



340B DRUG PRICING PROGRAM

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INTRODUCTION

The 340B Drug Pricing Program is a U.S. Federal government program that requires manufacturers to provide outpatient drugs at significantly reduced prices to underserved or vulnerable populations.

Objectives

- Background/intent of the program
- The process/eligible entities
- Current issues

340B PROGRAM

- Established in 1992 as part of the Public Health Service Act (PHSA)
- Administered by the **Health Resources and Services Administration (HRSA)** of the Department of Health and Human Services (HHS)

<http://www.hrsa.gov/opa/>

INTENT OF THE PROGRAM

- *Stretch* **scarce federal resources**
- *Reach* **more eligible patients**
- *Provide* **more comprehensive services**

THE PROCESS

MANUFACTURERS

COVERED ENTITIES

CONTRACT PHARMACIES

ELIGIBLE PATIENTS

MANUFACTURERS

- Participation *required* as a condition for Medicaid reimbursement
- 20-50% discounts to covered health care organizations for certain outpatient drugs

ELIGIBLE DRUGS

- Limited to **outpatient** use only
- Includes:
 - ❑ FDA-approved prescription drugs
 - ❑ Over-the-counter (OTC) drugs
 - Must be written on a prescription
 - ❑ Biological products that can be dispensed only by a prescription (other than vaccines)
 - ❑ FDA-approved insulin

THE PROCESS

MANUFACTURERS

COVERED ENTITIES

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ELIGIBLE PATIENTS

COVERED ENTITIES

- Nonprofit health care organizations including clinics that receive Federal grants or certain types of hospitals

Federal Grantees

- Federally Qualified Health Centers/Look-Alikes
- Native Hawaiian Health Centers
- Tribal/Urban Indian Health Centers
- Ryan White HIV/AIDS Program
- Black Lung Clinics
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Title X Family Planning Clinics
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics

COVERED ENTITIES

- Eligible hospitals, with the exception of CAHs, must meet a minimum disproportionate share adjustment percentage

$$\frac{\text{Medicare/Supplemental Security Income Days} + \text{Medicaid, Non-Medicare Days}}{\text{Total Medicare Days} + \text{Total Patient Days}}$$

Hospitals

- Disproportionate Share Hospitals
- Children's Hospitals
- Critical Access Hospitals
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals

COVERED ENTITIES

➤ Offsite facilities and clinics (child sites)

❑ Must be registered

❑ Eligibility based on most recently filed

Medicare cost report demonstrating:

1) Each facility or clinic listed on a line of the cost report that is reimbursable under Medicare

2) Services provided have associated outpatient Medicare costs and charges

COVERED ENTITIES

➤ Requirements:

1. Keep 340B database information accurate and up to date
 - Register outpatient facilities and contract pharmacy
2. Recertify eligibility each year
- 3. Prevent duplicate discounts**
 - Cannot obtain discounted price and bill Medicare/Medicaid
4. Prevent diversion to ineligible patients
5. Maintain auditable records documenting compliance with 340B requirements

THE PROCESS

MANUFACTURERS

COVERED ENTITIES

CONTRACT PHARMACIES

ELIGIBLE PATIENTS

CONTRACT PHARMACIES

- Covered entities have the option to contract pharmacies to dispense 340B drugs to their patients
 - ❑ Register each contract pharmacy
 - ❑ Ensure compliance with 340B requirements to prevent diversion and duplicate discounts

- Covered entities purchase the discounted drugs and maintain ownership at all times

THE PROCESS

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ELIGIBLE PATIENTS

ELIGIBLE PATIENTS

➤ Requirements:

1. **Relationship with a covered entity**, such that the covered entity maintains record of the individual's health care
2. **Receive health care services** from a provider who is either employed by or under contract with the covered entity
3. Receive health care services from a covered entity **consistent** with the services for which Federal funding has been provided

ELIGIBLE PATIENTS

- The intent of the 340B program is to...
provide more comprehensive services
- An individual is **NOT** considered eligible if the only health care service received by the covered entity is the dispensing of drugs

CURRENT ISSUES

- *Are covered entities truly serving a large population of low-income patients?*
- Example: Duke University Hospital, 2012
 - ❑ Only 5% of patient population uninsured
 - ❑ 67% of patients had commercial insurance
- Use of a disproportionate share percentage to determine eligibility **does not accurately reflect the share of provided uncompensated care**

CURRENT ISSUES

- *Are covered entities taking advantage of the program for financial gain?*
- Example: Duke University Hospital, 2012
 - ❑ Purchased \$65.8 million in drugs through the 340B program, saved \$48.3 million
 - ❑ Provided drugs to patients for \$135.5 million
 - \$69.7 million in profits

CURRENT ISSUES

- Covered entities are not prohibited from providing 340B drugs to individuals with private insurance,
- By billing 340B drugs to insured patients, covered entities are gaining the difference between what the insurance reimbursed and what they paid
- **Reinvest “profit” into providing more services to more underserved patients**
- Lack of oversight has raised suspicion as to whether or not profits are truly used in good faith

OMNIBUS GUIDANCE

- “Mega-guidance” for the 340B program as an attempt to clarify who is eligible to participate
- Draft released August 28, 2015
- New patient eligibility requirements, increased from three to six conditions

OMNIBUS GUIDANCE

➤ Patient eligibility

1. Receive a health care service at a 340B registered facility
2. Service must be provided by a provider who is employed by the covered entity or who is an independent contractor for the covered entity
 - Privileges or credentials at a covered entity not sufficient
3. Drug is prescribed by covered entity provider as a result of the service received

OMNIBUS GUIDANCE

➤ Patient eligibility, cont.

4. Health care provided must be consistent with scope of Federal grant, project, designation, or contract
5. Drug prescribed pursuant to a health care service that is classified as outpatient
6. Patient records must be accessible to the covered entity and demonstrate the covered entity is responsible for care

SUMMARY

- The 340B program has been successful in providing and expanding care for patients in need
- With the new guidance, HRSA provides a clearer definition of patient eligibility for 340B
- However, covered entity eligibility should be addressed to ensure that resources are being provided to the financially disadvantaged population that the program is intended to serve

REFERENCES

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THANK YOU

