



2024 NFPRHA
NATIONAL
CONFERENCE

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340B and Family Planning

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*I have no conflicts of interest to disclose.

TRAINING ROADMAP

- Expectations & Burning Questions
- Provider and Patient Eligibility
- Congressional Activity and Advocacy
- BREAK
- Interaction with Medicaid
- Compliance considerations

The 4-1-1 on 340B

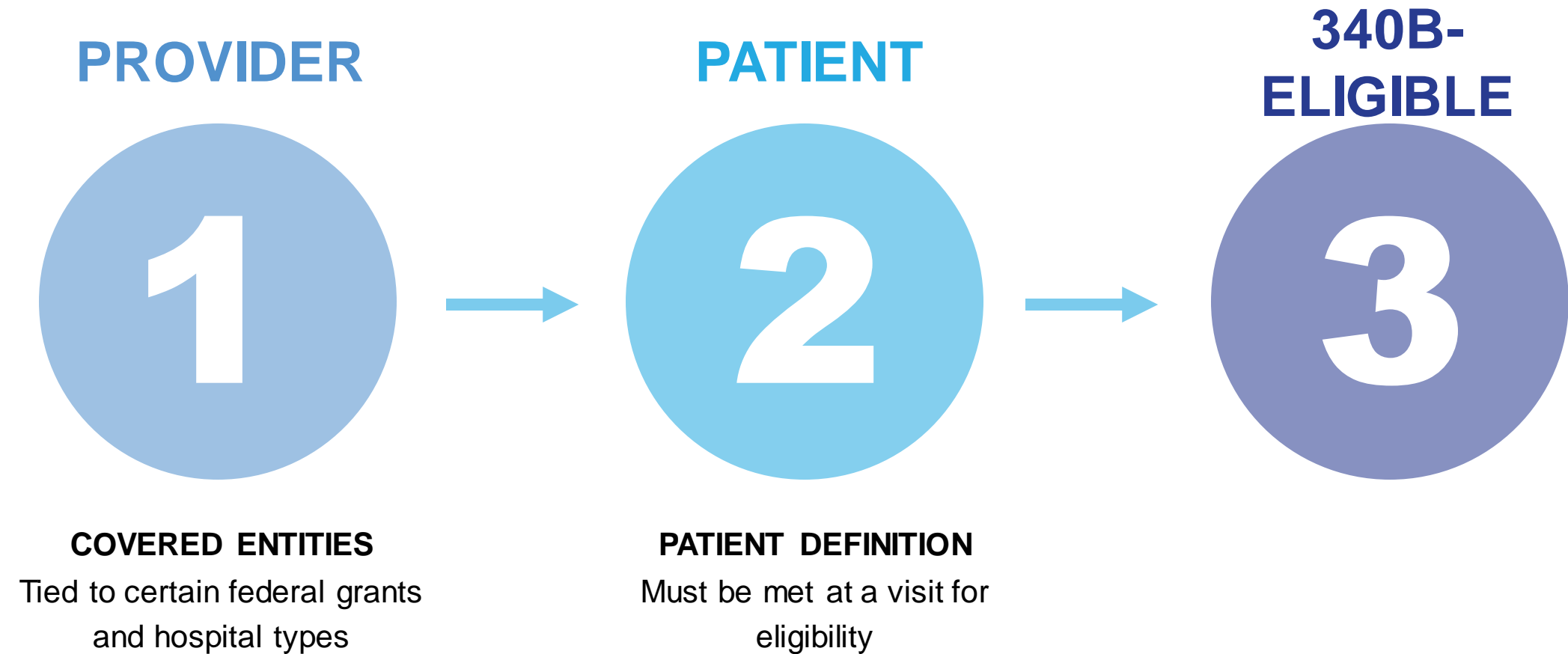
ENACTMENT Passed as part of Veteran's Health Care Act of 1992 to provide discounts on outpatient drugs to certain provider entities

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 providers (three women and one man) 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.

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.

OR

- Be a certain type of hospital (DSH, Children's, Free-standing Cancer, RRC, CAH, SCH)

Welcome to 340B OPAIS

REGISTRATION

What would you like to do?



