



340B: Issues and Opportunities in Pharmacy Automation

Safety Net Hospitals for Pharmaceutical Access

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Disclosure

Ted Slafsky declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, stock holdings, and honoraria.

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Overview

- About SNHPA
- About the *Drug Discount Monitor*
- 340B background
- Health reform and other developments
- 340B marketplace
- Technology challenges and opportunities
- Upcoming events

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Who is SNHPA?

- Represents 600+ hospitals in the 340B program – all hospital types
- At the table since inception of program in 1992
- Independent from both the drug industry and the government
- The only exclusive advocate for 340B hospitals
- Provides valuable technical support on all aspects of 340B

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Drug Discount Monitor

- Covers 340B, Medicaid rebates, Part D, Patient Assistant Programs, drug pricing litigation & investigations
- www.drugdiscountmonitor.com

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340B Basics

- Created by Congress to reduce safety net provider drug costs
- Administered by the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA)
- Requires drug manufacturers participating in Medicaid and/or Medicare Part B to sell “covered *outpatient* drugs” to “covered entities” at discounted prices

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Political Environment

- 340B has strong support but is subject to persistent threats
 - Industry allegations of diversion
 - Past efforts to eliminate the program
 - Several regulatory proposals and requirements that restrict program use and/or impose operational burdens

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340B Prices

- 25-50% lower than GPOs or other buying groups
- Companies required to provide best price
- Must monitor drug industry non-compliance

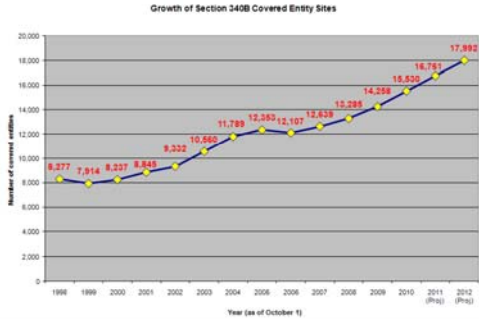
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340B Participants

- Over 15,000 entities now enrolled
- Over 800 manufacturers participate
- \$6 Billion in drug spending
- Multiplier effect: hundreds of vendors and consultants
- More getting into this business

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Growth of 340B Entities



Source: Office of Pharmacy Affairs, December 2010

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340B Eligible Entities

- Disproportionate Share Hospitals (DSH)
- Children's Hospitals
- Rural Hospitals
- Cancer Hospitals
- Federally Qualified Health Centers (FQHCs)
- FQHC Look-Alikes
- Title X Family Planning Clinics
- Comprehensive Hemophilia Treatment Centers
- Ryan White Programs
- STD/TB programs
- Urban/638 Tribal Programs

Types of 340B Hospitals

- Children's hospitals
- Critical access hospitals
- Disproportionate share (DSH) hospitals
- Freestanding cancer hospitals
- Rural referral centers
- Sole community hospitals

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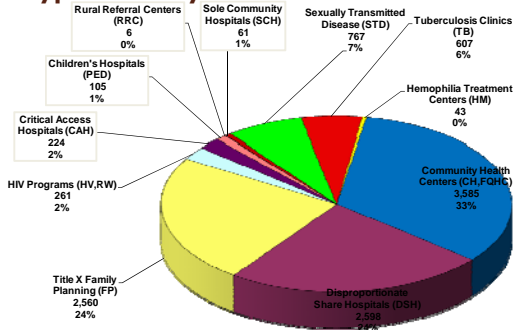
Eligibility and GPO Use

Covered Entity Type	Non-profit/govt. contract	DSH%	GPO Exclusion
Critical Access Hospital	Yes	No	No
Rural Referral Center	Yes	≥ 8%	No
Sole Community Hospital	Yes	≥ 8%	No
Free-standing Cancer Hospital	Yes	>11.75%	Yes
Children's Hospitals	Yes	>11.75%	Yes

Source: Office of Pharmacy Affairs, December 2010

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340B Participation by Type of Entity+



SOURCE: Apexus

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Major Changes to 340B in 2010

- Expansion to rural and free-standing cancer hospitals
- Tougher enforcement, esp. for overcharges
- Expansion of contract pharmacy options
- Orphan drug restriction for newly eligible hospital categories
 - Discounts restored for children's hospitals

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Implications of Reform

- Up to 1000 new hospitals now eligible
- Several hundred have enrolled already
- Small hospitals need even more help!

