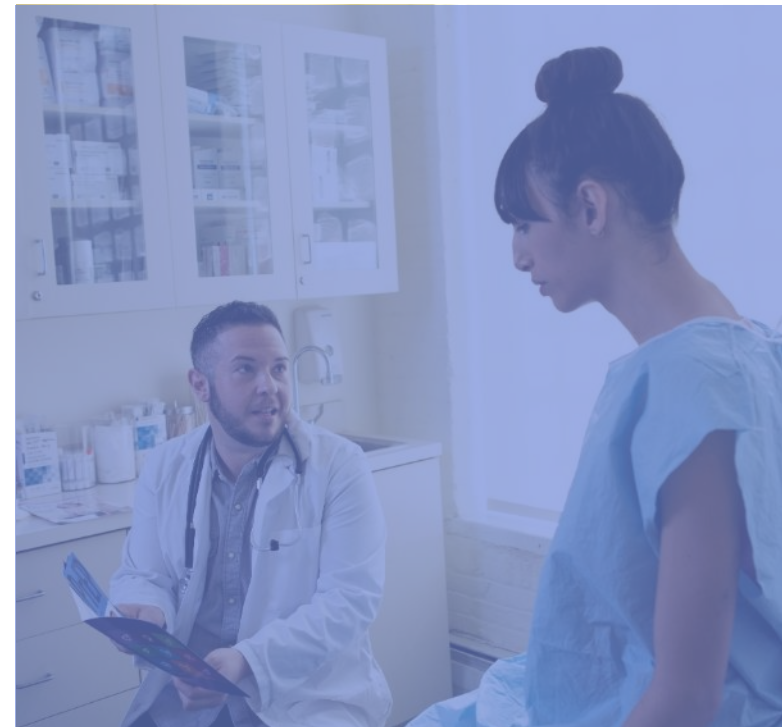
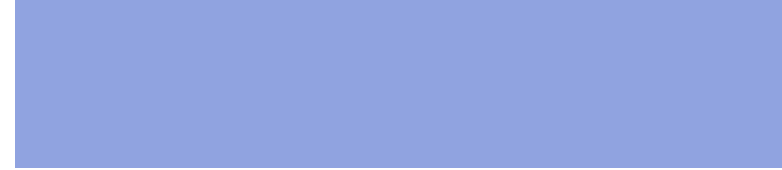
# COMPLIANCE

**IT'S A TEAM EFFORT**

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# DIVERSION

- Dispensing a 340B drug not someone not meeting 340B patient definition
- Transferring 340B drugs from 340B ID/CE to another (unless FQHC or hospital with parent/child registration)
- Dispensing a 340B drug in an inpatient setting





