



Advising the Congress on Medicare issues

The 340B Drug Pricing Program

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November 6, 2014

Outline

- Background on 340B program
- Program has grown substantially
- 340B statute does not define key terms, allows many providers to participate
- Concerns with HRSA's oversight
- Debate over scope of program

Background

- Members of Congress asked us to examine 340B program
- Program allows certain providers (“covered entities”) to obtain discounted prices on outpatient drugs (prescription drugs and biologicals other than vaccines)
- Manufacturers must offer discounts to entities to have drugs covered under Medicaid
- Discounts: 25-50% of average wholesale price
- Program managed by Health Resources and Services Administration (HRSA)

Types of providers eligible to participate in 340B

Provider type	DSH threshold	Other requirements
Federal grantee (e.g., FQHC)	n/a	none
DSH hospital, cancer hospital, children's hospital	> 11.75%	Must be (1) owned by state/local government, <u>or</u> (2) be a public/nonprofit hospital that is formally delegated governmental powers by state/local government, <u>or</u> (3) be a nonprofit hospital under contract with state/local government to provide services to low-income patients who are not eligible for Medicare or Medicaid
Critical access hospital	none	
Rural referral center, sole community hospital	≥ 8%	

Medicare pays for 340B drugs provided by covered entities to beneficiaries

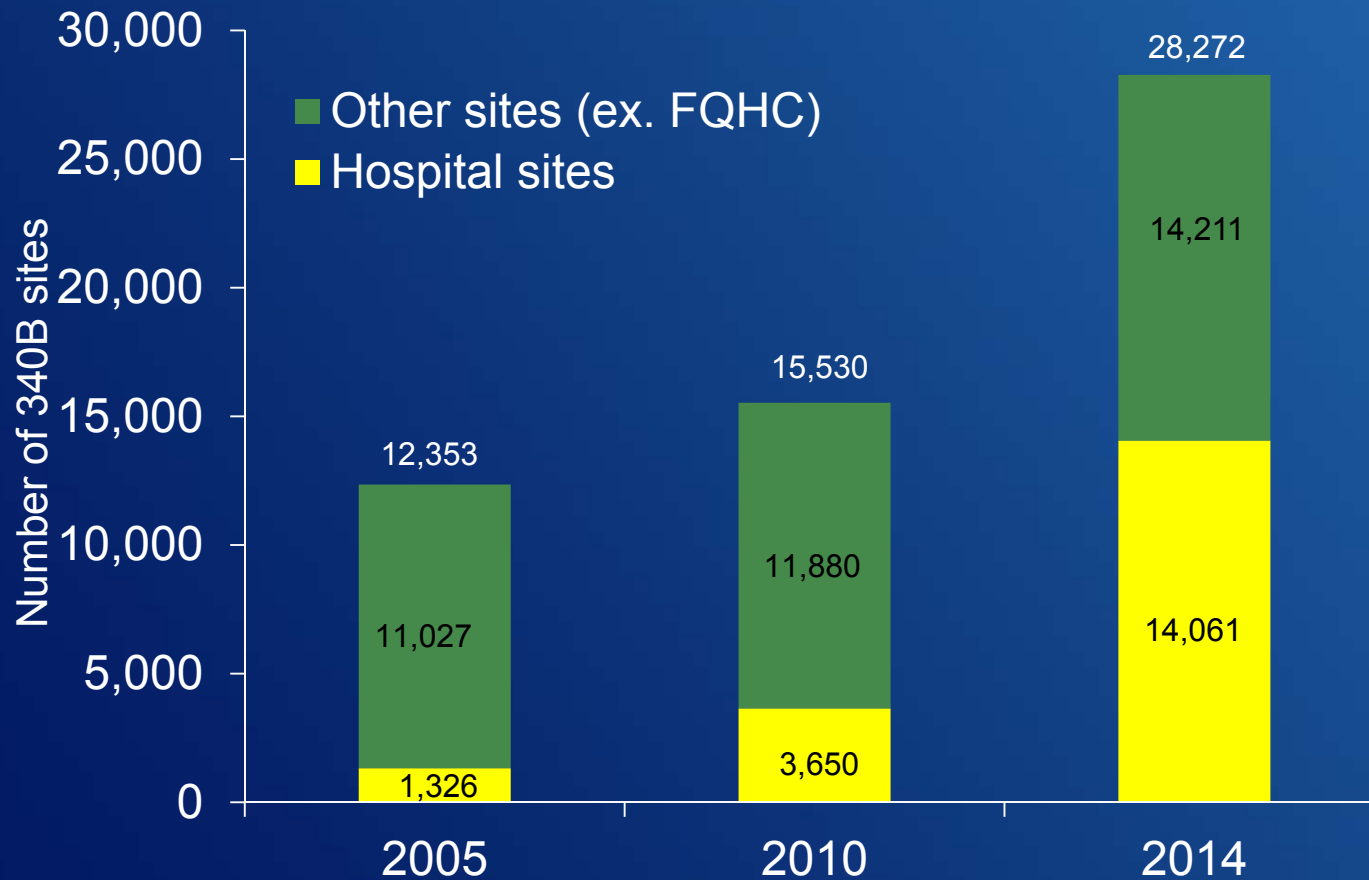
- Part B pays hospitals for outpatient drugs provided incident to a physician's service
- Under outpatient PPS, Medicare pays same rates for Part B drugs to 340B hospitals and non-340B hospitals, even though 340B hospitals can purchase outpatient drugs at steep discounts
- Part D plans may also pay for 340B drugs that are covered under Part D

