

340B DRUG PRICING PROGRAM: 2016 EXPECTED UPDATES



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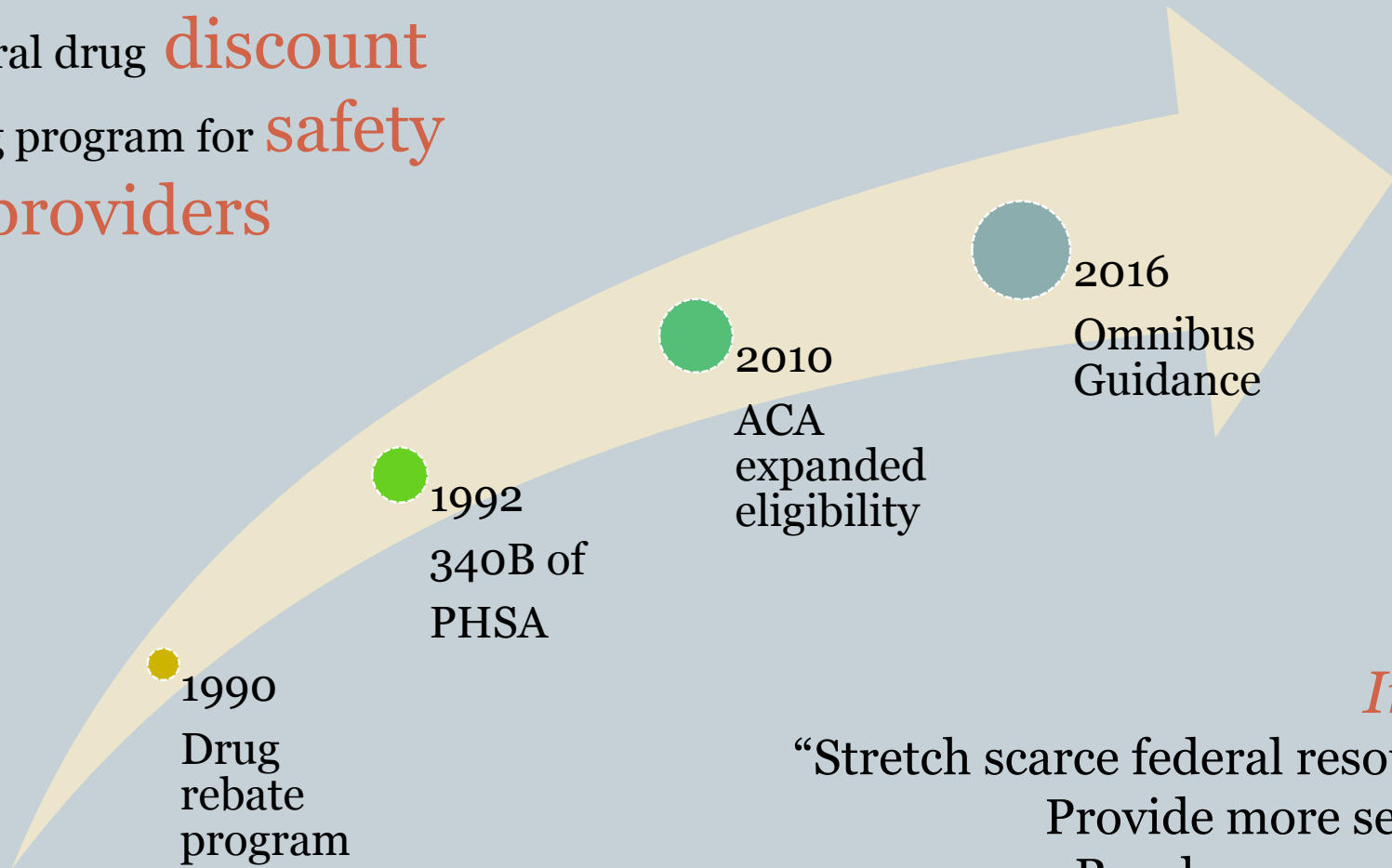
PRESENTATION OVERVIEW



- History on 340B
- 340B of today
- 340B expected updates
 - Definition of “patient”
 - Compliance
 - Eligibility criteria
- Implications of updates

WHAT IS 340B?