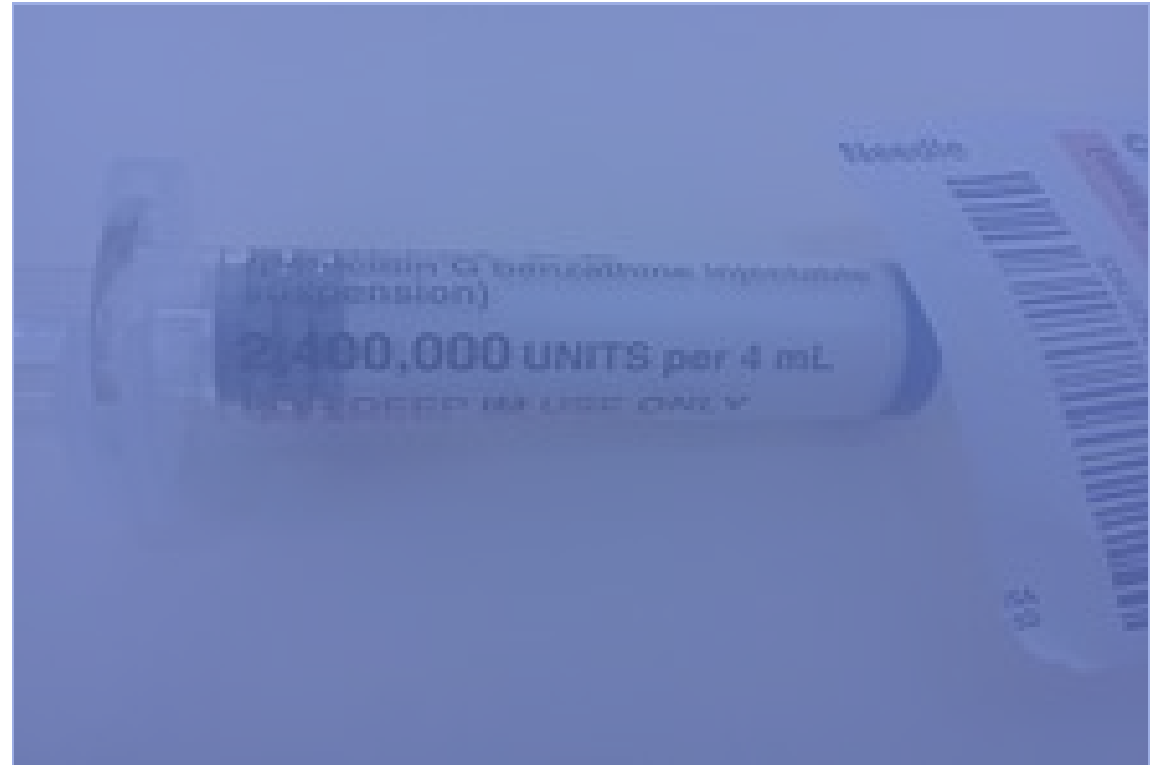


# COMBINED PURCHASING

- Can get permission from HRSA to purchase 340B drugs centrally and distribute to health centers
- New tool available to help with requesting permission
  - <https://www.340bpvp.com/education/340b-tools/> (Under grantees, operational/purchasing)

# BICILLIN

- Some flexibility due to severity of syphilis epidemic, issues with bicillin inventory
- 340B bicillin can be transferred to other sites to ensure all patients with syphilis are treated in a timely manner
- Should be prescribed under orders from med. director of STD entity, records of patients should be maintained at site
- Needs to be in P&Ps



DIVERSION

# LARC INSERTION

- If you refer to an outside provider for some insertions, can have process for using 340B IUDs, implants
- Should have contract or formal arrangement with provider, maintain health records for patient
- Needs to be P&Ps



DIVERSION



# 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 (in states that permit it).
- The rationale is that EPT is actually a treatment for your patient, because it is preventing reinfection.
- Should be reflected in your 340B policies and procedures.