Search



Reports/Files



I am a Participant

- Four annual registration periods (1st 15 days of each calendar quarter)
- 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

PARENT CHILD REGISTRATION

- Some entity types are permitted to register with parent-child designation (hospitals, FQHCs)
- Inventory may be transferred between the parent-child or child-child
- This type of registration is not currently permitted for Title X, STD, or other non-FQHC grantee entities





CONTRACT PHARMACY

- A 340B CE may engage in arrangements with retail pharmacies to dispense 340B drugs to the CE's patients
- Must audit at least annually
- CE responsible for compliance
- Target of manufacturers

RECERTIFICATION



- Must recertify annually during the designated time
- Authorizing official contacted by email
- Failure to recertify will result in termination from the 340B program
- 2024 Title X and STD recertification is 5/6-6/3



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 (except Medicaid)
- If patient definition is met, ANY drug prescribed at that visit can be 340B-priced
- Because of 3rd 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)
- Most OTC products and vaccines are not 340B-eligible

ELIGIBILITY FAQs

- How to register when you receive multiple funding streams
- Issues when one organization owns and operates multiple health centers
- STI 340B CEs and prescribing contraceptives
- Registering mobile health units

A photograph of two people, a woman with long brown hair and a person with short blonde hair, looking down at a book together. The image is overlaid with a semi-transparent blue filter. The title text is centered over the woman's face.

CONGRESSIONAL ACTIVITY AND ADVOCACY

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GROWTH IN ADVOCACY

- Some national partners have ramped up efforts to seek 340B legislation
- NACHC formed formal partnership with PhRMA called ASAP 340B
- 340B Health advocating for contract pharmacy legislation



CONGRESSIONAL INTEREST



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- Some members of Congress have long wanted to make changes to 340B, particularly with respect to hospital eligibility and an increase in transparency/reporting
- Senate “Gang of Six” proposing SUSTAIN 340B Act
- Success in this Congress remains uncertain

BREAK

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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

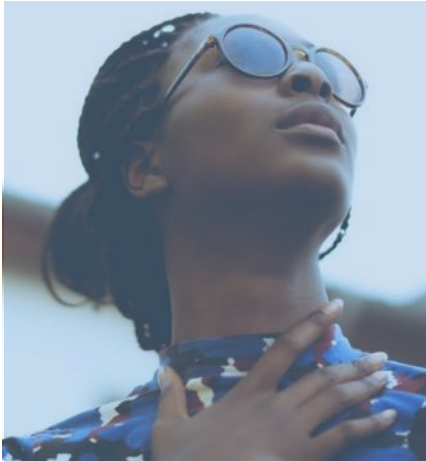


FEDERAL RULES

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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

