

The 340B Drug Pricing Program for Family Planning Providers in New York State

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January 24, 2024

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TRAINING ROADMAP

- Provider and Patient Eligibility
- 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

PROVIDER



COVERED ENTITIES

Tied to certain federal grants
and hospital types



PATIENT



PATIENT DEFINITION

Must be met at a visit for
eligibility



340B-ELIGIBLE





PROVIDER ELIGIBILITY

QUALIFYING AS A 340B COVERED ENTITY

National
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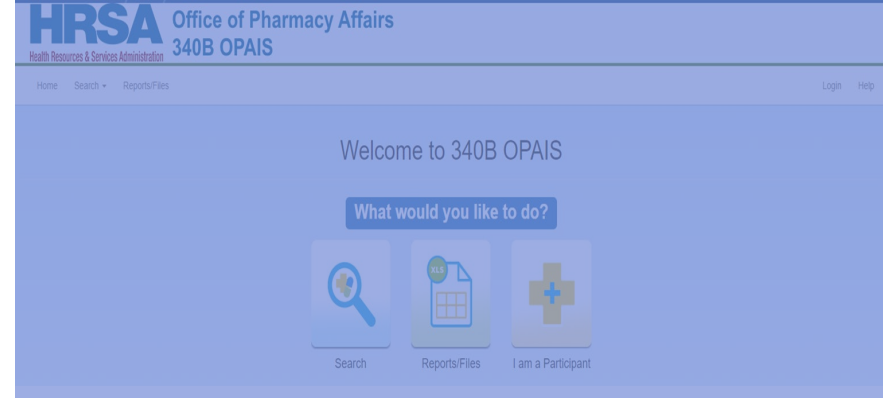


ELIGIBILITY REQUIREMENTS

- Receive funds from one of the designated grants: Title X, CDC 318, Ryan White, FQHC 330 grants (+ FQHC look-alikes), etc.*
- Be a certain type of hospital (DSH, Children's, Free-standing Cancer, RRC, CAH, SCH)
 - Must be public or private nonprofit AND formally granted gov't powers by state or local gov't OR under contract with state or local gov't to provide services to low-income individuals
 - Some hospital types also need to meet designated Medicare disproportionate share percentages

* Some hospitals can also qualify (DSH, children's, free-standing cancer, RRC, CAH, and sole community hospitals).

REGISTRATION



- Four annual registration periods (1st 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 contacted by email
- Failure to recertify will result in termination from the 340B program

REGISTRATION CONSIDERATIONS

- Entities with multiple qualifying funding streams
 - Not required to register under all funding streams
 - Decision should be made based on patient populations (more on that in a moment), compliance complexity, etc.



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)



ELIGIBILITY CONSIDERATIONS

- 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



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



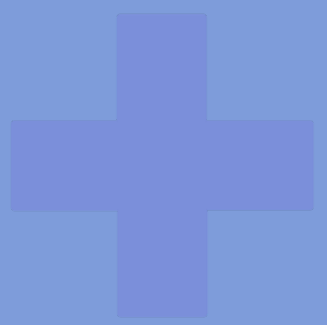
MEDICAID AND 340B

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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



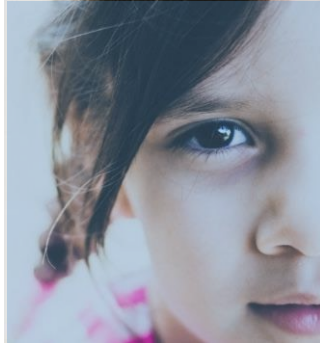
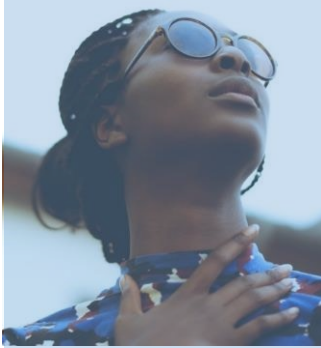