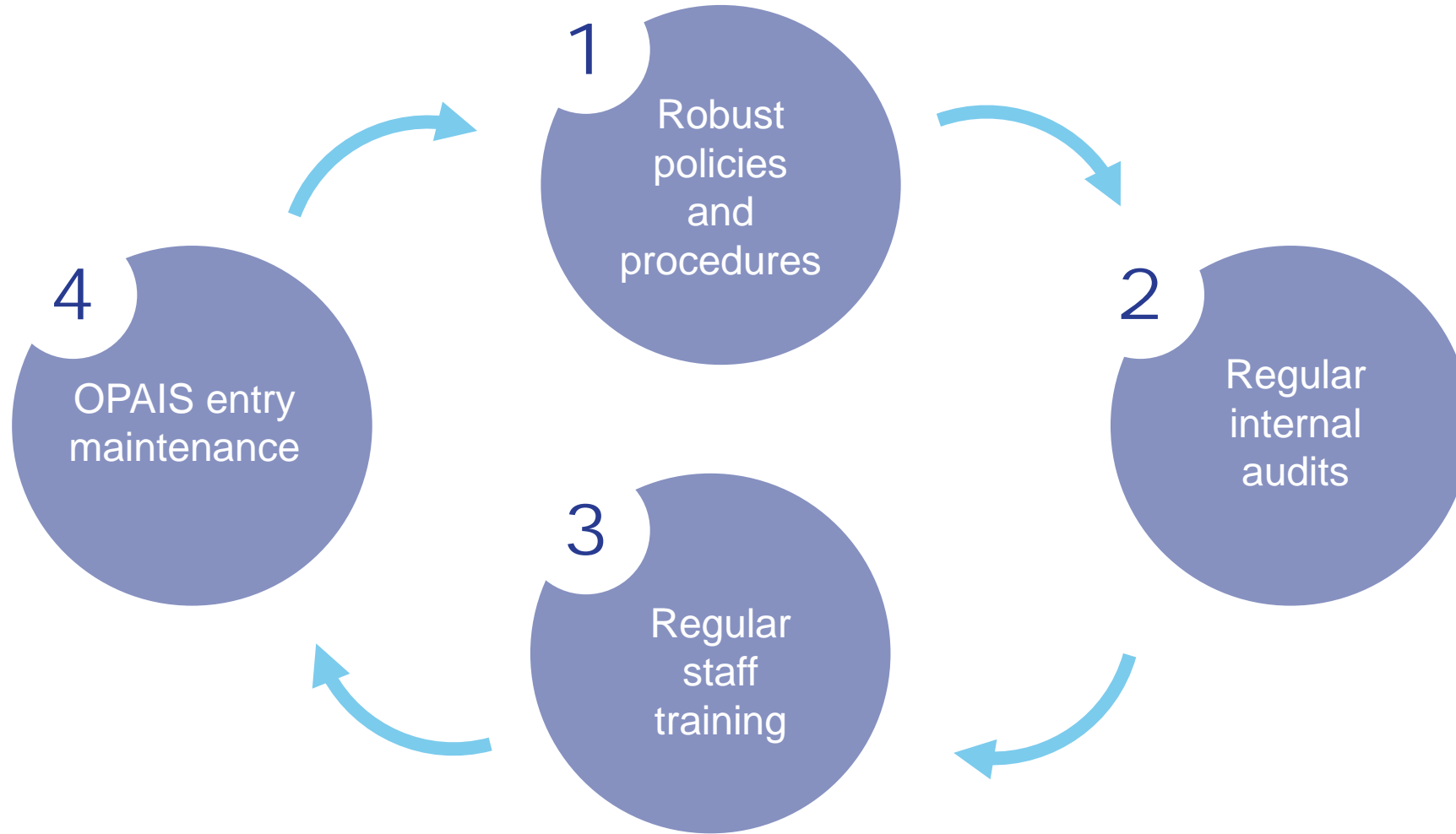




# DUPLICATE DISCOUNT

- 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

# ELEMENTS OF 340B COMPLIANCE





# POLICIES AND PROCEDURES

- Definition of patient/services consistent with grant
- Inventory management
- Responsible staff
- Internal audits and material breach
- Medicaid/prevention of duplicate discount
- Other areas that pose compliance risk



## INTERNAL AUDITS

- Chart reviews for diversion, duplicate discount
- Inventory management and tracking, incl. daily, monthly checks and system audits
- Any outside vendors, e.g. contract pharmacies
- **MATERIAL BREACH:** Must be defined by entity; if reached, must notify HRSA



# HRSA AUDIT PROCESS



COMPLIANCE

- Pre-audit data request
  - P&P manual
  - 340B drugs orders/prescriptions
  - List of providers authorized
  - Current 340B inventory
  - Listing of contract pharmacies
- On-site audit, including chart review

# CASE STUDY

- Simon is a patient at health department A, which qualifies for 340B with 318 STD funds. He tests positive for chlamydia and needs azithromycin. Health department A does not have azithromycin in its 318 340B inventory.
  - Can health department A pull azithromycin from its Ryan White inventory and give it to Simon?
  - Can health department A call another 340B entity and request azithromycin 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 an audit, 10 charts for Medicaid patients in a 100 record chart review indicate those patients were dispensed 340B-priced drugs. What actions should the entity take?



# THANK YOU



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