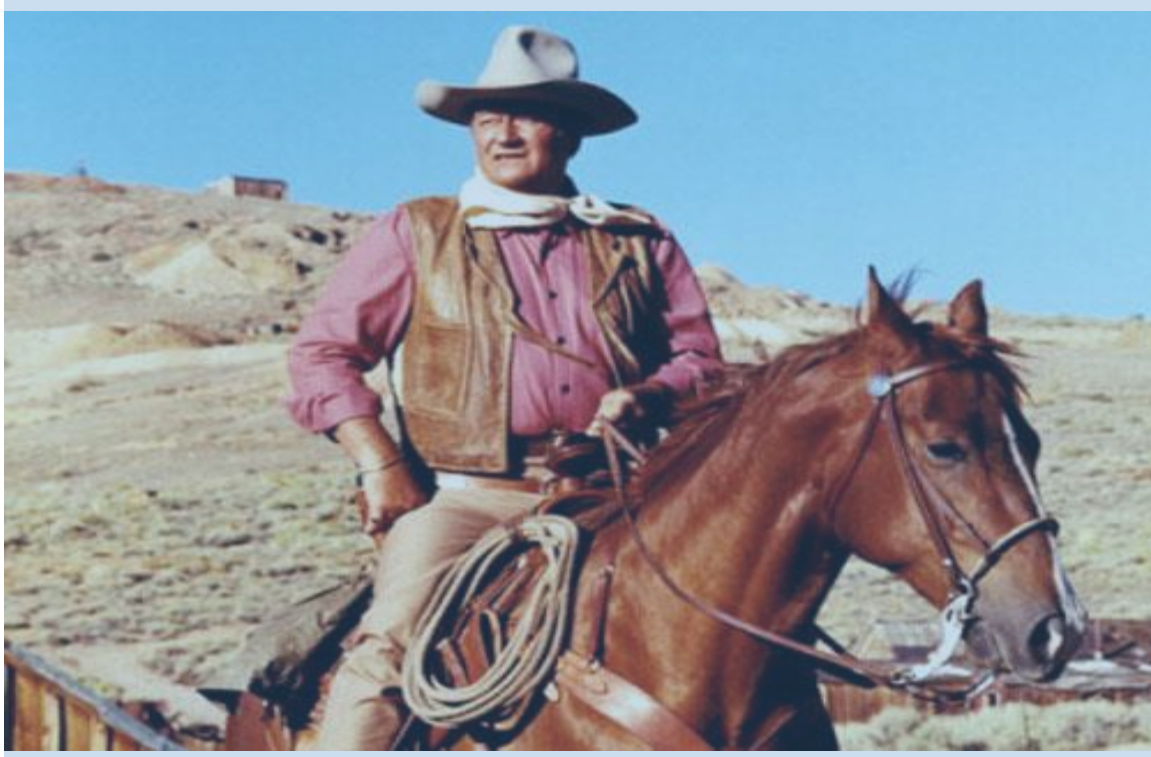




STATE RULES

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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

COMMON STATE POLICIES

- Requiring specific modifiers on claims that included 340B drugs
 - Usually UD modifier for 340B drugs billed for on a medical claim
- Requiring billing at actual acquisition cost (AAC) or exact invoice price
- Restricting use of contract pharmacies for Medicaid patients
- Not sure what your state's policies are—start here:
<https://www.340bpvp.com/resource-center/medicaid>

MEDICAID FAQs

- Ability to only purchase higher price products with 340B
- If you are carved in, can you bill Medicaid for medications that are not 340B-eligible
- Reimbursement and billing for MCOs

A photograph of three healthcare professionals, two men and one woman, seen from behind. They are wearing light blue scrubs and are hugging each other in a hallway. 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.

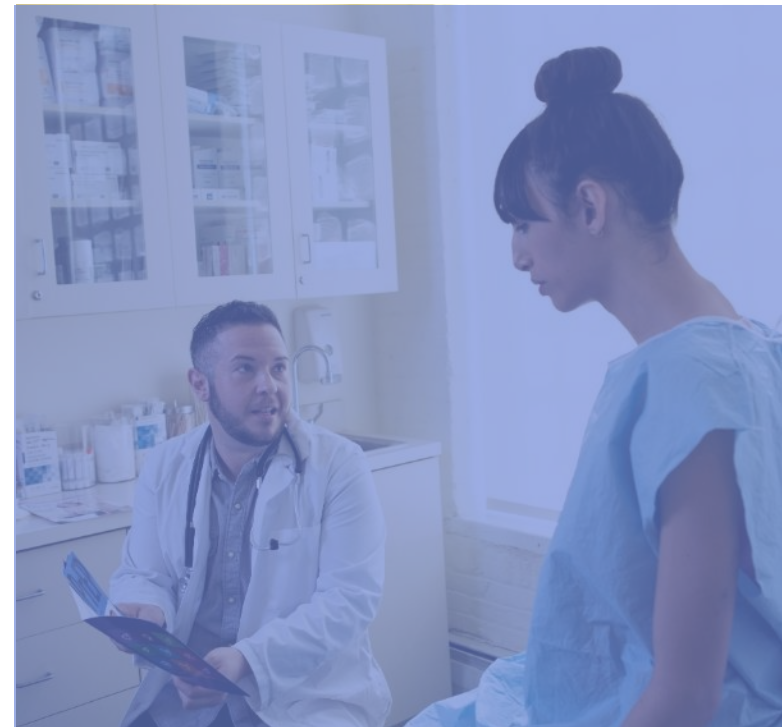
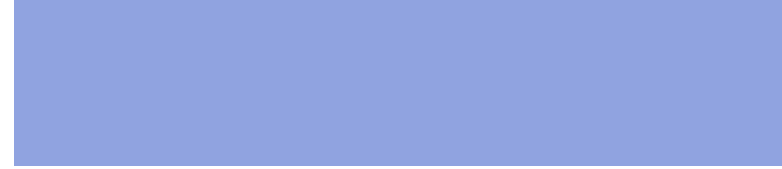
COMPLIANCE

IT'S A TEAM EFFORT

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DIVERSION

- Dispensing a 340B drug to someone that doesn't meet the 340B patient definition
- Transferring 340B drugs from 340B ID/CE to another (unless parent-child OR HRSA-approved combined purchasing arrangement)
- 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
- Tool available to help with requesting permission
 - <https://www.340bpvp.com/education/340b-tools/> (Under grantees, operational/purchasing)

