



340B for Beginners

The Power Behind the Program



Speakers



Danielle Mathers, 340B ACE
Senior Vice President, 340B
NPS Pharmacy



Kristin Andolfo, CPhT, 340B ACE
Senior Consultant, 340B
Ponaman Healthcare Consulting



Kevin Coffman, 340B ACE
National Sales Manager
Community Health Centers
Team
Cardinal Health



Objectives

- Understand the purpose and background of the 340B Program
- Learn who qualifies as a covered entity, and which patients and drugs are eligible
- Become familiar with key 340B acronyms and systems
- Understand the connections between 340B and HIV programs like Ryan White and ADAP

Decoding Key Acronyms & Tools

HRSA:

The Health Resources & Services Administration — administers the 340B Program

OPA:

Office of Pharmacy Affairs — a division within HRSA overseeing the 340B Program

OPAIS:

Office of Pharmacy Affairs Information System — where covered entities register and are listed publicly

340B PROGRAM OVERVIEW

When did it originate?

- **Government mandated** drug pricing program
- Established by Congress in **1992** (via Section 340B of the Public Health Service Act)
- Manufacturers **initiate 340B discounts** as a condition to participate in the federal Medicaid program
- The 340B drug discount program is **not federally funded**; it is funded by drug manufacturer discounts
- Program expansion allowed covered entities to contract with multiple community pharmacies in **2010**

How does it work?

- Manufacturers provide **25-50%** discounts on OP drugs to covered entities
- **Both insured and uninsured patients are eligible**
- Covered entities use savings from program at their discretion (i.e. reduce price of pharmaceuticals for patients, expand services and staff)
- Covered entity may contract with multiple community pharmacies to expand program and increase patient access to discounted drugs

DEFINITION

A **340B covered drug** is an **outpatient medication** that qualifies for discounted pricing under the **340B Drug Pricing Program** and meets the following criteria:

- **FDA-approved** prescription drug, biologic, or insulin
- Covered under **Section 1927(k) of the Social Security Act** Purchased by a **registered covered entity for outpatient use only**
- **Not subject to exclusion**, such as inpatient drugs, certain free samples, or drugs billed to Medicaid without proper carve-in procedures



- **HRSA's official 340B Prime Vendor**, offering support, education, and tools to covered entities.
- Provides **discounted pricing beyond 340B** through the Prime Vendor Program (PVP).
- Serves as a key resource for **compliance guidance, training, and policy clarification**.

COVERED ENTITY TYPES

Covered entities include non-profit healthcare organizations that receive funding from Federal programs or have certain Federal designations.

Federal Grantees

- Consolidated Health Centers (CH)
- Federally Qualified Health Centers (FQHCs) and (FQHCLAs)
- Sexually Transmitted Disease (STD) / Black Lung (BLCP) / Tuberculosis (TB) Clinics
- Healthcare for the Homeless, School Based Clinics and Migrant Health
- Family Planning Centers

Special Populations

- Urban Indian, Native Alaskan, Native Hawaiian

Ryan White/HIV

- Ryan White HIV/AIDS Program

Non-Grantees

- Disproportionate Share Hospitals (DSH)
- Critical Access Hospitals (CAH)
- Children's Hospitals (PED)
- Rural Referral Centers (RRC)

OPAIS REGISTRATION

OFFICE OF PHARMACY AFFAIRS INFORMATION SYSTEM (OPAIS)



OPAIS Registration

- Grantees register quarterly
 - (Jan, Apr, Jul, Oct)
- Must designate:
 - Authorizing Official (e.g., CEO)
 - Primary Contact (e.g., 340B Manager)



Annual Recertification

- Confirm accuracy of CE information, grant details, CP's

PROGRAM ADMINISTRATION AND OVERSIGHT



Health Resources and Services Administration (HRSA)/Office of Pharmacy Affairs (OPA) – Health and Human Services (HHS)

340B players in the market

Govern
program

Manage
database

Conduct
audits

Covered entities are those health care organizations eligible to participate in the 340B program.



