




## Legislation Expands Access to Section 340B Drug Pricing Program

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## Objectives

- Review 340B Program basics
- Discuss eligibility criteria
- Describe the enrollment process
- Outline 340B Program restrictions
- Discuss contracting with external pharmacies



## Section 340B Drug Pricing Program

- Federally mandated drug pricing program
- Intended to provide financial relief to those facilities that provide care to the medically underserved
- Medicaid Rebate Program (created 1990)
  - Drug companies must enter into a rebate agreement with HHS
  - Must pay a rebate to Medicaid based in part on the manufacturer's "best price"



## Section 340B Drug Pricing Program

- Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992:
  - Section 340B of the Public Health Service Act (42 U.S.C. § 256b) (PHSA),
  - Section 1927(a) of the Social Security Act (SSA)
- Interpretive Guidelines



## Section 340B Drug Pricing Program

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- **Pharmaceutical Pricing Agreement (PPA):** manufacturers participating in Medicaid must agree to comply with the requirements of Section 340B.
- Must provide front-end discounts on covered outpatient drugs purchased by specified government-supported facilities, called "covered entities," that serve the nation's most vulnerable patients.
- Manufacturers cannot sell covered drugs to a covered entity at a price greater than a statutory ceiling price.

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## 340B Ceiling Price

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- Maximum price that manufacturers can charge 340B covered for any covered outpatient drug.
- 340B discounted price is based on the Medicaid rebate formula, but the discount is built into the manufacturer's or wholesaler's selling price rather than paid as a post-purchase rebate.
- For brand name drugs, the 340B ceiling price is the lower of (a) the manufacturer's "best price" or (b) 15.1 percent off of the drug's average manufacturer price (AMP).

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## 340B Ceiling Price

- Brand name manufacturers must provide an additional discount on a covered outpatient drug if the price of the drug has increased faster than the rate of inflation
- For generic and over-the-counter drugs, the 340B ceiling price is 11 percent off of the drug's Average Manufacturer's Price (AMP)
- Covered entities are free to negotiate prices that are lower than the 340B ceiling price



## Prime Vendor Program

- Covered entities free to negotiate prices lower than 340B ceiling price
- Prime Vendor Program:
  - Intended to provide additional savings to 340B participants by helping covered entities negotiate discounts below the mandatory 340B ceiling price
  - Mission is to improve access to affordable medications for all 340B covered entities
  - Also provides access to other supportive services



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## Prime Vendor Program

- Currently managed by Apexus Inc.® through a contract awarded by HRSA
- Participation is free to all 340B covered entities, but the covered entity must enroll in the PVP

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## Potential Benefits of Participation

- Cost savings of 20%-50% on outpatient drug purchases
- Option to purchase outpatient drugs below 340B prices through participation in the 340B Prime Vendor Program (PVP)
- Option to negotiate reduced prices for inpatient drugs

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## Use of Discount

- 340B does not prescribe how the savings must be used or spent by the covered entity
- Savings as the result of the discount may be used to:
  - serve more patients
  - expand the hospital's formulary
  - expand available services
  - subsidize prescriptions for uninsured
  - any other purpose

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## 340B Program Administration

- Office of Pharmacy Affairs
- Located within the U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration's (HRSA)

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## Pharmacy Services Support Center

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- HRSA-funded federal contractor.
- Established in 2002 through a contract with HRSA to assist eligible safety-net providers optimize the value of the 340B Program.
- Non-profit organization based at the American Pharmacists Association (APhA).
- Provides program guidance and technical assistance to all 340B covered entities.

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## Eligible Entities

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- Section 340B(a)(4) of the PHSA and section 1927(a) of the SSA list the various types of organizations eligible to participate in and purchase discounted drugs under the 340B Program.
- Eligibility for participation in the 340B Program is strictly limited to the specific categories of entities specified in these statutes.

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## Previously Eligible Entities

- Prior to PPACA, eligible covered entities included (among others):
  - Federally qualified health centers (FQHCs), including FQHC-lookalikes
  - Ryan White/HIV clinics
  - Black lung clinics
  - Title X family planning clinics
  - State-operated AIDS drug assistance programs
  - Disproportionate share hospitals (with DSH > 11.75%)
  - Certain children's hospitals

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## Health Reform Legislation

- Patient Protection and Affordable Care Act (PPACA) (signed by President Obama on March 23, 2010); subsequently amended by the Health Care and Education Reconciliation Act of 2010 (signed by President Obama on March 30, 2010).
- Among other important changes, PPACA expands access to the Section 340B Drug Pricing Program (340B Program).