FEDERAL RULES

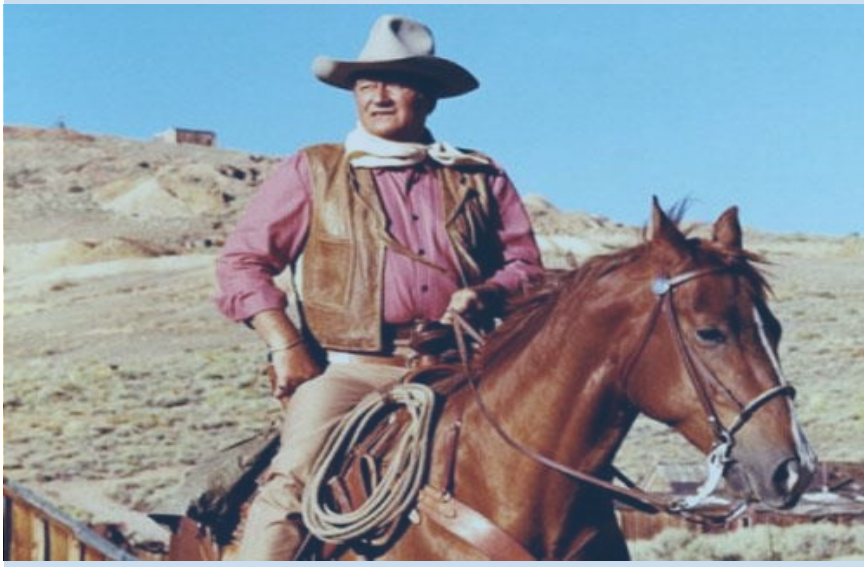
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CARVE IN or CARVE OUT

- 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



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

NEW YORK STATE RULES

The background is a solid blue color. On the right side, there are two large, overlapping, curved shapes that resemble the top half of circles or arcs. The outer arc is a darker shade of blue, and the inner arc is a lighter shade, creating a layered effect.



Department
of Health

Medicaid NYRx

- 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

SPECIFIC 340B BILLING PROCEDURES

- Carve in/carve out decision remains at the discretion of the covered entity
- Must bill Medicaid invoice price for 340B-priced medications
- If carved-in, must apply a UD modifier for all drugs billed to Medicaid on a medical claim form (837P)
- If carved-out, must include the NDC on claim form
- RESOURCE: [Medicaid Update \(June 2023, Volume 39, Number 11\), 340B Claim Reminder for Covered Entities and Contract Pharmacies](#)

CLINIC BILLING FOR CONTRACEPTIVES

ORAL CONTRACEPTIVE (OC)

1 CLAIM

APG CLAIM

Use **S4993** for OC (includes
Emergency Contraceptives
Plan B & Ella)

Not covered as a "stand-alone" Must be accompanied
by another service, e.g.,
evaluation and management
visit

OTHER CONTRACEPTIVE METHODS

1 CLAIM

APG CLAIM

Vaginal Ring - **J7303**
Patch - **J7304**
Depo-Provera Injection*
J1050

IMPLANT

2 CLAIMS

APG CLAIM

Insertion - **11981**
Removal - **11982**
Removal with reinsertion **11983**

ORDERED AMBULATORY CLAIM

Device - use **J7307**
Report acquisition cost by
invoice on the claim

NY BILLING GUIDANCE (CONT'D)

IUD 2 CLAIMS

APG CLAIM

Insertion - **58300**
Removal - **58301**

ORDERED AMBULATORY CLAIM

Device - use **J7296 (KYLEENA)**, **J7297 (LILETTA)**, or **J7298 (MIRENA)**, **J7300 (PARAGARD)**, **J7301 (SKYLA)**

Report acquisition cost by invoice on the claim

Contraceptive Ring 2 CLAIMS

APG CLAIM

Applicable medical visit code

ORDERED AMBULATORY CLAIM

Device - use **J7294** or **J7295**

Report acquisition cost by invoice on the claim

OVER-THE-COUNTER CONTRACEPTIVE

Emergency
Contraceptives

No Fiscal Order
Required

Females only

Male
Condoms

Fiscal Order
Required

Males and
Females

Female
Condoms

Fiscal Order
Required

Males and
Females

A photograph of three healthcare professionals, two women and one man, 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, bold, sans-serif capital letters across the center of the image.

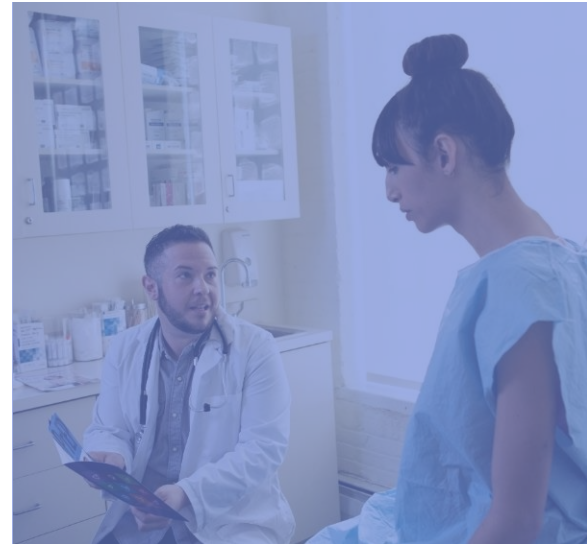
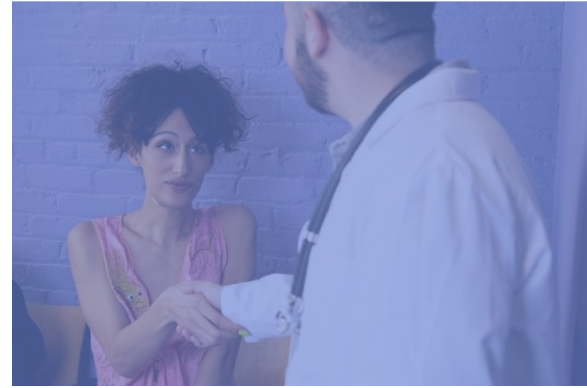
COMPLIANCE