Participating manufacturers
sell to covered entities at or below the ceiling price if they want their drugs to be covered by Medicaid



In-house pharmacies
are owned by covered entities and may or may not be in the same physical space as the medical sites



Contract pharmacies
that may contract with a covered entity to dispense 340B drugs to the entity's patients



The prime vendor
contracted by HRSA to provide training and technical assistance, and can negotiate sub-ceiling pricing



Wholesale distributors
purchase from the manufacturer and sell to entity



340B PATIENT ELIGIBILITY

THREE criteria to be considered a patient

- 1.** CE has established a relationship with the individual, which includes maintaining records of the individual's health care.
- 2.** The individual receives health care services from a health care professional who is either employed by the CE or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the individual's care remains with the CE.
- 3.** The individual receives a health care service or range of services for which grant funding has been provided



340B ELIGIBILITY CONTINUED



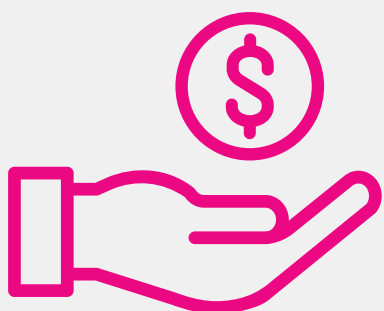
Provider Eligibility

Employed, contracted or referred providers where CE retains care responsibility.



Drug Eligibility

All drugs prescribed during an eligible encounter are 340B-eligible.



Payor Eligibility

340B drugs may be dispensed to all CE QUALIFYING patients

- EXCEPTION: FEE-FOR-SERVICE MEDICAID

MEDICAID AND 340B- KEY TERMS

DUPLICATE DISCOUNT:

Duplicate Discount Prohibition — Under federal law, drug manufacturers are not required to provide both a 340B discount and a Medicaid drug rebate for the same drug.

FFS:

Fee-For-Service Medicaid — the portion of the Medicaid program subject to duplicate discount protections under 340B

MEF:

Medicaid Exclusion File — used to identify entities that have opted to carve in Medicaid billing to avoid duplicate discounts

MCO:

Medicaid Managed Care Organizations — are private plans that administer Medicaid benefits and vary by state

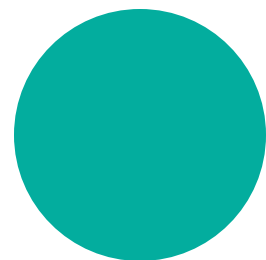
CARVE-IN/CARVE-OUT

CARVE-IN

- Carve-in = **using 340B drugs for Medicaid FFS patients**
- Must be listed on HRSA's Medicaid Exclusion File (MEF)
- Prevents duplicate discounts (340B + Medicaid rebate)
- Applies to FFS only — MCOs follow state-specific rules
- Must have clear, documented carve-in policy

CARVE-OUT

- Carve-out = **do not use 340B drugs for Medicaid FFS patients**
- MCOs follow state-specific rules
- Requires a clear policy and internal controls to enforce
- Contract pharmacies are required to carve-out FFS unless granted permission from



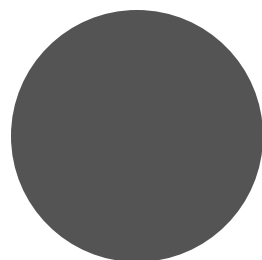
340B Contract Pharmacy

Enables covered entities without in-house pharmacies to still provide 340B drugs

Operates under a **formal, written agreement** with the covered entity (*Contract Pharmacy Services Agreement*)

Covered entity remains **fully responsible** for compliance, tracking, and preventing duplicate discounts

Used to **expand access** and improve convenience for patients



EDUCATIONAL RESOURCES

HRSA OPA

<https://340bopais.hrsa.gov/home>

Apexus

<https://www.340bpvp.com>

340B University

Live and On Demand
<https://www.apexus.com>

**National
Association
Community Health
Centers (NACHC)**

<http://www.nachc.org>

RWC 340B

<https://rwc340B.org>

Industry partners

All of the presenters
today
reach out!



Q&A + Key Takeaways



Danielle Mathers, 340B ACE
Senior Vice President, 340B
NPS Pharmacy
dmathers@npspharmacy.com
410-562-3806



Kristin Andolfo, CPhT, 340B ACE
Senior Consultant, 340B
Ponaman Healthcare Consulting
kristina@ponamanhc.com



Kevin Coffman, 340B ACE
National Sales Manager
Community Health Centers Team
Cardinal Health
kevin.coffman@cardinalhealth.com
720-219-8273

THANK YOU