340B program has grown substantially

- Number of sites providing 340B drugs increased by 9.6% per year, 2005-2014
- Number of participating hospital organizations increased by 15.5% per year, 2005-2014
- Spending by 340B providers to purchase drugs increased by 14.7% per year, 2005-2013
- Medicare spending at 340B DSH hospitals for drugs covered under Part B increased by 22.6% per year, 2004-2013

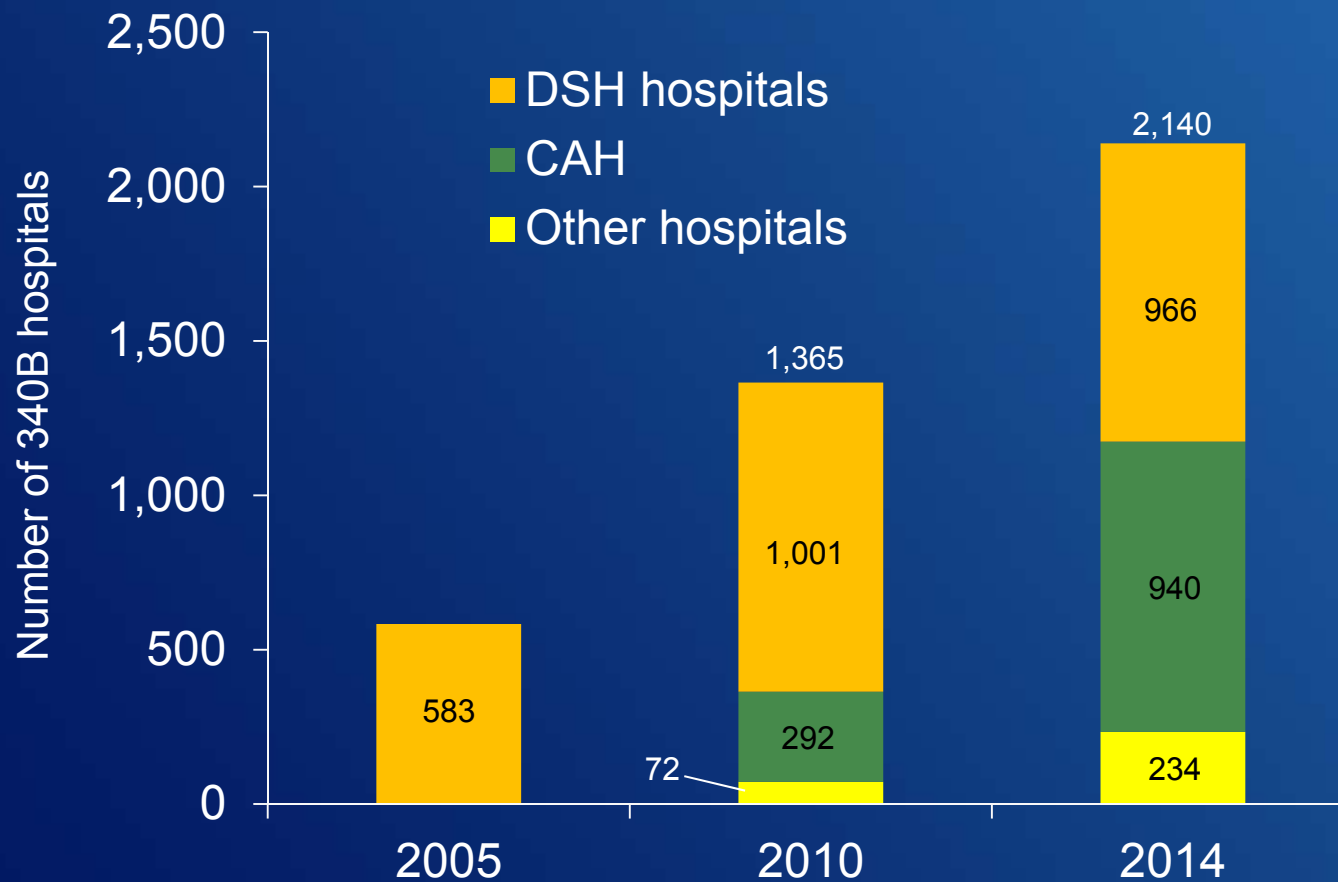
Sources: HRSA's database of 340B entities; Apexus; outpatient standard analytic claims files.