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Pricing Verification

- 340B providers need help in verifying prices.
- Ensure they are receiving correct 340B price
- Constant struggle for providers, wholesalers

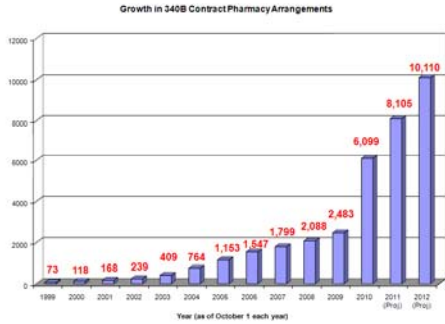
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Contract Pharmacy

- New April 5 guidelines on multiple contract pharmacy – providers may now contract with *more than one* outside pharmacy
- Will expand access to Rx Care
- Revenue opportunity from commercial and Part D patients
- Allows providers to capture a larger share of the pharmacy market using 340B
- Many considering outsourcing management to companies specializing in contract pharmacy administration

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Contract Pharmacy (cont'd)



Source: Office of Pharmacy Affairs, December 2010

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Contract Pharmacy (cont'd)

- Requires annual self-audit
- Annual certification
- Other compliance challenges

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Compliance

Three broad areas of compliance risk:

1. **Diversion** – Prohibition against reselling or transferring 340B drugs to anyone other than a “patient”
2. **Medicaid billing** – Must bill Medicaid at actual acquisition cost (AAC) subject to several important exceptions
3. **Group Purchasing Organization (GPO) exclusion** – DSH and children’s hospitals may not purchase covered outpatient drugs through a GPO or other group purchasing arrangement; no such restriction for rural hospitals

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Compliance: Areas of Concern

- Violating GPO exclusion (except rural hospitals)
 - Serving non-340B-eligible patients
 - Implementing Medicaid carve-out
 - When drugs are not covered or in short supply
- When must 340B drugs be billed at acquisition cost?

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Compliance: Areas of Concern (cont'd)

- Patient definition: who is eligible?
- 3-part test:
 - the CE has established a relationship with the individual such that the CE maintains records of the individual's health care; and
 - 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 care provided remains with the CE; and

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Compliance: Areas of Concern (cont'd)

- the individual receives a health care service or range of services from the CE 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. Hospitals are exempt from this requirement.

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Inventory Management

- Keeping track of outpatient/inpatient inventory
- Managing contract pharmacy relationship
- Can use virtual software or “in-house” IT system to separate inventory (physical separation not necessary)

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Inventory Management (cont'd)

- Virtual software
 - Several vendors offer software - from wholesalers to independent vendors
 - Helps identify eligible claims for audit trail
 - Data extracts from pharmacy software and orders from wholesaler account once “buckets” are full
- SNHPA has a decision-making tool to help hospitals select software

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Medicaid Billing

- Three options depending on state:
 - 1) Bill at AAC plus dispensing fee
 - 2) Use a Medicaid carve-out option
 - 3) Institute shared savings arrangements such as enhanced dispensing fees
- SNHPA is encouraging option 3 with CMS and states
- Billing restrictions do not apply for managed care

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Medicaid Billing

- Deficit Reduction Act of 2005: CMS told states that hospitals must report NDC information for physician-administered drugs
- Some states require 340B hospitals to bill at acquisition cost
- Substantial financial and operational burden on hospitals nationwide
- Litigation: SNHPA & UMCSN vs. CMS
- Maine model: 340B hospitals exempted from NDC reporting and billing at AAC

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Medicaid Billing (cont'd)

- Unless and until they are exempt from reporting, most 340B hospitals need software to enable them to report NDCs to the state
- Most pharmacy chargemaster's software cannot send more than one charge
- Difficult to identify 340B dispensed medication
- Few software solutions available
- Hospitals need help!

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Upcoming Events

7th Annual 340B Coalition Winter Conference (Co-hosted by Apexus)

February 9-11, 2011
Hotel Del Coronado
San Diego, CA

www.340Bwinterconference.org

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Upcoming Events (cont'd)

**15th Annual 340B
Coalition Conference
(Co-hosted by Apexus)**
July 11-13, 2011
Omni Shoreham Hotel
Washington, D.C.
www.340bconferences.org

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Additional Resources

Office of Pharmacy Affairs

- www.hrsa.gov/opa

340B Prime Vendor Program

- www.340Bpvp.com

Pharmacy Services Support Center

- 1-800-628-6297

- www.pssc.aphanet.org

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