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## Newly Eligible Entities\*

- Critical access hospitals (CAHs)
- Freestanding cancer hospitals
- Rural referral centers
- Sole community hospitals
- Children's hospitals\*\*

\* Must meet statutory requirements

\*\* Were previously eligible, but PPACA provided clarification



## Eligibility Criteria

### **All newly eligible entities must be:**

- Owned or operated by a unit of State or local government, or
- Is a public or private non-profit corporation formally granted governmental powers by a unit of State or local government, or
- Is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under Medicare or Medicaid.



# Eligibility Criteria

Children's Hospitals	Free-Standing Cancer Hospitals	Critical Access Hospitals	Rural Referral Centers	Sole Community Hospitals
A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the SSA	---	A critical access hospital as determined under section 1820(c) of the SSA	A rural referral center as defined by section 1886(d)(5)(C)(i) of the SSA	A sole community hospital as defined by section 1886(d)(5)(C)(iii) of the SSA
PPS-excluded	PPS-excluded	---	---	---
DSH > 11.75%*	DSH > 11.75%*	---	DSH ≥ 8.0%*	DSH ≥ 8.0%*
Does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.	Does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.	---	---	---

\* for the most recent cost reporting period



# Government Contract

- Covered entity must obtain a certification signed by an appropriate state or local government official that the entity is under contract to provide health care services to low-income individuals who do not qualify for Medicare or Medicaid.
- Submit certification form to the OPA during the enrollment process.



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## Enrollment

- Eligible covered entities must notify the OPA of intent to participate in the 340B Program.
- The process and type of information that must be submitted differs based upon the type of entity seeking to participate.
- In order to allow sufficient time for verification and processing of registration information, covered entities must submit required information at least one month before the quarter during which the covered entity wishes to commence participation (prior to the first of December, March, June, or September).

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## Enrollment (cont)

- Once the OPA receives, verifies, and processes the registration information, the covered entity is eligible to purchase pharmaceuticals at the 340B price commencing at the start of the next calendar quarter (the first of January, April, July, or August).
- Each covered entity then determines how it will order and receive the discounted drugs.

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## Enrollment (cont)

- Refer to the PSSC Web site at <http://pssc.aphanet.org/about/registrationprocess.htm#health> for detailed registration information.
- PSSC has not yet identified the recommended registration form/process for free-standing cancer hospitals, CAHs, rural referral centers, or sole community hospitals.

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## Retroactive Benefits?

- Statutory changes effective January 1, 2010
- HHS established a mechanism for children's hospital to obtain retroactive benefits
- It is unclear whether a similar mechanism will be implemented for entities newly eligible under PPACA

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## Program Restrictions (for covered entities)

- Prohibition on resale / diversion
- Prohibition on duplicate discounts
- Prohibition on obtaining a 340B discount on a drug purchased through a group purchasing organizations (GPO) (does not apply to CAHs, Rural Referral Centers, or Sole Community Hospitals)

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## Prohibition on Resale

- Covered entities may not sell (or other transfer) medications purchased under the 340B Program to persons who are not considered “patients” of the covered entity.
- The term “patient” is not defined in Section 340B.
- HRSA published guideline regarding the definition of a patient in October 1996.

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## Definition of “Patients”

- Three Requirements:

- (1) The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
- (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and



## Definition of “Patients” (cont)

- Three Requirements:

- (3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.



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## Definition of “Patients”

- Does not exclude employees of the covered entity
- Includes patients seeking refills (The refill would be a continuation of responsibility for the health care services provided by the covered entity. The covered entity would document the initial prescription for treatment in the record of health care, and the “refill” would be part of the range of health care services provided.)

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## Definition of “Patients”

- An individual will not be considered a “patient” of the covered entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
- 2007 HRSA published Proposed Guidelines revising the definition of “patient.” (not finalized)

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## Prohibition on Duplicate Discounts

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- State Medicaid programs receive rebates on drugs purchased for Medicaid patients.
- Drugs purchased through the 340B Program may not be subject to both a 340B discount and a Medicaid rebate.
- Covered Entity is prohibited from requesting payment from Medicaid for a drug purchased with a 340B discount, if the drug also is subject to a Medicaid rebate.