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

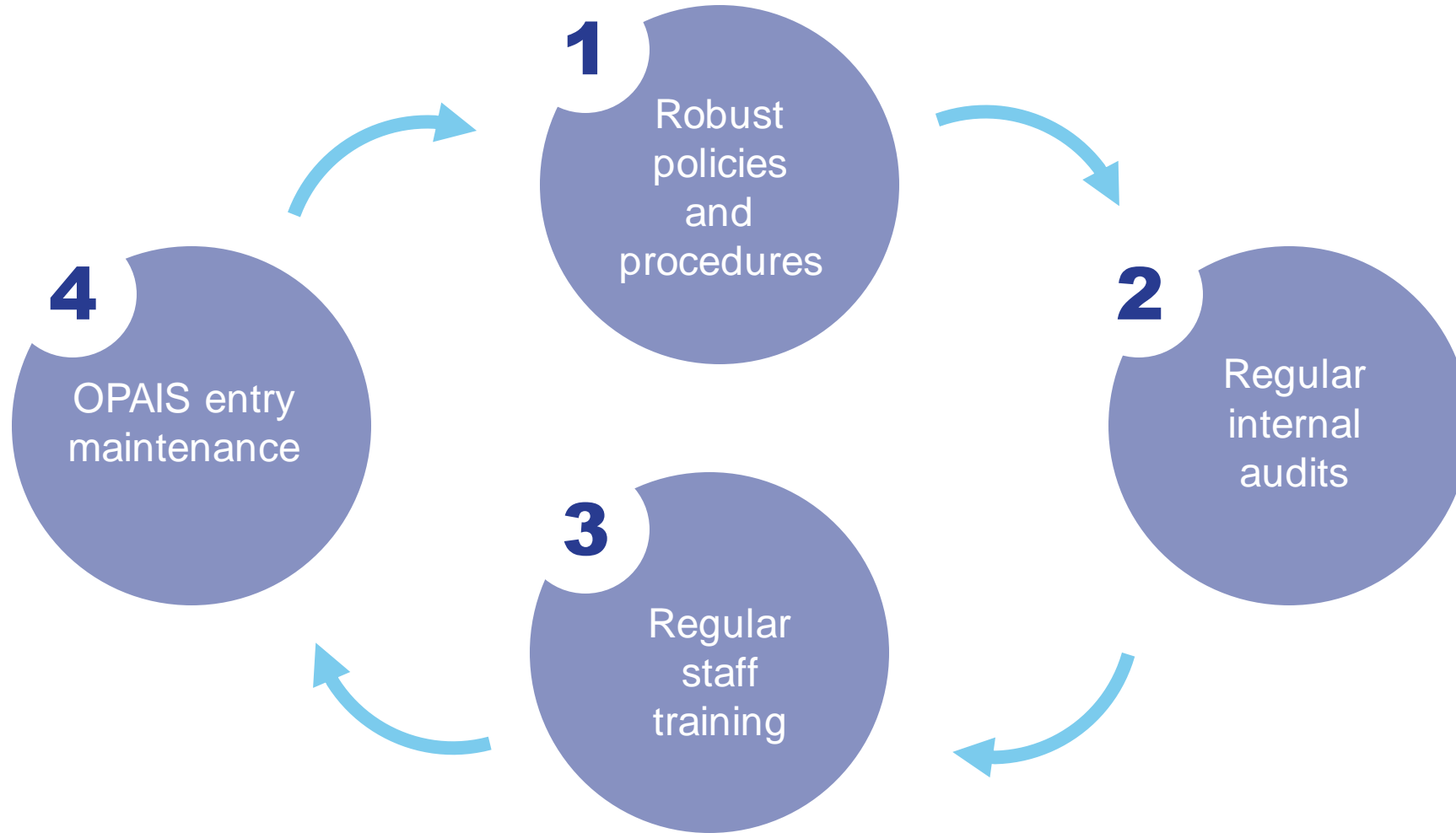
- If a patient meets the 340B patient definition at a visit and tests positive for an STD, you may use 340B drugs for EPT (in states that permit it).
- The rationale is that EPT is actually a treatment for your patient, because it is preventing reinfection.
- Should be reflected in your 340B policies 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

THANK YOU



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