National
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IT'S A TEAM EFFORT

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)

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 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



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

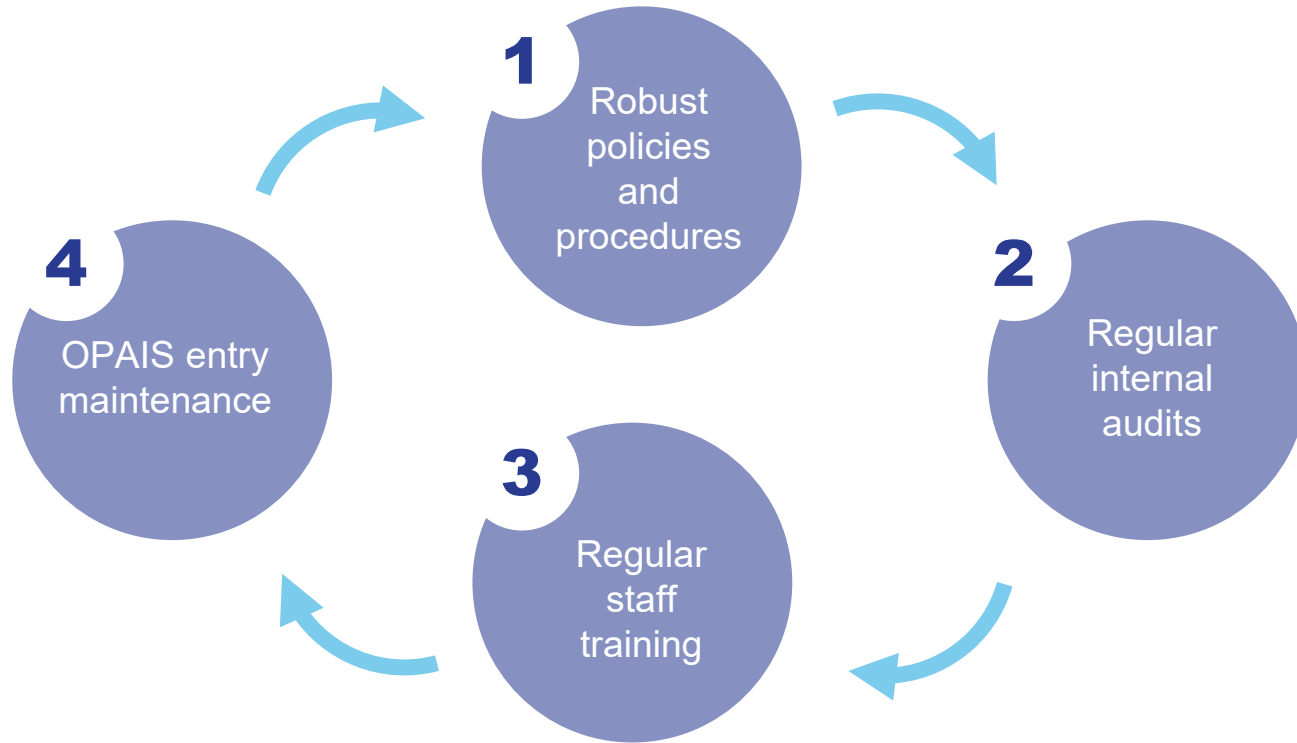
- If a patient meets the 340B patient definition at a visit and tests positive for an STD, you may use 340B drugs for EPT (in states that permit it).
- The rationale is that EPT is actually a treatment for your patient, because it is preventing reinfection.
- Should be reflected in your 340B policies 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
- In NY State, also must follow 340B claims guidance on slide 22

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

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>

Upcoming 340B Expert Panel



February 8, 12:00-1:00 pm

340B Expert Panel and Live Q&A for New York State Family Planning Programs

Looking for more guidance on the 340B Drug Pricing Program? Join us for this expert panel session as a follow-up to today's webinar.

Thank you!

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Contact | nysfptraining.org

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