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## Prohibition on Duplicate Discounts

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- Guidance from PSSC provides that the covered entity may bill Medicaid for 340B outpatient drugs used for Medicaid patients, but may only bill the 340B drugs at the acquisition price plus a dispensing fee established by the state Medicaid agency.
- PPACA requires the secretary of HHS to develop more detailed guidance describing the methods and options available to covered entities for billing state Medicaid agencies.

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## Covered and Excluded Drugs

- Covered:
  - Outpatient prescription drugs provided to patients of the covered entity
  - Over-the-counter drugs, if a prescriber writes a prescription for the drug.
- Excluded:
  - Vaccines and drugs given to the patient in inpatient care settings are excluded.
  - Orphan drugs (for newly eligible entities only)



## Expansion to Inpatient Drugs

- Potential expansion?



## In-House and Contract Pharmacies

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- Do not need an in-house pharmacy to participate in 340B
- Can use an in-house pharmacy and/or contract with one or more external retail or mail order pharmacies
- May use “ship to – bill to” process

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## Contract Pharmacies

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- Prior to April 5, 2010:
  - Covered Entities were limited to one pharmacy per site and covered entities could either operate an in-house pharmacy or contract with only one external pharmacy.
  - Covered entities seeking to use other types of pharmacy arrangements, or to implement both of the allowable methods of providing pharmacy services, were required to apply to OPA for an Alternative Method Demonstration Project (AMDP).

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## Contract Pharmacies

- After April 5, 2010:
  - March 5, 2010, the OPA published a Federal Register Notice (75 FR 10272) to finalize guidelines permitting a covered entity to use more than one pharmacy
  - New guidelines effective April 5, 2010 incorporate multiple pharmacies as a standard option for 340B-covered entities
  - May also contract with mail order pharmacies



## Contract Pharmacies

- No need to maintain separate inventories.
- Must provide the covered entity with financial statements, a detailed status report of collections, and a summary of receiving and dispensing records.
- Must work with the covered entity to establish and maintain a tracking system to prevent diversion.



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## Contracting

- Covered entity / contract pharmacy agreement
- Must include Essential Covered Entity Compliance Elements
- OPA will not review contracts and recommends that covered entities engage their legal counsel to review all contracts or other legal documents to ensure that all federal, state and local requirements are met

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## Contract Pharmacy Registration

- Submit to the Office of Pharmacy Affairs the *Contract Pharmacy Registration Form* and relevant addendum for each contract.
- Form signed by authorized individuals from the covered entity and the contract pharmacy.
- Review by legal counsel prior to submission

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## Anti-Kickback Statute Concerns

- Felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business.
- Civil and criminal penalties for violations (42 U.S.C. 1320a-7b(b)).
- May also risk exclusion from participation in federal programs.

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## Records and Audit

- Covered entities (and any contract pharmacy) must maintain accurate records documenting compliance with 340B Program requirements.
- Records maintained by the covered entity and any contract pharmacy pertaining to compliance with the 340B Program requirements are subject to audit by a participating manufacturer and/or the OPA to protect against diversion.

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## Penalties

- Prior to PPACA:
  - forfeiture of the discounts back to the manufacturer and/or
  - possible disqualification from the 340B Program
- PPACA directs the Secretary of HHS to implement new sanctions including:
  - repayment of discounts and applicable interest,
  - disqualification and prohibited re-entry
  - possible referral to OIG or other federal agencies for further review



## Next Steps

- Evaluate eligibility to participate
- Notify PSSC/OPA of intent to enroll
- Initiate financial and strategic planning
- Comply with all 340B Program requirements
- Maintain documentation
- Watch for final guidelines and resubmit information
- Send written requests to manufacturers



## Resources

- HRSA Pharmacy Services Support Center (PSSC):  
<http://pssc.aphanet.org>
- HRSA Office of Pharmacy Affairs:  
<http://www.hrsa.gov/opa/>
- 340B Prime Vendor Program:  
<https://www.340bpvp.com/public/>
- Legal Resources from HRSA:  
<http://www.hrsa.gov/opa/legalresources.htm>



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# Questions and Answers



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