A federal drug **discount**
pricing program for **safety**
net providers



Intent
“Stretch scarce federal resources”
Provide more services
Reach more patients

KEY PLAYERS IN 340B



US Dept of Human Health
Services (HHS)

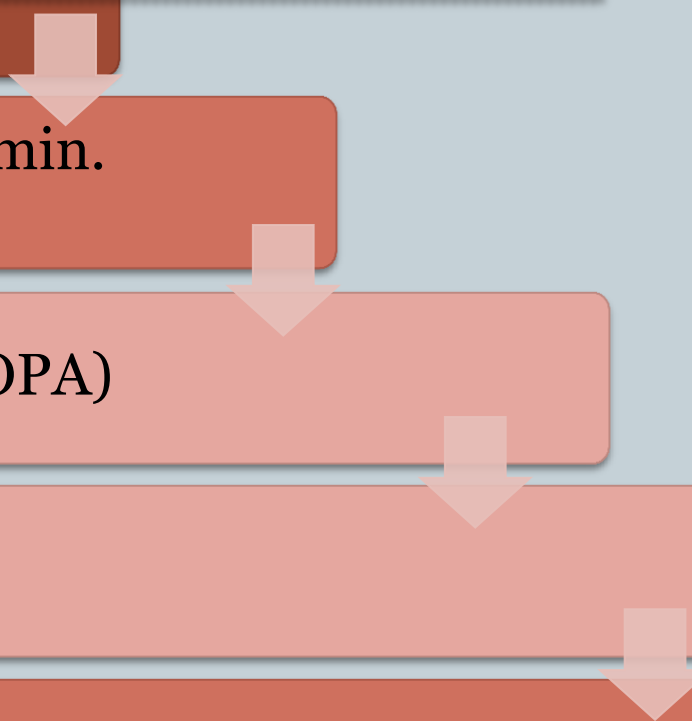
Drug Manufacturers

Health Resources & Services Admin.
(HRSA)

Office of Pharmacy Affairs (OPA)

Covered entities (CE)

Patients



ELIGIBLE COVERED ENTITIES



HEALTH CENTERS	HOSPITALS
Federally Qualified Health Ctrs (FQHC)	Children's Hospitals
FQHC Look-Alikes	Critical Access Hospitals
Native Hawaiian Health Ctrs	Disproportionate Share Hospitals (DSH)
Tribal/Urban Indian Health Centers	Free Standing Cancer Hospitals
	Rural Referral Ctrs
SPECIALIZED CLINICS	Sole Community Hospitals
Black Lung Clinics	
Comprehensive Hemophilia Diagnostic Treatment Ctrs	RYAN WHITE HIV/AIDS PROGRAM GRANTEEES
Title X Family Planning Clinics	
Sexually Transmitted Disease Clinics	
Tuberculosis Clinics	

DRUGS COVERED UNDER 340B



Covered	NOT covered
FDA-approved drugs	Inpatient
Prescribed OTCs	Orphan drugs
Biologics	Vaccines

FACTORS DRIVING HRSA UPDATES



- Huge growth of 340B
- Definition of patient
- Compliance
 - CE: Diversion & Duplicate discounts
 - Drug manufacturers
- Contract pharmacies

OVERVIEW OF 2016 UPDATES



- Omnibus Guidance (“mega-guidance”)
 - Definition of patient
 - Compliance
 - Eligibility criteria changes

DEFINITION OF “PATIENT”



Current:

1. CE has established relationship with patient & maintains patient's health care record
2. Patient receives health care services from health care professional employed/contracted with CE
3. Health care services is consistent with range of services from CE

CURRENT DEFINITION OF “PATIENT”



Must satisfy 3 criteria

1. CE has established relationship with patient & maintains patient's health care record
2. Patient receives health care services from health care professional employed/contracted/have special arrangements with CE
3. Health care services is consistent with range of services from CE

NEW DEFINITION OF “PATIENT”



Must satisfy 6 criteria

1. Patient receives health care services from health care professional *directly* employed/contracted with CE
 1. Most impacted: hospitals
2. Not qualified: medication orders written while “inpatient” status
 1. Impacts: discharge prescriptions
3. Not qualified: Medications prescribed to patients who only received infusion service

CHANGES TO ELIGIBILITY



1. Sites of care

1. Outpatient clinics part of a CE must have Medicare charges
2. Medicare disproportionate share hospital (DSH)
 1. > 11.75% for Children's Hospitals, Disproportionate Share Hospitals, and Free Standing Cancer Hospitals
 2. $\geq 8\%$ for Rural Referral Centers, Sole Community Hospitals

2. Drugs no longer eligible

1. "Bundle-billed" drugs
2. Drugs prescribed by non-340B site referred to by CE

COMPLIANCE



CE must detect & report to manufacturers promptly:

1. **Diversion**
 1. Eligible drug, ineligible patient
2. **Duplicate discounting**
 1. 340B & Medicaid
 1. Contract pharmacies

**Records must
be maintained
& auditable!**

Drug manufacturers

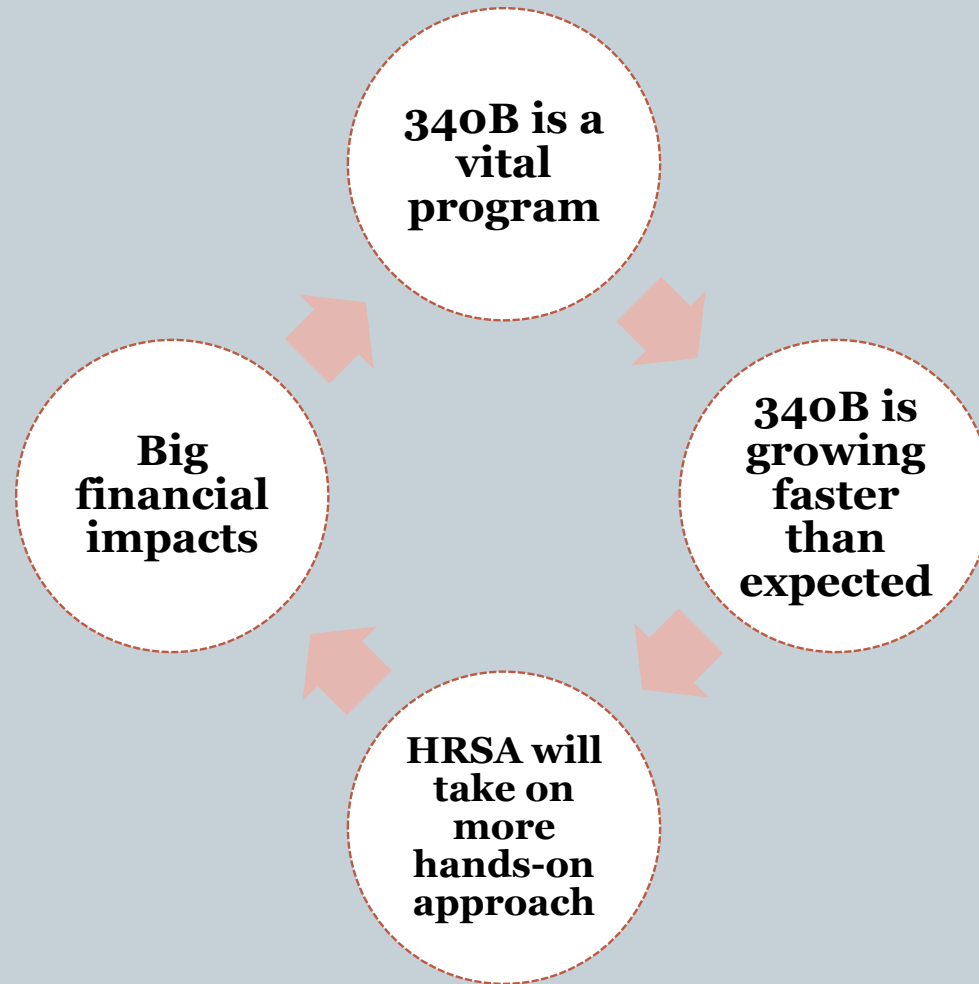
- Must maintain ceiling price to CE's

IMPACT OF EXPECTED UPDATES



- All parties affected
 - CE's
 - Patients
 - Drug manufacturers
 - Contract pharmacies
 - Outpatient pharmacies

KEY POINTS



THANK YOU!



Questions?

REFERENCES



- 340B Drug Pricing Program. Federal Register.
<https://www.federalregister.gov/articles/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance#h-15>. Accessed June 8, 2016.
- 340B Drug Pricing Program. HRSA.
<http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/index.html>. Accessed June 8, 2016.
- 340B Drug Pricing Program Mega-Guidance: A quick summary of key changes and 4 ways hospitals can prepare. Cardinal Health.
<http://www.cardinalhealth.com/en/thought-leadership/possible-changes-to-340b-drug-pricing-program.html>. Accessed June 7, 2016.
- Summary of HRSA Proposed Mega-Guidance.
http://www.340bhealth.org/files/Summary_of_HRSAs_Proposed_Mega-Guidance.pdf. Accessed June 7, 2016.