Growth in sites providing 340B drugs



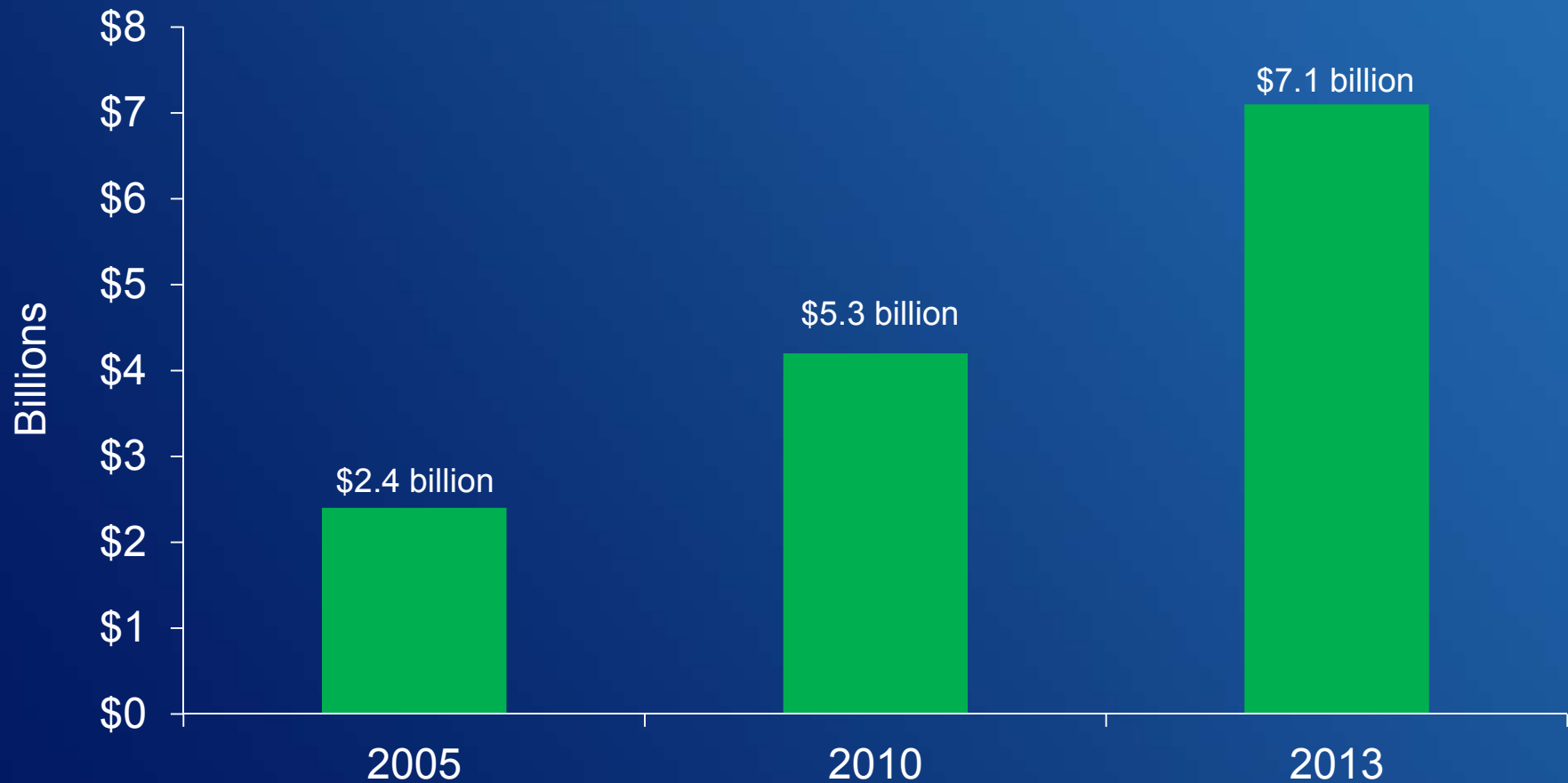
Source: HRSA's database of 340B entities

