

340B Expert Panel and Live Q&A

Mindy McGrath | February 8, 2024



New York State
Family Planning
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Recap of 340B Webinar



Eligibility: Two-step Process

PROVIDER



PATIENT



**340B-
ELIGIBLE**



COVERED ENTITIES

Tied to certain federal grants
and hospital types

PATIENT DEFINITION

Must be met at a visit for
eligibility

Eligibility Requirements: Providers

- Receive funds from one of the designated grants, including Title X, CDC 318 STD program, Ryan White, FQHC 330 grants (+FQHC look-alikes), etc.
 - Organizations with multiple qualifying funding streams are not required to register under each one.
- Be a type of hospital (disproportionate share, children's, free-standing cancer, rural referral centers, critical access, or sole community hospital)

Patient Definition

- Established relationship between the patient and the 340B covered entity (usually documented in a medical record)
- 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)
- Patient receives health care service(s) consistent with the grant through which the covered entity gained 340B eligibility (only applies to non-hospital entities)

Medicaid and 340B



Carve In or Carve Out

- Carve in=ALL drugs dispensed to fee-for-service (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

New York State Rules

- As of April 1, 2023, transition of most Medicaid outpatient drug claims from managed care to FFS Medicaid NYRx
 - INCLUDED: Covered outpatient drugs (340B-priced and non-340B-priced) and other products covered under the Medicaid Pharmacy Program, including prescription and over-the-counter drugs, diabetic and incontinence supplies.
 - NOT INCLUDED: Physician-administered (J-code) drugs
 - Resource: [FAQ on Transition of the Pharmacy Benefit from Medicaid Managed Care to new Medicaid NYRx program, July 26, 2023](#)



Compliance



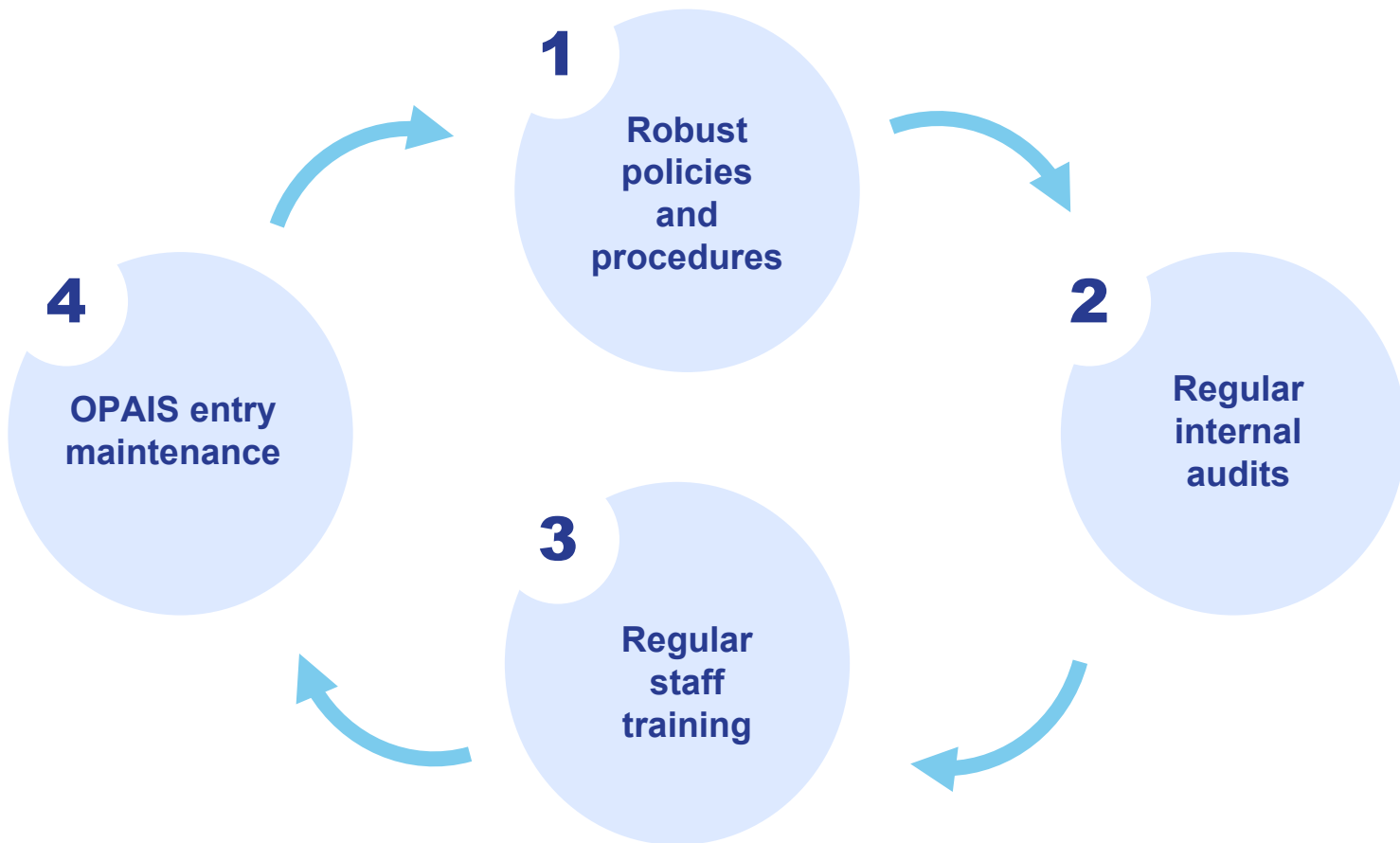
Diversion

- 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

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



Q&A and Discussion





Resources

- **Collection of 340B tools from Apexus:**
<https://www.340bpvp.com/resource-center/340b-tools>
- **Sample HRSA Audit Data Request:**
<https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf>
- **340B Medicaid policies by state resource:**
<https://www.340bpvp.com/resource-center/medicaid>
- **HRSA OPAIS (340B database):**
<https://340bopais.hrsa.gov/home>
- **HHS Office of Pharmacy Affairs website:**
<https://www.hrsa.gov/opa>

Thank you!

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