Growth in hospital organizations providing 340B drugs



Preliminary data subject to change

Growth in spending on 340B drugs by 340B providers



Preliminary data subject to change

Source: Apexus

Medicare spending for Part B drugs: 340B DSH hospitals vs. all hospitals

	Medicare spending (billions)		Annual growth, '04-'13
	2004	2013	
340B DSH	\$0.5	\$3.4	22.6%
All hospitals	\$2.5	\$7.2	12.7%

Sources: Outpatient standard analytic claims files, HRSA's database of 340B entities.

340B DSH hospitals are 20% of Medicare acute care hospitals but accounted for 46% of Part B drug spending at hospitals in 2013, up from 22% in 2004.

340B statute does not define eligible patient

- Covered entities permitted to provide 340B drugs only to their patients, but statute does not define “a patient of the entity”
- HRSA’s definition of eligible patient of a hospital
 - Individual with whom the hospital has a relationship (must maintain individual’s health care records)
 - Individual receives health services from health professional employed by hospital or who provides care under contract or other arrangements (e.g., referral for consultation); responsibility for care remains with hospital

340B statute allows many hospitals to qualify; does not restrict use of revenue

- Broad criteria for hospitals to qualify for program
 - 65% of IPPS hospitals had DSH > 11.75% and were government-owned or nonprofit
 - 94% of CAHs were government-owned or nonprofit
- Hospitals can generate revenue from 340B drugs if payments for drugs exceed the costs
- Because statute does not restrict how revenue can be used, hospitals can use revenue for any purpose
 - E.g., expand services, serve more patients, invest in capital, cover overhead costs

Concerns about HRSA's oversight of 340B

- GAO and OIG raised concerns about HRSA's ability to ensure compliance with program by entities and manufacturers
- HRSA primarily relies on program participants to ensure their own compliance
- HRSA began auditing small number of entities in 2012
- Difficult to enforce rules when key terms in statute (eligible patient) are unclear
- HRSA working on rule to address issues

Covered entities can use outside pharmacies to provide 340B drugs

- 82% of entities dispense 340B drugs through in-house pharmacies; 18% through outside pharmacies (HRSA)
- Contract pharmacy arrangements grew rapidly since 2010
- Concerns about use of contract pharmacies raised by HRSA audits, OIG
 - Some pharmacies provide 340B drugs to individuals who are not patients of the entity
 - Lack of consistency in how entities identify eligible patients

Debate between drug manufacturers and 340B hospitals over scope of program

- Drug manufacturers
 - Reconsider eligibility criteria for hospitals and limit contract pharmacy arrangements
 - Program's focus should be to help patients who are poor or uninsured access outpatient drugs
- Hospitals
 - Keep current rules for hospital eligibility
 - Preserve ability to use revenue from program for any purpose
 - Program essential to maintain hospital services and mission

Conference report on legislation that established 340B program

“...the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

- U.S. House of Representatives. 1992. *The Medicaid drug rebate amendments of 1992*. Report 102-384, part 2. 102nd Cong., 2nd sess.

Potential Medicare issue related to 340B

- Under outpatient PPS, Medicare pays same rates for Part B drugs to 340B hospitals and non-340B hospitals
- Medicare and beneficiaries could pay less for Part B drugs provided by 340B hospitals but this would reduce hospitals' 340B revenue

Discussion

- Clarifications
- Additional information for chapter on 340B program?